Framework Contract SANCO/2008/01/055 Lot 1: Provision of Evaluation, Impact Assessment and Related Services to the Commission in the Areas of Public Health, Consumer Protection and Food Chain

Specific Contract: Mid-Term Evaluation of the Health Programme

CASE STUDY REPORT

Report prepared by

"Public Health Evaluation and Impact Assessment Consortium" (PHEIAC)

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HP Action In-depth Case Studies

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1. Introduction

A major source of evidence for the evaluation came from an assessment of 14 actions funded under the Health Programme (2008-2013). The sample of 14 actions was selected in conjunction with DG SANCO by applying the following criteria:

- A proportionate sample of actions from all three strands, namely 8 actions under Health Security (HS); 10 actions under Health Promotion (HP); and 7 actions under Health Information (HI);
- A sample of actions financed by the different financing mechanisms envisaged by the Programme, covering tenders; direct agreements (DA); grants for projects (PR); grants for conferences (CF); operating grants (OG); and joint actions (JA). Joint actions awarded in 2010 have not been taken into account as negotiation procedures for these have only started.
- Actions with different levels of budget, attempting to cover both big and small projects;
- Actions being undertaken in old and new Member States. It should be highlighted that the composition of the sample (with more actions in the old Member States) reflects that there are fewer actions funded in the new Member States. Countries covered in the sample include: The Netherlands, Ireland, Denmark, Finland, Spain, the UK, Slovenia, Lithuania, Portugal, Greece, Italy, France, Germany and Estonia;
- A majority of actions that started between 2008 and mid-2009, complemented by a reduced number of actions that were awarded funding in 2010, in order to ensure that project deliverables have been produced.

DG SANCO and the EAHC were asked to provide the study team with the following documents for the assessment of each action:

- Project proposals
- Minutes / Notes from the EU MS Programme Committee consulted as part of the evaluation process
- Minutes / Notes from the Evaluation committee
- Minutes / Notes from the consensus meetings
- Minutes / Notes from the negotiations
- Award Agreements
- Interim / (and where available) Final Reports of actions

The following table presents the sample of 14 actions assessed:

Table 1 – Sample of 14 actions

ACTION NR	STRAND	PRIORITY AREA	YEAR	PROJECT NR	ACRONYM	NAME	TYPE OF ACTION	COUNTRY	FUNDING
Health Information									
1	HI	Health indicators	2008	20082391	JA FOR ECHIM	Joint Action for European Community Health Indicators and Monitoring	JA	FI	1,500,000.00
2	HI	Monitoring, consistency and quality assurance of health information	2008	20081311R	EURONEOSTAT II	European Information System to Monitor Short and Long-Term Morbidity to Improve Quality of Care and Patient-Safety for Very-Low-Birth-Weight Infants	PR	ES	650,000.00
3	HI	Dissemination and application of health information	2009	20095302	OECD-HEALTHDATA	OECD- HEALTHDATA	DA	FR	400,000.00

ACTION NR	STRAND	PRIORITY AREA	YEAR	PROJECT NR	ACRONYM	NAME	TYPE OF ACTION	COUNTRY	FUNDING
Health Promotion									
4	HP	Addiction prevention	2008	20081211	CLUB HEALTH	CLUB HEALTH - Healthy and Safer Nightlife of Youth	PR	SI	700,000.00
5	HP	HIV- AIDS	2008	20084252	5ECCSRAD	5th European Conference on Clinical and Social Research on AIDS and Drugs	CF	LT	100,000.00
6	HS	Safety of blood, tissues, cells, organs	2008	20081101	EFRETOS	European Framework for Evaluation of Organ Transplants	PR	NL	750,000.00
7	HP	Prevention of major and rare diseases	2009	20093204	EURORDIS_FY_2010	EURORDIS_FY_2010	OG	FR	733,388.00
8	HP	HIV / AIDS	2008	20083271	AIDS ACTION EUROPE	AIDS Action Europe: Public Policy Dialogue and Linking and Learning	OG	NL	200,000.00

ACTION NR	STRAND	PRIORITY AREA	YEAR	PROJECT NR	ACRONYM	NAME	TYPE OF ACTION	COUNTRY	FUNDING
9	HP	Addiction prevention	2009	20091220	Take Care	A European information and awareness campaign targeted on the need for old people to stop any unnecessary use of antibiotics	PR	DE	900,000.00
10	HP	Implementation of EU Action Plan on environment and health 2004-2012	2008	20081217	RADPAR	Radon Prevention and Remediation	PR	GR	750,000.00
11	HP	Promote healthier ways of life and reduce major diseases and injuries by tackling health determinants	2009	20095201	UNAIDS	UNAIDS Awareness raising on HIV/AIDS	DA		400,000.00

ACTION NR	STRAND	PRIORITY AREA	YEAR	PROJECT NR	ACRONYM	NAME	TYPE OF ACTION	COUNTRY	FUNDING
Health Security									
12	HS	Safety of nanomaterials (Annex — point 1.2.1)	2009	20092101	NANOGENOTOX	Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard	JA	FR	2,890,268.00
13	HS	Improve citizens safety	2008	20081106	EFHRAN	European Health Risk Assessment Network on Electromagnetic Fields Exposure	PR	IT	600,000.00
14	HS	Assessment of incidence and causes of allergies (Annex - Point 1.2.1)	2008	507976	NVITO NV	VITO NV - SANCO/2008/C7-015/SI2.507976	Tender		100,000.00

The purpose of this in-depth assessment was to get a better understanding of the compatibility of the actions with the Health Programme's objectives, the usefulness of the different financing mechanisms, and where possible, the outputs, outcomes and impacts of the actions.

The assessment of the 14 actions has been an important source of evidence for the evaluation. It has contributed significantly in terms of providing answers to the evaluation questions. In addition, the evidence stemming from this exercise has provided some new detailed insights into actions for DG SANCO.

It is important to note that in the case of the majority of the 14 actions only Intermediate Reports have been produced. Therefore, an assessment of the final outputs, outcomes and impact achieved by the action has only been possible to a limited extent.

Interviews with Action Leaders / verification through EAHC officials

In addition to the desk research, the study team has carried out interviews with all 14 action leaders in order to gain further insights and an up to date report on how the action is progressing. More specifically, these interviews included issues on:

- Involvement of decision makers (design of project / exploitation of results)
- Dissemination strategies
- Sustainability
- Impact to be expected

In addition, PHEIAC has verified and confirmed the perceptions of action leaders with the relevant project officers in the EAHC who are responsible for the individual actions by sending them the case studies as well as the responses of action leaders.

Finally, the information collected during the case studies was inserted into an excel spreadsheet which allowed an overall assessment and comparison of financing mechanisms, topic areas, objectives and priority areas of actions funded under the Health Programme.

The external experts on the evaluation team played a significant role in developing the approach to examining the 14 actions and have taken responsibility for quality assuring the final outputs of this exercise.

Case Study Content

By way of an introduction to the case studies the following text describes the approach to this exercise:

Areas assessed in Case Studies

The case studies examine and assess various aspects of HP actions including:

- Origins of the action (i.e. is it a follow-up to an action funded under the previous Public Health Programme under the DG RTD Framework Programme?)
- Action's overall objectives / Intervention logic (Input, expected outputs, expected aims/outcomes)

- Compatibility with the principles / objectives of the Health Strategy
- Relationship with other initiatives (international, EU, national, regional)
- Rationale behind the selection procedures
- EU added value (the evaluation team assessed the EU added value using and refining an approach suggested by the EAHC; see explanations under EQ 14 and in the Case Study Report, which is a separate document to this report).
- Dissemination
- Sustainability

EU Added Value Assessment

The EAHC has developed seven ways on which to assess **European added value**, developed on the basis of the subsidiary principle and the Lisbon Treaty.[1] For the case studies, the evaluation team approached the assessment of EU added value by taking the following steps:

1. Refinement of the seven EU Added Value criteria initially developed by the EAHC;

2. Assessment of the actions against each EU Added Value criterion (based on a RAG scoring system as presented below);

Red: **No** EU added value foreseen.
Amber: EU added value **potentially**;
(Light) **Green:** EU added value **likely**;
(Dark) **Green:** EU added value **almost certain**.

3. Data has also been presented in aggregated form (all 14 actions together). This has provided a general idea (or a "picture") of where most of the EU Added Value is evident across the sample of 14 actions;

4. Conclusions were drawn at Programme level based on the "picture" across the 14 Actions.

5. Recommendations on how future calls should be structured for applicants to consider more carefully the EU added value likely to result from their actions.

Project Success Criteria

The evaluation team has developed a table of **project success criteria**, taking into account a strategic document developed by the EAHC.[2]

The following criteria are included in the table of project success criteria:

- Well-defined and SMART objectives;
- Evidence base;
- Clear target groups;
- Clear dissemination plan;

[1] The assessment criteria included (1) Implementing EU legislation; (2) Economies of scale; (3) Promotion of best practice; (4) Benchmarking for decision making; (5) Cross border threats; (6) Free movement of persons; (7) Networking. For further explanations, please refer to Evaluation Question 14 of the main report.
[2] Guy Dargent, "EU Health Programme evaluation" EAHC; provided to the evaluation team by Michel Pletschette.

- Estimated population reached / targeted by the action;
- Matching of project's deliverables (if any) with project's objectives;
- Use of multipliers;
- Evaluation
- Sustainability plan

The 14 case studies have been assessed against these project success criteria, and the assessment is included in the case study document.

Summary and Summary Assessment

Closely linked to the Project Success Criteria, each case study has a summary section (providing an overview of the action, the health issue to which it is targeted, its origins etc.) and a summary assessment table. The summary assessment table represents a judgement on the extent to which the action is fulfilling certain criteria – and there is evidence to support this. The following criteria have been examined:

Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)

Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved as associated partners	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)

The following scoring scale has been applied:

O	Not evident
+	Evident to a little extent
++	Evident to some extent
+++	Evident to a great extent
N/A	Not applicable / Information not available

The purpose of this summary assessment is to provide the reader with a quick insight into how the action is fairing against these key criteria.

2. RADPAR

2.1 Summary

The general objective of the RADPAR project is to assist in the reduction of the public health burden of lung cancers due to exposure to radon in EU Member States. Radon is considered by the World Health Organization (WHO) to be the second cause of lung cancer after cigarette smoke and is implicated in 15% of lung cancer cases.

Through its deliverables, RADPAR sets out to heighten awareness of *1. the health burden of radon in the EU* and of *2. the technical means available to control radon*. In particular, an important aspect of the project is the transfer of this information to new and accession Member States where radon control strategies are presently almost non-existent which demonstrates potential EU added-value.

The World Health Organisation (WHO) through the International Radon Project, along with many public health bodies at national level (both within and outside of the EU) are committed to research and other activities focused on radon prevention and remediation. In this context, there is little doubt that the RADPAR project is addressing a legitimate public health risk.

It should be noted that the majority of project outputs are still to be delivered so making an assessment of impact at this stage is not possible. However, based on intentions the following assessment of the Action has been made.

Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved as associated & collaborating partners	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
+++	+++	+++	+++	+++	+++	+++	12	+++	1. Implementing EU legislation: 1.0 2. Economies of scale: 1.0 3. Promotion of best practice: 2.0 4. Benchmarking for decision making: 0.5 5. Cross border threats: 1.8 6. Free movement of persons: 0.0 7. Networking: 2.0
RADPAR objectives are aligned to the HP objectives and the Priorities specified in the 2008 AWP.	- General objective is to assist in the reduction of the public health burden of lung cancers due to exposure to radon in EU Member States. Radon is considered by the WHO to be the second cause of lung cancer. - RADPAR sets out to heighten awareness of 1. the health burden of radon in the EU and of 2. the technical means available to control radon. - Important aspect is transfer of this information to new and accession Member States where radon control strategies are presently almost non-existent demonstrating potential EU added-value.	Strong evidence base exists from: - Previous JRC Projects (e.g. RFM) - WHO International Radon Project - Wide range of projects, initiatives, organisations looking at this public health risk in MSs and internationally.	- Previous JRC Projects (e.g. REM) - Prioritisation of Building Materials as indoor pollution sources (BUMA) - Thirteen European Case Controlled Studies on Radon in homes and risk of lung cancer. - Alpha Risk (Chronic Rad Epid) project (FI6R-516483, under the EC 6th Framework Programme, 2004-2009). - Radon Epidemiology project (FP5). - Lung Cancer and Residential Radon in a Mediterranean Area" project (FP4).	Significant concern at MS and international level. - International WHO International Radon Project - IAEA International Atomic Energy agency - United Nations Scientific Committee on the Effects of Atomic Radiation - International Commission on Radiological Protection.	Target groups defined in the proposal: - Policy makers / Decision makers - Health and construction industry professionals and associations - High risk groups Smokers and ex-smokers - General public	- Dissemination approach detailed in interim report. - Project results to be disseminated as widely as possible both to relevant stakeholders (such as decision makers, health and construction industry professionals and associations), but also to the general public. - Channels: + Website + Six monthly newsletters on the project's progress/findings + Development of mailing list database of potential end users. +Partners encouraged to publish results in journals, national and international forums and	- 1 Lead Partner - 11 Associated Partners - 7 Collaborating Partners	- Comprehensive evaluation plan submitted as part of Interim Report - Indicators developed at outcome (specific objective indicators) and output level (process indicators).	Particularly strong in: 1. Promotion of Best Practice Strive to expand strategies to reduce the health burden from radon to the EU population, develop radon risk communication strategies and approaches for different population target groups in the EU, establish measurement procedures for radon sources and control technologies, assess cost-effectiveness of existing and potential radon prevention and remediation strategies in the EU, design training courses for radon measurement, prevention, remediation, and cost effectiveness analysis, and assess the potential conflicts between energy conservation in buildings and radon exposure reduction. 2. Networking: RADPAR supports existing networking activities of those individuals and entities involved in the field of the effects of radon on public health. 3. Cross border threats: - Standardisation of measurement procedures for radon sources and control strategies, Assessment of cost effectiveness of existing and potential radon, Assessment of the health buden to the general population from exposure to radon. - Development of Radon Risk Communication Strategies including raising awareness of 1. radon proof building material and 2. building material that contains radon

0	Not evident
+	Evident to a little extent
++	Evident to some extent
+++	Evident to a great extent
N/A	Not applicable / Information not available

2.2 Key Facts

Calls for proposals:	2008
Proposal title:	Radon Prevention and Remediation
Acronym:	RADPAR
Financing mechanism:	Project
Start date:	9th May 2009
Duration (in months):	36 months
EC contribution:	€ 1,007,996 (57%)
Total:	€ 1,758,757
Overall score achieved in Consolidated Evaluation Report:	Total = 71

Total criteria block: A, B, C	A: 33 B: 19 C: 19
Main partner:	University of West Macedonia
Number of associated partners:	11
Number of collaborating partners:	7
Priority area:	Promote Health (HP-2008)
Action:	Improve the quality of physical environment and reduce accidents and injuries 3.3.5. Reference in WP 2008 2.2.4. Reference in HP 2008 - 2013
Typology[3]:	Development action

2.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[4]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria. Please note that these criteria will be further refined for the Draft Final Report.

Project Success Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**RADPAR objectives relate to 1. network and to 2. produce/disseminate information:** The general objective of the RADPAR project is to assist in the reduction of the public health burden of lung cancers due to exposure to radon in EU Member States. See Section 1.7 for specific objectives. Based on the desk research exercise the RADPAR objectives are aligned to the HP objectives and the Priorities specified in the 2008 AWP.

[3] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).
[4] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Project Success Criteria	Notes / Comments
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Development Action**: Strong evidence base exists from: - Previous JRC Projects (e.g. REM) - WHO International Radon Project - Wide range of projects, initiatives, organisations looking at this public health risk in MSs and internationally. (See Context section and timeline below)
Clear target groups	Target groups defined in the proposal: - Policy makers / Decision makers - Health and construction industry professionals and associations - High risk groups – Smokers and ex-smokers - General public
Clear dissemination plan (concerns **implementation projects only**) and Use of multipliers – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	Dissemination approach detailed in interim report. - Project results to be disseminated as widely as possible both to relevant stakeholders (such as decision makers, health and construction industry professionals and associations), but also to the general public. **- Channels:** + Website + Six monthly newsletters on the project's progress/findings + Development of mailing list database of potential end users. +Partners encouraged to publish results in journals, national and international forums and conferences. +Workshop on project results to existing and new MS where radon exposure control policies are at a very preliminary stage of development.
Estimate the population reached (or targeted) by the action	TBC
Matching of project's deliverables (if any) with project's objectives	Final Report not available to confirm this.
Evaluation (provision of indicators)	Evaluation plan was part of the initial RADPAR proposal but was fine-tuned during the contract negotiations. Work-package specific evaluation

Project Success Criteria	Notes / Comments
	indicators and actions were described in more detail, and several aspects with respective core indicators were included in the grant agreement.
Sustainability plan	In the absence of EU funding it is likely that the Action would have been undertaken but with a less ambitious scope. Those involved in RADPAR are keen to pursue follow-on projects that build on the results of the project. Where funding will come from is yet to be determined.

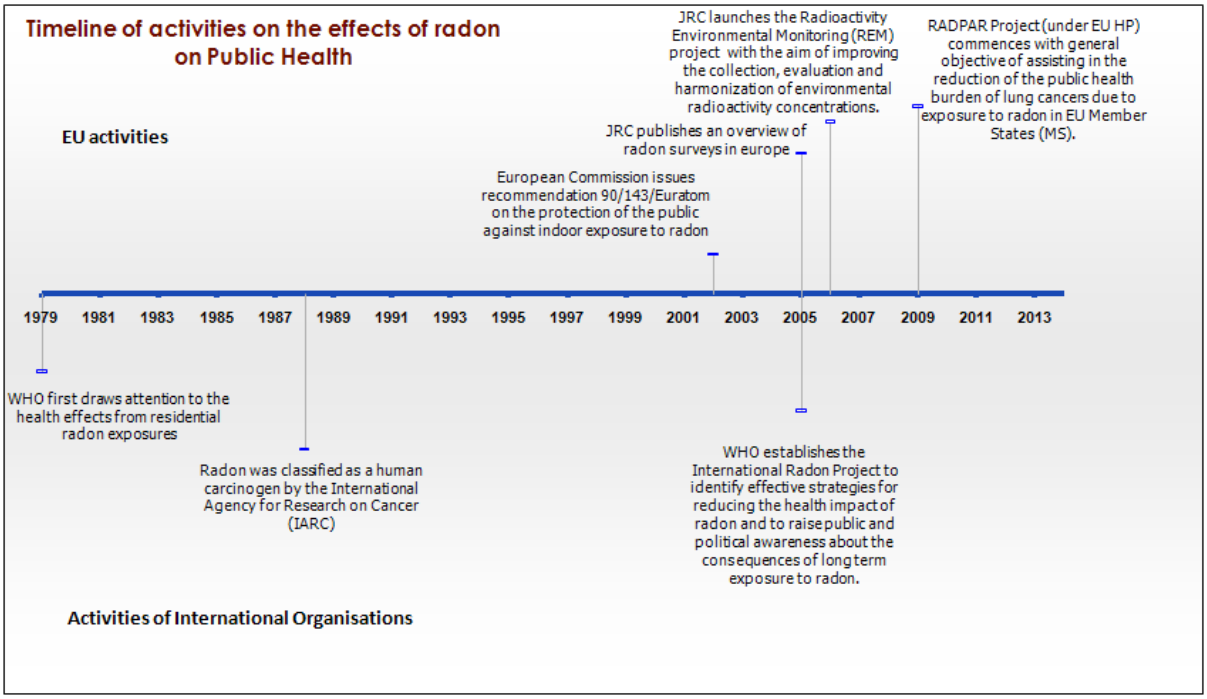
2.4 Introduction

Radon is an ubiquitous naturally occurring radioactive gas which is produced in the radioactive decay chain of uranium in the ground. It is classified as a Group 1 human carcinogen by IARC (International Agency for Research on Cancer). It is also considered by the WHO (World Health Organization) to be the second cause of lung cancer after cigarette smoke. During the past four years the WHO International Radon Project has assessed and made recommendations on many issues in relation to radon exposure as a public health problem on a global basis. The RADPAR project is focused on a number of these issues within the framework of EU Member States.

2.5 Background / Policy Context

In order to gauge and make a judgement on the extent to which the RADPAR project is tackling a serious public health issue, the case study examines what other public health interventions have taken place and the organisations involved in coordinating/funding these activities. The figure below provides a brief overview of how activities on the effects of radon on Public Health have evolved over the last 30 years.

Figure 1 – Timeline of a sample of activities / developments on the effects of radon on Public Health



There is currently no regulation or directive in Europe concerning radon. However, in 1990 the European Commission issued recommendation 90/143/Euratom on the protection of the public against indoor exposure to radon. This recommendation defined 400 Bq.m-3 as the level for considering remedial action in existing dwellings and 200 Bq.m-3 as the reference level for new dwellings[5]. It has served as a reference for the development of policies against radon exposure in many countries. Although the recommendation sets the framework policy on indoor radon, there are diverse approaches in Europe: some countries do not have any regulations and many others have adopted an indoor radon level within the range 200–400 Bq.m-3 as the level for action or the reference level for new buildings. Only a few responsible authorities have developed detailed legislation specifying levels above which financial support for mitigation can be provided.

Radon levels in indoor air can be lowered in a number of ways, from sealing cracks in floors and walls to increasing the ventilation rate of the building. Under-floor sump and extraction methods are considered to be the most efficient. Prevention of radon exposure in new buildings can be implemented through appropriate provisions in the construction phase. National building codes cover the issue of exposure to natural radiation in building construction and ventilation sections.

In addition, all European Union Member States already have or are drawing up provisions for implementing basic safety standards for the health protection of the general public, and workers in particular, in case of a significant increase in exposure due to natural radiation sources (including radon) in work places, as laid down in Title VII of Council Directive 96/29/Euratom[6].

5 Commission recommendation on the protection of the public against indoor exposure to radon (90/143/Euroatom). Brussels, Commission of the European Communities, 1990 (http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/90143_en.pdf, accessed 4 April 2007).

6 Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. Brussels, Commission of the

In 2006, the JRC launched the Radioactivity Environmental Monitoring (REM) project[7] with the aim of improving the collection, evaluation and harmonization of environmental radioactivity concentrations and the modelling of the migration of radioactivity in the environment. A central activity of REM is the monitoring and mapping of indoor radon[8].

The World Health Organization first drew attention to the health effects from residential radon exposures in 1979, through a European working group on indoor air quality. Further, radon was classified as a human carcinogen in 1988 by the International Agency for Research on Cancer (IARC), the WHO specialised cancer research agency. In 1993, a WHO international workshop on indoor radon involving scientists and radon experts from Europe, North America and Asia, was a first step towards a unified approach to controlling radon exposures and advising on the communication of associated health risks.
In 2005, WHO established the International Radon Project to identify effective strategies for reducing the health impact of radon and to raise public and political awareness about the consequences of long term exposure to radon. Participants and contributors from more than 30 countries worked together towards a global understanding of a wide range of issues associated with indoor radon.

The WHO handbook on indoor radon[9] provides detailed recommendations on reducing health risks from radon and sound policy options for preventing and mitigating radon exposure, such as reliable radon levels measurements, control measures for radon in new dwellings, radon reduction in old dwellings and assessment of their costs and benefits.

The RADPAR project has been positioned as a complimentary action to the WHO International Radon project in the European region and its outcomes are envisaged to help serve as a practical platform for use in other regions of the world.

2.6 Origins of HP project

Previous studies (see section 1.7 on similar initiatives) including numerous funded by the EU have shown the great complexity of the radon problem. Their findings suggest the need for new and bigger efforts to understand the subject. It is clear that only a joint European effort can provide the necessary experience and diversity of circumstances to provide an insight into this complex problem.

2.7 Project Partners

Main Partner	Country	Organisation

European Communities, 1996 (http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9629_en.pdf, accessed 4 April 2007).

[7] Radioactivity Environmental Monitoring project [web site]. Brussels, European Commission, Joint Research Centre, 2006 (http://rem.jrc.cec.eu.int/, accessed 4 April 2007).

[8] European Forum on Radon Mapping [web site]. Brussels, European Commission, Joint Research Centre, 2005 (http://radonmapping.jrc.it/index.php?id=36, accessed 4 April 2007).

[9] WHO handbook on indoor radon - a public health perspective, Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241547673_eng.pdf accessed 17 December 2009)

		Status
University of West Macedonia	**Greece**	**Public**

Associated Partners	**Country**	**Organisation Status**
Bundesamt fur Strahlenschutz (BfS),	**Germany**	**Public**
Johannes Gutenberg Universitat (Uni-Mainz)	**Germany**	**Public**
University of Oxford	**UK**	**Public**
Centre Scientifique et Technique du Batiment (CSTB)	**France**	**Public**
Institute Superiore di Sanita (ISS)	**Italy**	**Public**
Austrian Agency for Health and Food Safety (AGES)	**Austria**	**Public**
Norwegian Radiation Protection Authority (NRPA)	**Norway**	**Public**
Radiation and Nuclear Safety Authority (STUK)	**Finland**	**Public**
International Bureau for Environmental Studies (IBES)	**Belgium**	**Private**
National Radiation Protection Institute (SURO)	**Czech Republic**	**Public**
Universitat Bremen (Uni-Bremen)	**Germany**	**Public**

2.8 Overall project objectives / Intervention logic

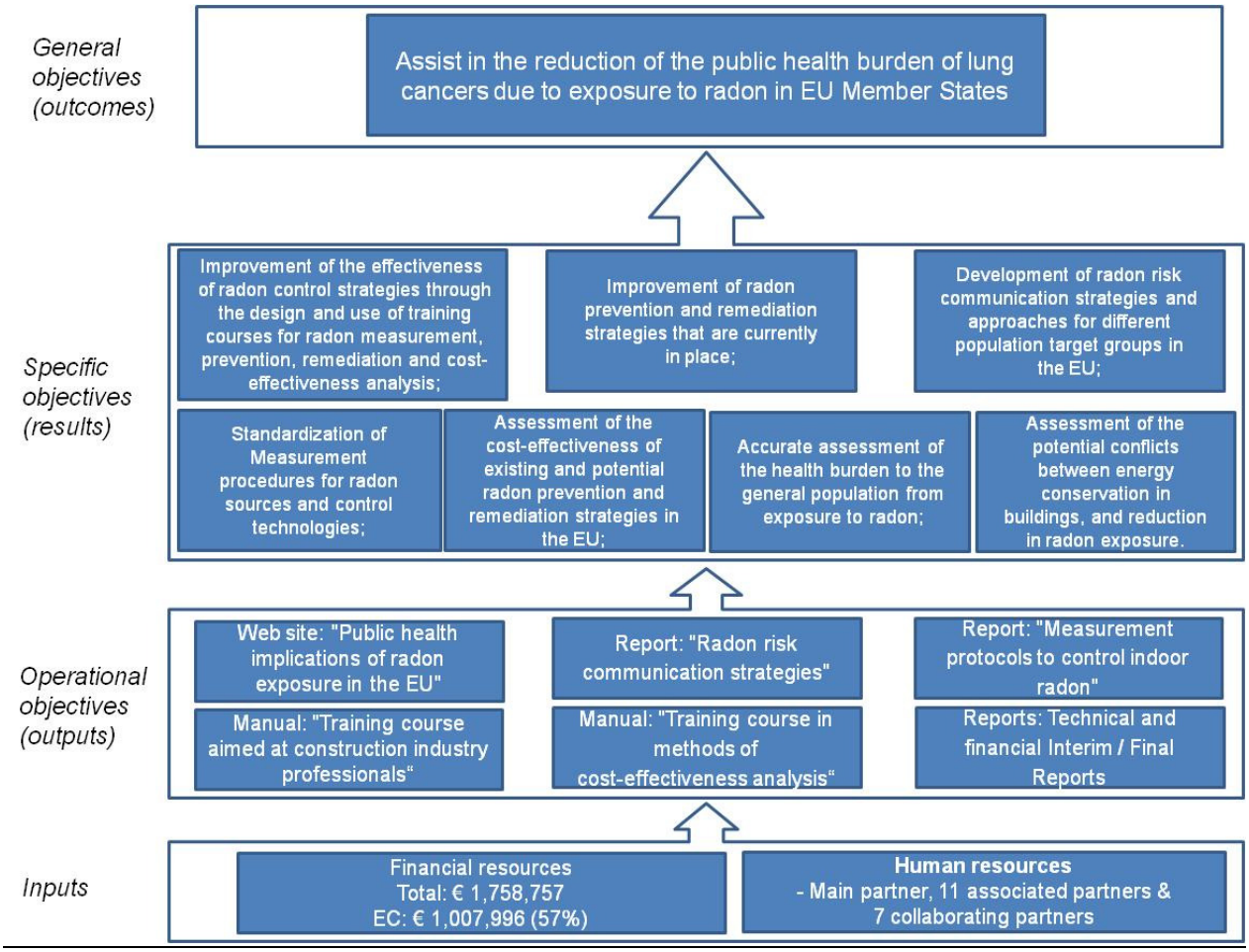
The general objective of this project is to assist in the reduction of the public health burden of lung cancers due to exposure to radon in EU Member States.

By means of its deliverables it is expected that the project will heighten awareness of the health burden of radon in the EU and of the technical means available to control radon. An important aspect of the project will be the transfer of this information to new and accession Member States where radon control strategies are presently almost non-existent.

Based on an analysis of the proposal and interim report, the diagram below depicts the project's complete intervention logic. It shows a clear sequence of the general and specific objectives the RADPAR project intends to achieve, the expected outputs, and the key inputs. The diagram also reflects a general clear differentiation between the specific objectives and the outputs of the action. The only comment to the intervention logic raised by the evaluation team concerns the fact that the first specific objective "Improvement of the effectiveness of radon control strategies through the design and use of training courses for radon measurement, prevention, remediation and cost-effectiveness analysis" includes both a result and an output. The evaluation team considers that it would be more appropriate to split this objective into two so that the result can be the improvement of the effectiveness of radon control strategies and the output can be the design design and use of training courses for

radon measurement, prevention, remediation and cost-effectiveness analysis. More specific details on each of these aspects is presented below.

Figure 2 - Intervention logic diagram for RADPAR



Inputs

Please find below a table detailing the RADPAR budget providing costs for all inputs including staff, travel, equipment etc.:

RADPAR Budget Overview		
E1a: Staff (public officials)	€ 750,761	
E1b: Staff (non public officials)	€ 471,938	
Total Staff (E1a + E1b)		**€ 1,222,699**
E2a: Travel	€ 81,200	
E2b: Subsistence allowances	€ 99,012	
Total E2 – Travel Costs and subsistence allowances (E2a + E2b)		**€ 180,212**
Total E3 – Equipment		€ 4,800
Total E4 – Consumables & supplies linked to the project		€ 27,000

RADPAR Budget Overview		
Total E5 – Subcontracting costs	€ 148,000	
Total E6 – Other costs	€ 61,000	
Total Direct Eligible Cost		**€ 1,643,711**
Total E7-Overheads	€ 115,046	
Total Indirect Eligible Cost		**€ 115,046**
TOTAL EXPENDITURE		**€ 1,758,757**

Expected outputs:

Expected outputs	Achieved outputs (as per Interim Report)
Web site: "Public health implications of radon exposure in the EU"	Delivered: Month 6 (Online at March 2010)
Report: "Radon risk communication strategies"	
Report: "Measurement protocols to control indoor radon"	
Manual: "Training course aimed at construction industry professionals"	
Manual: "Training course in methods of cost-effectiveness analysis"	
Report: "Potential conflicts between energy conservation and radon control"	
Reports: Technical and financial Interim Reports according to EC requirements	Delivered: Month 14
Reports: Technical and financial Final Report according to EC requirements	
Reports: Evaluation Committee Reports	Delivered: Month 14 (First Evaluation Committee Report)

Expected aims/outcomes:

Aim	Indicators	Result (as per Interim Report)
Improvement of existing radon control strategies. The quality of the statements made on the effectiveness, deficiencies and recommended improvements of existing radon control strategies will be evaluated.	**Indicator 1:** At least 80% of all available national strategies (of the 27 EU members) reviewed and suggestions provided by the end of the project. **Indicator 2:** Proportion of	No evidence currently available

Aim	Indicators	Result (as per Interim Report)
	existing strategies with identified need for improvement that are actually revised or will be revised by the responsible national or other stakeholders. **Indicator 3:** 50% of suggested revisions taken up. N.b. It should be noted that strategy and policy changes may only be effected over a long time period; therefore the willingness of national or other stakeholders to consider RADPAR suggestions will be assessed and included in Indicator 2.	
Radon risk communication strategies. The risk communication strategies developed for radon will be compared with risk communication strategies currently used in some MS for radon and other environmental health hazards.	**Indicator 1:** At least one contact per EU country contacted (27 total) **Indicator 2:** At least 20 contacts with interest in cooperation, and minimum 1 per category overall	No evidence currently available
Measurement protocols. The quality of the measurement protocols developed here will be compared with equivalent protocols presently in use in MS for other air pollutants.	**Indicator:** Existence and quality of comparative assessment of radon measurement in at least 5 other existing indoor protocols	No evidence currently available
Spreadsheet model. A spread sheet model to calculate cost effectiveness of existing and potential radon prevention and remediation strategies will be developed.	**Indicator:** The spreadsheet based model should be used by a relevant institution in at least 3 countries in addition to the UK, by the end of the project.	No evidence currently available
Training courses. The two training courses developed in this project will be compared and benchmarked against training courses on radon	**Indicator:** The number of positive expressions of interest in adopting these courses from Member States.	No evidence currently available

Aim	Indicators	Result (as per Interim Report)
control and cost effectiveness already available in some MS.		
Conflicts between energy conservation in buildings and radon exposure reduction. The implications of radon control strategies for energy conservation for a number of typical and new building scenarios will be used to evaluate the economic and social significance of the radon exposure reduction.	**Indicator:** The degree of interest in this topic generated by RADPAR in the building design and construction industries as evidenced by the number of expressions of interest from those sectors.	No evidence currently available

2.9 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 2 as set out in the Health Strategy (2008-2013). Objective 2: Protecting citizens from health threats: Health threats include infectious diseases (e.g. HIV/AIDS, tuberculosis, Creutzfeldt Jacob Disease, etc.) and **threats emerging from physical, chemical or biological sources**, including those relating to terrorist acts and environmental agents (e.g. **ionising and non-ionising radiation** and noise).

2.10 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified the following initiatives:

1. **Other EU / DG SANCO projects**
    a. Prioritisation of Building Materials as indoor pollution sources (BUMA), *DG Sanco Public Health Programme 2003 – 2008. Contract no.: 2005307 (2006-2009).*
    b. Thirteen European Case Controlled Studies on Radon in homes and risk of lung cancer: collaborative analysis of individual data from 13 European case-control studies to determine the risk of lung cancer associated with exposure at home to the radioactive disintegration products of naturally occurring radon gas. Studies show appreciable hazards from residential radon, particularly for smokers and recent ex-smokers, and indicate that it is responsible for about 2% of all deaths from cancer in Europe.
    c. Alpha Risk (Chronic Rad Epid) project (FI6R-516483, under the EC 6th Framework Programme, 2004-2009).
    d. Radon Epidemiology project (FIGH-CT1999-00008, under the EC 5th Framework Programme, 1999-2004);
    e. Lung Cancer and Residential Radon in a Mediterranean Area" project (F14P-CT96-0055, under the EC 4th Framework Programme, 1996-1999);

f. Physical and Chemical Exposure Unit (PCE), supporting DG SANCO's IAQ experts group by leading WG 1 on "Information and education to the public on practices to improve indoor air quality".

2. **International Organisations involved in examining the effects of radon on public health:**
   a. WHO International Radon Project
   b. IAEA International Atomic Energy agency, http://www.iaea.org/ coordinated the International Radon Metrology Programme (IRMP). A system of reference, technical support, and regional co-ordinating laboratories established to assist in assuring comparability of radon measurements obtained by different institutions worldwide.
   c. United Nations Scientific Committee on the Effects of Atomic Radiation
   d. International Commission on Radiological Protection

3. **Member State organisations involved in examining the effects of radon on public health:**
   a. Austria: Federal Ministry of Agriculture, Forestry, Environment and Water Management, http://www.lebensministerium.at
   b. Belgium: Federal Agency for Nuclear Control (FANC), http://www.fanc.fgov.be
   c. Czech Republic: National Radiation Protection Institute (SURO), http://www.suro.cz/
   d. Denmark: Danish Energy Authority, Ministry of Climate and Energy (ENS), http://www.ens.dk
   e. Finland: Radiation and Nuclear SafetyAuthority, (STUK), http://www.stuk.fi
   f. France: Institut de Radioprotection et de Sûreté Nucléaire (IRSN), http://www.irsn.fr
      Nuclear Energy Agency (NEA), http://www.nea.fr
   g. Germany: The Federal Office for Radiation Protection (BfS), http://www.bfs.de
   h. Greece: Greek Atomic Energy Commission (EEAE), http://www.eeae.gr
   i. Hungary: Hungarian Atomic Energy Authority (HAEA), http://www.haea.gov.hu
   j. Ireland: Radiological Protection Institute of Ireland (RPII), http://www.rpii.ie
   k. Italy: Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA), http://www.enea.it
   l. Luxembourg: Service de l' Energie de l' Etat (ILNAS), http://www.ilnas.public.lu
   m. Norway: Norwegian Radiation Protection Authority (NRPA), http://www.nrpa.no
   n. Spain: Consejo de Seguridad Nuclear (CSN), http://www.csn.es
   o. Sweden: Swedish Radiation Safety Authority (SSM), http://www.stralsakerhetsmyndigheten.se
   p. United Kingdom: Health Protection Agency, http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/Radon/

4. **3rd countries involved in examining the effects of radon on public health**:

a. Federal Office of Public Health of Switzerland, http://www.bag.admin.ch/themen/strahlung/
b. US Environmental Protection Agency, http://www.epa.gov/radon/
c. American Association of Radon Scientists and Technologists, http://www.aarst.org/

2.11 Rationale behind selection procedures (consistency with HP objectives)

The evaluation report concluded that the RADPAR proposal fully met the objectives of the Health Programme and the priority areas in the 2008 Work Plan. More specifically, the project addresses the following points:

1. Complement actions taken within the European Environment and Health Action plan 2004-2010.
2. Addressing people's exposure to toxic substances in indoor air settings.
3. Targeting actions at vulnerable groups (the proposal contains a specific WP on communication, this will be used to address remedial measures in MS to prevent/avoid high radon concentrations indoor).
4. The Work Plan 2008 calls for preventive and remedial measures to reduce exposure to radon in MS (this is part of an EU strategy on a number of key indoor pollutants. There is a need to develop targeted public health actions/support for MS on radon given its public health significance).

2.12 Involvement of decision makers (design of project / exploitation of results):

Based on the number of projects (at MS, EU and internationally) it is evident that this is considered a serious public health issue by many governments. It is envisaged that the results of this project will be considered carefully and potentially used for determining future policy and decision making by the at EU and MS level.

2.13 Dissemination

Target Audience

The aim is to disseminate the results of the RADPAR project as widely as possible. Relevant stakeholders include:
- Policy makers / Decision makers
- Health and construction industry professionals and associations
- High risk groups – Smokers and ex-smokers
- General public

Tools

Website
The project's website (http://web.jrc.ec.europa.eu/radpar/) is the main dissemination channel. It became operational in month six (M6), in line with the Grant Agreement. The website was developed by JRC (Joint Research Centre) which is responsible for administering the site. Proposals and ideas for further developing the site are put forward by all Collaborative Partners and it is continuously updated in parallel with the evolution of the project. The

website is linked to the DG SANCOs Inter-service website on Indoor Air Quality and associated health effects.

Newsletters
During the first year of the project two newsletters were produced and distributed. The first newsletter was released in month 3, detailing the project′s aim and objectives and highlighting the fact that RADPAR. The second newsletter was released on month 13, detailing the project′s progress, results and achievements. Both newsletters are available in electronic form on the project‟s website in the section "Newsletter". The website carries the capability of allowing members of the general public to subscribe and receive the Project‟s newsletters upon their release.

Printed material
One of the main goals of RADPAR is to establish ways for the best possible communication of its results to a wide audience. There is strong encouragement for the publication of the results by all partners. Mechanisms include publications in journals, national and international forums and conferences as well as printed material such as flyers. In this respect, flyers were distributed at:
- The HEMIPCD Workshop on "Building material emissions to indoor air. Opportunities /consequences for Belgian companies" which was held in Brussels, on the 21st of January 2010;
- The Fifth Ministerial Conference on Environment and Health, EAHC, "Protecting children's health in a changing environment" which was held in Parma, Italy on 10-12 of March 2010;
- The 1st Annual RADPAR meeting in Ispra, Italy on 10-11 May 2010;
- The IRPA (International Radiation Protection Association) congress in Helsinki on 15-18 of June 2010.

In addition, in the context of the Fifth Ministerial Conference on Environment and Health, specific information was compiled according to the template provided by EAHC.

Mailing list/relevant stakeholders
At the end of the first year a mailing list with relevant organisations from the end-user community was under development. All partners are committed to exploit their individual contacts and collaborations at local and national scale and disseminate the project outcomes amongst them. This will be aided by a mailing list of potential end users and relevant stakeholders who will be willing to receive information material (e.g. newsletter). The stakeholder groups were identified and belong to the following categories:
- National policy/decision makers;
- Radiation protection agencies;
- Housing construction companies;
- Radon remediation companies;
- House financing and insurance companies;
- Environmental protection NGOs;
- Relevant general public groups.

Workshop

Towards the end of the project a workshop on Radon Prevention and Remediation Workshop will be organised. Selected members of the targeted end-user groups such as radon measurement, prevention and remediation companies and health agencies will be invited to participate.

2.14 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value Radon fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		RADPAR Project
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	1.0
3.	Promotion of best practice:	2.0
4.	Benchmarking for decision making:	0.5
5.	Cross border threats:	1.8
6.	Free movement of persons:	0.0
7.	Networking:	2.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

2.15 Sustainability

In the absence of EU funding it is likely that the Action would have been undertaken but with a less ambitious scope. Health Programme funding is considered to have raised the profile of the project to some extent. In terms of what the future holds those involved in RADPAR are keen to pursue follow-on projects that build on the results of the project.

2.16 Impact

Like many of the HP Actions, RADPAR is an ongoing Action and many of the final outputs will be delivered towards the end of the project. In this sense it is too early to be able to gauge any impact the project has had or is having. There are plans to run a workshop at the end of the RADPAR to which stakeholders outside the project will be invited and asked to

provide their assessment on the results. This will provide a good insight into how the results might be taken up and essentially what kind of impact the project could have. The Action Leader believes RADPAR complements other activities at Member State or EU level and goes a long way to promoting policy transfer and shared best practices between the Member States.

3. EFHRAN

3.1 Summary

Electromagnetic fields of all frequencies represent one of the most common and fastest growing environmental influences, about which anxiety and speculation are spreading. All populations are now exposed to varying degrees of EMF, and the levels will continue to increase as technology advances.

The extent and diversity of EMF research activities makes it difficult to provide relevant, authoritative and timely input for policy development. There is a risk that some of this work could be misinterpreted or inappropriately applied to other sources or exposure conditions. In the context of the EU, it was envisaged that initiatives such as EMF-NET would address these issues properly. EFHRAN aims to take this further with the establishment of a risk assessment network on EMF that focuses on 1. Monitoring and searching for evidence of the health risks related to EMF exposure, 2. Characterising and quantifying these risks, 3. Enhancing the EC's ability to respond rapidly to health issues and concerns related to EMF and 4. Improving the knowledge base and dissemination of material on issues related to EMF and health.

On the basis of evidence reviewed the EFHRAN project can be considered to be dealing with an important area of public health. The establishment of an EU network providing relevant information to specific target groups in this area seems to be an appropriate overarching objective of the project. While several outputs have been delivered there is still limited information on the results of this project.

Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved as associated & collaborating partners	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
+++	++	+++	+++	+++	++	++	15	+++	1. Implementing EU legislation: 1.0 2. Economies of scale: 1.5 3. Promotion of best practice: 2.3 4. Benchmarking for decision making: 0.5 5. Crossborder threats: 1.5 6. Free movement of persons: 0.0 7. Networking: 3.0
EFHRAN proposal met the objectives of the Health Programme and the priority areas in the 2008 AWP.	Deemed an important area of public health and an EMF network is well suited to provide highly relevant information to risk managers and other target groups.	Strong evidence base exists from: - Previous EU HP Projects (e.g. EMF-NET) - Previous EU FP Projects - Wide range of projects, initiatives, organisations looking at this public health risk in MSs and internationally. - WHO International EMF Project	Previous EU Projects include: EMF-NET EMFnEAR GUARD	- WHO International EMF project - International Commission on Non-Ionizing Radiation Protection (ICNRP) - International Agency of Research on Cancer (IARC)	Principal stakeholders are considered to be government and health authorities (both at the EU level and Member State levels). Other stakeholders such as consumer associations, industry, regulatory bodies and scientific community.	Dissemination approach outlines target audiences, multipliers including 1) EC services and governmental authorities 2) Collaborating partners. 3) Other initiatives on EMF and health (COST BM0704 in Europe, WHO EMF project, outside Europe, etc.) and channels including: website, newsletters, presentations at conferences and workshops.	- 1 Lead Partner - 6 Associated Partners - 16 Collaborating Partners	Evaluation strategy in place and based on a Project Evaluation Plan (PEP). Responsibility of Evaluation Board. The PEP allows evaluation of 1. the implementation and 2. the success of project activities at both Consortium and single participant level against the project objectives and needs. The PEP makes use of a Logic Model (PEPLM).	Particularly strong in: 2. Economies of Scale - Proposal outlines the fact that only a European risk assessment network is large enough to make fruitful use of EMF-NET risk analysis, as a bridge between knowledge and action. Experience of EMF-NET in providing risk analysis, confirms that this type of initiatives makes sense only at European level. 3.Promotion of Best Practice - Europe is leading the world in the study of EMF and health issues. EFHRAN will allow Europe to continue playing a leading role in this field, serving as forerunner for all other countries worldwide. 7.Networking - A network is at the heart of this intervention. General objective of EFHRAN is "to establish a European health risk assessment network on EMF".

3.2 Key Facts

Calls for proposals:	2008
Proposal title:	European Health Risk Assessment Network on EMF
Acronym:	EFHRAN
Financing mechanism:	Project
Starting date:	February 1st 2009
Duration (in months):	36 months
EC contribution:	€ 600,000 (60%)
Total:	€ 1,000,000
Overall score achieved in Consolidated Evaluation Report:	71
Total criteria block: A, B, C	A: 31 B: 19 C: 21
Main partner:	Istituto di Ingegneria Biomedica, Consiglio Nazionale delle Ricerche – CNR-ISIB
Number of associated partners:	7 – IT, HU, DK, SP, FR, SL, UK
Number of collaborating partners:	16
Priority area:	**3.2.2.3.** *Risk Assessment Thematic Networks, to promote the establishment of a thematic network of scientific excellence for exchange and collaboration on a critical issue such as the possible impact to health of EMF.*
Action:	**3.2.2.** *Improve citizens' safety.*
Typology[10]:	Development action

3.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[11]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria. Please note that these criteria will be further refined for the Draft Final Report.

Project Success Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results)	**EFHRAN objectives relate to 1. network and to 2. produce/disseminate information:** The general objective of the EFHRAN project is to **establish a European health risk assessment network on EMF**. More specifically, EFHRAN

[10] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[11] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Project Success Criteria	Notes / Comments
- **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	intends to: i) Monitor and search for any evidence of health risks related to EMF exposure; ii) Characterize and, where appropriate, quantify potential health risk posed by EMF exposure; iii) Enhance the EC's ability to respond rapidly to health issues and concerns related to EMF using scientifically sound advice and analyses; iv) Improve the compilation of knowledge and its dissemination on issues related to EMF and health. Based on the desk research exercise the EFHRAN objectives are aligned to the HP objectives and the Priorities specified in the 2008 AWP. More specifically EFHRAN is directly aligned with 3.2.2.3. Risk Assessment Thematic Networks, to promote the establishment of a thematic network of scientific excellence for exchange and collaboration on a critical issue such as the possible impact to health of EMF.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Development Action**: Strong evidence base exists from: - Previous EU HP Projects (e.g. EMF-NET) - Previous EU FP Projects - Wide range of projects, initiatives, organisations looking at this public health risk in MSs and internationally. - WHO International EMF Project (See Context section and timeline below)
Clear target groups	Target groups defined in the proposal: Principal stakeholders are considered to be government and health authorities (both at the EU level and Member State levels) and the aim is that EFHRAN provides the first coordinated European health risk assessment on EMF exposure. There is also an intention to disseminate material to other stakeholders such as consumer associations, industry, regulatory bodies and scientific community.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use	Dissemination approach outlines target audiences, multipliers including 1) EC services and governmental authorities 2) Collaborating partners. 3) Other initiatives on EMF and health (COST

Project Success Criteria	Notes / Comments
the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	BM0704 in Europe, WHO EMF project, outside Europe, etc.) and channels including: website, newsletters, presentations at conferences and workshops.
Estimate the population reached (or targeted) by the action	No information available (see multipliers)
Matching of project's deliverables (if any) with project's objectives	Final Report not available to confirm this.
Use of multipliers	EFHRAN also intends to make effective use of communication multipliers including: 1) EC services and governmental authorities. Being recipients of project outcomes, they will mirror them among EC DGs and the Member States. 2) Collaborating partners. They could act as additional national mirrors for project activities. 3) Other initiatives on EMF and health (COST BM0704 in Europe, WHO EMF project, outside Europe, etc.).
Evaluation (provision of indicators)	Evaluation is the responsibility of an Evaluation Board (EB). The evaluation strategy is based on a Project Evaluation Plan (PEP). The PEP allows evaluation of 1. the implementation and 2. the success of project activities at both Consortium and single participant level against the project objectives and needs. The PEP makes use of a Logic Model (PEPLM), to be applied and evaluated during the project lifetime. PEPLM links project outcomes (short-, intermediate- and long-term) with project activities, outputs and inputs (or resources) in a systematic and visual way (table format) to present and share the Consortium understanding of the relationships among the resources that are operating in the project, the strategies/activities that EFHRAN is planning to provide/do, and the changes/results that EFHRAN is achieving, also in terms of impact generated in the various concerned audiences (EC, Member States authorities, etc.).
Sustainability plan	It is envisaged that the output of EFHRAN (a European EMF Risk Assessment Network) will form the input to an approach to EMF Risk Management.

3.4 Introduction

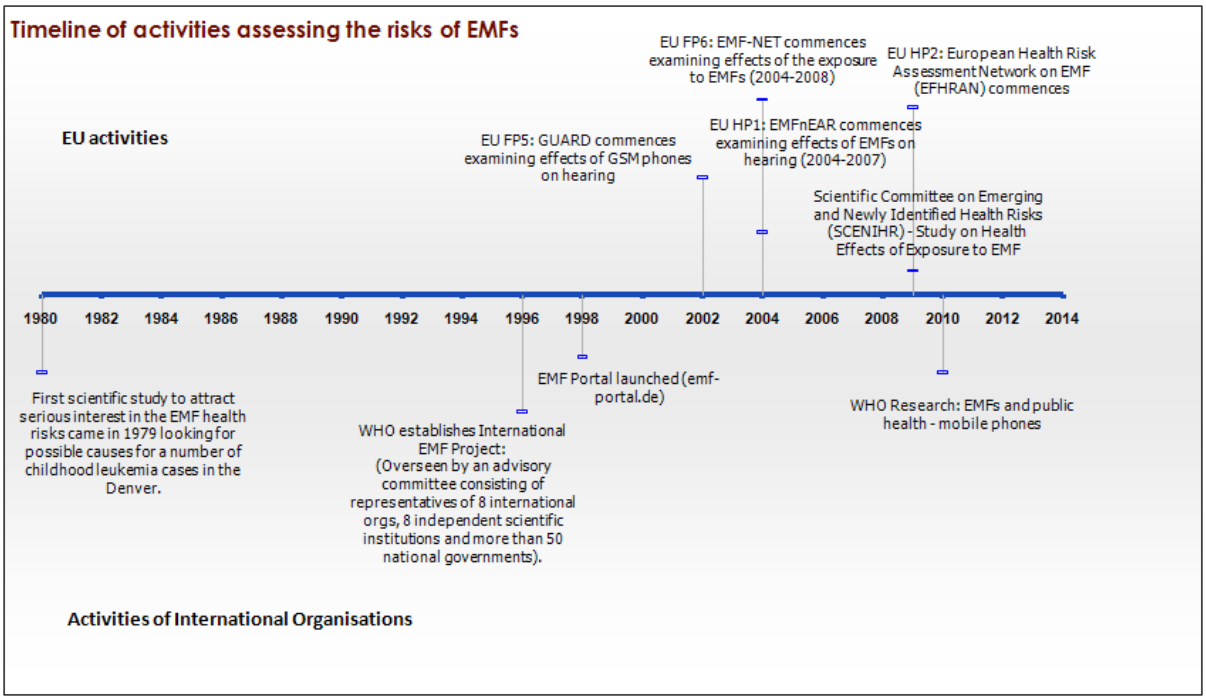
EMF is short for electromagnetic fields or sometimes known as electromagnetic radiation (EMR) or electromagnetic energy (EME). Electromagnetic fields are present everywhere in our environment - the earth, sun and ionosphere are all natural sources of EMF.

Electric and magnetic fields are part of the spectrum of electromagnetic energy which extends from static electric and magnetic fields, mains power frequencies (50/60Hz) through radiofrequency, infrared, and visible light to X-rays.

Electromagnetic fields of all frequencies represent one of the most common and fastest growing environmental influences, about which anxiety and speculation are spreading. All populations are now exposed to varying degrees of EMF, and the levels will continue to increase as technology advances.

3.5 Background / Policy Context

Figure 3 – Timeline of activities assessing the risk of EMFs



Europe is facing the burden of environmental exposures to new agents, potentially detrimental to health. Among them, electromagnetic fields (EMF) are one of the most diffuse and ubiquitous, especially as many new EMF-based technologies are being developed and commercialized.

The extent and diversity of EMF research activities makes it difficult to provide relevant, authoritative and timely input for policy development. There is a risk that some of this work could be misinterpreted or inappropriately applied to other sources or exposure conditions. In the context of the EU, it was envisaged that initiatives such as EMF-NET would address these issues properly. EFHRAN aims to take this further still.

EFHRAN activities and objectives are in line with Priority Areas of the 2008 Annual Work Plan 2008. The establishment of a risk assessment network on EMF and health is of strategic importance for Europe, contributing to improving the health of Europeans, by setting priorities, if and when needed, for interventions. This addresses the priority **3.2.2.3.** *Risk Assessment Thematic Networks, to promote the establishment of a thematic network of scientific excellence for exchange and collaboration on a critical issue such as the possible impact to health of EMF*.

The EFHRAN project aims to identify risks to health posed by EMF exposure and evaluate any possible impact and will complement national measures in tackling any avoidable health effects due to exposure, in line with the general priority action **3.2.2.** *Improve citizens' safety*.

3.6 Origins of HP project

Research on the health effects of EMF has been and is being carried out with the support of numerous international, national public and private funding bodies. Section 1.7 outlines some of the activities that preceded EFHRAN and were likely to have influenced it's being in some way or another. There are several pieces of research, mainly funded under the EU's Research Framework Programme, which the EHFRAN project leads on from. The most recent of these is EMF-NET, an initiative providing up-to-date scientific information on EMF and health issues in Europe which ran between 2004 and 2008.

3.7 Project Partners

Main Partner	Country	Organisation Status
Istituto di Ingegneria Biomedica, Consiglio Nazionale delle Ricerche – CNR-ISIB	**Italy**	**Public**

Associated Partners	Country	Organisation Status
National "Fréderic Joliot-Curie" Research Institute for Radiobiology and Radiohygiene – NRIRR	**Hungary**	**Public**
Università degli Studi di Genova – UNIGE	**Italy**	**Public**
Kraeftens Bekaempelse, Institute of Cancer Epidemiology – DCS	**Denmark**	**Private**
Fundació Centre de Recerca en Epidemiologia Ambiental – CREAL	**Spain**	**Private**
Centre National de la Recherche Scientifique – CNRS	**France**	**Public**
Institute of Non-ionizing Radiation – INIS	**Slovenia**	**Private**
Health Protection Agency – HPA	**UK**	**Public**

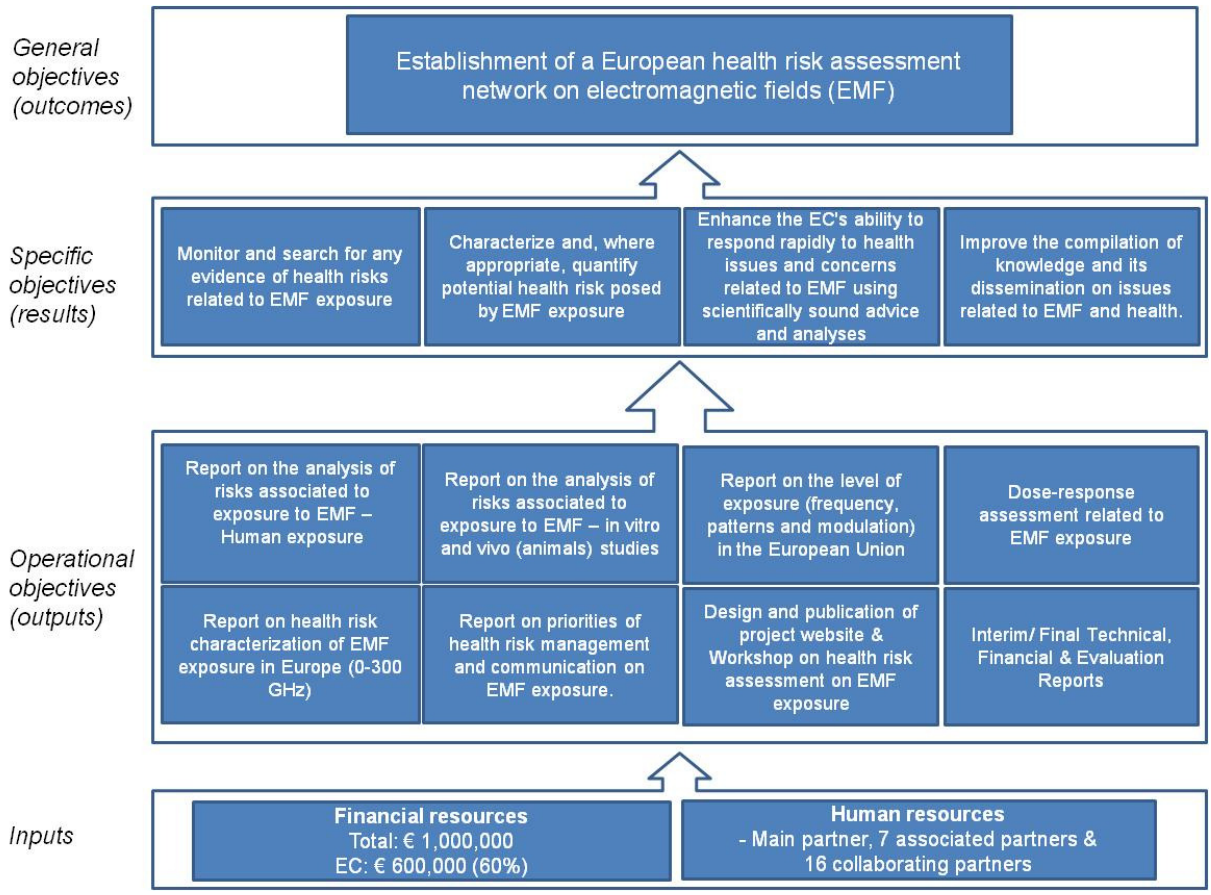
3.8 Overall project objectives / Intervention logic

The general objective of the EFHRAN project is to establish a European health risk assessment network on EMF. This network will make use of the expertise and experience in risk analysis of EMF-NET.

EFHRAN will facilitate effective health risk management and communication on EMF issues by EC and Member State authorities.

Based on an analysis of the proposal and interim report, the diagram below depicts the project's complete intervention logic. It shows a clear sequence of the general and specific objectives the EFHRAN project intends to achieve, the expected outputs, and the key inputs. The diagram also reflects a clear differentiation between the specific objectives and the outputs of the action. More specific details on each of these aspects is presented below.

Figure 4 - Intervention logic diagram for EFHRAN



Inputs:

Please find below a table detailing the EFHRAN budget providing costs for all inputs including staff, travel, equipment etc.:

Budget Overview		
E1a: Staff (public officials)	€ 80,340	
E1b: Staff (non public officials)	€ 998,934	
Total Staff (E1a + E1b)		**€ 1,079,274**
E2a: Travel	€ 76,200	
E2b: Subsistence allowances	€ 55,140	
Total E2 - Travel Costs and subsistence allowances (E2a + E2b)		**€ 131,340**
Total E3 – Equipment		€ 4,000
Total E4 - Consumables & supplies linked to the project		€ 16,500

Budget Overview		
Total E5 - Subcontracting costs	€ 0	
Total E6 - Other costs	€ 13,800	
Total Direct Eligible Cost		**€ 1,244,914**
Total E7-Overheads	€ 84,451	
Total Indirect Eligible Cost		**€ 84,451**
TOTAL EXPENDITURE		**€ 1,329,365**

Expected outputs:

Expected outputs	Achieved outputs (as per Interim Report)
Report on the analysis of risks associated to exposure to EMF – Human exposure	Due date: February 2010 Actual date: July 2010
Report on the analysis of risks associated to exposure to EMF – in vitro and vivo (animals) studies	Due date: July 2010 Actual date: July 2010
Report on the level of exposure (frequency, patterns and modulation) in the European Union	Due date: August 2010 Actual date: August 2010
Dose-response assessment related to EMF exposure	
Report on health risk characterization of EMF exposure in Europe (0-300 GHz)	
Report on priorities of health risk management and communication on EMF exposure.	
Interim Technical and Financial Reports	Actual date: August 2010
Final Technical and Financial Reports	
Design and publication of project website	Actual date: May 2009
Workshop on health risk assessment on EMF exposure	
Report on evaluation activities	

Expected aims/outcomes:

Aim	Indicators	Result (as per Interim Report)
To monitor, analyze and identify health risks due to EMF exposure on the basis of human studies.	EMF Risks & Hazards Percentage of the topics analyzed versus the estimated foreseen total mass of data.	No evidence currently available
To monitor, analyze and identify health risks due to EMF exposure on the basis of in vitro/in vivo studies	EMF Risks & Hazards Percentage of the topics analyzed versus the estimated foreseen total mass of data.	No evidence currently available
Quantitative EMF exposure assessment	EMF exposure assessment Percentage of the coverage of that task with respect to type of devices and geographical	No evidence currently available

Aim	Indicators	Result (as per Interim Report)
	coverage.	
Exposure-response assessment and related metric on EMF exposure	EMF Dose-response Percentage of the dose-response relationships defined versus the total risks identified in risk analysis.	No evidence currently available
Risk characterization and related indicators	EMF Risk assessment Percentage of the risk characterizations defined vs. the total risks identified in risk analysis/dose-response relationships.	No evidence currently available
Input to communication and risk management processes	The indicator is related of possible impact that, considering the time schedule of the activities, could be measured only after the end of the project	No evidence currently available

3.9 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 2 as set out in the Health Strategy (2008-2013). Objective 2: Protecting citizens from health threats: Health threats include infectious diseases (e.g. HIV/AIDS, tuberculosis, Creutzfeldt Jacob Disease, etc.) and **threats emerging from physical, chemical or biological sources**, including those relating to terrorist acts and environmental agents (e.g. **ionising and non-ionising radiation** and noise).

3.10 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified the following initiatives:

2. Other EU / DG SANCO projects

a. FP7 Projects:
- SEAWIND Sound exposure and risk assessment of wireless network devices
- MOBI-KIDs - Investigating cancer, mobiles and kids

b. EMF-NET: Effects of the exposure to electromagnetic fields: From Science to Public Health and Safer Workplace (March 1, 2004 - August 31, 2008 – Funded by the EC's 6th Framework Programme). The EMF-NET Consortium involves 41 participants, including all the coordinators of the EC (FP5) projects, coordinators of research projects at European national level (Finland,

France, Germany, Greece, Hungary, Italy, UK), and representatives of other EC and international activities, such as EC COST ACTION 281 and the WHO EMF project, associations of industries and manufactures, regulatory bodies, scientific associations, and trade union associations.
>> http://web.jrc.ec.europa.eu/emf-net/index.cfm

c. 2004-2007: Exposure at UMTS Electromagnetic Fields: Study on Potential Adverse Effects on Hearing EMFnEAR . Funded by EC Framework of the Programme of Community Action in the Field of Public Health
>>EMFnEAR website

d. 2002-2004: Perform B - In-vitro and in-vivo Replication Studies Related to Mobile Telephones and Base Stations.

e. 2002-2004: Potential adverse effects of GSM cellular phones on hearing GUARD. Funded by the European Commission - 5th Framework Programme.
>>GUARD website

f. 2002-2004: Risk evaluation of potential hazards from low energy electromagnetic field exposure using sensitive in vitro methods REFLEX. Funded by the European Commission - 5th Framework Programme.
>>Reflex

g. 2001-2004: THz-BRIDGE - Tera-Hertz Radiation in Biological Research, Investigation on Diagnostics and Study on Potential Genotoxic Effects**.** Funded by the European Commission - 5th Framework Programme.
>>Thz-Bridge

h. 2000-2004: International Case-Control Studies of Cancer Risk in Relation to Mobile Telephone Use – INTERPHONE. A project funded by the European Commission under the programme "Quality of Life and Management of Living Resources", Key Action 4 "Environment and Health".

i. >> European Cooperation in the Field of Scientific and Technical Research (COST): COST BM0704

j. >> European Cooperation in the Field of Scientific and Technical Research (COST): COST 281 - Potential Health Implications from Mobile Communication Systems

3. International Organisations involved in examining the effects of radon on public health:

a. WHO International EMF Project: As part of its Charter to protect public health and in response to public concern, the World Health Organization (WHO) established the International EMF Project in 1996 to assess the scientific evidence of possible health effects of EMF in the frequency range from 0 to 300 GHz. The EMF Project is open to any WHO Member State government, i.e. department of health, or representatives of other national institutions

concerned with radiation protection. The project is fully funded by participating countries and agencies.
>> International EMF Project
>> WHO Handbook "Establishing a dialogue on Risks from Electromagnetic Fields"

b. International Commission on Non-Ionizing Radiation Protection (ICNRP)
c. Bioelectromagnetics Society (BEMS)
d. IEEE Electromagnetic Compatibility Society
e. IEEE Standards in Education Web Portal
f. International Agency of Research on Cancer (IARC)

4. **Member State organisations involved in examining the effects of radon on public health:**
   a. EMF Portal (Germany): The EMF-Portal is a web-based information platform regarding the effects of electromagnetic fields on humans and on interaction with biological systems or body aids. It is provided for scientists, politicians, lawyers, physicians and interested citizens who want to be able make their own informed decisions.
   >> EMF Portal

   b. UK Stakeholder Advisory Group on EMFs

5. **3rd countries involved in examining the effects of radon on public health**:
   a. US:
   >> National Institute for Occupational Safety and Health (NIOSH), USA
   >> Federal Communications Commission (FCC), USA

   b. Japan:
   >> Telecommunications Bureau of the Ministry of Internal Affairs and Communications, Japan

   c. Switzerland
   >> Fact sheets on different EMF sources, Federal Office of Public Health (FOPH), Switzerland

6. **Other relevant Studies conducted in the area of EMF:**

1. >> Health Effects of Exposure to EMF. European Commission (SCENIHR), February 2009
2. >> Possible effects of Electromagnetic Fields (EMF) on Human Health. European Commission (SCENIHR), March 2007
3. >> National Institute of Environmental Health Sciences: NIEHS guide to EMF

3.11 Rationale behind selection procedures (consistency with HP objectives)

The evaluation report concluded that the EFHRAN proposal fully met the objectives of the Health Programme and the priority areas in the 2008 Work Plan. It went on to say that it deemed this an important area of public health and the network is well suited to provide highly relevant information to risk managers and other target groups, including the general

public. It will also help to transfer knowledge from more experienced to less experienced partners.

3.12 Involvement of decision makers (design of project / exploitation of results):

There is no evidence to suggest that policy/decision makers were directly involved in the design of the project. However it is evident at EU level, in certain MSs and further afield that this is considered a serious public health issue. The fact that there have been numerous interventions targeting the issue demonstrates some level of commitment by policy makers. It is envisaged that the results of this project will certainly be examined closely and potentially used for determining future policy and decision making by the Commission and Member States.

3.13 Dissemination

Target Audience

The principal stakeholders are considered to be government and health authorities (both at the EU level and Member State levels) and the aim is that EFHRAN provides the first coordinated European health risk assessment on EMF exposure.

There is also an intention to disseminate material to other stakeholders such as consumer associations, industry, regulatory bodies and scientific community. The plan is that this will take place indirectly, mainly through governmental agencies themselves, as well as through communications and fact sheets on the project website.

Tools

Website
During the first year of the project the EHFRAN website (http://efhran.polimi.it) has been the main channel through which the communication has taken place. The website contains all the information related to the project ranging from its objectives and the partners involved through to the latest project outputs including papers and presentations from recent conferences.

Email
Project results and developments have also been communicated via email. The project currently has a database of 250 email addresses in Europe and beyond.

Conferences, workshops and meetings
Several partners have also had the opportunity to present the EFHRAN project at conferences and meetings involving entities that have a direct interest in this area of public health. For example, during the first year at: *International EMF Project, 14th and 15th International Advisory Committee Meeting, WHO, Joint Meeting of the European BioElectromagnetics Association and the Bioelectromagnetics Society.*

Use of Multipliers
The project also intends to make effective use of communication multipliers including:

1) EC services and governmental authorities. Being recipients of project outcomes, they will mirror them among EC DGs and the Member States.

2) Collaborating partners. They could act as additional national mirrors for project activities.
3) Other initiatives on EMF and health (COST BM0704 in Europe, WHO EMF project, outside Europe, etc.).

3.14 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value EFHRAN fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		EFHRAN Project
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	1.5
3.	Promotion of best practice:	2.3
4.	Benchmarking for decision making:	0.5
5.	Cross border threats:	1.5
6.	Free movement of persons:	0.0
7.	Networking:	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

3.15 Sustainability

In terms of project sustainability the Action leader was clear in that the output of EHFRAN (a European EMF Risk Assessment Network) should form the input to an approach to EMF Risk Management. The results of the EFHRAN project should prove useful for the risk management strategies and activities in the future. In some MSs this might mean new legislation and regulation.

The Action Leader is of the view that this type of project is about producing well founded independent scientific information. While the EFHRAN project seeks to provide information to a whole range of stakeholders including decision makers, the Action Leader explained that it was not the role of anyone on the project to "influence" stakeholders. Additionally, the

"owner" of the project outputs is the EC and it should be playing a dissemination role once the project comes to an end along with project partners.

3.16 Impact to be expected

It is currently too early to provide information on the indicators specified against the outcomes of the project. According to the Action Leader, one empirical metric that will be used to measure impact is the extent to which the results of EFHRAN are cited in future reports, studies and presentations. As mentioned under sustainability, it is envisaged that the results of EFHRAN will feed into the development of future Risk Management strategies and activities. In order to provide further insight into impact there are plans to survey stakeholders (and key experts in the field) towards the end of the project in order to get their input on what is likely to come from the results of EFHRAN.

4. JA for ECHIM

4.1 Summary

JA for ECHIM is a three-year project to develop and implement health indicators and health monitoring in the EU and all EU Member States. The aim of the project is to consolidate and expand the ECHI Indicator system towards a sustainable health monitoring system in Europe. The focus is on collecting and disseminating comparable health data and information based on the ECHI shortlist. The work is carried out in close collaboration with Member States, the EC, Eurostat, WHO/Euro, OECD and other international organisations with the aim of supporting the EU Health Strategy.

ECHIM is the first serious effort to simultaneously improve health data and indicators as well as their analysis in all Member States and in the EU. The proposal document argues that the use and utility of health indicators is essential for national health policy. The consolidated evaluation report agrees that there is no question of the project's contribution to the Second Public Health Programme, but that there is still a need to produce the evidence that the indicators system has an impact on policy making decisions at national level.

Based on the first interim report (submitted in March 2010, one year into the project) the project is going to plan. The report acknowledges some expected delays, in particular as not all of the Member States involved have been able to commit the necessary resources during the first year of the project. At a central level, the interim report highlights that the overlaps of Commission actions (central data base) and the original tasks of ECHIM has led to a delay of 6 to 12 months in the implementation of the Joint Action.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to which Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
JA for ECHIM	+++	+++	++	+++	+++	+	+	15	++	EU Added Value Criteria / JA FOR ECHIM / Joint Action 1. Implementing EU legislation: 1.0 2. Economies of scale: 0.5 3. Promotion of best practice: 0.0 4. Benchmarking for decision making: 1.8 5. Cross border threats 0.0 6. Free movement of persons: 0.0 7. Networking: 3.0
	Action addresses the HP objectives and those of the 2008 AWP by transfering the ECHI system to all EU Member States towards a sustainable monitoring system in Europe.	The action has a strong rationale for funding, as it is fundamental for generating and disseminating health information.	The strategic relevance of the action is given, though there are concerns about the ultimate impacts on health of the ECHI system proposed.	ECHIM continues the work of the previous ECHI, ECHI-2 and ECHIM projects.	There are several projects on the development of health indicators in Europe. However, ECHIM is the first effort to simultaneously improve health data and indicators as well as their analysis in all Member States.	Target groups are not very well defined / quantifiable. Those mentioned in the proposal are: - National experts in R&D centres and key persons in MS administrations; - Network of health indicator experts at EU/international levels, including DG SANCO network, Eurostat, WHO and OECD; - Organisations in the areas of health promotion and adequacy and quality of care.	A high level dissemination plan is set out in the proposal which does not provide too much detail on the action's intended communication. Methods proposed include: - website - Meetings - local channels - Scientific journals	- 1 Lead partner - 4 Associated partners - 12 Collaborating partners	a) Process evaluation: Processes and information dissemination at EU and MS level will be monitored by the main partner; b) Outcome evaluation: Assessment of the indicators refined and developed, completeness of the Documentation Sheets, completeness of the ECHIM products website and database, number of new indicators and data sources implemented in each of the Member States, guidelines prepared and made available, information disseminated, health data becoming available, descriptive tabulation for the EU health report prepared, final report published.	Particularly strong in: 7. Networking - it is a very relevant aspect of the action and one of the keys to its success; 4. Benchmarking for decision making - the action aims to produce the evidence that the indicators system has an impact on policy making.

4.2 Key Facts

Calls for proposals:	2008
Proposal title:	Joint Action for European Community Health Indicators and Monitoring
Acronym:	JA FOR ECHIM
Financing mechanism:	Joint Action
Starting date:	1st January 2009
Duration (in months):	36 months
EC contribution:	€ 1,498,473
Overall score achieved in Consolidated Evaluation Report:	73
Total criteria block: A, B, C	A: 36; B: 19; C: 18
Main partner:	National Institute for Health and Welfare (THL), Finland
Number of associated partners:	4
Number of collaborating partners:	12
Priority area:	3. GENERATE AND DISSEMINATE HEALTH INFORMATION AND KNOWLEDGE (HI-2008)
Action:	3.1 Development of a sustainable health monitoring system
Typology[12]:	Implementation action

4.3 Overview of project success criteria

The following table of project success criteria has been developed based on a strategic document produced by the EAHC "EU Health Programme Evaluation"[13]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

[12] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[13] The document was developed by Guy Dargent and Michel Pletschette.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	The action addresses the following 3 objectives: **Objective to produce/disseminate information:** One of the aims is collecting and disseminating comparable health data and information based on the ECHI shortlist. **Objective to improve the performance of the health system**: The project aims at consolidating and expanding the ECHI Indicator system towards a sustainable health monitoring system in Europe. **Objective to network** –JA for ECHIM aims at developing and implementing health indicators and health monitoring in the EU and all EU Member States.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Implementation action**: JA for ECHIM is the backbone for implementing health indicators in Member States and at EU-level. It is expected to result in comprehensive and comparable information on health in all MSs. The main added value of the action is to contribute with comparable data on health in the different Member States. The intervention is composed of country specific implementation plans guiding the work of national experts and key persons in the Member State administrations. The international network of health indicator experts will support the development of indicators and their implementation in all countries.
Clear target groups	Target groups relatively well defined/quantifiable following the concept of providing comparable health information among and between EU Member States: Target groups are decision/policy makers that are using health information statistics to base action on, such as: – Health Ministry key officials, key persons in Statistical Offices, in Public Health Institutes, and in organisations involved in data provision. The latter can be chiefs in the hospitals, in local authorities and also in regional governments. They can also be private research organisations. Depending on the organisation of health care provision the number of contact persons at regional and local level can become very large.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and	A very high level dissemination plan is set out in the proposal which does not provide too much detail on the action's intended communication. The main tasks listed are as follows: – To communicate with key stakeholders at EU level and in

Criteria	Notes / Comments
effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	Member States. – To produce information material and distribute it via the website, e-mail and other means at EU level and to Member States' administrations. – To support MS level implementation processes by communications. – To communicate findings and proposals to the relevant scientific communities. The methods proposed include: – Using the project's progress website (www.echim.org), the future ECHIM products website, the EU public health portal (links) and e-mail to spread information. – Informing about progress and proposals in the meetings of WP Indicators and in other suitable DG SANCO meetings. – Spreading information to Member States through suitable local channels selected in co-operation with national representatives. – Publishing articles about the project, its findings and proposals in scientific journals. – Speaking about the project in European scientific and professional meetings.
Estimate the population reached (or targeted) by the action	The population reached by this action would be defined as: – The fraction of population in participating Member States, which, based on the comparable information provided through the successfully implemented ECHI indicator system, would be positively affected by actions/ decisions/ programmes to prevent ill health, that otherwise would not have been detected.
Matching of project's deliverables (if any) with project's objectives	According to the Interim Report available, the action has been run according to the original plan outlined in the agreement. A large proportion of the work has meant that the involved MSs need to be actively involved in creating national plans and initiating implementation. Not all of them have been able commit the necessary resources meaning that there have been some (expected) delays. On the central level the overlaps of Commission actions (central data base) and the original tasks of ECHIM has created problems and delays in the joint action, as the Report highlights that ECHIM was not informed of such a situation. Overall, in the interview with the project leader, it was also highlighted that the financial crisis affecting the EU also led to some delays in the implementation of the work packages, in particular due to the difficulties encountered at Member State

Criteria	Notes / Comments
	level.
Use of multipliers	N/A
Evaluation (provision of indicators)	An external evaluation is proposed and indicators defined to an acceptable degree of detail: **For Implementation of Health Indicators:** **Process indicators:** Input (by country and in all countries): a) Preparatory steps - Negotiations in the country initiated: in 50% by 09/2010, in remainder by 02/2011 - Communication in place: in 50% by 12/2009, in remainder by 06/2010 - Negotiations successful (i.e. leading toward an implementation plan): 30% by 03/2010, 50% by 09/2010, 100% by 06/2011. b) Implementation plan - Drafting of plans in progress: 30% by 03/2010, 60% by 09/2010, remainder by 03/2011 - Implementation plans accepted by ECHIM and by country: 30% by 03/2010; remainder by 03/2011 c) Output: Health information system: - Implementation work in progress: 30% by 09/2010, remainder by 03/2011 - Health indicators (number) and topics implemented: probably not a relevant indicator, indicator to be assessed by 3/2010 - Health data available (number, percentage and topics): indicator to be determined by 3/2010 **- Outcome indicators:** Coverage and its improvements: - Coverage of ECHI Indicators: average of countries 50 % by 03/2011 - Coverage of data sources: average of countries 50% by 03/2011 - Test version of new data flow and data available as a prototype: prototype by 6/2011(qualitative indicator) - For maintenance of ECHI Indicators: Number of indicators

Criteria	Notes / Comments
	added and deleted: enumerated by 9/2011.
Sustainability plan	Even though there is no reference to a sustainability plan in the proposal, being a Joint Action between EC and EU Member States, sustainability is, for instance, addressed by integrating the ECHI database in DG SANCO Health Information activities, namely the HEIDI datatool (http://ec.europa.eu/health/indicators/indicators/index_en.htm). Nevertheless, sustainability of Member State activities shall be further developed in the remainder of the Joint Action.

4.4 Introduction

Health monitoring comprises the gathering, analysis, presentation, dissemination and interpretation of health and welfare information for health policy and planning. Such a development in all Member States takes years of continued work and commitment, and needs a long-term vision.

ECHIM (2005–2008) laid the foundation for indicator implementation. It defined the ECHI shortlist to its current form, checked the availability of data in Member States by ECHIM Survey and Bilateral Discussions, and produced the Final Report where the whole process was documented. It was a logical continuum of ECHI and ECHI-2, but still a theoretical project and preparation for the next practical phase. Joint Action for ECHIM develops indicators and intends to implement them in all Member States. It is one of the few practical development and implementation actions in the Health Information Strand.

The project is highlighted to be of strategic relevance as it is the backbone for implementing comparable health indicators in Member States and at EU level. It will result in comprehensive and comparable information on health in all Member States. Without its efforts the EU would continue to have very uneven data on health in different Member States without any comparability.

4.5 Background / Policy Context

Public health policies aim at maintaining and improving the health of citizens, including the reduction of health inequalities. These policies have to be based on factual information, in other words on relevant data and indicators.

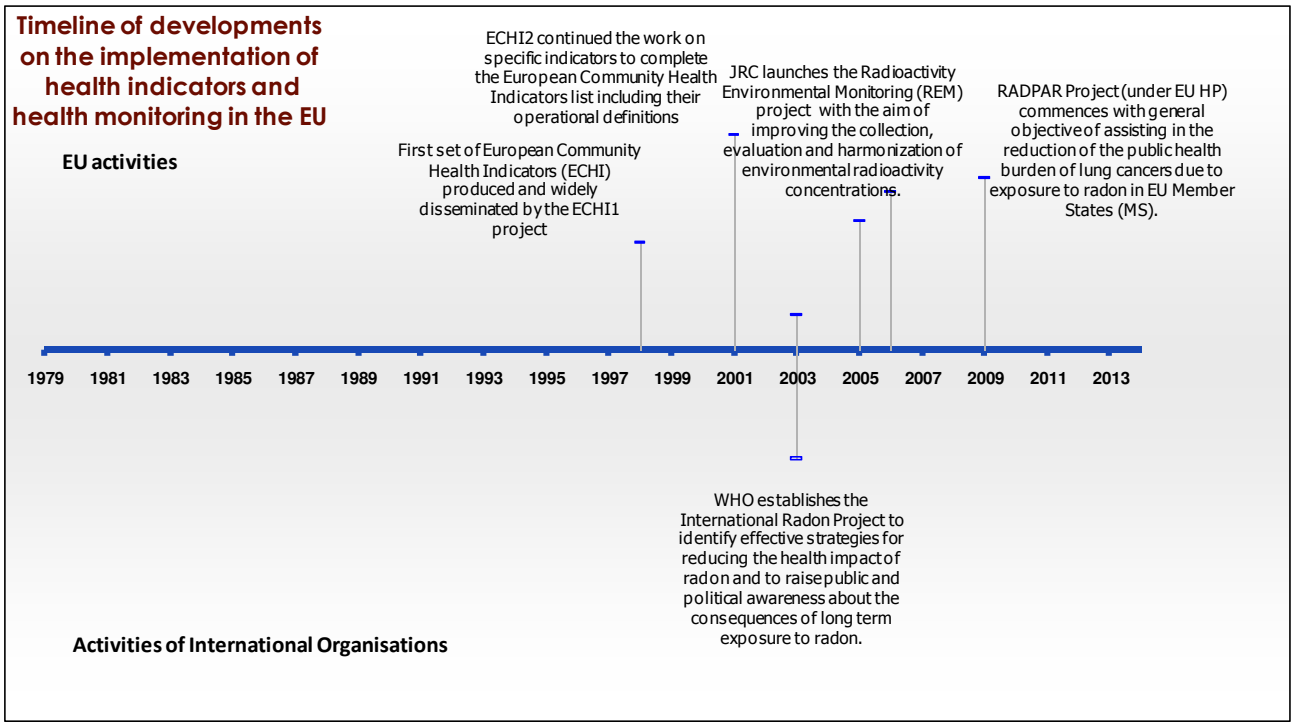
Well targeted promotion and protection of health are impossible without a comprehensive health information system. The European Parliament has been calling for an effective health monitoring system since the 1990s. In 2009 (when JA for ECHIM was awarded funding by the Commission) that system had been under construction in the EU for more than 11 years.

Key outcomes so far have included the ECHI indicators and plans for European Health Interview Survey and European Health Examination Survey. Working Party Indicators and ECHIM have been successful in creating a solid foundation for implementing health indicators in the Member States. In the future, analysis of the results on health trends and health differences between Member States and population groups will allow the EU and its Member States to assess health needs, to target health policy interventions and assess their effects as well as to plan health care. Major implementation efforts will be needed in the years to come.

The work of JA for ECHIM is firmly anchored to major previous achievements: it leans on previous EU work (Public Health Programme, Eurostat), and in particular builds strongly on its predecessors ECHI, ECHI-2 and ECHIM projects. The knowledge of European health surveys and health survey networks is based on national experiences but especially on HIS/HES and EUHSID projects and their survey database, FEHES (Feasibility of a European Health Examination Survey), EHRM (European Health Risk Monitoring Project) and previous WHO work such as EUROHIS and MONICA. Furthermore, the contributions of Eurostat working groups and task forces and the progress made in the European Health Interview Survey (EHIS) and European Health Survey System (EHSS) are also taken into account.

The figure below provides a brief overview of the development of the health information system in the EU.

Figure 5 - Timeline of developments on the implementation of health indicators and health monitoring in the EU



JA for ECHIM is of particular relevance in terms of the current Health Information strategy of the EC, which has adopted a knowledge management approach where the main focus is on analysing, disseminating and applying health information at European level, including customising information for specific users. The Commission's strategy aims to set priorities for European health information in order to help measure progress towards increasing the number of healthy life years, focusing on the major part of the burden of ill-health. Furthermore, its goal is to develop information regarding key determinants of ill-health and interventions to address them. In co-operation with ECDC, as well as other relevant agencies and bodies the strategy aims to ensure that information is provided on threats to health, including but not limited to communicable diseases. Health strategy wishes also to develop better information on healthcare quality and outcomes, focusing in particular on avoidable mortality as a result of healthcare, as well as better information on the efficient and effective use of innovations in healthcare, and better information on cross-border aspects of health systems.

The increased recognition of need for regional (sub-national) indicators should be also noted since regions are gaining importance in political and administrative terms in the European Union. This work has been mainly done under the auspices of ISARE (Indicateurs de Santé dans les Régions de l'Europe) project where regions were classified and indicators developed.

4.6 Origins of HP project

As highlighted in the previous section, ECHIM continues the work of the previous ECHI, ECHI-2 and ECHIM projects:

The origin of ECHIM can be traced back to the Health Monitoring programme 1998-2002[14]. Many of the topic specific projects co-funded hereunder have contributed to the definition and collection of indicators, hence one could say that ECHIM feeds from many important sources. The more recent familiar sources, to name a few, comprise reports on the organisation of health monitoring, initial indicator projects (since 2000), in particular ECHI (1998-2001) and ECHI-2 (2002-2004) (health indicators) and EUHPID (health promotion indicators), other content-specific projects such as those concerning health determinants, diabetes, respiratory and cardiovascular diseases, and horizontal projects such as EUPHIX (data presentation), EUHSID (or HIS/HES, a database comprising all European national HISs and HESs), ISARE III (regional indicators), and FEHES (Feasibility of a European Health Examination Survey).

The predecessor ECHIM project (2005-2008) was selected for funding by the European Commission in 2005 in order to put the ECHI system (European Community Health Indicators) in place.[15] The aim of the previous ECHIM project was to lay the foundation for the further development of health indicators and to initiate the implementation of these health indicators in all EU Member States.

Through Joint Action for ECHIM, the long-term theoretical expert work on indicators initiated more than 10 years ago can now be implemented. Financing for joint actions is provided by the European Commission and forms the basis for a common effort by Member States.

4.7 Overall project objectives / Intervention logic

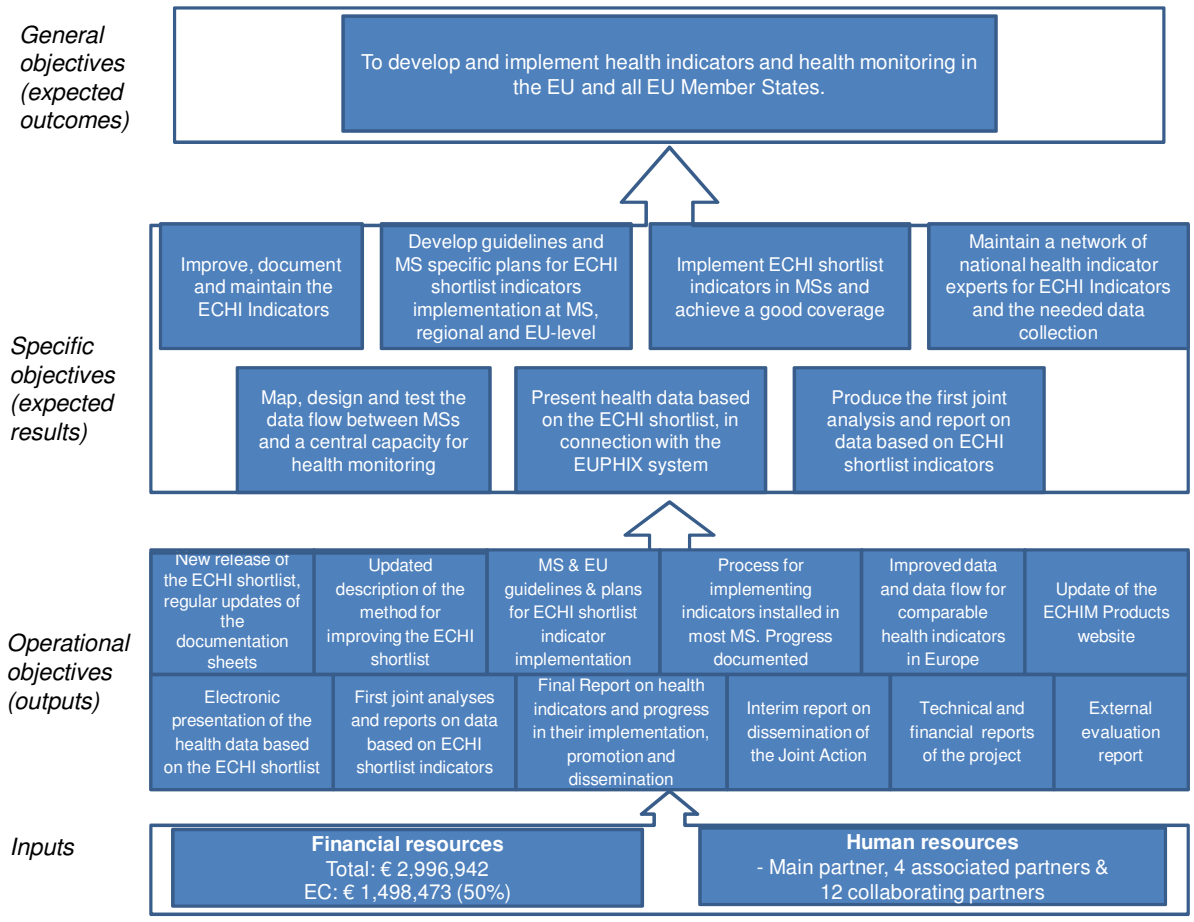
The general objective of the Joint Action for ECHIM is to consolidate and expand the ECHI Indicator system towards a sustainable health monitoring system in Europe. The focus is on collecting and disseminating comparable health data and information based on the ECHI shortlist. The work is being carried out in close collaboration with Member States, the EC, Eurostat, WHO/Euro, OECD and other international organisations with the aim of supporting the EU Health Strategy.

Based on an analysis of the proposal, the diagram below depicts the action's complete intervention logic. As reflected in the graph, the general objective clearly reflects the overall aim of the action. However, there is some overlapping at the next two levels between the specific objectives and the expected outputs, as some of the specific objectives could be considered as outputs.. More specific details on each of these aspects is presented below.

[14] See, for example, http://ec.europa.eu/health/programme/policy/eight_programmes/monitoring/index_en.htm and http://ec.europa.eu/health/indicators/indicators/index_en.htm.

[15] ECHIM was funded by the Commission under the Programme of Community Action in the Field of Public Health 2003–2008/Strand of Health Information and Knowledge.

Figure 6 - Intervention logic of JA for ECHIM



Inputs:

Please find below a table detailing the JA for ECHIM budget providing costs for all inputs including staff, travel, equipment etc.:

JA for ECHIM Budget Overview		
E1a: Staff (public officials)	€ 1,195,247	
E1b: Staff (non public officials)	€ 1,251,162	
Total Staff (E1a + E1b)		**€ 2,446,409**
Total E2 – Travel costs and subsistence allowances	€ 168,840	
Total E3 – Equipment	€ 18,000	
Total E4 – Consumables & supplies linked to the project	€ 0	
Total E5 – Subcontracting costs	€ 47,000	
Total E6 – Other costs	€ 120,634	
Total Direct Eligible Costs		**€ 2,800,883**
Total E7-Overheads	€ 196,059	
Total Indirect Eligible Costs		**€ 196,059**
TOTAL EXPENDITURES		**€ 2,996,942**

Expected outputs:

As reflected in the table below, the majority of the expected outputs listed in the proposal are on-going tasks according to the Interim Report of the action.

Expected outputs (as per proposal)	**Nature**	**Achieved outputs (as per Technical Implementation Report)**
A new release of the ECHI shortlist, regular updates of the Documentation sheets	Improvement and refinement of existing indicator definitions as well as some additions and possibly deletions	On-going task as per Interim Report
Updated description of the method for improving the ECHI shortlist	Procedure accurately documented	On-going task as per Interim Report
MS and EU specific guidelines and plans for ECHI shortlist indicator implementation	Preparation of international and EU-specific guidelines, which will serve as a reference for the MS and regional guidelines	On-going task as per Interim Report
An ongoing process for implementing health indicators installed in most MS and progress documented	Progress and outcome documented in the Final Report	N/A
Improved data and data flow for comparable health indicators in Europe with documented description	Detailed description of data flow mapping and design for comparable health indicators in Europe produced by JA for ECHIM.	On-going task as per Interim Report
Update of the ECHIM Products website containing all relevant meta-information on ECHI Indicators	The information includes the Documentation Sheets, the implementation status in the Member States, and the results of the data flow inventory	On-going task as per Interim Report
The electronic presentation of the health data based on the ECHI shortlist, in connection with the EUPHIX system	Data connected with all shortlist indicators will be presented for as many MS as possible and as advanced as possible	Included in the DG SANCO Health Information activities, namely the HEIDI data tool
The first joint analyses and reports on data based on ECHI shortlist indicators	Report containing the outcomes and interpretations of the first analyses of the enhanced data set	On-going task as per Interim Report

The Final Report of the JA for ECHIM on health indicators and progress in their implementation, promotion and dissemination	Final Report will be published consolidating the experience of the first 3 years of JA for ECHIM	N/A
An Interim report on dissemination of the Joint Action	Promotional and training materials and a newsletter will be issued to support the implementation process	On-going task as per Interim Report
Technical reports according to the specifications of EAHC	Technical and Financial reports will be prepared	On-going task as per Interim Report
External evaluation report	External evaluation report will be prepared	N/A

Expected aims/outcomes:

The expected outcomes are: new releases of the ECHI shortlist at 2–3 year intervals; a formal method to evaluate and update the ECHI shortlist; country specific guidelines for ECHI shortlist indicator implementation; an ongoing process for implementing health indicators to be implemented in most MSs by 2013; enhanced data and methods for analysing and presenting comparable health indicators in Europe; the first joint analyses and reports on data based on ECHI shortlist indicators by 2011; a website containing all relevant information on ECHI Indicators; the presentation of data for the health indicators in an existing website system, an interim Joint Action for ECHIM report on health indicators and their implementation by 2011.

Aim (as per proposal)	**Indicator**	**Outcomes (as per Technical Implementation Report)**
1. To improve, document and maintain the ECHI Indicators	For Implementation of ECHI Indicators (Objectives 1 to 3): • Country negotiations initiated, communications in place, negotiations successful (100% in June 2011) • Implementation plans accepted by ECHIM and by country • Implementation work in progress and health data available • Increased coverage of ECHI indicators and data sources • Test version of new data flow and	*Ongoing tasks as per Interim Report*
2. To develop guidelines and MS specific plans for ECHI shortlist indicators implementation at MS, regional and EU-level, as needed		
3. To implement ECHI shortlist indicators in MSs and to achieve a good coverage		

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
	data available as prototype	
4. To maintain a network of national health indicator experts for ECHI Indicators and the needed data collection	For maintenance of ECHI Indicators (Objectives 4 and 5): • Number of indicators added and deleted – enumerated by 09/2011	*Ongoing tasks as per Interim Report*
5. To map, design and test the data flow between MSs and a central capacity for health monitoring		
6. To present health data based on the ECHI shortlist, in connection with the EUPHIX system	For documentation of ECHI Indicators (Objectives 6 and 7): • Project websites and EC Public Health Portal up-to-date regarding health indicators, Documentation Sheets and progress of implementation	*Ongoing tasks as per Interim Report*
7. To produce the first joint analysis and report on data based on ECHI shortlist indicators		

4.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Principle 1 as set out in the Health Strategy (2008-2013):

- A strategy based on shared health values – Action: System of European Community Health Indicators with common mechanisms for collection of comparable health data at all levels, including a Communication on an exchange of health-related information (Commission).

4.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

JA for ECHIM and its predecessors (ECHI I, ECHI II and ECHIM) are considered to be a key action for the development of the EU health information system. In particular, the use and utility of health indicators is highlighted to be essential for national health policy.

There are quite a few related indicator projects that JA for ECHIM interacts with/has as reference. The majority of the projects listed below are developed at EU level with assistance from the Member States. These are:

1. Other EU / DG SANCO recent projects[16]

[16] As highlighted above, the origin of ECHIM can be traced back to the Health Monitoring programme 1998-2002 . Many of the topic specific projects co-funded hereunder have contributed to the definition and collection of indicators, hence the list of other EU/DG SANCO projects could be broadened to include earlier projects.

- **ECHI – European Community Health Indicators project (co-funded by DG SANCO, 2004-2007)**: The predecessor of ECHIM resulted in a database which contains data for almost half of the ECHI shortlist indicators. For the indicators where it is considered useful or appropriate, stratification by gender and age is applied. The database also generates diagrams and thematic maps.
- **EUPHIX – European Public Health Information, Knowledge & Data Management System (co-funded by DG SANCO, 2003-2006)**: The aim of the EUPHIX is to develop a prototype for a sustainable, web-based health information system for the EU, providing health professionals, policy makers and other interested users with relevant, structured information on issues of public health across the EU.
- **EUHSID – European Health Surveys Information Database (co-funded by DG SANCO, 2004-2007)**: The project maintains and updates a database of the characteristics of major Health Interview Surveys (HIS) and Health Examination Surveys (HES) in Europe. Its main objectives are to gather information on health survey design, questions and examination protocols, follow the development of recommendations and new instruments or protocols for health surveys, assess and enhance comparability of health surveys and standardise health surveys at a European level.
- **EHES – European Health Examination Survey (co-funded by DG SANCO, 2009-2011)**: The survey includes an interview and physiological and clinical measurements. The countries can include various additional measurements in the survey, such as functional capacity of the elderly. The purpose of the EHES is to provide data for the national and Europe wide planning and evaluation of health policies, health promotion and research.
- **ISARE – Health Indicators in the European Regions (co-funded by DG SANCO, 2003-2006)**: This was a pilot project to test the feasibility of gathering health data at sub-national level within the EU. Over time, this project should lead to recommendations permitting easier integration of regional health data into the European databases.
- **MINDFUL – Mental Health Information and Determinants for the European Level (co-funded by DG SANCO, 2003-2006)**: The aim of MINDFUL was to improve the status of mental health information within the EU by building on previous work in this area and also by widening the scope of the mental health monitoring systems to cover – not only mental ill-health – but also positive mental health and mental health promotion and prevention of mental disorders. The MINDFUL-35 list of mental health indicators is based on the ECHI lists.
- **FEHES – Feasibility of a European Health Examination Survey (co-funded by DG SANCO, 2005-2007)**: The objective is to contribute to the development of the European Health Survey System by examining and analysing the feasibility of carrying out a European Health Examination Survey (HES) or repeated HESs in EU Member States.
- **EUROTHINE – Tackling Health Inequalities in Europe (co-funded by DG SANCO, 2003-2006)**: The project aims at facilitating such mutual learning by collecting and analysing information from different European countries that will help policy-makers at the European and national level to develop rational strategies for tackling socioeconomic inequalities in health.
- **EHEMU – European Health Expectancy Monitoring Unit (co-funded by DG SANCO, 2003-2006)**: The main aim of EHEMU is to provide a central facility for the co-ordinated analysis and synthesis of life and health expectancies to add the quality

dimension to the quantity of life lived by the European populations, provide evidence of inequalities between Member States and highlight potential targets for public health strategies both nationally and at a pan-European level.

- **EURO-URHIS – European Urban Health Indicators System (co-funded by DG SANCO, 2006-2008)**: The project aims to develop a comprehensive urban health information and knowledge system to help to identify and prioritise urban health problems, enable the monitoring of the effects of actions taken to address them, ensure timely access to information, contribute in building advocacy, communication and education strategies.
- **EGOHID – European Global Oral Health Indicators development, phase II (co-funded by DG SANCO, 2005-2008)**: The general objective of EGOHID is to support EU MS in their efforts to reduce the public heath impact of morbidity and disability related to oral diseases. As part of the Health Information and Knowledge System, the oral health project objective is to provide quality, relevant and timely data, information and knowledge in order to support public health decision-making at European, national, sub-national and local level.
- **EUPHORIC – European Public Health Outcome Research and Indicators Collection (co-funded by DG SANCO, 2003-2007)**: The project aims to define a common set of outcome indicators in some clinically relevant areas and validate them among the participating European countries.

2. International Organisations involved developing health indicators:

- **OECD Health Care Quality Indicators Project**: The objective of the OECD HCQI Project is to track health care quality by developing a set of indicators that are based on comparable data and can be used to raise questions for further investigation on quality differences across countries.

4.10 Rationale behind selection procedures (consistency with HP objectives)

The evaluation report concluded that the JA for ECHIM meets the objectives of the Health Programme (2008-2013) and the Annual Work Plan, more explicitly objective 3.4.1.2. Health indicators of the 2008 Work Programme:

Objectives of Priority area (AWP 2008, p. 52)
Further development of the ECHI system to cover a broad range of health indicators from all Member States (creation of fact sheets definitions, implementation of ECHI in each member State and at EU level, design of further steps, design on a EU level plan for the health information system and test the data flow between Member States and a central EU capacity for health monitoring). Activities to develop the ECHI shortlist related to the development of health promotion, prevention, and public policy indicators, including tobacco control. [Financing mechanism: Call for tender or joint action]

The evaluation report also concluded the following points for the JA for ECHIM proposal:

- Taking into account the objective of the project which is to transfer the ECHI system in all the Member States, there is no question of the project's potential for contribution under the PHP.

- The strategic relevance judged to be good even if the contribution to health is not demonstrated.
- Even though a lot of Member States are participating and the transfer of EU indicators quality label into the MS indicators system represents an EU added value, there are important concerns about the ultimate impacts on health of such a system.
- Geographical coverage is good but not enough – all Member States would have to participate
- The information brought by indicators is an important factor but no impact on citizens' health has been demonstrated so far. It is important to show that the indicators system has an impact on policy making decision. The dataset has to be used in order to have an impact on national policy
- Ambitious intentions, but would be important to dig deeper into how these intentions will be achieved
- Commission concerned about the Return on Investment, and the duplication of roles between the project and Eurostat, OECD, WHO database. In addition, the project seemed to the Commission to be quite isolated in the context of the EU Health Strategy.
- Evaluation and dissemination strategies – not clearly or adequately developed in the proposal
- No clear management strategy. The main question for the Commission was if the project represented good value for money.

In light of the points above, but also taking into account that the work of the applicants is the best there is in Europe in the field, the Evaluation Committee highlighted that the main points that needed to be addressed by the applicants during the negotiation procedure were:

- a supervision and monitoring of the project to be put in action and external dissemination to be re-worked
- clear need of an external evaluation of the project
- evidence on the impact of indicators on citizens' health to be provided
- the budget allocated to the MS through the budget category "other costs" to be explained with all details
- more MS to be taken on board as associated partners
- the budget to be reduced to 3.5 million Euros and the co-funding to be limited to 50% which is the basis of a joint action.

4.11 Involvement of decision makers (design of project / exploitation of results):

According to the action leader, the main target group and working party of JA for ECHIM are the local experts and administrators appointed to work in each of the countries. These people have been kept involved in the design and implementation of the action, and they are also involved in the exploitation of the results through their participation in national implementation teams that work under the coordination of the action leader.

4.12 Dissemination

The main purpose of the communication of JA for ECHIM is to support negotiations, planning stages and implementation work at country and EU-level. According to Work Package n° 7 (Dissemination of results) in the Grant Agreement, the main target groups at EU-level are Commissioners, DG SANCO, Eurostat, other key directorates and key persons in parliaments. Most of the communication work is however expected to be carried out at country level, where planning and agreements take place. Communication at this level will be planned jointly by JA for ECHIM and the country experts. Important target groups are National and Regional Ministries of Health in the Member States, National and Regional Public Health Institutes and Health Observatories, National Statistical Offices, and all organisations (hospitals, primary care facilities) involved in data gathering.

The proposal does not reveal much detail on the dissemination strategy of JA for ECHIM, and has been criticised for that in the evaluation report. It acknowledges that in addition to communication with key stakeholder groups there will be dissemination actions to the public, the media and experts involved at EU and country level, but that the dissemination strategy towards each group will be designed during the project as the needs will be assessed depending on the results achieved during the planning and negotiation phases. There are some general details on the dissemination channels that will be used to communicate progress to experts, such as leaflets, websites, scientific meetings (i.e. EUPHA, IEA, Chronic Disease societies) and papers, but overall there is concern about the practical absence of a dissemination plan for JA for ECHIM. The proposal highlights that the most important contributions in this field will be available towards the end of the action and later when achievements can be included.

Dissemination of results (as per proposal)	Dissemination of results (as per Technical Implementation Report)
Using the project progress website, the ECHIM Products website, the EU public health portal and e-mail to spread information	√
Informing about progress and proposals in the meetings of WP Indicators and in other suitable DG SANCO meetings	√
Spreading information to MSs through suitable local channels selected in co-operation with national representatives	√
Publishing articles about the project, its findings and proposals in scientific journals	√
Presenting the project and its results/outcomes in European scientific and professional meetings	√
Creating visual elements and layouts for promotional and dissemination materials	In progress as per Interim Report

According to the interview with the action leader, JA for ECHIM appointed a communications officer at central level and there have been efforts to duplicate this role in the different countries in order to help with the dissemination process and actions. Many of

the national teams have shown reluctance to rely on a communications officer to disseminate the work, so this role has not been implemented uniformly in the different countries. So far it has been the experts and administrators who have been tasked with the exploitation of the results in many countries, though there have been countries that have appointed a communications officer. In these cases, the dissemination has worked reasonably well so far though there is still some resistance to accept a communications role in the team.

4.13 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the JA for ECHIM fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		JA FOR ECHIM Joint Action
1.	**Implementing EU legislation:**	1.0
2.	**Economies of scale:**	0.5
3.	**Promotion of best practice:**	0.0
4.	**Benchmarking for decision making:**	1.8
5.	**Cross border threats:**	0.0
6.	**Free movement of persons:**	0.0
7.	**Networking:**	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

4.14 Sustainability

ECHIM is defined by its action leader as a continuous set of work which aims to result in a permanent flow of activity, even though the Commission's financing mechanisms and financing instruments are temporary given the fact that JA for ECHIM is nevertheless focusing on a concrete time bound task, which is implementing the list of indicators and making it operational with data.

The action is working towards securing a permanent funding scheme, but in the meantime they are having a hard time in finding the funds to secure the project. By definition, national funding is difficult to obtain because the action is aimed at an aggregated EU level. In addition, the action leader points out that the implementation of JA for ECHIM has coincided with the recent financial crisis in Europe that has affected many of the Member States' economies, thus making it difficult to obtain funding from national sources.

4.15 Impact to be expected

The expected main impact is to have the ECHI indicators used in all countries. The expected main outcome is the availability and use of these indicators in the different countries. According to the interview with the action leader, the proportion of ECHI indicators that are available and used in each country can be measured by the local national implementation teams.

5. TAKE CARE

5.1 Summary

Alcohol consumption of children and adolescents is subject to various influences like cultural habits, legal regulations, availability, acceptance, etc. These influencing factors, however, are not the same in all European countries.

The prevention project TAKE CARE is aimed at testing selected strategies towards responsible alcohol consumption for adolescents in Europe. Ten European partner institutions take part in this project. The LWL-Coordination Office for Drug-Related Issues in Münster, Germany is the project executing body and at the same time responsible for the project coordination.

The project is mainly focused on youths between 12 and 21 years noted with risky alcohol consumption. It aims at keeping adolescents to the legal provisions as set in the respective national laws and at hindering alcohol consumption before the set minimum age. Above the minimum age, the project will enforce responsible use of alcohol by the younger generations thus minimising the risk of alcohol dependency and related health impacts as well as deviant behaviour.

The most characteristic feature of this project is the implementation of a multilevel approach involving youth, parents, key persons and retail employees. The approach uses results from the evaluated German 'SeM – Sekundäre Suchtprävention im Mehrebenenansatz' intervention to be adjusted by a qualitative best practice analysis in all participating countries. Young people are to be trained to strengthen their risk competence. Street workers and prevention experts gain access to them on public places especially where drinking is noted, around cultural celebration, in hospitals or emergency services. Their parents and related key persons will get support to develop a clear and reflected attitude towards alcohol consumption. Retailers and their employees will be given information and training for the everyday selling situation based on a Belgium model.

Based on the consensus report, the project has a strong potential to contribute to improve the knowledge on drinking of young persons. Working in the local context and with retailers is interesting but the project should benefit from cooperation with other similar projects. As per the available documentation, the project has not yet produced an Interim Report so details on the progress are not available.

The figure below provides a summary of the case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
Take Care	+++	++	++	++	+++	+++	++	13	++	1. Implementing EU legislation: 1.0 2. Economies of scale: 0.5 3. Promotion of best practice: 2.3 4. Benchmarking for decision making: 1.5 5. Cross border threats: 0.3 6. Free movement of persons: 0.0 7. Networking: 2.0
	Action addresses the HP objectives and those of the 2009 AWP by testing selected strategies towards responsible alcohol consumption for adolescents in Europe.	Take Care meets the objectives of the Health Programme and of the 2009 Work Plan. The action has a strong potential contributing to improve the knowledge on drinking of young persons, though the evaluation report highlighted several concerns in the proposal.	The action seems to build on a robust evidence base and has has adequately selected its target groups, though it could involve other Member States to create a common platform on these topics. The target group of this action are youths between 12 and 21 years of agewith risky alcohol consumption. This represents an innovation, because the majority of this kind of studies is focused on teenagers over 15 years old. However, another issue raised is that the sample is too small to provide generalised findings.	The action is based on the multilevel approach of the German project SeM, transfering its approach to participating partner countries.	One of the action's key strengths is its European character. Knowledge and best practice from as many countries as possible are shared and established, and the action also follows a number of other related EU / DG SANCO projects.	Target groups are well defined and quantifiable. They include: - Young people; - Parents and affiliated persons - key persons retail employees	The action's dissemination plan relies heavily on the dissemination plan that was foreseen to be developed and implemented by the different partners. This excessive reliance on partners' strategies was highlighted as a cause of concern in the evaluation report.	- 1 Lead partner - 10 Associated Partners - 8 Collaborating Partners	The proposal outlines that the project implementation process will be accompanied by a scientific evaluation of an independent scientific institution. This will guarantee that all developed tools are effective and efficient in regard to the specific target groups. However, it's not very clear how the action is going to implement this in practice.	Particularly strong in: 3. Promotion of best practice - The best practice element of the TAKE CARE action is important for its success. The first specific objective of the project involved conducting a best practice research of valued procedures and projects in different Member States. 7. Networking - The project's budget includes budget lines for communication with other networks and relevant actors at an international level.

5.2 Key Facts

Calls for proposals:	2009
Proposal title:	Strategy towards responsible alcohol consumption for adolescents in Europe
Acronym:	TAKE CARE
Financing mechanism:	Project
Starting date:	1st March 2010
Duration (in months):	33 months
EC contribution:	€ 900,000.00
Overall score achieved in Consolidated Evaluation Report:	74
Total criteria block: A, B, C	A: 33; B: 22; C: 19
Main partner:	Landschaftsverband Westfalen Lippe (LWL), Germany
Number of associated partners:	10
Number of collaborating partners:	8
Priority area:	3.3 PROMOTE HEALTH (HP-2009)
Action:	3.3.2 Promote healthier ways of life and reduce major diseases and injuries by tackling health determinants
Typology[17]:	Pilot development action

[17] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2)

5.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[18]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to reduce risk:** The project is aimed at testing selected strategies towards responsible alcohol consumption for adolescents in Europe. It is mainly focused on youths between 12 and 21 years noted with risky alcohol consumption. It aims at keeping adolescents to the legal provisions as set in the respective national laws and at hindering alcohol consumption before the set minimum age. Above the minimum age, the project will enforce responsible use of alcohol by the younger generations thus minimising the risk of alcohol dependency and related health impacts as well as deviant behaviour. One of the main drawbacks in terms of reducing risk at EU level is that the project is targeted at relatively few young persons so it should be taken as a qualitative study. Hence, applicability of the evidence of this study on a European level needs to be demonstrated.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Pilot development action**: It takes evidence from an intervention approach in one country and trying to pilot test its transferability to other Member States.
Clear target groups	Target groups well defined/quantifiable. Those mentioned in the proposal are: – Young people: 440 young people between 12 and 21 years noticed with risky alcohol consumption are the main target group. They are divided into two subgroups: 1. 12-16/18 years old, when alcohol consumption is not allowed by country law, 2. adolescents and young adults up

Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[18] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
	to 21 years old which are allowed to drink alcohol by law but are noticed for heavy drinking. – Parents and affiliated persons (440) – Key persons (165): Those who have contact with young people and are accepted by them, namely employees from youth centres, street workers, volunteering students or trainers. – Retail employees (550): People selling alcohol at petrol stations, in supermarkets or in bars. These people are to be trained about the legal settings and about how to deal with young people who want to buy alcohol not permitted by law or who are drunk already.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	The dissemination strategy for the TAKE CARE project relies heavily on the dissemination plan that was foreseen to be developed and implemented by the different partners. In the proposal, emphasis was made on the use of existing resources, tools, channels and networks to communicate on the results of the project. The excessive reliance on partners' strategies was highlighted as a cause of concern in the evaluation report as in practice it meant the absence of an integrated dissemination plan for the TAKE CARE project. Another point highlighted in the evaluation report was that there was a need to adapt specific dissemination strategies to the different target groups addressed by the action. The dissemination tool-kit that was developed in the proposal includes: – Set up of a website, with information on the project and public deliverables regularly published – Development of a project logo – Design of a promotional leaflet – Design and distribution of a quarterly newsletter to relevant regional, national and international bodies and specialist institutions – Design and implementation of a dissemination plan executed by partners at regional and national levels – Organisation of a final conference, featuring the transferral of practical results and the provision of information to political stakeholders
Estimate the population reached (or targeted) by the action	According to the proposal (based on EU statistics) the main target groups to be addressed by the project represent 30-35% of the whole population. A sample

Criteria	Notes / Comments
	will be directly reached by the project. Assuming a snowball effect from the sample that will be directly reached by the project, it is estimated that about 6.500 people will be reached.
Matching of project's deliverables (if any) with project's objectives	Interim and Final Reports not available to confirm this.
Use of multipliers	Project partners can be taken to be the main multipliers of the information on the action in their own countries.
Evaluation (provision of indicators)	Evaluation strategy: One of the partners is an evaluation institute in Austria (pro mente OÖ) who will be in charge of coordinating the evaluation work package of the project. The internal evaluation of the project will be assessed against a detailed plan of technical and financial milestones that will be elaborated at the outset of the project. The evaluation of the project's effectiveness is foreseen to be conducted by external experts, who are expected to produce an independent scientific report. Some of the key indicators that will be used to measure the overall impacts achieved are the number of participants remaining in the programme and the actual reduction in drinking and changing of attitudes at the end of the implementation phase. Process indicators will identify the number of young people, parents and key persons trained as described in the implementation manual (i.e. it is expected that at least 1,050 persons are to participate), the number of information material spread out, the number of participants at the final conference and national conferences, the number of disseminated copies of the finalised European manual distributed, the number of entries on the project's website. The evaluators will participate in all workshops and conferences and will use a mixture of qualitative and quantitative data collection methods to collect information, such as questionnaires and focus groups discussions with project participants.
Sustainability plan	N/A

5.4 Introduction

The prevention project TAKE CARE is aimed at testing selected strategies towards responsible alcohol consumption for adolescents in Europe. The most characteristic issue in this project is the implementation of a multilevel approach. Four different target groups

(adolescents, parents, retail employees and key persons) are addressed using target group specific methods in a specific town or district:

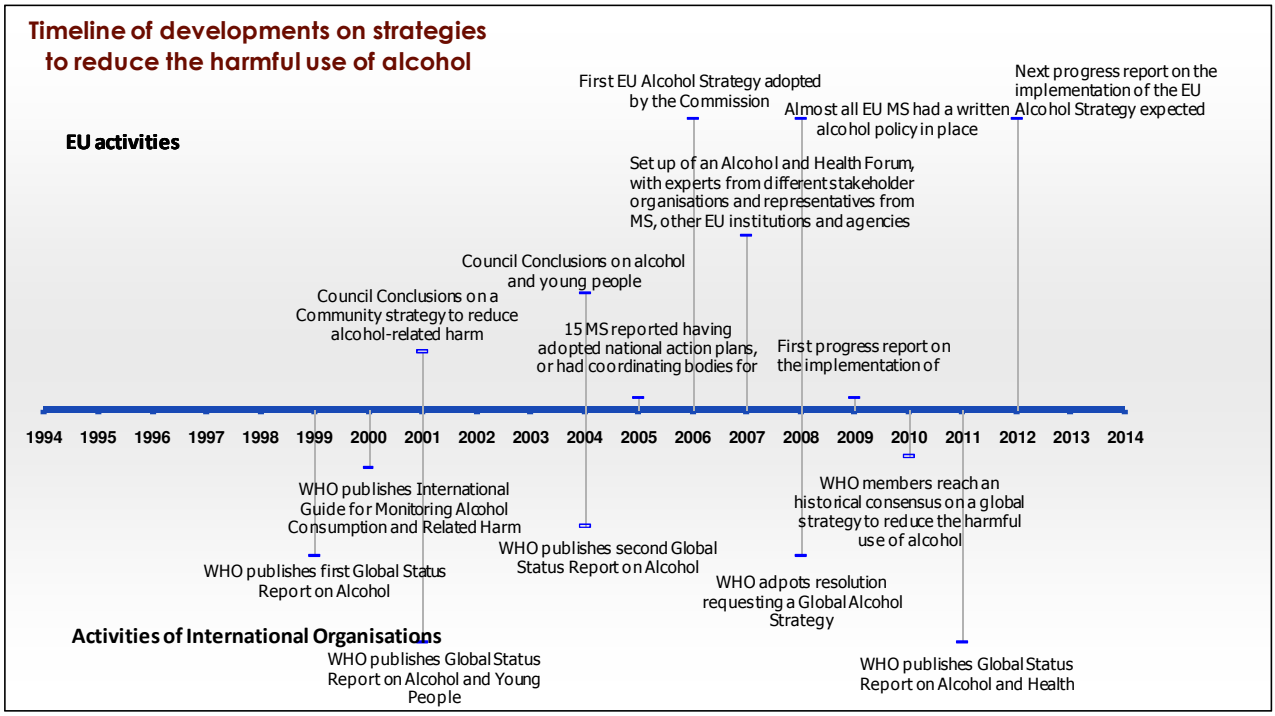
- Young people will be trained to strengthen their risk competence. Street workers and prevention experts gain access to them on public places especially where drinking is noted, around cultural celebration, in hospitals or emergency services.
- Their parents and related key persons will get support to develop a clear and reflected attitude towards alcohol consumption.
- Retailers and their employees will be given information and training for the everyday selling situation based on a Belgium model.

As the project covers a wide area of countries, it is expected to contribute to the formation of a common evidence base at EU level, especially as the outcomes will be applicable to all other EU Member States, including those not originally included in the project.

5.5 Background / Policy Context

The figure below provides an overview of the activities and public health interventions that have taken place and the organisations involved in developing strategies to reduce the harmful effects of alcohol over the last 15 years.

Figure 7 - Timeline of developments on strategies to reduce the harmful use of alcohol



Europe in particular has the highest alcohol consumption per capita in the world and the use of alcohol is firmly anchored in the cultures of the EU countries. Consumption among minors and binge drinking (five or more alcoholic drinks at a single setting) represent a serious problem. According to recent Eurobarometer data from 2010 the majority of young people are often unaware of the dangers and risks involved in consuming alcohol. Adults (parents, key persons) are not generally aware of their responsibilities as role models. And retail agents often do not recognise the role they play in providing minors with alcohol.

According to information provided by the project coordinator, measures and policies in this field are primarily geared to primary prevention and do not aim to target multiple stakeholder groups. Different projects targeting young people who are consumers of alcohol exist in Europe, but the social environment is generally not involved. The German project SeM, which developed a multi-level approach for young migrants consuming alcohol, was taken as a reference for the design and implementation of the TAKE CARE project.

It should be highlighted that although that TAKE CARE is following a novel and innovative approach for intervention, there are other projects in the field taking into account the social environment and targeting multiple stakeholder groups (eg. FASE, AMMIE, EWA, APYN, EUDAP2, IATPAD and others)[19].

5.6 Origins of HP project

TAKE CARE is based on the successfully evaluated multilevel approach of the German project SeM. Given that the project has a European scope, the first task was to verify whether the original approach can be transferred to the participating partner countries or whether adaptations are required and further good ideas can be integrated. In general the project partners have no objections against taking over the SeM methods. Some (minor) country and culture specific adoptions were considered, which will be tested and evaluated in the pilot phase 2011.

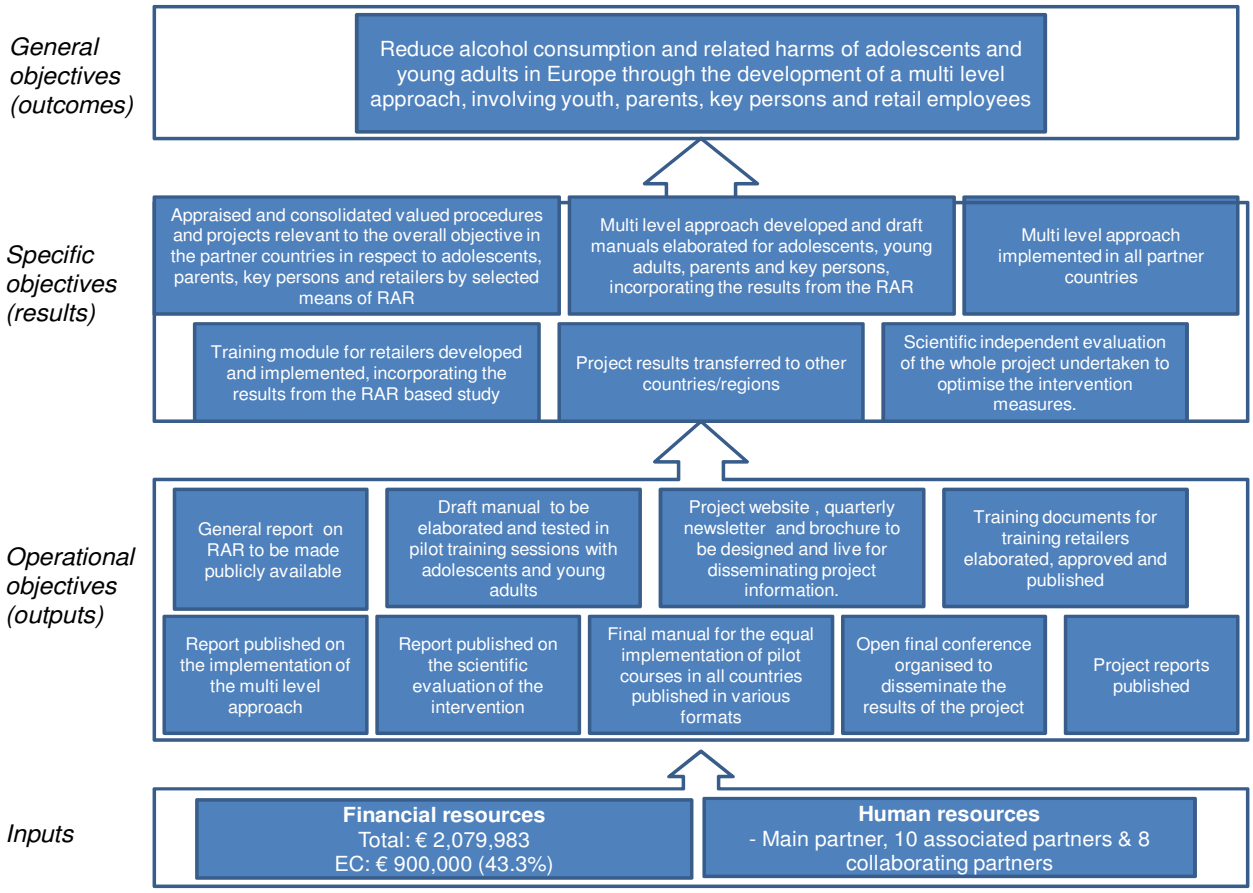
5.7 Overall project objectives / Intervention logic

The overall objective of the project is the reduction of alcohol consumption and related harms of adolescents and young adults in Europe. It is mainly focusing on youths between 12 and 21 years noted with risky alcohol consumption. It aims at keeping adolescents to the legal provisions as set in the respective national laws and at hindering alcohol consumption before the set minimum age. Above the minimum age, the project aims at enforcing responsible use of alcohol by the younger generations thus minimising the risk of alcohol dependency and related health impacts as well as deviant behaviour.

Based on an analysis of the proposal, the diagram above depicts the project's complete intervention logic. As reflected in the graph, the general objective clearly reflects the overall aim of the action. However, there is some overlapping at the next two levels between the specific objectives and the expected outputs, as some of the specific objectives could be considered as outputs. More specific details on each of these aspects is presented below.

Figure 8 - Intervention logic of the TAKE CARE project

[19] See http://ec.europa.eu/eahc/health/highlights13.html



Inputs:

Please find below a table detailing the TAKE CARE budget providing costs for all inputs including staff, travel, equipment etc.:

TAKE CARE Budget Overview		
E1a: Staff (public officials)	€ 323,376	
E1b: Staff (non public officials)	€ 1,175,578	
Total Staff (E1a + E1b)		**€ 1,498,954**
Total E2 – Travel costs and subsistence allowances		€ 162,733
Total E3 – Equipment		€ 0
Total E4 - Consumables & supplies linked to the project		€ 0
Total E5 - Subcontracting costs		€ 116,988
Total E6 - Other costs		€ 165,240
Total Direct Eligible Costs		**€ 1,943,915**
Total E7-Overheads		€ 136,068
Total Indirect Eligible Costs		**€ 136,068**
TOTAL EXPENDITURES		**€ 2,079,983**

Expected outputs:

As reflected in the table below, the expected outputs listed in the proposal have not been assessed against achieved outputs as the Interim and Final Reports for this project are still not available:

Expected outputs (as per proposal)	**Nature**	**Achieved outputs (as per Technical Implementation Report)**
General report to be made publicly available	Report on RAR	Interim/Final Reports still not available
Draft manual to be elaborated for use in pilot training	Draft Manual	Interim/Final Reports still not available
Manual to be tested in pilot training sessions with adolescents and young adults	Country reports on pilot training	Interim/Final Reports still not available
Website to be designed. Quarterly newsletter to be disseminated. Brochure to be published.	Promotion material	Interim/Final Reports still not available
Training documents to be elaborated, approved and published	Material for training retailers	Interim/Final Reports still not available
Report to be published on the implementation of the multi level approach	Report on the implementation of the multi level approach	Interim/Final Reports still not available
Report to be published on the scientific evaluation of the intervention	Evaluation Report	Interim/Final Reports still not available
Final manual for the equal implementation of pilot courses in all countries to be published in various formats	Final Manual	Interim/Final Reports still not available
Open final conference to be organised to disseminate the results of the project	Final Conference	Interim/Final Reports still not available
Project reports prepared on a regular basis by lead partner	Project Reports	Interim/Final Reports still not available

Expected aims/outcomes:

As reflected in the table below, the expected outcomes listed in the proposal have not been assessed against achieved outputs as the Interim and Final Reports for this project are still not available:

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
1. To appraise and consolidate valued procedures and projects (best practices) relevant to the overall objective in the partner countries especially in respect to adolescents, parents, key persons and retailers by selected means of RAR	• Common understanding of RAR database. • Knowledge about existence of good practice and valued procedures on alcohol prevention • 10 prevention experts of the associated partner are qualified to conduct RAR • Finding of country-specific adaptation for the common manual	Interim/Final Reports still not available
2. To develop a multi level approach and elaborate draft manuals for adolescents and young adults, parents and key persons, incorporating the results from the RAR with participation of young people	• Target groups and country specific adaption of SeM manual based on the RAR results • Establishment of a common understanding to compare project interventions • Participation of young people	Interim/Final Reports still not available
3. To implement the multi level approach in all partner countries as lined out in the implementation manual	• Awareness of alcohol drinking risks, change of risky behaviours, keeping adolescents to the legal provisions • Compliance with legal provisions, strengthening of education, supportive attitudes • Key persons qualified to motivate young people to reflect on their risky drinking behaviour • High quality intervention implementation ensured in all countries	Interim/Final Reports still not available
4. To develop and implement a training module for retailers, incorporating the results from the RAR based study	• Target groups and country specific implementation manual • Information on national legal provisions, dealing with difficult selling situations	Interim/Final Reports still not available
5. To transfer the project results to other countries / regions	• Knowledge exchange • Target groups final manual based on country experiences	Interim/Final Reports still not available

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
	• Dissemination of project results and evaluation of impacts	
6. To undertake a scientific independent evaluation of the whole project to optimise the intervention measures	• Collecting adequate information from participants • Conducting evaluation measures in all countries • Collecting adequate information from all countries • Acknowledging the impact of the intervention measures	Interim/Final Reports still not available

5.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 1 as set out in the Health Strategy (2008-2013):

- Fostering good health in an ageing Europe - Healthy ageing must be supported by actions to promote health and prevent disease throughout the lifespan by tackling key issues including poor nutrition, physical activity, alcohol, drugs and tobacco consumption, environmental risks, traffic accidents, and accidents in the home.

5.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

One of the key strengths of this project is its European character. Rather than each country working individually, knowledge and best practice from as many countries as possible are shared and established. It avoids reinvention or duplication within the countries and uses already existing successful concepts such as SeM by LWL. The partners represent a huge variety of countries in the EU, which ensures the transferability of the outcomes.

The project follows other related projects:

1. Other EU / DG SANCO projects

- **PHP - Pathways for Health Project on drink driving, binge drinking (co-funded by DG SANCO, 2006-2007**): managed by the German Centre for Addiction Issues in cooperation with European partner organisations. The aim of the project was to strengthen the exchange of programmes and practices and to improve the knowledge of all people who are involved and interested in alcohol policy. This includes the support of the EU Member States and other European countries in the development of strategies to reduce alcohol related harm. It was funded by The European Commission, and the Ministries of Health of Portugal, Germany, France and Finland.

- **ECAT - Empower the Community in response to Alcohol Threats (co-funded by DG SANCO, 2006-2008)**: managed by VAD, a Belgian non-profit association for alcohol and other drug problems (in cooperation with other European partners), it ran as an EC-co-funded project from December 2006 to November 2008 in six participating countries. The aim of the project was to raise the effectiveness of alcohol prevention campaigns through the elaboration of tailored messages towards different target groups and through the embedding of the campaigns in a local alcohol policy and inclusive approach.

TAKE CARE also complements the following more recent projects:

- **FASE - Focus on Alcohol Safe Environment (co-funded by DG SANCO, 2008-2010)**: coordinated by the National Foundation for Alcohol Prevention in The Netherlands (in cooperation with other European partners) and co-funded by the EC, the project was aimed at reducing the impact of harmful and hazardous alcohol consumption on the economy (e.g. reduce absenteeism, drinking during working hours, working with a hangover and unemployment) through building capacity at country and European levels.
- **Building Capacity - Implementing Coordinated Alcohol Policy in Europe (co-funded by DG SANCO, 2007-2010)**: led by the Institute of Public Health of the Republic of Slovenia (in cooperation with other European partners), the project aimed to create an alcohol policy network and to enhance European, country-wide, regional and municipal level capacities to develop, implement and monitor alcohol policy.
- **Healthy Nightlife Toolbox (co-funded by DG SANCO, 2007-2011):** led by the Trimbos Institute, the project aimed to support the identification and implementation of effective preventive interventions that address emerging trends in alcohol and drug use in nightlife settings, especially regarding ecstasy, cocaine, amphetamines & cannabis.
- **Club Health (co-funded by DG SANCO, 2009-2012):** led by Institute for Research and Development "Utrip", the project aims to reduce in particular alcohol / drug use, underage / binge drinking, smoking, road traffic and other accidents, deliberate injuries and violence among youth with a focus on specific environments of nightlife; to facilitate more consistent implementation of strategies and laws in the field of youth risk behaviour; and to increase sensitivity of media, advertising industry and politically relevant actors on their responsibility for action.

2. Good practice identified at national level in a number of Member States:

As part of the research in partner countries, good practice projects have been identified in a number of Member States, including Belgium, Cyprus, Denmark, Germany, Ireland, Slovakia and Slovenia. Of local or national scope, and targeted at different affected groups, these projects provide a good overview of specific actions in the field of risky alcohol consumption of adolescents in Europe.

5.10 Rationale behind selection procedures (consistency with HP objectives)

The evaluation report concluded that TAKE CARE meets the objectives of the Health Programme (2008-2013) and the Annual Work Plan, as highlighted by the following table:

Objectives of Priority areas
Alcohol (AWP 2009, Annex — point 2.2.1): In line with the Commission's Communication on an EU strategy to support Member States in reducing alcohol-related harm, and in order to further develop

Objectives of Priority areas
policies to reduce alcohol-related harm, a particular priority will be given to projects focusing on (...) curbing under-age drinking: identify and bring together good practice concerning issues such as education directed at children, their parents and retail employees. Of particular importance is the enforcement of the legal age limits for selling alcohol.

In addition, the evaluation report concluded the following points for the TAKE CARE proposal:

- The project has a strong potential to contribute to improve the knowledge on drinking of young persons. Working in the local context and with retailers is interesting.
- Project responds to priority area but added European value is not clear. The project should benefit from cooperation with other similar projects.
- Social and cultural aspects are taken in account but adaptation of methods to different countries could improve.
- Geographical coverage is good, but important countries are lacking.
- The budget is a concern. There should be a substantial reduction of budget including no. of working days. Other cost must be justified.
- The project is recommended for funding based on the condition to include also more associated partners (France and Portugal) and more countries from Eastern Europe.

5.11 Involvement of decision makers (design of project / exploitation of results):

As highlighted by the project coordinator, Take Care was developed within the network of associated and collaborating partners – all of them decision makers within their countries at national, regional or local levels respectively. The project is composed of governmental organisations and not-for-profit organisations. The team was assembled by assessing the degree of centralisation of alcohol prevention related strategies and actions in the different countries, and by selecting the adequate partners. For instance, in those countries where decision making happens at a regional level, regional partners were identified to be part of the project. Equally, in those countries where decision making is more centralised, national partners were invited to join the team.

In terms of the exploitation of results, the same network of partners will be disseminating the expected results of the action at different levels – namely European, national, regional, and district/local levels. At European level, the project has its own website and distributes a newsletter that currently reaches 410 addressees, including practitioners and political decision makers. At national level, the project's results are communicated by the different partners through national TV stations, conferences, etc. At regional level, partners have their own newsletters with tailored content, they draft and publish articles in local newspapers, they are invited to radio shows, etc. At district/local level, flyers and brochures are produced and distributed.

5.12 Dissemination

The dissemination strategy for the TAKE CARE project relies heavily on the dissemination plan that was foreseen to be developed and implemented by the different partners. In the proposal, emphasis was made on the use of existing resources, tools, channels and networks

to communicate on the results of the project. Led by the project coordinator, the proposal highlighted that the success of the plan relied to a great extent on the efforts of the partners in the different countries. But the excessive reliance on partners' strategies was highlighted as a cause of concern in the evaluation report as in practice it meant the absence of an integrated dissemination plan for the TAKE CARE project.

The table below provides an overview of the dissemination tool-kit that was developed in the proposal. In practice, some of the tools are live (website, project logo, promotional leaflet, quarterly newsletter), whereas the lack of reports make it difficult to assess the status of the dissemination plan, and the effectiveness/relevance of the different tools developed so far.

Dissemination of results (as per proposal)	**Dissemination of results (as per Technical Implementation Report)**
Set up of a website, with information on the project and public deliverables regularly published	√
Development of a project logo	√
Design of a promotional leaflet	√
Design and distribution of a quarterly newsletter to relevant regional, national and international bodies and specialist institutions	√
Design and implementation of a dissemination plan executed by partners at regional and national levels	N/A
Organisation of a final conference, featuring the transferral of practical results and the provision of information to political stakeholders	N/A

The proposal does not clearly identify which target groups are to be reached through the dissemination strategy of the project, but highlights that "important stakeholders to be addressed by the project will be identified at the outset of the project as background information for the dissemination plan". There is a general reference in the proposal to the target audiences of the quarterly newsletter, namely relevant regional, national and international bodies, specialist institutions and other interested individuals.

5.13 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the action Take Care fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		TAKE CARE Project
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	0.5
3.	Promotion of best practice:	2.3
4.	Benchmarking for decision making:	1.5
5.	Cross border threats:	0.3
6.	Free movement of persons:	0.0
7.	Networking:	2.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

5.14 Sustainability

According to the project coordinator, if Take Care achieves its expected outcomes, it will continue to be sustainable once the funding through the Health Programme has come to an end. The Landschaftsverband Westfalen-Lippe (LWL), the main partner of the Take Care project, has relevant experience through many of the former projects that they led. They are confident that when EU funding comes to an end, financial support will switch to national and regional donors. Associated and collaborating partners in the different countries will be instrumental to making this happen.

5.15 Impact to be expected

The action intends to have two main impacts. Firstly, it expects to contribute to a change of attitude and behaviour among the target groups (youngsters, parents, retailers, key persons), namely through increased knowledge on the harmful effects of alcohol. Secondly, it aims at reaching influential target groups who are normally not interested in this topic. The impact is envisaged to be achieved through a European manual for adolescents and young adults, parents and key persons, a toolbox and other relevant supporting material, all of which will be disseminated by seminars, a public European final conference and by posting the project results on the Internet, among other measures.

One of the partners is an evaluation institute in Austria (pro mente OÖ) who will be in charge of coordinating the evaluation work package of the project.

The internal evaluation of the project will be assessed against a detailed plan of technical and financial milestones that will be elaborated at the outset of the project.

The evaluation of the project's effectiveness is foreseen to be conducted by external experts, who are expected to produce an independent scientific report. Some of the key indicators that will be used to measure the overall impacts achieved are the number of participants remaining in the programme and the actual reduction in drinking and changing of attitudes at the end of the implementation phase. Process indicators will identify the number of young people, parents and key persons trained as described in the implementation manual (i.e. it is expected that at least 1,050 persons are to participate), the number of information material spread out, the number of participants at the final conference and national conferences, the number of disseminated copies of the finalised European manual distributed, the number of entries on the project's website.

The evaluators will participate in all workshops and conferences and will use a mixture of qualitative and quantitative data collection methods to collect information, such as questionnaires and focus groups discussions with project participants.

6. EURONEOSTAT II

6.1 Summary

EURONEOSTAT II's aim is to expand the Information System set by EuroNeoStat (SANCO 05/116) to further assess and improve the quality of care provided to those infants by performing Internet-based comparisons of the outcomes of units to those of other units to identify areas to improve care and monitor the success of the initiatives implemented. EuroNeoStat has developed a consensus set of standardised perinatal indicators and definitions.

The subject is a relevant public health issue and has been taken up by International Organisations as well as the European Commission.

There were some issues with the EuroNeoStat II proposal, and the project was put on hold for a while, but based on the Interim Report, the project seems to be running to plan now.

The two key points of added value of EuroNeoStat II are the promotion of best practice and networking. In both areas the action scores high.

One of the biggest concerns is the sustainability of the action. During the interview with the action leader it was explained that it is extremely challenging to maintain registers, such as the one developed by EuroNeoStat II, without external funding.

One of EuroNeoStat II big successes seems to be the introduction of four indicators to measure the action's impact on patient care. While it is not yet possible to make a judgment of the impact of the action, it was noted that units across Europe (at regional and national level) have taken up the concept of EuroNeoStat II and have started to set up their own registers.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
EURONEOSTAT II	+++	+++	++	+++	+++	+	++	24	++	1. Implementing EU legislation: 1.0 2. Economies of scale: 1.0 3. Promotion of best practice: 2.3 4. Benchmarking for decision making: 0.5 5. Cross border threats: 2.3 6. Free movement of persons: 0.0 7. Networking: 3.0
	Action addresses the HP objectives and those of the 2009 AWP by creating a network in the area of Neonatal Health for the collection of data.	The action has a strong rationale for funding, given that it has developed a consensus set of standardised perinatal indicators and definitions. However, the evaluation report criticised several points in the proposal, which were sufficiently addressed by the project leader.	Until the predecessor action funded under the PHP, no European systematic recording of specific morbidity and morbidity data existed, though VLGA and VLBW short and long term morbidity for the improvement of care and patient safety are a priority.	The action ties in with other work undertaken in the same area.	The issue addressed by the action is a major cause of concern in all Member States.	Target groups not very well defined and quantifiable. Those mentioned in the proposal are: - All live-born infants of VLGA and VLBW cared at over 100 European NICUs at partner institutions and at other regional and national networks.	A dissemination plan is set out in the proposal and includes classic methods, though they are not very specific: - abstracts and communications; - scientific papers; - webiste; - presentations and conferences	- 1 Lead Partners - 11 Associated Partners - 15 Collaborating Partners	The action has an internal evaluation process in place; WP Leaders will evaluate their own WPS. The Project Coordinator should receive these documents from each WP Leader and document the Project Technical Progress Report. This document will be evaluated by the Management Committee in order to monitor the state of the projec.	Particularly strong in: 3. Promotion of best practice - Data could be used to develop educational packages aiming to improve the performances of European NICUs . 5. Cross border threats - Certainly a threat/risk for a MSs. 7. Networking - The action is set out as an e-Network for neonatal units across the EU.

6.2 Key specification

Calls for proposals:	2008 – The Evaluation Committee had stopped the negotiation until the delivery of the EURONEOSTAT I final report; thus, first on reserve list, accepted later.
Proposal title:	Expanded European Information System to Monitor Short and Long Term outcomes and Improve Quality of Care and Safety for Very-Low-Birth-weight infants
Acronym:	EURONEOSTAT II
Financing mechanism:	Project
Starting date:	1st November 2009 (originally 1 January 2009, but delayed due to a decision by the Evaluation Committee)
Duration (in months):	36 months
EC contribution:	€ 649,969.98
Overall score achieved in Consolidated Evaluation Report:	64
Total criteria block: A, B, C	A: 27; B: 17; C: 20
Main partner:	Fundación Vasca de Innovación e Investigación Sanitarias, Spain
Number of associated partners:	11
Number of collaborating partners:	15
Priority area:	3. GENERATE AND DISSEMINATE HEALTH INFORMATION AND KNOWLEDGE (HI-2008)
Action:	3.1 Development of a sustainable health monitoring system
Typology[20]:	Development project

[20] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

6.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[21]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to network:** The action is set out as a network in the area of Neonatal Health for the collection of data. The objective of the project is to expand the information system set by the predecessor project and to perform comparisons of research (exchange of knowledge).
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Development project**: Until setting up EuroNeoStat I (the predecessor project), there was no European systematic recording of specific morbidity and morbidity data. However, maintaining such a system and expanding it to more countries seems justified since data already exist, but might not always be used.
Clear target groups	Target groups well defined, but not quantifiable. Those mentioned in the proposal are: - All live-born infants of VLGA (gestation <32 weeks) and VLBW (birthweight <1,501 g) cared at over 100 European NICUs at partner's institutions and at other regional (Basque country and Navarre, Emilia Romania, England, Lazio...) and national networks (England, Estonia, Norway, Portugal, Spain, Switzerland, Sweden…).
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been	A dissemination plan is set out in the proposal and includes the classical methods, though not very specific: 1) abstracts and communications sent to

[21] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	different neonatal, perinatal and paediatric medical scientific meetings; 2) scientific papers about different aspects of the project's results submitted to international journals with impact factor; 3) main results will be shown on EURONEOSTAT's website and 4) presented at forums, symposium, seminars and conferences. Moreover, other less traditional dissemination methods will also be used: a) dissemination of knowledge via related websites of societies and official bodies; b) word-of-moth approach at any meetings attended by Partners.
Estimate the population reached (or targeted) by the action	N/A
Matching of project's deliverables (if any) with project's objectives	According to the Interim Report available, the project's website is constantly renewed and updated, both for consortium, neonatal professionals and society in general. Relevant congress and conferences are also used for contrasting project's advances with other colleagues. More deliverables are expected in the future.
Use of multipliers	N/A
Evaluation (provision of indicators)	Strategy of self-evaluation: Each partner will be required to formally report to the different Work Package (WP) Leaders on progress and achievement of specific deliverables in compliance with the work programme every six months. These will include: 1) short description of activities; 2) percentage completion; 3) estimated time completion; 4) actual man-months spent and other costs; 5) milestones achieved; 6) deviations from the objectives and incidents. The Project Coordinator should receive these documents from each WP Leader and document the Project Technical

Criteria	Notes / Comments
	Progress Report. The document will be evaluated by the Management Committee in order to monitor the state of the project and arrange the adequate corrective actions, if needed.
Sustainability plan	The action does not have a sustainability plan. According to the action leader, sustainability is the biggest concern, as the register developed by the action won't sustain without external funding.

6.4 Introduction

EuroNeoStat II plans to expand the aims of the **European Information System** for **monitoring short and long-term morbidity** in order to improve quality of care and patient safety, developed by EuroNeoStat, on the consequences of premature babies of very low gestation (<32 wks) and birthweight (<1501 g) from neonatal units **from 17 MS and 7 others from EDTA/EEA** or the vicinity.

The project aims to eventually **expand the Information System to all European and other countries**, such as India, West Asia and North Africa (Mediterranean side) by

- Enlarging the number of babies in the cohorts;
- Expanding perinatal indicators;
- Expanding baby numbers and the age at neurodevelopmental follow-up;
- Technical aspects.

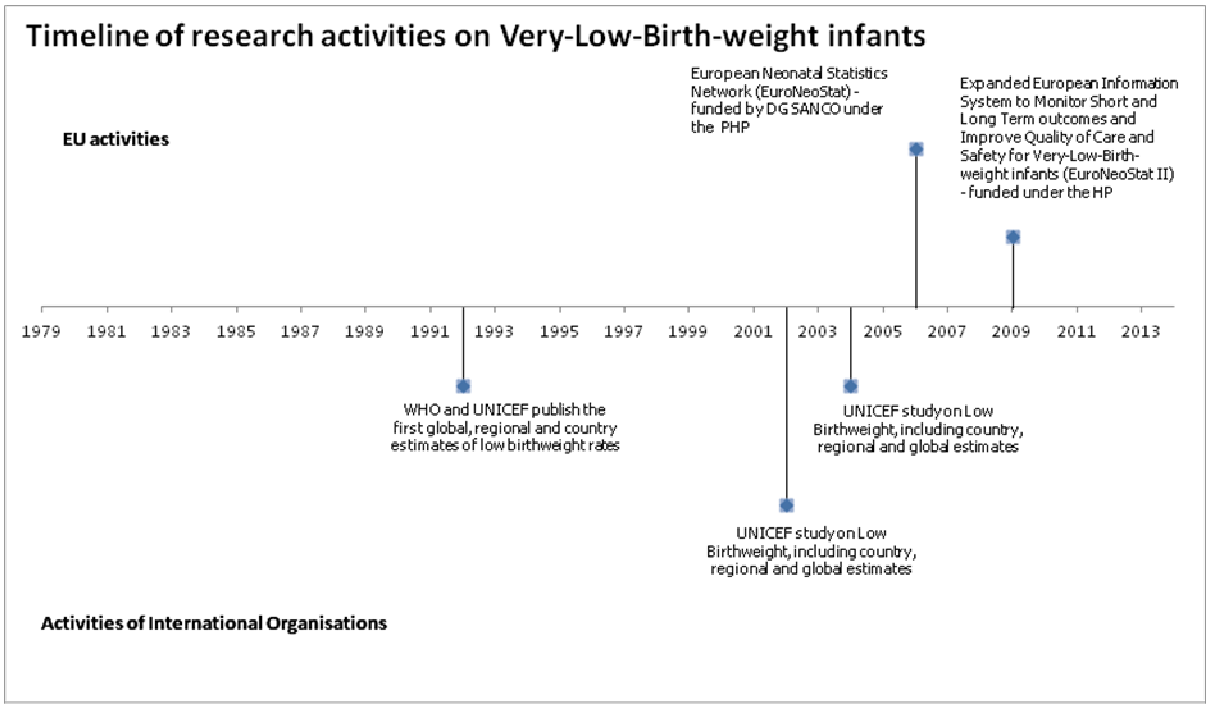
6.5 Origins of HP project

The project is largely based on the project "EuroNeoStat", which was funded under the Health Programme 2003-2008.

6.6 Background / Policy Context

In order to gauge and make a judgement on the extent to which EuroNeoStat II is tackling a serious public health issue, the case study examines what other public health interventions have taken place and the organisations involved in coordinating/funding these activities. The figure below provides a brief overview of how activities related to EuroNeoStat II have developed over the last years.

Figure 9 – Timeline of a sample of activities / developments related to EuroNeoStat II



According to an UNICEF study from 2004, half of all low birthweight babies are born in South-central Asia, where more than a quarter (27 per cent) of all infants weigh less than 2,500 g at birth. Low birthweight levels in sub-Saharan Africa are around 15 per cent.[22] Central and South America have, on average, much lower rates (10 per cent), while in the Caribbean the level (14 per cent) is almost as high as in sub-Saharan Africa. About 10 per cent of births in Oceania are low birthweight births.

A reduction of at least one-third in the proportion of infants with low birth weight is one of the seven major goals for the "A World Fit for Children" programme of the United Nations between 2000 and 2010.[23] One of the major challenges in measuring the incidence of low birthweight is the fact that more than half of infants in the developing world are not weighed. In the past, most estimates of low birthweight for developing countries were based on data compiled from health facilities. Monitoring improvements in low birth weight is thus being given high priority within the UN system, as well as by national governments and the international nutrition community.

The WHO and UNICEF published the first global, regional and country estimates of low birthweight rates in 1992, including data derived from hospital studies, vital registration data, health service records and some surveys.[24]

European health care systems are not uniform, but all Member States offer government-paid access to NICUs and perinatal centres. Birth of these babies at such centres diminishes the need for postnatal transfers. A further advantage of regionalisation to facilitate access of VLBW infants to intensive care is that it makes it easier to keep track of every such baby born within a given area.

[22] World Health Organisation and United Nations Children's Fund, *Low Birthweight*, *Country, Regional and Global Estimates*, Geneva: WHO and UNICEF, 2004.
[23] http://www.unicef.org/specialsession/docs_new/documents/A-RES-S27-2E.pdf
[24] World Health Organisation and United Nations Children's Fund. *Low birth weight: a tabulation of available information.* Geneva: WHO and UNICEF, 1992.

There are several neonatal networks in other areas of the world and in some European countries (including Belgium, Ireland, Portugal, and Spain) and regions (e.g. the Basque Country and Navarre, Lazio, and England's Regional Networks). However, there was no Europe-wide network to allow comparisons of outcomes for VLGA/VLBW infants, specifically designed to identify differences in perinatal care in the different European countries.

EuroNeoStat, the predecessor of EuroNeoStat II and funded under the previous Health Programme, has developed a consensus set of standardised perinatal indicators with uniform definitions, composed of perinatal risk and protective factors, selected neonatal interventions, and short-term outcomes.

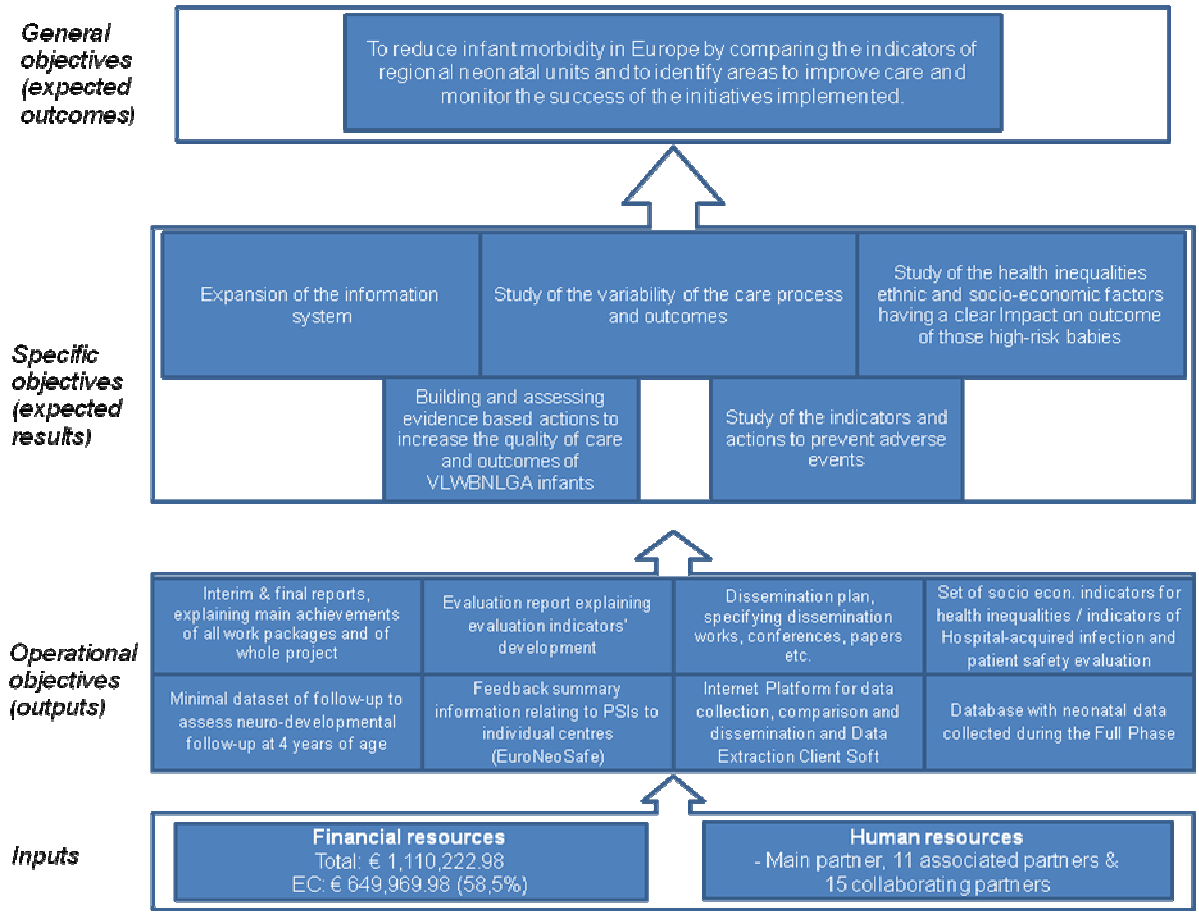
EURONEOSTAT II has been positioned as a complementary action to the existing surveys in Europe and its outcomes are envisaged to improve quality and care and patient safety on the consequences of premature babies of very low gestation and birthweight. Through its development of a consensus set of standardised perinatal indicators and definitions, it can be seen as a somewhat unique action in Europe.

6.7 Overall project objectives / Intervention logic

EuroNeoStat II's mission is that all Very Low Gestation (VLGA, gestation <32 wks) and Very Low Birth Weight (VLBW, birthweight <1500 g) infant born in Europe, receive the best possible health care no matter where born by preventing existing inequalities and that all Neonatal Units use the indicators developed, to assess the quality of care provided and implement strategies to improve outcome.

Based on an analysis of the proposal, the diagram below depicts the project's complete intervention logic. It shows a clear sequence of the general and specific objectives EuroNeoStat II intends to achieve, the expected outputs, and the key inputs. The diagram also reflects a clear differentiation between the specific objectives and the outputs of the action. More specific details on each of these aspects are presented below.

Figure 10 – Intervention logic diagram for EuroNeoStat



Inputs:

The following table details the budget of EURONEOSTAT II, providing costs for all inputs, including staff and overheads:

Expenditures	
Direct eligible costs	
E1. Staff	891,108.78
a. Costs pertaining to public officials	460,253.00
b. Costs not pertaining to public officials	430,855.78
E2. Travel costs and subsistence allowances	86,800.00
E3. Equipment	0.00
E4. Consumables and supplies directly linked to the project	0.00
E5. Subcontracting costs	49,215.00
E6. Other costs	10,500.00
Total direct eligible costs	1,037,623.78
Indirect eligible costs	
E7. Overheads	72,599.20
Total indirect eligible costs	72,599.20
Total – Expenditures	**1,110,222.98**

Incomes	
I1. Commission funding	649,969.98

I2. Contribution pertaining to public officials	460,253.00
I3. Applicant's financial contribution	0.00
I4. Income generated by the project	0.00
I5. Other external resources	0.00
Total – Incomes	**1,110,222.98**

Commission funding %	**58,54%**

Source: Grant Agreement for EURONEOSTAT II - 20081311

Expected outputs:

The table below describes the expected outputs that were outlined in the proposal and Interim Report, including the way each would be disseminated and the expected date of delivery of each output:

Title	Description	Date of delivery or achievement	Ways to disseminate
Annual Interim Report	Report explaining main achievements related to all work packages	M 13	Circulation to associated partners, collaborating partners and European Commission
Final report	Project's final report explaining whole project's main achievements and problems and other important issues	M 36	Circulation to associated partners, collaborating partners and European Commission
Evaluation report	Detailed evaluation report explaining evaluation indicators' development and if necessary target values deviation	M 36	Circulation to associated partners, collaborating partners and European Commission
Dissemination Plan	Report specifying dissemination works, conferences, papers, posters, etc. to develop and the kind of information to communicate to the general public	M 13	Abstracts, Conference Papers, Posters, Communications to Medical Meetings, Scientific Papers
Socio economic indicators	Set of socio economical indicators for health inequalities	M 13	Circulation to associated partners, collaborating partners and European Commission
Hospital-acquired infections indicators	Set of indicators of Hospital-acquired infection and patient safety evaluation	M 13	Circulation to associated partners, collaborating partners and European Commission

Title	Description	Date of delivery or achievement	Ways to disseminate
Follow-up at 4 years age	Minimal dataset of follow-up to assess neuro-developmental follow-up at 4 years of age	M 13	Data of each NICU will only be available of such NICU, and general information will be public
EuroNeoSafe	The feedback summary information relating to PSIs to individual centres following data analysis. It helps to promote an increase of the importance of patient safety and incident reporting	M 28	Data of each NICU will only be available of such NICU, and general information will be public
Internet Platform	Internet Platform for data collection, comparison and dissemination and Data Extraction Client Soft	M25	Data of each NICU will only be available of such NICU, and general information will be public
Database	Database with neonatal data collected during the Full Phase (in advance of month 36 of collection)	M 36	Data of each NICU will only be available of such NICU, and general information will be public

Expected aims/outcomes:

The table below contrasts the expected aims/outcomes that were outlined in the proposal with those documented in the Interim Report of EURONEOSTAT II.

Aim	Indicator	Result (as per Interim Report)
Expansion of the information system	Nº MS sending data directly by e-tool / year	The WP leader Dr. Marina Cuttini has performed a systematic review of the literature, a several number of socio-economical indicators were proposed in the last ENS II SC Meeting at Copenhagen (maternal age and level of education, ethnicity, occupation and single household, among others). The list was been discussed, reduced and distributed throughout partners, after ethical and political issues regarding to confidentiality laws and legislation for each country were taken into account. Also feasibility was a main issue discussed when

Aim	Indicator	Result (as per Interim Report)
		selecting the indicators. The list will be agreed and implemented to start collecting data on them for the next cohort of babies born in 2011, at least in a number of associated partners.
Study of the variability of the care process and outcomes	Nº standardised comparisons / year Impact on infection on neonatal mortality and morbidity	Data for 2009 is yet in completed, since is going to be considered closed in December 2010, to deliver its report not later than June 2011. Data collection flow and timing is a problem and data collection process is a time consuming task and prolonged in time, mainly due to data reception and the cleaning processes. As an example, at November 2010, the 2009 cohort still can't be considered complete as some neonatal Units still haven't sent data and/or answered queries. A set data collection time deadline was proposed, discussed and modified in the last ENS II SC meeting held in Copenhagen, according to some partner's situation (mainly, national, regional or individual network).
Study of the health inequalities ethnic and socio-economic factors having a clear Impact on outcome of those high-risk babies	Socio-economic impact at 2 years age Nº units using 4 year follow-up	
Building and assessing evidence based actions to increase the quality of care and outcomes of VLWBNLGA infants	Nº NICU sending data directly by e-tool / year Nº units using 4 year follow-up	
Study of the indicators and actions to prevent adverse	Nº PSI reports on database / unit	

Aim	Indicator	Result (as per Interim Report)
events		

This project's main outcome is related to regional neonatal unit's indicators comparison, being possible to know where they could improve their work and thus reduce infant morbidity. Moreover, a tested on-line educational package for the prevention of nosocomila infection and software to report incidents and near-misses will be made available to the interested stakeholders.

6.8 Action compatible with the principle / objectives in the Health Strategy

N/A

6.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

The project ties in with other work undertaken in the same area, as outlined below:

1. **Other DG SANCO projects**
    a. PeriStat (perinatal project)
    b. EuroCat (malformation registry)
    c. SCPE (Cerebral Palsy registry)

2. **International Organisations:**
    a. International Collaboration of Neonatal Networks (ICONN) – meeting in Bilbao, November 2010

3. **3rd countries:**
    a. Canadian Neonatal Network (CNN)
    b. NICDH (National Institute of Child Health & Human Development) neonatal network (USA)
    c. Egyptian Neonatal Network (EGNN)
    d. South American Network from SIBEN
    e. Australian and New Zeeland network (ANZNN).

4. **European conferences:**
    a. The project was presented at several national meetings by Steering Committee Members, as well as at European (XII European Congress of Prenatal Medicine and Portuguese Congress of neonatology held in Granada and Lisbon) and the 8th international (International Congress of Paediatrics and the Global Congress of Prenatal medicine, held in Johannesburg and Barcelona) scientific meetings.
    b. The project was also presented at the Tertiary Section meeting of the European Academy of Paediatrics (EAP) in Brussels, December 2010, where an invitation to present it to the planarity session on 2011 was received.

6.10 Rationale behind selection procedures (consistency with HP objectives):

According to the proposal, EuroNeoStat II addresses the following priority areas of the Health Programme:

Objectives of Priority areas	Covered by project according to proposal
3.4.1.4. "health survey data for child and adolescent population …"	The project will analyse the health of infants born prematurely
3.3.2 "Reduction of health inequalities between EU regions... Potential synergies between the existing networks	The project is designed to detect health inequalities that might exist between patients, units, regions... and will have synergies with other SANCO networks (Peristat, Eurocat and SCPE)
3.3.3.4 "Nutrition, overweight and obesity related health issues..."	The project will study growth status at birth and up to 4 years.
3.4.1.3 "Surveillance networks and best practise on ... necessary networks needing further development in operating the health information system at European level"	The project will generate and disseminate health information and exchange best practices to promote health.
3.4.1.2 "Health indicators: Assess the impact of … on the Healthy Life Years indicators..."	

However, the consolidated evaluation report was quite critical towards the proposal submitted and concluded that negotiations should stop until the delivery of the EURONEOSTAT I final report in order to take into account the comments provided on the previous project, and then to resubmit the proposal for EURONEOSTAT II.

More specifically, the evaluation report made the following comments:

- Good potential, but some parts not relevant for the HP
- Good points addressed: inequalities, patient safety
- Points not addressed: promoting health with focus on children or obesity

6.11 Involvement of decision makers (design of project / exploitation of results):

During the interview with the action leader of EuroNeoStat II it was explained that at the design stage of the action, the action leader tried to make contact with national policy makers. However, these approaches were not very successful, therefore the main point of contact for the action leader were other scientists who helped developing the idea of the action further.

6.12 Dissemination

According to the proposal, the dissemination strategy includes the following methods:

1) Abstracts and communications sent to different neonatal, perinatal and paediatric medical scientific meetings;
2) Scientific papers about different aspects of the project's results submitted to international journals with impact factor;
3) Main results will be shown on the EuroNeoStat website;
4) Presented at forums, symposium, seminars and conferences.

Moreover, the proposal foresees that knowledge will be disseminated via related websites of societies and official bodies, and by word-of-mouth approach at any meetings attended by partners.

While in the proposal no specific target groups for the dissemination of results were specified, the action leader explained that the action is mainly targeting European societies of perinatal medicine, which are known to most of the academics in the field. In addition, a report with some preliminary action results has been sent to authorities throughout Europe. Therefore, the action leader was confident that all national authorities know about the action. However, in order to improve the outreach of the action, it was planned to organise a conference on the topic, making use of EU funding. However, no funding for the conference could be secured.

In terms of actual numbers of people reached, the action leader stated that 150 neonatal units have been included in the dissemination of results, each of them with an average size of 100 people or more. This means that ca. 15,000 professionals in Europe have been successfully targeted by EuroNeoStat II's dissemination strategy.

6.13 EU-added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value EURONEOSTAT II fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		EURONEOSTATII
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	1.0
3.	Promotion of best practice:	2.3
4.	Benchmarking for decision making:	0.5
5.	Cross border threats:	0.5
6.	Free movement of persons:	0.0
7.	Networking:	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

6.14 Sustainability

During the interview, the action leader pointed out that sustainability of the action is one of the main concerns. The action leader explained that EuroNeoStat II did not receive funding at first, because the predecessor action had not come to an end yet and the proposal for EuroNeoStat II needed to be improved based on the results of the first action. However, the action leader explained that it was almost impossible to maintain the register developed by the first EuroNeoStat without funding, and that the transition period between the first and the second action was very difficult, as no funding was available for almost one year. The action leader pointed out that it would not be possible to maintain the EuroNeoStat II register again without funding from the European Commission after the action has come to an end. It was therefore suggested that DG SANCO should separate funding registers from funding actions, in order to guarantee sustainability of registers in Europe.

6.15 Impact to be expected

According to the action leader the impact of EuroNeoStat II is positive and encouraging. He pointed out that some regional, but also national units across the EU are setting up similar networks.

In comparison to the first edition of EuroNeoStat, four sets of indicators have been introduced under EuroNeoStat II to measure the impact on patient care. The action leader explained that with these indicators, they are now able to measure the care and improvement throughout units across Europe.

7. 5ECCSRAD

7.1 Summary

The overall objective of the 5th European Conference on Clinical and Social Research on AIDS and Drugs was to increase capacity for development and implementation of effective addiction prevention strategies in relation with HIV/AIDS prevention, care and support throughout the EU and Candidate Countries by scaling up clinical, public health and social sciences research and best practice.

There is no doubt that the Conference is fully in line with 2008 Health Programme priorities.

Based on the evidence collected, the conference has successfully contributed to strengthening European networking on HIV/AIDS and related issues. The scientific programme aimed to offer all participants innovative topics with balanced lectures and symposia on recent developments in the field of HIV medicine and on the methods and results of social and behavioural research on AIDS and related issues. The dissemination of the conference outputs has been effective, and the monitoring of users of these outputs has been working well.

The figure below provides a summary outline for this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to which Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
5ECCSRAD	+++	++	N/A	+++	+++	+++	+++	1	+++	1. Implementing EU legislation: 1.0 2. Economies of scale: 1.0 3. Promotion of best practice: 3.0 4. Benchmarking for decision making: 1.0 5. Cross border threats: 1.5 6. Free movement of persons: 0.0 7. Networking: 2.0
	The action fully meets the objectives if the Health Programme and the priority areas in the 2008 Work Plan. The proposal was regarded of an overall exceptional quality in the evaluation report.	While the conference successfully contributes to European networking on HIV/AIDS, the rationale for the action does not seem too strong, given that other international initiatives exist and can be regarded as being important.	No evidence base specified in the proposal.	The action ties well in with other work undertaken at EU level.	The action clearly addresses a cause of concern in MSs and internationally.	The action has a clearly defined set of target groups, including: - specialists acting in the field of addiction and drug related blood-born infectious diseases - representatives from youth organisations, NGOs, private sector etc. - policy makers.	The action has a clear dissemination plan, proceeding during the conference and dissemination through the conference's website.	- 1 Lead Partner - Conference participants came from more than 46 different countries	- A scientific committee was constituted with regard to experiences gained through previous conferences; - A participants' satisfactory survey was carried out, using a number of different indicators - the use of the conference website was closely monitored	Particularly strong in: 3. Promotion of best practice - The proposal specifie that the conference will scaled up and disseminate scientific researches on prioritised issues of the conference. 5. Cross border threats - The conference features an organised section on capacity building in the field o development and implementation of outlined proble areas prevention. 7. Networking - the conference features organised debates aimed on mobilising comprehensive and broader civil society and community actions to fight stigma and discrimination, disseminated results of the section.

7.2 Key facts

Calls for proposals:	2008 – Call for proposals for Conferences (Single Beneficiary)
Proposal title:	5th European Conference on Clinical and Social Research on AIDS and Drugs
Acronym:	5ECCSRAD
Financing mechanism:	Conference

Starting date:	28.04.2009 (Conference date)
Duration (in months):	7 months (duration of preparation)
EC contribution:	€100,000
Overall score achieved in Consolidated Evaluation Report:	82
Total criteria block: A, B, C	A) 58; b) 24
Main partner:	Lietuvos AIDS centras (Lithuania)
Number of associated partners:	0
Number of collaborating partners:	0
Priority area:	2. Promote Health (HP-2008)
Action:	2.2.1 Addiction prevention (3.3.4. in AWP 2008)
Typology[25]:	Development/Demonstration project

7.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[26]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to produce / disseminate information:** The objective of the conference is to increase capacity for development and implementation of effective addiction prevention strategies in relation with HIV/AIDS prevention, care and support throughout EU and Candidate Countries.

[25] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).
[26] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Development/demonstration action**: however, action is a conference, no evidence base specified in the proposal
Clear target groups	Target group: Specialists acting in the field of addiction and drug related blood-born infectious diseases (clinical/public health/social sciences, primary and secondary prevention, early intervention, providing care and support for PLWHA and vulnerable groups): • Representatives from youth organisations, NGOs, private sector, PLWHA community; • Policy makers; • stakeholders receiving the outcomes of the conference implementation are PLWHA and people touched by addiction problem.
Clear dissemination plan – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	• proceeding during the conference providing deliverables to participants and after the conference via the conference's web site for one year; • dissemination of material through National AIDS ambassadors, NGOs and other active networks (i.e. the European AIDS treatment group) and Organizing Committee members' actions; • It was envisaged that information about getting results of the conference would be disseminated via international media through press releases.
Estimate the population reached (or targeted) by the action	583 participants from more than 46 different countries
Matching of project's deliverables (if any) with project's objectives	Deliverables were abstract book and USB key with speakers' presentations, which were divided for clinical, public health and social sciences –researches related with addiction and drug-related blood-borne infectious diseases. However, the action leader confirmed that no manual of best practices, as

Criteria	Notes / Comments
	intended in the proposal, was published, due to financial problems.
Use of multipliers	N/A
Evaluation (provision of indicators)	The Follow up and evaluation plan include the concrete purpose and indicators for the implementation of the objectives and related activities: • Keeping the timetable (do the ongoing activities correspond to the time table); • Reaching the quality and quantity of the audience and stakeholders (do the scope of the participants and stakeholders addresses defined regional, professional and quantitative indicators formulated in the proposal); • Addressing the materials and implementing activities related with the prioritized areas (did the above mentioned sections aimed on each objective implemented during the conference, did the dissemination of the deliverables strategy implemented, etc.).
Sustainability plan	Results of the conference were available for half a year after the event on the conference's website. Other than that no sustainability plans exist, though interested parties can contact the lead partner of the action to ask for results.

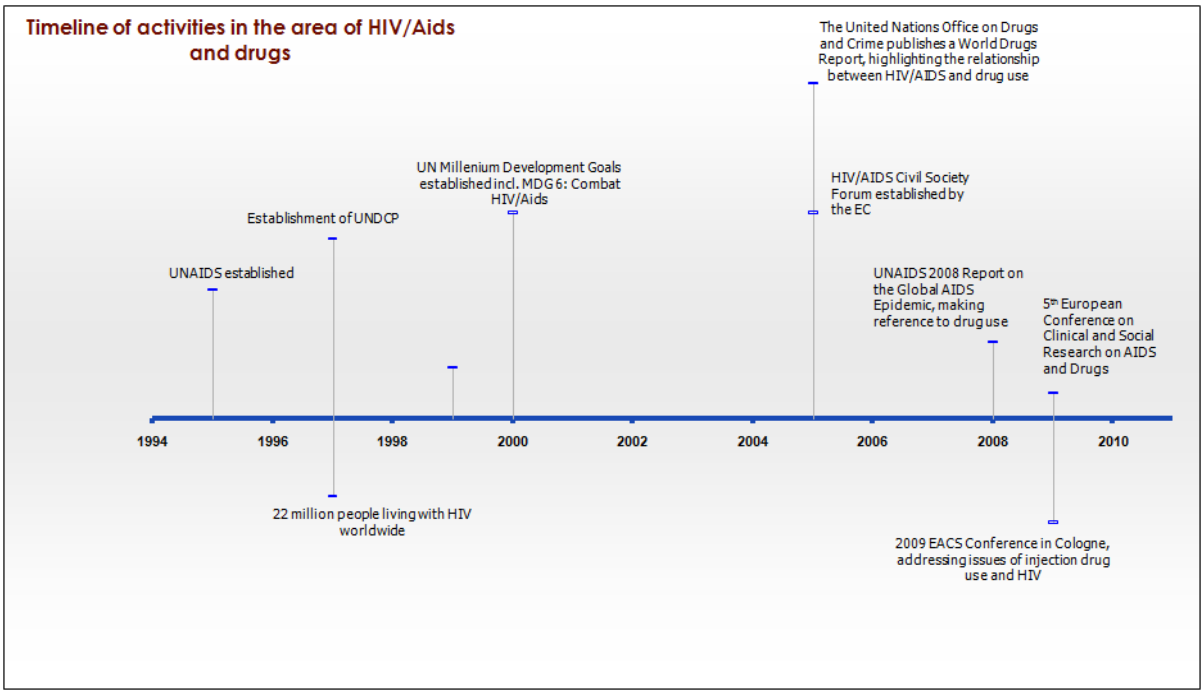
7.4 Introduction

The AIDS Centre in Lithuania organised the 5th European Conference on Clinical and Social Research on AIDS and Drugs in April 2009. The conference's aim was to strengthen European networking on HIV/AIDS and related issues and the scientific program aimed to offer all participants innovative topics with balanced lectures and symposia on recent developments in the field of HIV medicine on the methods and results of social and behavioural research on AIDS and related issues. Opportunities for oral and poster presentations were given to participants.

7.5 Background / Policy Context

In order to assess and make a judgment on the extent on which the 5ECCSRAD Conference is tackling a serious health issue, this case study examines what other public health interventions have taken place and the organisations involved in coordinating / funding these activities. The following timeline provides an overview of the developments in the field of AIDS and Drugs.

Figure 11 – Developments in the field of AIDS and Drugs



Drug abuse is one of the primary ways HIV is spread. Since the first HIV/AIDS case from injecting drug use (IDU) was diagnosed in New York in 1981, it is estimated that nowadays more than 5% of all HIV infections are related to injecting drug use with infected needles. Risky sexual behaviour under the influence of drugs, whether they are injected or taken some other way, is another leading cause of HIV transmission.

In 1995, the **Joint United Nations Programme on HIV and AIDS** (UNAIDS) was established, with the mission to lead, strengthen and support an expanded response to HIV and AIDS that includes preventing transmission of HIV, providing care and support to those already living with the virus, reducing the vulnerability of individuals and communities to HIV and alleviating the impact of the epidemic.

In 1997, the **United Nations established an Office on Drugs and Crime** (UNODC) by combining the United Nations International Drug Control Program (UNDCP) and the Crime Prevention and Criminal Justice Division in the United Nations Office at Vienna. The division was renamed the United Nations Office on Drugs and Crime in 2002. UNODC is also a cosponsor of UNAIDS since 1999.

Between 1996 and 1998, the number of countries reporting HIV infection among injecting drug users increased by nearly 40%.

UNODC publishes a yearly World Drug Report, presenting a comprehensive assessment of the international drug problem. In 2005, UNODC's World Drug Report highlighted the relationship between HIV/AIDS and drug use.[27] Especially in Eastern Europe and Central Asia, HIV/AIDS is spread primarily by injection drug use (IDU) via the sharing of needles.

Among the estimated 16 million people injecting drugs worldwide, one in five are likely to be HIV positive. Because young people are also often more likely to use drugs, UNODC is targeting this population with a campaign to raise awareness about drug use and its connection to the spread of HIV and AIDS.

[27] http://www.unodc.org/pdf/WDR_2005/volume_1_chap3.pdf

The *2008 Report on the Global AIDS Epidemic*, issued in July by the Joint United Nations Programme on HIV/AIDS (UNAIDS), reports that the global percentage of people living with HIV has stabilised at an estimated 33 million people who are HIV-positive. Two-thirds of those people live in Africa, and almost three-quarters of AIDS deaths during 2007 occurred in Africa. The report stresses that HIV prevention programs still fail to reach the majority of high-risk populations, such as ***injecting drug users***, women, children, sex workers, and men who have sex with men. These high-risk populations also face considerable barriers to HIV treatment access, which UNAIDS attributes to "institutionalized discrimination." Among the report's recommendations are those calling for full implementation of evidence-informed policies and programs; adoption of long-term strategic planning and evaluation mechanisms; increased investment in evidence-based prevention approaches; and reducing gender inequities, stigma, discrimination, and marginalization.

Internationally as well as the European level, HIV/AIDS conferences have been set up, providing a platform for scientists, clinicians and other stakeholders to discuss and interact. In recent years, these conferences have been focusing on topics related drug use and HIV/AIDS.

At the international level, an **International AIDS Conference** is held since 1985 by the **International Aids society (IAS)** every year or every two years. The conference is the largest regular conference on any health or development issue and provides a forum for the interaction of science, community and leadership. These conferences also provide an opportunity to intensify political and financial commitments to AIDS, and include the largest international conference scholarship programme in HIV/AIDS.

In Europe, the **European AIDS Clinical Society** (EACS), a not-for-profit scientific society of European clinicians and researchers, active in the field of HIV/AIDS, hosts every 2 years a European conference held in a major European city. In addition, a series of European AIDS Conferences on the Methods and Results of Social and Behavioural Research on AIDS have all represented European milestones and have been organised with support primarily from the European Commission, the WHO and UNAIDS. The conferences facilitate consultations, discussions and updated information dissemination on the latest research, lessons learned and best practices among an important spectrum of HIV/AIDS researchers, practitioners, programme managers and policy makers. At the 2009 **EACS Conference in Cologne**, a joint EACS/IAS session on Harm Reduction addressed the issues of injection drug use (IDU) and HIV, particularly in Eastern Europe.

The 5ECCSRAD conference is therefore positioned well as a complementary action to conferences previously done in the field.

7.6 Origins of HP project

A predecessor conference, the 4th European AIDS Conference on the Methods and Results of Social and Behavioural Research, had been organised in 2002 under the patronage of the Prime Minister if the Republic of Lithuania, and hosted by the Queen of Sweden. Each of the European AIDS Conferences on Methods and Results of Social and Behavioural Research on AIDS has represented important European milestones and has been organised with support primarily from the European Commission, WHO and UNIADS.

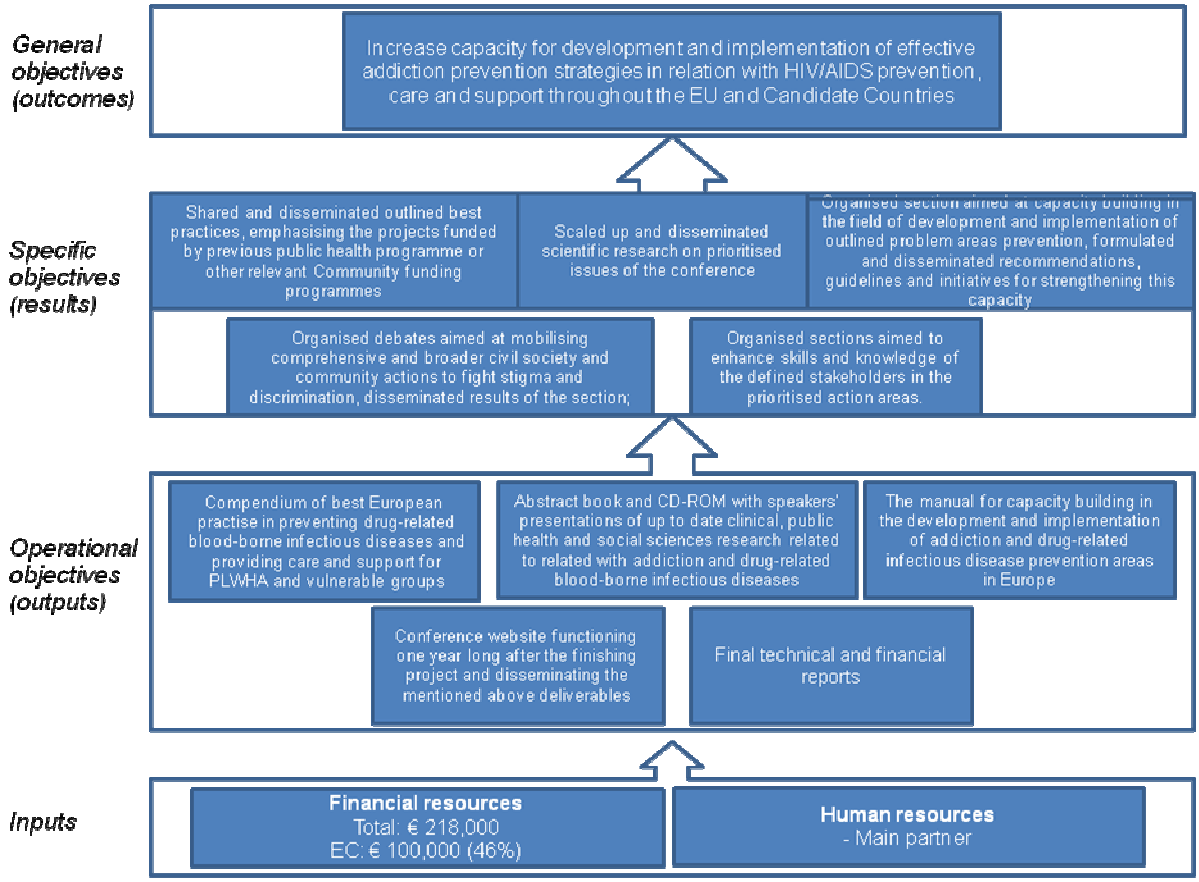
7.7 Overall project objectives / Intervention logic

The overall objective of the conference was to increase capacity for development and implementation of effective addiction prevention strategies in relation with HIV/AIDS

prevention, care and support throughout the EU and Candidate Countries by scaling up clinical, public health and social sciences research and best practice.

Based on an analysis of the proposal and interim report, the diagram below depicts the project's complete intervention logic. As reflected in the graph, the general objective clearly reflects the overall aim of the action. However, there is some overlapping at the next two levels between the specific objectives and the expected outputs, as some of the specific objectives could be considered as outputs. More specific details on each of these aspects is presented below.

Figure 12 – Intervention logic diagram for 5 ECCSRAD



Inputs:

The table below details 5ECCSRAD's budget providing costs for all inputs:

Expenditures	
Direct eligible costs	€
E.1. Staff	25,000
E.2. Travel costs and subsistence allowances	27,000
E.3. Equipment(1)	25,000
E.4. Consumables and supplies	34,000
E.5. Subcontracting costs	59,000
E.6. Other costs(2)	32,000
Total direct eligible costs	*202,000*
Indirect eligible costs	

E.7. Overheads(3)	16,000
Total indirect eligible costs	*16,000*
Total expenditures	**€218,000**

Expected outputs:

Expected outputs (as per proposal)	**Nature**	**Achieved outputs (as per Technical Implementation Report)**
1. Compendium of best European practise in preventing drug-related blood-borne infectious diseases and providing care and support for PLWHA and vulnerable groups.	1. Compendium	1. Compendium was published, based on the best European practice examples (preventive, care and support programmes, directed on working with different risk groups, implementing innovating methods, having clear results of programme's impact evaluation)
2. Abstract book and CD-ROM with speakers' presentations of up to date clinical, public health and social sciences research related to related with addiction and drug-related blood-borne infectious diseases.	2. Proceedings abstract book and CD-ROM	2. Abstract book was published based on the scientific abstracts submitted.
3. The manual for capacity building in the development and implementation of addiction and drug-related infectious disease prevention areas in Europe.	3. Manual	1. Interactive manual disseminated for conference participants and stakeholders, in which recommendations, guidelines and initiatives for strengthening capacity in the framed field during the special session of the conference are summarised
2. Conference website functioning one year long after the finishing project and disseminating the mentioned above deliverables.	4. Website	4. Website recommendations, guidelines and initiatives for strengthening capacity in the framed field during the special session of the conference are available

Expected outputs (as per proposal)	Nature	Achieved outputs (as per Technical Implementation Report)
3. Final technical and financial reports	5. Report	5. Paper and electronic version to EAHC/EC, when approved to be uploaded on the website, dissemination to the conference attendees, partners, OC and SC members and other stakeholders

Expected aims/outcomes:

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
1. Shared and disseminated outlined best practices, emphasising the projects funded by previous public health programme or other relevant Community funding programmes;	N/A	*Same as aim.*
2. Scaled up and disseminated scientific research on prioritised issues of the conference;	N/A	*Same as aim.*
3. Organised section aimed at capacity building in the field of development and implementation of outlined problem areas prevention, formulated and disseminated recommendations, guidelines and initiatives for strengthening this capacity;	N/A	*Same as aim.*
4. Organised debates aimed at mobilising comprehensive and broader civil society and community actions to fight stigma and discrimination,	N/A	*Same as aim.*

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
disseminated results of the section;		
5. Organised sections aimed to enhance skills and knowledge of the defined stakeholders in the prioritised action areas.	N/A	*Same as aim.*

7.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with two of the principles / strategic objectives set out in the Health Strategy (2008-2013):

- **Principle 3:** Health in All Policies (HIAP) - the coordinated approach to combat HIV/AIDS in the EU and Neighbourhood countries[28];

- **Strategic objective 1:** Fostering good health in an ageing Europe - Healthy ageing must be supported by actions to promote health and prevent disease throughout the lifespan by tackling key issues including poor nutrition, physical activity, alcohol, drugs and tobacco consumption, environmental risks, traffic accidents, and accidents in the home.

7.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the conference ties in with other work in the same area, the evaluation has identified the following initiatives:

<u>Other EU/DG SANCO Initiatives</u>

The EU funded projects listed below are HIV and AIDS related projects that are funded within the 1st or 2nd EU Public Health Programme (they don't necessarily have a formalised working relation with AIDS Action Europe):

- A Database on Public Health Projects in North Eastern Europe and its neighbouring countries
- aids & mobility europe
- BORDERNETwork. Highly active prevention: scale up HIV/AIDS/STI prevention, diagnostic and therapy across sectors and borders in CEE and SEE
- CONNECTIONS - Integrated responses to drugs and related infections across the European criminal justice systems
- Correlation - European Network Social Inclusion & Health
- ENCAP - Expanding Network for Coordinated and Comprehensive Actions on HIV/AIDS Prevention among IDUs and Bridging Population
- European MSM Internet Survey (EMIS)

[28] COM(2005) 654.

- Eurosupport 6: Developing a training and resource package to improve the sexual and reproductive health of people living with HIV
- Everywhere Project
- H-CUBE. HBV-HCV-HIV: Three different and serious threats for European young people. A Network to study and face these challenges in the EU.
- HIV community-based testing practices in Europe (hiv-cobatest)
- Scientific review of national drug treatment guidelines
- Sialon capacity building in HIV/syphilis prevalence estimation using non-invasive methods among msm in southern and eastern Europe
- TAMPEP 8: European Network for HIV/STI Prevention and Health Promotion among Migrant Sex Workers
- YOUNG AND HIV: European network to arrange an innovative prevention campaign and to exchange good practices-experiences in Europe (sunflower)

International Organisations involved in HIV/AIDS and drugs research

- WHO
- ECDC
- EMCDDA
- EHRN
- UNESCO
- UNODC
- European AIDS Clinical Society (EACS)

Examples of national initiatives / Centres in EU Member States

- Lietuvos AIDS centras (LAC)
- National Centres for AIDS Prevention and Control
- AIDS and Clinic Immunology Research Centre (Poland)
- Helmholtz Zentrum Muenchen, Germany

etc.

7.10 Rationale behind selection procedures (consistency with HP objectives):

The evaluation report concluded that the 5ECCSRAD conference proposal fully met the objectives of the Health Programme and the priority areas in the 2008 Work Plan, in particular the following two priority areas:

Objectives of Priority areas
2.2.1 (HP – Annex) Address health determinants to promote and improve physical and mental health, creating supportive environments for healthy lifestyles and preventing disease; take action on key factors (…) **and sexual health, and on addiction-related determinants** such as tobacco, alcohol, illegal drugs and pharmaceuticals used improperly (…).
3.3.4. (AWP 2008) *Addiction prevention* - Actions to promote health through tackling addiction related health determinants will build on the activities funded in the first public health programme. Activities will be in line with the approach set out in the Commission communication on an EU strategy to support Member States in reducing alcohol-related harm, the EU Drugs Strategy and Action Plan, the Council Recommendation on Drugs, the Drug Prevention and Information Programme under the framework of the General Programme "Fundamental Rights and Justice" and the Green Paper "Towards a Europe free

Objectives of Priority areas
from tobacco smoke – policy options at EU level" as well as the overall EU approach on tobacco control.

More specifically, the evaluation report included the following comments:

- Application of an overall exceptional quality (topic and content are very relevant, information provided in the proposal exceeds requirements of the application form);
- Topic of conference is totally in line with 2008 Health Programme priorities; the key issues are very relevant to Community activities in the area;
- Very good value for money in terms of cost/participant.

7.11 Involvement of decision makers (design of project / exploitation of results):

The interview with the action leader confirmed that the Centre for Communicable Diseases and AIDS, the lead organisation of this action, is an expert in the field and was mainly involved in the design of the conference, in conjunction with DG SANCO and the EAHC.

7.12 Dissemination

Dissemination of results (as per proposal)	Dissemination of results (as per Technical Implementation Report)
Providing deliverables to participants during the conference	√
Website where results will be available for one year after the end of the conference	√
Through National AIDS ambassadors, NGO and other active networks and Organizing Committee members actions	√
Information about getting results of the conference disseminated via the international media during organised press releases	√

During an interview undertaken, the action leader confirmed that the main means for dissemination was the conference's website. Information on the website was available one year before the start of the conference, and for half a year after the conference. All the outputs of the conference were made public on the website, as well as all documents.

The interview with the action leader also revealed that the action did not manage to publish the manual of best practices, as intended in the proposal, due to financial problems. This was explained to DG SANCO and not further problems were encountered.

Target groups:
As envisaged in the proposal, participants of the conference were representatives of the majority of EU Member States as well as of EFTA-EEA countries, candidate and neighbouring countries:

- **Specialists** acting in the field of addiction and drug related blood-borne infectious diseases (clinical/public health/social sciences, primary and secondary prevention, early intervention, providing care and support for PLWHA and vulnerable groups, representatives of Health determinants projects funded by the Health Programme 2003-2007);
- Representatives from youth organisations, NGOs, private sector, PLWHA community;
- **Policy makers** (at national, regional and international levels);
- Stakeholders receiving the outputs of the conference implementation are PLWHA and people affected by addiction problems.

71 of the 583 participants received scholarships to attend the conference, enabling those stakeholders with fewer resources to attend the event. Thus, the conference was able to attend to reach a wide geographical and professional range of participants.

In addition, during the interview with the action leader, data on the visitors of the conference website was made available. According to this information, the website attracted more than 18,000 visitors, viewing more than 75,000 pages in total. Website users mostly came from the USA, Canada and Nigeria, as well as from all EU countries, Russia, Ukraine and Moldova, and some of them were from Asia. None of the website users left any feedback or comments on the website though.

7.13 Monitoring processes

During the first Organizing Committee (OC) meeting the plan for the follow-up and evaluation was prepared and the responsible people nominated. The Scientific Committee (SC) was constituted according to the experience gained through previous conferences and collaborating experience with the specialists in the field.

The follow up and evaluation plan included the concrete **purpose** and **indicators** for the implementation of each objective and the related activities:

- Stick to the agreed timetable;
- Reaching the quality and quantity of the audience and stakeholders (do the scope of the participants and stakeholders address the regional, professional and quantitative indicators defined in the proposal?);
- The results of the action's performance indicators and the level to which the set objectives were reached are presented in the final report.

In addition, a participants' satisfactory survey was carried out, using the following indicators:

- participants' satisfaction in registration process;
- conference materials;
- speakers;
- facilities;
- satisfactory in sessions' content;
- staff;
- participants were asked to provide further recommendation for the conference organisers compared with mentioned above indicators.

Finally, as stated above, the use of the conference's website was closely monitored by the lead contractor, and statistics have been produced according to the country of origin of website users and the pages they have been viewing.

7.14 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the action 5ECCSRAD fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		5ECCSRAD
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	1.0
3.	Promotion of best practice:	3.0
4.	Benchmarking for decision making:	1.0
5.	Cross border threats:	0.5
6.	Free movement of persons:	0.0
7.	Networking:	2.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

7.15 Sustainability

The action leader confirmed that all deliverables of the conference were available on the conference's website for half a year after the event, and were then taken offline. It was assumed that this was due to contractual reasons between the Centre for Communicable Diseases and AIDS and DG SANCO. However, the action leader confirmed that conference results and outputs would be made available to any interested party contacting the Centre, though this has not been the case to date.

7.16 Impact to be expected

During the interview, the action leader confirmed that the intended impacts of the conference were achieved. The conference was structured in a way to disseminate EU best practice as well as to cover the dissemination of clinical and scientific research results. In addition, attendants were able to network with each other.

8. AIDS ACTION EUROPE

8.1 Summary

The general objective of the OG is to support the ongoing work of Aids Action Europe, i.e. to unite civil society to work towards a more effective response to the HIV epidemic in Europe (and Central Asia), to support NGOs to make an effective contribution to European HIV/AIDS policies, to facilitate continuous exchange among NGOs on good practices and lessons learned and to manage effectively the AAE network.

There is no doubt that the subject of HIV/Aids is a legitimate public health issue, with the WHO as well as many other international and nation public health bodies working towards solutions to the multi-facetted problems relating to HIV/Aids. The strong networking character of the action, bringing together civil society organisations from all EU Member States and facilitating knowledge sharing and exchange of best practice, has a high added value from a EU perspective as it supports the coordination of the EU response to HIV/Aids as a major health threat and enables an exchange of information between civil society and policy makers.

Based on the final report and action leader statement it can be said that the OG went according to plan. AAE has received further funding from the EU Health Programme in 2010 and 2011 to continuously support the organisation's mission to unite civil society to work towards a more effective response to the HIV epidemic in Europe and Central Asia.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
Aids Action Europe	+++	+++	+++	+++	+++	+++	+++	1	++	1. Implementing EU legislation: 2.0 2. Economies of scale: 1.5 3. Promotion of best practice: 3.0 4. Benchmarking for decision making: 0.0 5. Cross border threats: 2.3 6. Free movement of persons: 0.0 7. Networking: 3.0
	Action meets the objectives of the HP and of the 2008 Work Plan by promoting collaboration amongst HIV/AIDS related initiatives in Europe.	The action conciders a legitimate public health issue. With its strong networking character, bringing together civil society organisations from all EU Member States and facilitating knowledhe sharing, the action has a high added value.	Evidence was presented in the proposal, making reference to a number of other organisations working in the same field.	The action ties well in with previous EU funded research and actions, including DG SANCO and DG Research's Framework Programmes.	Numerous complementary initiatives were identified at international, EU as well as national level.	Clear target groups have been identified, such as European NGOs working on HIV/AIDSm as well as European networks and projects, including those funded by the Commission.	The dissemination plan evolves around the two streams of the action, "Public policy dialogue" and "Linking and learning". For both streams, dissemination strategies have been set out in the proposal, including: - websites - meeting reports - e-news - press releases - clearinghouse update newsletter - direct mailing - events	Aids Action Europe is an Operating Grant with a single beneficiary. However, organisations from all EU MS are involved in the action as members of the network.	- Internal: Annual technical and financial reports. - External evaluation: Financial annual report reviewed and cleared by external auditing company KPMG. For the last programming period 2004-2008, an independent external content evaluation of Aids Action Europe was carried out mid-2009.	Particularly strong in: 3. Promotion of best practice - One of the project's 3 main objectives is to facilitate continuous exchange among NGOs on good practices and lessons learned related to HIV and AIDS. 5. Cross border threats - Europe is facing a growing HIV/AIDS epidemic, and EU countries are among those countries worldwide where the number of new HIV infections is still rising. 7. Networking - One of the project's main objectives is to facilitate continuous exchange among NGOs of the AAE network through linking and learning.

8.2 Key facts

Calls for proposals:	2008
Proposal title:	AIDS Action Europe: Public Policy Dialogue and Linking & Learning
Acronym:	AIDS Action Europe

Financing mechanism:	Operating Grant
Starting date:	1st January 2009
Duration (in months):	12 months
EC contribution:	€167.394,35
Overall score achieved in Consolidated Evaluation Report:	87
Total criteria block: A, B, C	A: 24; B: 33; C: 30
Main partner:	Stichting Aids Fonds - Soa Aids Nederland (SANL) on behalf of AAE
Number of associated partners:	None (see above)
Number of collaborating partners:	All of Aids Action Europe's member organisations (ca. 400 NGOs, national networks, AIDS service organisations, activists and community based groups of people living with HIV29)
Strand:	2. **promote health** and reduce health inequalities, increasing healthy life years and promoting healthy ageing (HI-2008)
Action:	**333/3333** (Core funding support for HIV/AIDS prevention network(s))
Typology[30]:	**Implementation action**

8.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[31]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's	**Objective to produce/disseminate information:** The OG aims to disseminate information amongst its members and enable NGOs to make an effective contribution to European HIV/AIDS

[29] http://www.aidsactioneurope.org/index.php?id=157

[30] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[31] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	policies through public policy dialogue (PPD), and therefore disseminating information (e.g. regarding the needs of people affected by HIV/Aids) to decision makers **Objective to network:** the objective of the OG is to facilitate continuous exchange among NGOs on good practices and lessons learned related to HIV and AIDS through linking and learning (L&L), primarily through maintenance and promotion of Clearinghouse database and provide platform for other European networks and projects
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Implementation action**
Clear target groups	European NGOs working on HIV/AIDS. These include AAE members (currently 257, target 240), a very diverse group including service NGOs, adolescent reproductive health service providers, community-based groups of PLHIV, NGOs working in the broader field of health, rights or education, MSM groups, migrant networks, women's groups and national expertise centres. Activities were not restricted to members only. They tried to reach out to as many European NGOs as possible, including those who are a member of the EU Civil Society Forum on HIV and AIDS. European networks and projects, including those funded by the Commission.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	Public Policy Dialogue On the action's website a dedicated page for disseminating information about the EU HIV/AIDS Civil Society Forum was built, which is still operating now. Meeting reports. Quarterly e-news.

Criteria	Notes / Comments
	Open letters / statements to stakeholders. Calls for action and petitions were signed (NAT online petition for equality directive). Press releases. However, the online discussion forum around the development of the new EU policy was cancelled. Linking & Learning. clearinghouse online tool (which disseminate the results of the action's activities and provides European NGOs and other relevant stakeholders to disseminate the results of their activities) Website / members section on website Banners or links on other websites such as the World AIDS Campaign Quarterly e-news disseminated 4 times in 2009. The bimonthly clearinghouse update newsletter Through direct mailing AAE approached specific NGOs regularly in 2009. Representation at different events
Estimate the population reached (or targeted) by the action	400 NGOs, national networks, AIDS service organisations, activists and community based groups of people living with HIV, covering all European countries.
Matching of project's deliverables (if any) with project's objectives	The action has 11 deliverables, including dissemination of information via website and newsletter, as well as facilitation of collaboration through online tools, which support networking as one of the OG's main objectives
Use of multipliers	The member organisations of the network can be seen as multipliers, disseminating information at regional and local level.
Evaluation (provision of indicators)	*External evaluation procedure* • The financial annual report of SANL was reviewed and cleared by the external audit company KPMG. • An independent external content evaluation of all SANL programmes, including AAE, for the period 2004-2008 was carried out mid 2009.

Criteria	Notes / Comments
Sustainability plan	**Sustainability of PPD actions:** The work will optimise inclusion of civil society and PLHIV in key European policies and thus to better adapt these to their needs. The strong links with EC Civil Society Forum and Think Tank will secure wider application and effectiveness of actions and thus contribute to better coordinated response to the epidemic. **L&L actions:** The clearinghouse facilitates access to good practices, which helps NGOs to develop effective and sustainable interventions and not duplicate or re-invent. It enables NGOs and others to stay up to date with respect to pertinent developments in the field of HIV and to find potential partner organisations through use of the website. AAE is working on alternative funding strategies to further its aim to secure sustainability of its programs and actions.

8.4 Introduction

Europe is facing a growing HIV/AIDS epidemic. The UN Secretary General stated in the 2008 UNGASS report that Ukraine, Russia and EU countries are among those countries worldwide where the number of new HIV infections is still rising. The EU Health Programme 2008-2013 also emphasises that HIV is a public health threat.

With the Operating Grant funded under the Health Programme, AAE aims to support NGOs to make an effective contribution to European HIV/AIDS policies, facilitate continuous exchange among NGOs on good practices and lessons learned, and manage effectively the AAE network.

8.5 Background / Policy Context

HIV/Aids has been on the international and national health agenda since the early 1980s, when the Acquired Immune Deficiency Syndrome has first been discovered (1981) and HIV (initially called HTLV-III or LAV) has been identified as the cause of AIDS (1984). The subsequent years saw a rapid spread of the disease: in 1990, around 8 million people were living with HIV worldwide. By 1997, around 22 million people were living with HIV worldwide. The Joint United Nations Programme on AIDS (UNAIDS) was established in 1995, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) was established in 2002. Statistics for the end of 2009 indicate that around 33.3 million people are living with HIV. Each year around 2.6 million more people become infected with HIV and 1.8 million die of AIDS.

Although HIV and AIDS are found in all parts of the world, some areas are more afflicted than others. The worst affected region is sub-Saharan Africa, where in a few countries more than one in five adults is infected with HIV. The epidemic is spreading most rapidly in

Eastern Europe and Central Asia, where the number of people living with HIV increased by 54.2% between 2001 and 2009.

The EU has established major bodies for the exchange of information and the coordination of activities in the field of HIV/Aids, addressing Member States and neighbouring countries. Areas where EU initiatives are taking place include:

- Prevention
  - E.g. the 2009 Commission communication on combating HIV/AIDS in the EU and neighbouring countries identifies policies to help reduce the number of new infections and improve the quality of life for people living with HIV/AIDS.

- Transmission
  - E.g. every year around 8.500 individuals die in the EU because of drug overdose, 2.100 die of HIV/AIDS attributable to drug use and 3.000 people become infected with HIV because of drugs. EU countries and the European Commission have developed together, over the past two decades, a European approach to dealing with drugs sustainably.

- Treatment and care
  - E.g. the EU has consistently led efforts to widen access to vital medicines in developing countries and to strike the right balance between the intellectual property rights of pharmaceutical companies and the need to ensure that medicines are available for poor countries facing public health crises.

- Patient rights and working conditions
  - E.g. the European Community has enacted the Racial Equality Directive and Employment Framework Directive. The two Directives define a set of principles that offer everyone in the EU a common minimum level of legal protection against discrimination.

- EU neighbours
  - E.g. the EU regularly exchanges information and advises candidate countries and potential candidates on EU health policy, and evaluates the progress they are making in incorporating EU health policy rules into their own legislation.

- Surveillance
  - E.g. the 2008 epidemiology report on HIV/AIDS is the result of monitoring by the European Centre for Disease Prevention and Control (ECDC) and WHO Europe. The ECDC and Commission also cooperate on specific monitoring projects, e.g. on implementation of the Dublin declaration on fighting HIV/AIDS in the EU and Central Asia.

- EC Health Indicators
  - E.g. the ECHI (European Community Health Indicators) project was carried out under the Health Monitoring Programme and the Community Public Health Programme 2003-2008. The result is a list of 88 'indicators' for the public health field arranged according to a conceptual view on health and health determinants.

- European Health Information

- E.g. the European Union Public Health Information System (EUPHIX) provides data on HIV/Aids.

- Statistics
  - E.g. the European Centre for Disease Prevention and Control provides HIV/Aids statistics

- Research
  - E.g. the European and Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases of HIV/AIDS, malaria and tuberculosis.

The EU is also active in developing countries and at global level and provides considerable support to the 'Global Fund' and other institutions.

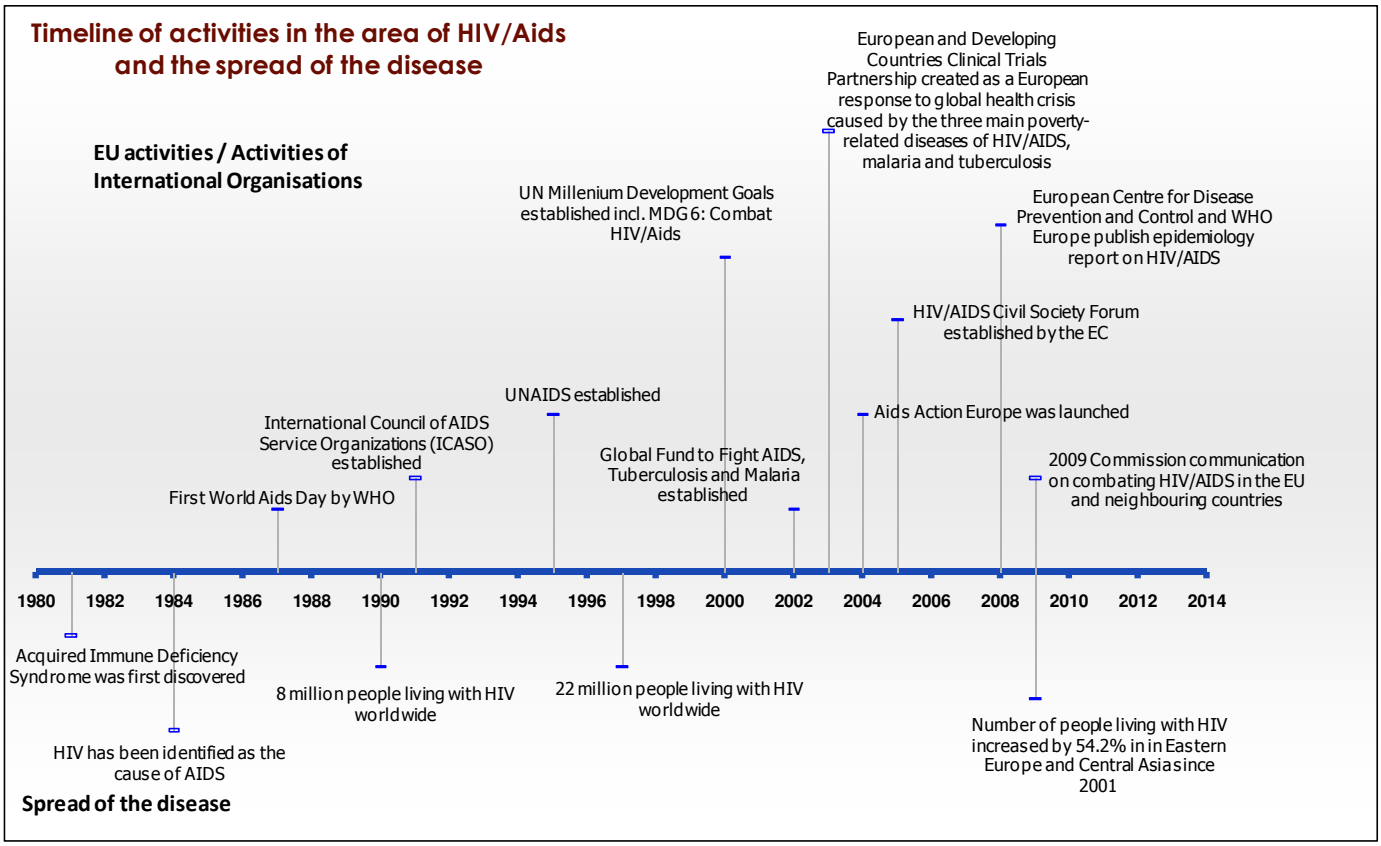
Important European declarations in the area of HIV/Aids include the 2004 "Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia", the 2004 "Vilnius Declaration on Measures to strengthen Responses to HIV/AIDS in the European Union and in Neighbouring Countries" and the 2007 "Bremen Declaration on Responsibility and Partnership - Together Against HIV/AIDS".

AIDS Action Europe is not the first European structure for civil society collaboration on AIDS and follows a long history of European collaboration among NGOs active in the fight against HIV/AIDS, e.g. the European Council of AIDS Service Organizations (EuroCASO), which was the European Partner of the International Council of AIDS Service Organizations (ICASO) preceded AAE.

AAE was initiated at the International AIDS Conference 2002 in Barcelona, where a number of European NGOs met to discuss the need for a new European NGO initiative to move beyond networking towards a European NGO partnership with a strong focus on policy, advocacy and practical support. AIDS Action Europe was launched in 2004 and has grown to be one of the largest HIV-related networks in the region, reaching beyond the borders of the European Union and covering all 53 countries in Europe and Central Asia. Members comprise a diversity of about 400 NGOs, national networks, AIDS service organisations, activists and community based groups of people living with HIV.

AAE is also a member of the EU HIV/AIDS Think Tank, a forum to exchange information between the Commission, the Member States, Candidate and EEA countries, and the co-chair of the HIV/AIDS Civil Society Forum, an informal advisory body established in 2005 by the European Commission to facilitate the participation of NGOs and networks, including those representing People Living with HIV/AIDS, in European policy development and implementation as well as to exchange information. The figure below presents an overview of the development of activities in the area of HIV/Aids and the spread of the disease.

Figure 13 - Overview of the development of activities in the area of HIV/AIDS and the spread of the disease



8.6 Origins of HP project

AIDS Action Europe was launched in 2004 and aims to promote collaboration amongst HIV/Aids – related initiatives in Europe. Since its start, AAE has focused on increasing public policy dialogue with a variety of stakeholders, on advocacy for European HIV policies and dissemination of good practices, primarily through the EC funded project European Partners in Action on AIDS (EPAA). The activities set out in the proposal are a continuation and dissemination of some of this work.

NGOs have proven very effective in tackling the challenges of responding to the epidemic and in reaching vulnerable groups. The Health Programme 2008-2013 recognises that NGOs and specialised networks can play an important role in meeting its objectives. A range of initiatives to support NGOs in their work on HIV/Aids has been funded through the previous and current EU Health Programme (see section 1.7 on similar initiatives). A broad range of HIV/Aids related research projects have also been funded under the EU Framework for Research and Technological Development (FP6 / FP7).

8.7 Overall project objectives / Intervention logic:

AAE plans to:

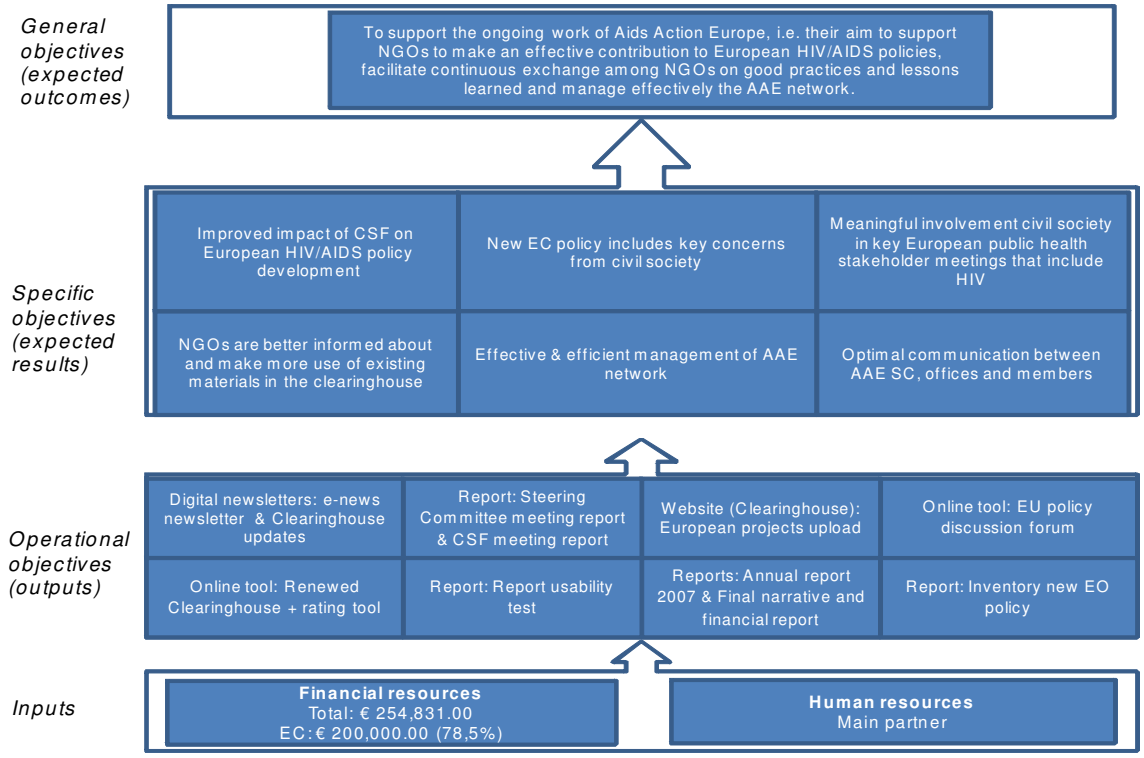
- enable NGOs to make an effective contribution to European HIV/AIDS policies through public policy dialogue (PPD), primarily through co-chairing of the EU HIV/AIDS Civil Society Forum (CSF), connecting to the EU HIV/AIDS Think Tank

(TT), involvement in development of new EU HIV/AIDS policy and in key European events;

- facilitate continuous exchange among NGOs on good practices and lessons learned related to HIV and AIDS through linking and learning (L&L), primarily through maintenance and promotion of Clearinghouse database and provide platform for other European networks and projects;
- manage effectively the work programme and network. Overall governance by AAE SC & programme implementation by Amsterdam office (manager, communication officer, assistant & financial officer).

Based on an analysis of the proposal and final reports the diagram below depicts the action's complete intervention logic. It shows a clear sequence of the general and specific objectives AIDS Action Europe intends to achieve, the expected outputs, and the key inputs. The diagram also reflects a clear differentiation between the specific objectives and the outputs of the action. More specific details on each of these aspects is presented below.

Figure 14 – Intervention logic for Aids Action Europe



Inputs:

Please find below a table detailing the Aids Action Europe budget providing costs for all inputs including staff, travel, equipment etc.:

Aids Action Europe Budget Overview		
E1: Staff	€ 160,160	
E2: Travel costs and subsistence allowances	€ 18,500	
E3 - Equipment		€ 0

Aids Action Europe Budget Overview		
E4 - Consumables & supplies linked to the project	€ 3,500	
E5 - Subcontracting costs	€ 15,000	
E6 - Other costs	€ 41,000	
Total Direct Eligible Cost		€ 238,160
Total E7-Overheads		€ 16,671
Total Indirect Eligible Cost		€ 16,671
TOTAL EXPENDITURE		**€ 254,831**

Expected outputs:

Expected outputs	Achieved outputs (as per Final Report)
Digital newsletter: e-news newsletter	M3, M6, M9, M12
Digital newsletter: Clearinghouse update	M2, M4, M7, M8, M10, M12
Report: Steering Committee meeting report	SC meeting report: sent to AAE SC M4 & M10. On website M5& M10.
Report: CSF meeting report	Meeting report CSF1 sent & posted M7, Meeting CSF2: presentations on website M12, full report available early 2010
Online tool: EU policy discussion forum	Technical facility built unto AAE website but not used. Alternative consultation rounds held with CSF and AAE SC members at CSF meetings and via email-list. **Justification:** Commission did not allow public consultation on the draft EU Communication on HIV/AIDS.
Online tool: Renewed Clearinghouse + rating tool	M6
Report: Report usability test	Evaluation of the usability of the E-news
Report: Annual report 2007	M5 available on website in English and Russian
Report: Inventory new EO policy	M4 inventory report CSF and AAE SC sent to Commission, additional consultation feed-back presented to Commission on M8,9,10 & 11
Website (Clearinghouse): European projects upload	By M12 there were 13 EU projects profiled on the website, and 7 EU funded projects have materials available in the clearinghouse
Report: Final narrative and financial report	M12+2

Expected aims/outcomes:

Aim	Indicator	Result (as per Final Report)
Improved impact of CSF on European HIV/AIDS policy development	**Indicator 1:** 90% of AAE tasks, as defined in the minutes of 2 CSF meetings, are carried out; the main results of CSF meetings are on the agenda of TT	**Outcome 1:** achieved. The action list resulting from each CSF meeting was reviewed at every conference call of the CSF coordination team and all activities for which AAE was responsible were carried out(action lists are always included in the CSF meeting reports). The CSF was informed about the status of the implementation of the action list at each subsequent CSF meeting (this update is also included in the reports). The first agenda item of the TT meetings consisted of a report from the CSF meeting.
New EC policy includes key concerns from civil society	**Indicator 1**: 40% of AAE members & 90% of CSF members provide input for the new EU policy through inventory **Indicator 2:** 50% of key priorities resulting from NGO inventory are included in new EU policy	**Outcome 1:** partially achieved. 100% of CSF members provided input at the 2 meetings and/or through the inventory following the March meeting. Due to the Commission's decision to hold a targeted consultation instead of an open one, AAE was not allowed to consult AAE members during the development of the new Communication. As alternative solution AAE had a discussion on several drafts of the Communication with the AAE SC. **Outcome 2:** achieved. Final report states that almost all priorities are reflected in the new Communication, even though AAE would have liked to see some issues highlighted stronger.
Meaningful involvement civil society in key European public health stakeholder meetings	**Indicator 1:** Inclusion of civil society as active contributors for agenda setting in 2 European stakeholder meetings	**Outcome 1:** achieved. The list of meetings shows that AAE contributed pro-actively to the agenda of several meetings.

Aim	Indicator	Result (as per Final Report)
that include HIV		
NGOs are better informed about and make more use of existing materials in the clearinghouse	**Indicator 1**: number of downloads from the clearinghouse has increased by 15% **Indicator 2:** number of uploads to the clearinghouse has increased by 10% **Indicator 3:** number of accountholders for the clearinghouse has grown by 10% **Indicator 4:** 11 recommendations from usability test implemented	**Outcome 1:** achieved. The number of good practices that were downloaded from the clearinghouse rose by 23% to 33101. **Outcome 2:** achieved. The number of uploaded good practices grew from 554 in 2008 to 779 in 2009. **Outcome 3:** achieved. 84 new account holders for the clearinghouse. **Outcome 4:** achieved. 11 recommendations from the usability test have been implemented, including: • News banner • Peer review ribbon rating system • Download tracking
Effective & efficient management of AAE network	**Indicator 1:** minutes of 2 SC meetings and 8 conference calls **Indicator 2:** annual report 2008	**Outcome 1:** achieved. The minutes of the meetings are available on the website in English (see annex 12 and 13). Minutes of the conference call have a confidential status. **Outcome 2:** achieved. Report available in English on website.
Optimal communication	**Indicator 1:** quarterly e-news, website	**Outcome 1:** achieved.

Aim	Indicator	Result (as per Final Report)
between AAE SC, offices and members	announcements, direct mailings	The website was updated regularly The e-news were disseminated 4 times in 2009 Direct mailings were used to communicate with members (e.g. inviting members to update their profile on website, press releases)

8.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Health Strategy objective 2: Protecting citizens from health threats. Health threats include infectious diseases (e.g. **HIV/AIDS**, tuberculosis, Creutzfeldt Jacob Disease, etc.) and threats emerging from physical, chemical or biological sources, including those relating to terrorist acts and environmental agents (e.g. ionising and non-ionising radiation and noise).

8.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the OG ties in with other work in the same area the evaluation has identified numerous initiatives:

1. Other EU / DG SANCO projects

The EU funded projects listed below are HIV and AIDS related projects that are funded within the 1st or 2nd EU Public Health Programme (they don't necessarily have a formalised working relation with AIDS Action Europe):

- Aids & Mobility Europe (HP 1, 2007)
- BORDERNETwork. Highly active prevention: scale up HIV/AIDS/STI prevention, diagnostic and therapy across sectors and borders in CEE and SEE (HP 2, 2009)
- CONNECTIONS - Integrated responses to drugs and related infections across the European criminal justice systems (HP 1, 2006)
- Correlation - European Network Social Inclusion & Health (HP 1, 2004)
- ENCAP - Expanding Network for Coordinated and Comprehensive Actions on HIV/AIDS Prevention among IDUs and Bridging Population (HP 1, 2005)
- Eurosupport 6: Developing a training and resource package to improve the sexual and reproductive health of people living with HIV (HP 2, 2008)
- Everywhere Project (HP 1, 2007)
- H-CUBE. HBV-HCV-HIV: Three different and serious threats for European young people. A Network to study and face these challenges in the EU. (HP2, 2008)
- Sialon: capacity building in HIV/Syphilis prevalence estimation using non-invasive methods among msm in southern and eastern Europe (HP 1, 2007)
- TAMPEP 8: European Network for HIV/STI Prevention and Health Promotion among Migrant Sex Workers (HP 1, 2006)

The projects listed below are HIV and Aids related projects funded under DG Research's Framework Programmes (FP6 / FP7):

- NEAT European AIDS treatment Network (FP6, 2007)
- AVIP AIDS VACCINE INTEGRATED PROJECT (FP6, 2004)
- HIVEVO Intra-patient evolution of HIV (FP7, 2011)
- SILENT HIV Paving the way toward HIV eradication/control (FP7, 2010)

2. International organizations involved in HIV/Aids related policy and advocacy

- With the aim of supporting civil society in Eastern Europe and Central Asia (EECA), AIDS Action Europe launched this region-wide project 'ROST'- Responding to HIV through Organisational Support and Technical Cooperation in EECA', which will be implemented by ***AIDS Foundation East-West (AFEW).*** The project includes the organisation of regional capacity development seminars on advocacy and resource mobilisation for AIDS Action Europe member organisations.
- AIDS Accountability International
- International Aids Society

3. Initiatives in Member States associated with AAE

- Deutsche Aids Stiftung
- Estonian Network of PLHIV
- HIV Danmark

4. Initiatives in third countries associated with AAE

- Belarusian AIDS Network
- All-Ukrainian network of PLHIV
- For Family and Health Pan-Armenian Association

8.10 Rationale behind selection procedures (consistency with HP objectives):

The evaluation report highlighted that the action complies with the following priority area of the 2008 Work Plan:

Objectives of Priority areas
2008 Work Plan item 3.3.3.3: Core funding support for HIV/AIDS prevention network(s).

The main comments in the evaluation report included:

Although members of the panel felt that this OG could be considered as an action of significant EU added value, the superficial presentation of the OG has been criticised in the Evaluation report, as the organisation seems to have the capacity to make a better submission and the tasks are important in the opinion of the panel.

- Two of the members of the panel considered that this OG could be considered as an action of significant EU added value, in terms that HIV/AIDS prevention and management is one of the areas where there are important inequalities on health between the EU MS and regions.
- Doubts about the possible overlapping with current or previously funded activities.

- Need to include better definition of the objectives, including as well the indicators for the dissemination strategy.

8.11 Involvement of decision makers (design of project / exploitation of results):

The action leader stated that Stichting Aids Fonds - Soa Aids Nederland (SANL) was targeting NGOs to involve them in the design of the action. The steering committee of SANL, including 12 NGOs and networks elected from among their member organisations, were strongly involved. In addition, the organizations carried out a wider consultation with all their member organizations at the time of project design.

It was also stated that the action was developed as a follow up of a previous three year project of Aids Action Europe. Certain aspects that arose from the previous project, e.g. Clearinghouse and Civil Society Forum co-chairing, became more and more important for the network and SANL applied for HP 2008-13 funding to make their work in this respect more sustainable.

In terms of the exploitation of results, the action leader stated that the EC directly, as well as UNAIDS, WHO Europe Office, ECDC (European Centre for Disease Control) are expected to benefit from the outcomes of the action. Governmental policy makers from MS, on the other hand, were not specifically targeted by the action.

8.12 Level to which outputs / results contribute to / are in line with the HP objectives:

The outputs as specified above (Objective 1: development of a new EU Communication on HIV/AIDS; Objective 2: Facilitation of Linking & Learning through updated website, members' section on website, update of Pan-European clearinghouse on HIV and AIDS etc); Objective 3 (Overall governance was carried out by the AAE Steering Committee (SC) through regular conference calls and 2 AAE SC meetings in Amsterdam and Budapest) are in line with HP objective 3: Generate and disseminate health information and knowledge.

8.13 Dissemination (incl. resources)

The OG has mainly followed the dissemination strategy set out in the proposal. Information on resources was not provided in the Proposal or Final Report. Results of AAE's work were communicated in the following ways:

Public Policy Dialogue

On the action's website a dedicated page for disseminating information about the EU HIV/AIDS Civil Society Forum was built, which is still operating now.

Meeting reports of the civil society forum were also shared through the CSF listserv.

Relevant policy and advocacy information was shared through quarterly e-news.

Open letters / statements to stakeholders.

Calls for action and petitions were signed (NAT online petition for equality directive).

Press releases

However, the online discussion forum around the development of the new EU policy was cancelled. AAE set up application on website, making it technically possible to do this work. Entire process of developing a new communication on HIV and AIDS was delayed and in the end AAE were not given the permission to openly consult the members of AAE.

Linking & Learning

The main tool for linking and learning is the clearinghouse (which disseminate the results of the action's activities and provides European NGOs and other relevant stakeholders to disseminate the results of their activities)

The members section provided another opportunity for European NGOs to link to and learn from each other. In 2009 AAE also built a similar section for AAE partners as well as for projects fundded by the European Commission related to HIV and AIDS.

Website used to disseminate announcements, vacancies, calls for action, events etc

Banners or links on other websites such as the World AIDS Campaign

Quarterly e-news disseminated 4 times in 2009.

The bimonthly clearinghouse update newsletter was disseminated to communicate the latest uploads in the clearinghouse and the most popular downloads. In July, the update also provided an overview of the changes that were made to the clearinghouse. In addition, a peer review section was added, allowing the visitors to rate the publications in the clearinghouse. New opportunities for linking and learning were also created by building a technically sophisticated link between the members profiles on the AAE website and the topics and target groups in the clearinghouse.

Through direct mailing AAE approached specific NGOs regularly in 2009. For example to ask them to update their profile in the members section of AAE's website, or to invite them to upload their good practices to the clearinghouse.

Representation at different events provided further opportunities for disseminating the results of AAE's activities.

The OG was successful in addressing all target groups stated in the proposal. Target groups reached were:

Primary target groups

European NGOs working on HIV/AIDS. These include AAE members (currently 257, target 240), a very diverse group including service NGOs, adolescent reproductive health service providers, community-based groups of PLHIV, NGOs working in the broader field of health, rights or education, MSM groups, migrant networks, women's groups and national expertise centres. Activities were not restricted to members only. They tried to reach out to as many European NGOs as possible, including those who are a member of the EU Civil Society Forum on HIV and AIDS.

European networks and projects, including those funded by the Commission

Secondary target groups

- Policy-makers (including Think Tank representatives), private sector, WHO Europe, UNAIDS, other ICASO regional offices through mailings, meetings, clearinghouse, etc.
- Internal target groups, namely the office staff and the steering committee members.

8.14 Monitoring processes

- The AAE SC and office monitored the implementation of the work plan at the 2 SC meetings and through in-between conference calls. Each SC meeting ended with an evaluation round on preparations, content and logistics.
- SANL also required an annual technical and financial report from AAE over 2008. This report was included in the annual report of SANL. A separate annual report in English was produced.
- *External evaluation procedure:* The financial annual report of SANL was reviewed and cleared by the external audit company KPMG.
- An independent external content evaluation of all SANL programmes, including AAE, for the period 2004-2008 was carried out mid 2009.

8.15 EU Added Value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value Aids Action Europe fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and final report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		Aids Action Europe
1.	**Implementing EU legislation:**	2.0
2.	**Economies of scale:**	1.5
3.	**Promotion of best practice:**	3.0
4.	**Benchmarking for decision making:**	0.0
5.	**Cross border threats:**	2.3
6.	**Free movement of persons:**	0.0
7.	**Networking:**	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

8.16 Sustainability

Sustainability of PPD actions: The work will optimise inclusion of civil society and PLHIV in key European policies and thus to better adapt these to their needs. The strong links with CSF and TT will secure wider application and effectiveness of actions and thus contribute to better coordinated response to the epidemic.

L&L actions: The clearinghouse facilitates access to good practices, which helps NGOs to develop effective and sustainable interventions and not duplicate or re-invent. It enables NGOs and others to stay up to date with respect to pertinent developments in the field of HIV and to find potential partner organisations through use of the website. AAE is working on alternative funding strategies to further its aim to secure sustainability of its programs and actions.

AAE's efforts have achieved that in the new European Union Equity Directive, the rights of people living with HIV were guaranteed. As a result of extensive advocacy together with National AIDS Trust, EATG and CSF members, the European Parliament agreed the suggested amendment to the Directive. The action leader stated that SANL are planning to do a mid-term evaluation regarding this revised policy framework, to see what the impact of having the new framework has been so far. The organisation is currently working on a questionnaire in preparation of the evaluation.

8.17 Impact to be expected

The funding from the HP 2008-13 has supported the ongoing work of Aids Action Europe, i.e. their aim to support NGOs to make an effective contribution to European HIV/AIDS policies, facilitate continuous exchange among NGOs on good practices and lessons learned and manage effectively the AAE network.

As stated by the action leader, the most important specific impact of the OG was that the organisation was able to have an impact on the EU framework on HIV/Aids: as stated above, the efforts of the organisation have achieved a change in the European Union Equity Directive, ensuring that the rights of people living with HIV are more protected.

9. NANOGENOTOX

9.1 Summary

Nanotoxicology is a branch of bionanoscience which deals with the study and application of toxicity of nanomaterials.[1] Nanomaterials become highly active at nanometer dimensions (particles <100 nm diameter). Nanotoxicological studies are intended to determine whether and to what extent these properties may pose a threat to the environment and to human beings.

The general objective of the Nanogenotox Joint Action is to complement, support and add value to the Member States' policies and to contribute to increasing the safe use of nanomaterials (MNs) in the European Union by (1) Strengthening, expanding and sharing the knowledge required for the assessment of the hazard, exposure and overall risk of MNs at the European level; (2) Accelerating the exploitation of existing data; and (3) Promoting the establishment of robust methodologies throughout the EU.

Nanotoxicology is a relatively new field of research, and there is little doubt that the subject of the Joint Action project focuses on a legitimate public health issue. Nanomaterials are being used in a variety of areas e.g. disease treatment or solar power generation. Yet, despite the fact that so many nanomaterials are in commercial use, very little is known about their effects on health.

A range of similar interventions to this Joint Action have been funded through DG Research's FP6 / FP7, reflecting the growing awareness of the need for scientific knowledge and evidence of the health and safety hazards of nanotechnology products.

The action's design, facilitating the collaboration of a large number of research institutions from several EU countries, can be seen as a promising set up to harness EU added value by bringing together the knowledge and expertise from different Member States and paving the way for a more coordinated European response to the health threats potentially caused by nanomaterials.

As stated by the action leader, the project is making good progress. There have been several difficulties regarding the access to the nanomaterials which were meant to be supplied by industry, however the project leader stated to be confident that this issue will be resolved soon.

Interim / final reports are not currently available for the JA. The figure below provides a summary of this case study with the information that was made available to the evaluation team:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to which Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
NANOGENOTOX	+++	+++	+++	+++	++	+++	++	13	++	1. Implementing EU legislation: 1.3 2. Economies of scale: 1.5 3. Promotion of best practice: 2.7 4. Benchmarking for decision making: 2.5 5. Cross border threats: 1.8 6. Free movement of persons: 0.0 7. Networking: 3.0
	The Action meets the objectives of the HP and of the 2009 AWP by complementing, supporting and adding value to the MSs policies and by increasing the safe use of Nanomaterials in the EU.	Nanomaterials are being used in a variety of areas, but very little is know about their effect on health. The action takes a systematic approach to addressing this issue with clear objectives and connections with relevant previous international initiatives.	The proposal clearly states that there is a lack of scientific knowledge and absence of evidence of the health and safety hazards of nanotechnology products. The action will therefore help to increase the safe use of nanomaterials.	The action ties well in with numerous initiatives at internationa, European and national level. It will accelerate the exploitation of existing data from previous and ongoing EU FP6 and FP7 projects.	Nanogenotoxicology has emerged as an individual discipline over the last decade, and has seen a rapid increase in both international and national research initiatives. It is still a relatively new field though.	The action clearly targets for different audiences: - regulatory authorities and market surveillance bodies; - respective industries; - policy-making bodies; - general public	The proposal foresees that proactive dissemination activities will be undertaken through 3 tasks: - stakeholder landscape; - tools for raising awareness; - organisation and participation in international events However, the dissemination plan could improve in terms of detail and structure.	- 1 Lead contractor - 16 Associated partners; - 10 Collaborating partners	The General Assembly is in charge of monitoring all activities towards the objectives of the action in order to deliver what was promised on time and on budget; The Steering Committee controls the execution of the JA on a quarterly basis with regard to the performance indicators and monitors corrective actions.	Particularly strong in: 3. Promotion of best practice - One of the expected outcomes is the promotion of a robust reliable methodology at the European level in order to be used for testing potential genotoxicity of MNs by exchanging best practices through a round robin test involving 11 European States including New Member States. 4. Benchmarking for decision making - The aim of the project is the establishment of a robust methodology/strategy which is currently not available for MN. 7. Networking - The project has 16 associated and 10 collaborating partners, and can therefore seen to be facilitating networking amongst research institutions in Nanotechnology as a relatively small field of research, although the main aim of the project is not to establish a network as such.

9.2 Key facts

Calls for proposals:	2009
Proposal title:	Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard
Acronym:	Nanogenotox
Financing mechanism:	Joint Action
Starting date:	01/11/2009
Duration (in months):	36
EC contribution:	2,890.268,00 €
Overall score achieved in Consolidated Evaluation Report:	83
Total criteria block: A, B, C	A: 33; B: 23; C: 27
Main partner:	Agence française de sécurité sanitaire de l'environnement et du travail (AFSSET)
Number of associated partners:	16
Number of collaborating partners:	10
Strand:	HS
Action:	322 (Improve citizens' safety) / 3223 (Safety of nanomaterials: Joint Action on the safety of nanomaterials: (i) to strengthen, expand, and share the knowledge required for the assessment of the hazard, exposure, and overall risk of nanomaterials; (ii) to accelerate the exploitation of existing data and the exchange of best practices in risk assessment and management; and (iii) to promote the establishment of robust methodologies throughout the EU.)
Typology[32]:	Development action

[32] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

9.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[33]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to reduce risk:** The target population is well defined: since the nanomaterials are everywhere, the final target group includes all EU citizens. Policy makers are as an intermediate target group also well defined. **Objective to produce / disseminate information:** **The** general objective of the Nanogenotox Joint Action is to contribute to increasing the safe use of nanomaterials (MNs) in the European Union by (1) Strengthening, expanding and sharing the knowledge required for the assessment of the hazard, exposure and overall risk of MNs at the European level; (2) Accelerating the exploitation of existing data; AND (3) Promoting the establishment of robust methodologies throughout the EU.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	Development action Lack of evidence base for the toxicity of nanomaterials is reason for projects.
Clear target groups	Target groups: - The regulatory authorities and market surveillance bodies - The respective industries - The policy-making bodies. - The general public
Clear dissemination plan – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	The proposal foresees that proactive dissemination activities will be undertaken through 3 tasks: • T1 Stakeholder landscape: Stakeholder groups will be identified and consulted. Links will be made with related on-going research initiatives, EU projects and

[33] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
	networks. • T2 Tools for Raising Awareness: Design of the project's identity and logo, a project website presenting up-to-date information will be set up. A leaflet will be published at the start of the project, followed by a newsletter every 6 months, and a final project public report will be produced. • T3 Organisation and participation in International Events: A final congress will be organised targeting participants from the scientific community and health regulatory bodies. Targeted sessions in international events will be proposed.
Estimate the population reached (or targeted) by the action	N/A
Matching of project's deliverables (if any) with project's objectives	Project has nine deliverables that all match the project's objectives to generate knowledge on the toxicity of nanomaterials, e.g. • Characterisation of MNs (nanomaterials) • In vitro genotoxicity testing strategy for nanomaterials including database • MN data sets with requested physicochemical properties
Use of multipliers	The 17 research institutions involved in the project will disseminate information in their Member States
Evaluation (provision of indicators)	A large number of indicators has been provided for each of the individual aims of the project. Various monitoring activities have been listed in the proposal, with the General Assembly in charge of ensuring that the project's objectives are met. No further evaluation strategy has been mentioned.
Sustainability plan	The proposal did not provide information on sustainability. Interim / final reports are not available.

9.4 Introduction

Nanotechnology is a highly strategic industrial and economic sector revealing enormous potential benefits for many societal and environmental domains. Human exposure to manufactured nanomaterials (MNs) used in consumer products may occur during several phases of their life cycle, from synthesis, production and inclusion in the products to the release of MNs to the environment (through industrial emissions or product disposal). Nanotoxicology is thus attracting the attention of the public and of governments worldwide. The lack of scientific knowledge and absence of evidence of the health and safety hazards of

nanotechnology products, however, make regulation very difficult. The general objective of the JA is to complement, support and add value to the Member States' policies and to contribute to increasing the safe use of MNs in the European Union.

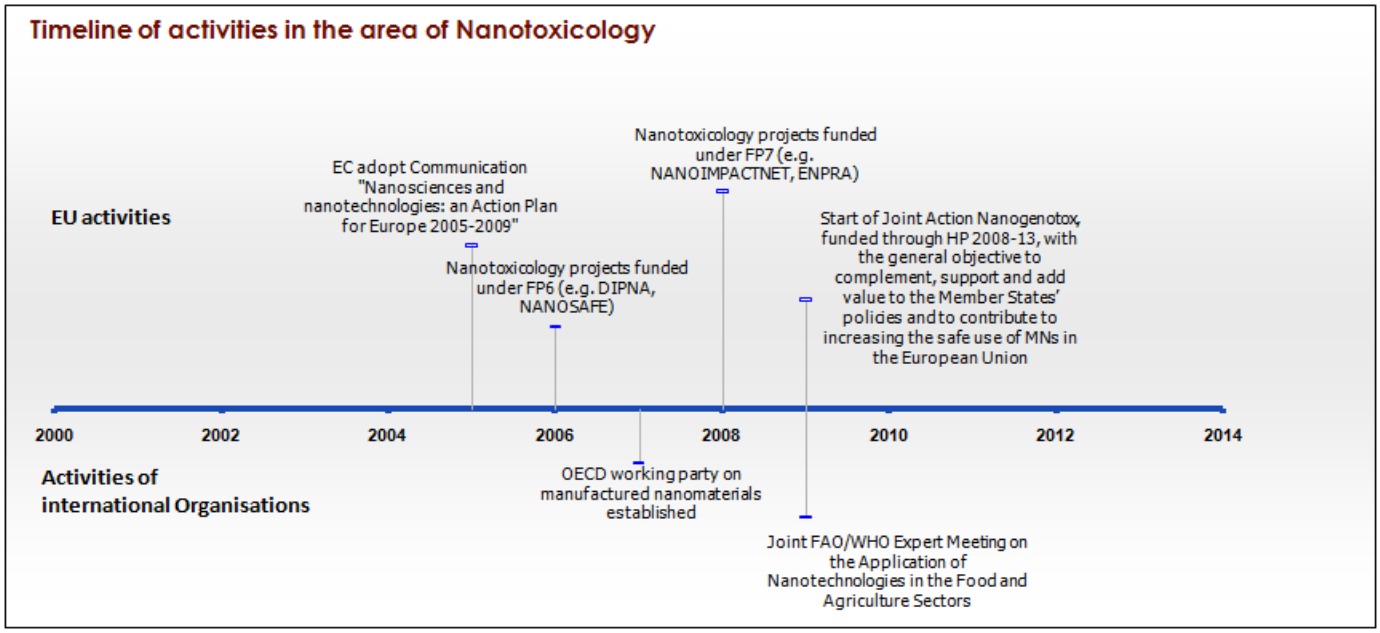
9.5 Origins of HP project

Nanotoxicology is a relatively new field of research, and the lack of scientific knowledge and absence of evidence of the health and safety hazards of nanotechnology products make regulation very difficult. There is therefore a need for new initiatives aimed at generating knowledge on the effect of nanomaterials on health. This need is reflected in the rapid growth of nanotoxicology research in recent years (see section on similar initiatives).

9.6 Background / policy context

In order to gauge and make a judgement on the extent to which the JA is tackling a serious public health issue, the case study examines what other public health interventions in the field of nanotoxicology have taken place and the organisations involved in coordinating/funding these activities. The figure below presents an overview of the development of activities in the field of Nanotoxicology:

Figure 15 – Development of activities in the field of Nanotoxicology



General research and development on nanoscale-science has been growing worldwide. Government authorities in several countries have established funding and coordinating mechanisms to support their national nanotechnology research programmes.

Nanotoxicology has emerged as an individual discipline over the last decade, and has seen a rapid increase in both international and national research initiatives. Several initiatives in the field of nanotoxicology have been funded through the FP6 / FP7 research framework programmes (see section 1.8 on similar initiatives).

On 7 June 2005, the European Commission adopted the Communication "Nanosciences and nanotechnologies: an Action Plan for Europe 2005-2009" (COM(2005) 243), which includes a recommendation to support transnational networking and integration of resources in the area of nanotoxicology.

Lead partner of the JA, AFSSET, who focuses on coordinating expertise in assessing risks related to the general and occupational environments, has published 2 reports on nanomaterials and health and has launched a project on the health risk assessment of nanomaterials for consumers for which exposure scenarios will be developed. AFSSET is also involved in the OECD working party on manufactured nanomaterials, which was established in 2007.

A Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications took place on 1-5 June 2009. The meeting aimed to identify knowledge gaps including issues on food safety, review current risk assessment procedures, consequently support further food safety research and develop global guidance on adequate and accurate methodologies to assess potential food safety risks that may arise from nanoparticles. A report, including information on nanotoxicology, was published subsequent to the meeting[34].

The Nanogenotox project endeavours to facilitate close collaboration of 27 research institutes in the field of nanotoxicology, with the aim to generate knowledge in this new field of research and to contribute to increasing the safe use of nanomaterials (MNs) in the European Union.

9.7 Overall project objectives / Intervention logic

According to the proposal, the JA intends to improve citizens' health security by:

(i)Strengthening, expanding and sharing the knowledge required for the assessment of the hazard, exposure and overall risk of MNs at the European level. The JA provides a genuine European dimension since it involves a significant number of institutions from many Member States. It will contribute to building a strategy able to generate relevant and reliable data for Public Health authorities to assess the risk of nanomaterials.

(ii)Accelerating the exploitation of existing data (using previous and ongoing EU FP6 and FP7 projects e.g. NANOSTRAND, NANOSAFE, NANOSH, NANOINTERACT) and the exchange of best practices in risk assessment and management, thus minimising the potentially harmful long-term effects of MNs. The JA will thus contribute to giving society alert signals for genotoxic substances. It will constitute the first step towards the creation of a future programme based on long-term animal studies or epidemiological population surveillance by Public Health authorities.

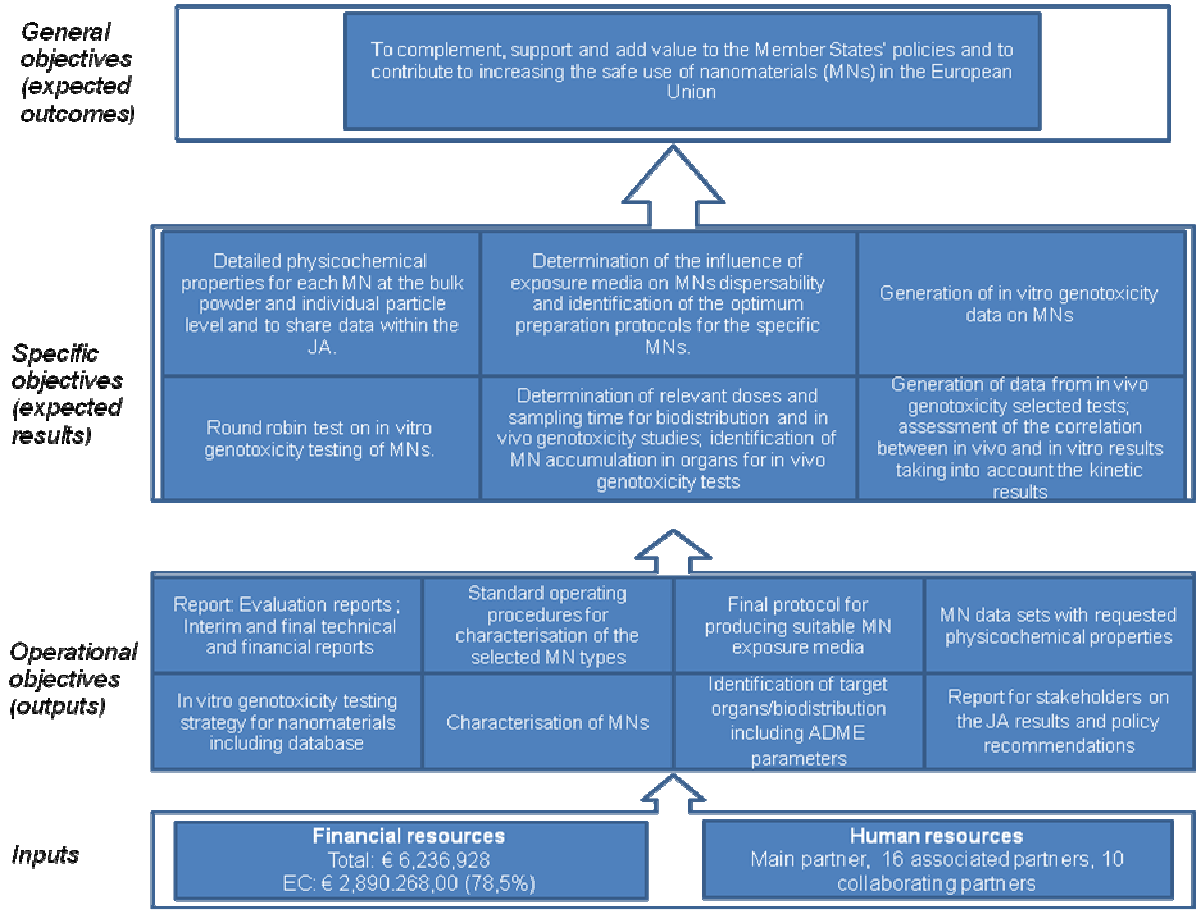
(iii)Promoting the establishment of robust methodologies throughout the EU. In order to make available a robust methodology (specific and sensitive) to screen potentially genotoxic MNs,fully characterised MNs widely used in consumer products will be tested with standard in vitro assays completed with specific tests. Taking into account these results, a ring test (among the participating Member State laboratories) for the relevant assays will be performed in order to establish a robust methodology to be used by the regulatory control bodies and

[34] http://whqlibdoc.who.int/publications/2010/9789241563932_eng.pdf

industrials to check for possible genotoxicity using alternative techniques to animal experimentation. In vivo assays will be conducted to characterise the toxicokinetics of selected MNs and compared to in vitro data.

Based on an analysis of the proposal and additional documentation available, the diagram below depicts the action's complete intervention logic. As reflected in the graph, the general objective clearly reflects the overall aim of the action. However, there is some confusion on how the specific objectives described feed onto the general objective, and many of the specific objectives can be taken as outputs. In particular, it appears that the intervention logic that was developed from the information available in the proposal, has not taken into account what in the opinion of the evaluation team should be the specific objectives of the action, namely: (1) Strengthening, expanding and sharing the knowledge required for the assessment of the hazard, exposure and overall risk of MNs at the European level; (2) Accelerating the exploitation of existing data; and (3) Promoting the establishment of robust methodologies throughout the EU. Please note that interim and final reports were not yet available at the time of analysis.

Figure 16 – Intervention logic for Nanogenotox



Inputs:

The following table sets out the costs of all partners on the projects:

Description	Costs in €
E1 – Staff total	**4,171,129**
E1a - Costs pertaining to public officials	1,356,531

E1b - Costs not pertaining to public officials	2,814,598
E2a – Travel costs	107,140
E2b – Subsistence allowances	69,482
E3 - Equipment	162,500
E4 – Consumables and supplies	1,107,240
E5 – Subcontracting costs	177,500
E6 – Other costs	44,960
E7 - Overheads	396,977
Total (all partners)	***6,236,928***

Expected outputs:

Expected outputs	Achieved outputs (as per Interim- / Final Report)
Report: Evaluation reports (WP 3)	No evidence currently available.
Standard operating procedures for characterisation of the selected MN types (WP 4)	No evidence currently available.
Final protocol for producing suitable MN exposure media (WP 4)	No evidence currently available.
MN data sets with requested physicochemical properties (WP 4)	No evidence currently available.
In vitro genotoxicity testing strategy for nanomaterials including database (WP 5)	No evidence currently available.
Characterisation of MNs for their clastogenic/aneugenic effects or DNA damage potentials and correlation analysis (WP 6)	No evidence currently available.
Identification of target organs and biodistribution including ADME parameters (WP 7)	No evidence currently available.
Report for stakeholders on the JA results and policy recommendations (WP 2)	No evidence currently available.
Interim and final technical and financial reports (WP1)	No evidence currently available.

Expected aims/outcomes:

Aim	**Indicator**	**Result (as per Interim Report)**
To obtain detailed physicochemical properties for each MN at the bulk powder and individual particle level and to share data within the JA.	Complete data sets of physicochemical characteristics will be established for each MN resulting from measurements of key parameters issued from the SOP. (WP4)	No evidence currently available.
To determine the influence of exposure media on MNs dispersability and to identify the optimum preparation protocols for the specific MNs.	SOP for MNs including MN suspension in test media will be provided for the other 3 scientific work packages. The SOP will	No evidence currently available.

Aim	**Indicator**	**Result (as per Interim Report)**
	take into account the results from key parameters of intrinsic properties. (WP4)	
To generate in vitro genotoxicity data on MNs	The in vitro genotoxicity data obtained are robust enough to be used to design the ring test and devise an in vitro genotoxicity testing strategy for MNs.(WP5)	No evidence currently available.
To perform a round robin test on in vitro genotoxicity testing of MNs.	The ring test data show adequate reproducibility so that an in vitro genotoxicity testing strategy for MNs can be devised. (WP5)	No evidence currently available.
To determine relevant doses and sampling time for biodistribution and in vivo genotoxicity studies, and to identify MN accumulation in organs for in vivo genotoxicity tests (intravenous route for all selected MNs, and oral route for SiO2 and TiO2)	Determination of ADME parameters for each MN type after intravenous (IV) and oral administration; and identification of target organs and doses for genotoxicity studies: listing of organs potentially at risk for genotoxicity effects of MN. (WP7)	No evidence currently available.
To generate data from in vivo genotoxicity selected tests, and to assess the correlation between in vivo and in vitro results taking into account the kinetic results	Completing a database that compiles the genotoxicological parameters obtained with all the MNs tested; and to get a correlation rate between in vivo and in vitro results (MNs will be classified as genotoxic or non genotoxic) taking into account the kinetic results. (WP6)	No evidence currently available.

Level to which outputs / results contribute to / are in line with the HP objectives:

The expected outcomes of the JA target crucial items of the Health Programme by facilitating overall safety evaluation for MNs (scopes 2 and 3), sharing knowledge on identified MNs (scope 1) and filling the gaps in risk assessment through genotoxicity ring testing (scopes 1, 2 and 3).

9.8 Action compatible with the principle / objectives in the Health Strategy

The general objective of the JA is to complement, support and add value to the Member States' policies and to contribute to increasing the safe use of MNs in the European Union. The project is therefore compatible with OBJECTIVE 2: PROTECTING CITIZENS FROM HEALTH THREATS of the Health Strategy. Health threats include infectious diseases (e.g. HIV/AIDS, tuberculosis, Creutzfeldt Jacob Disease, etc.) and **threats emerging from physical, chemical or biological sources**, including those relating to terrorist acts and environmental agents (e.g. ionising and non-ionising radiation and noise).

9.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

1. **Fit with other EU / DG SANCO projects:**
   The project will accelerate the exploitation of existing data (using previous and ongoing EU FP6 and FP7 projects)) and the exchange of best practices in risk assessment and management. EU FP6 and FP7 projects include:
   - NANOSTRAND (FP6)
   - NANOSAFE (FP6)
   - NANOSH (FP6)
   - NANOINTERACT (FP6)
   - DIPNA (FP6)
   - NANOTOX (FP6)
   - NANOIMPACTNET (FP7)
   - ENPRA (FP7)

   Other relevant EU initiatives:
   - **NANOfutures:** European Technology Integration and Innovation Platform (ETIP) in Nanotechnology: http://www.nanofutures.eu/
   - **NanoImpactNet** is a multidisciplinary European network on the health and environmental impact of nanomaterials: http://www.nanoimpactnet.eu
   - EU **NanoSafety Cluster** is an initiative to maximise the synergies between the existing FP6 and FP7 projects addressing all aspects of nanosafety including toxicology, ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment and standardisation: http://www.nanosafetycluster.eu

2. **Relevant interventions of International Organisations**
   The action complements other ongoing activities of international organisations, e.g.:
   - OECD WPMN Sponsorship Programme for the Testing of Manufactured Nanomaterials
   - The International Centre for Technology Assessment (ICTA) works towards adequate oversight of nanotechnology through its Nanotechnology Project NanoAction

3. **Relevant interventions in MS**
   - Centre for Pharmaceutical Nanoscience and Nanotoxicology, Copenhagen
   - NanoTrust, Austria: NanoTrust is a research project for the integrative analysis of the state of knowledge on the health and environmental risks of nanotechnology. http://nanotrust.ac.at/
   - SAFENANO, UK: SAFENANO is a venture by the Institute of Occupational Medicine (IOM). The initiative was designed to help industrial and academic communities to quantify and control the risks to their workforce, as well as to consumers, the general population collage and the environment, through both information provision and consultancy services. http://www.safenano.org
   - Information platform Nano-Safety (in German only): http://www.nano-sicherheit.de

4. **Relevant interventions in third countries**
   - Penn Nanotoxicology Alliance (US): consists of the Center of Excellence in Environmental Toxicology (CEET), the Targeted Therapeutics and Nanomedicine Program of the ITMAT/CTSA, the Nanotechnology Institute (NTI), and the Nano-Bio Interface Center (supports Pilot Projects in Nanotoxicology).
   - Major studies[35] carried out:
     - Oberdörster, Günter; *et al.* (July 2005). "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles". *Environmental Health Perspectives* **113** (7): 823–39.
     - Kashiwada S (Nov 2006). "Distribution of nanoparticles in the see-through medaka (Oryzias latipes)". *Environ Health Perspect.* **114** (11): 1697–702.

9.10 Rationale behind selection procedures (consistency with HP objectives):

The Evaluation report states that the Joint Action should be funded due to its scope, usefulness and high potential for EU leadership.

Main comments in Evaluation report include: “This Joint Action has a high potential for EU leadership, has a wide coverage and will help to increase the safe use of nanomaterials. It has to be funded. The budget is high but acceptable with regard to the objective.”

9.11 Involvement of decision makers (design of project / exploitation of results):

The project leader stated that the relevant ministries in the EU Member States were asked if they would be interested in participating in this action. The individual Member States then addressed research institutions in their country and invited them to take part in the action. Once this was determined, the design of the action was then developed by the scientists and researchers, who were commissioned by the ministries of participating MS. In terms of the exploitation of the results, the involvement of decision makers at MS level was envisaged.

[35] Links to studies on Nanotoxicology:
http://sei.nnin.org/sei_resource.taf?_function=search&rc_id=14

9.12 Dissemination (incl. resources)

The proposal foresees that proactive dissemination activities will be undertaken through 3 tasks:

- T1 Stakeholder landscape: Stakeholder groups will be identified and consulted. Links will be made with related on-going research initiatives, EU projects and networks.
- T2 Tools for Raising Awareness: Design of the project's identity and logo, a project website presenting up-to-date information will be set up. A leaflet will be published at the start of the project, followed by a newsletter every 6 months, and a final project public report will be produced.
- T3 Organisation and participation in International Events: A final congress will be organised targeting participants from the scientific community and health regulatory bodies. Targeted sessions in international events will be proposed.

The action leader further stated that information is currently being disseminated through a leaflet and a website, as well as a newsletter that is being sent out every 6 months. It was stated that the lead organisation conducted a stakeholder consultation with 5 stakeholder groups. Another stakeholder consultation has been planned. There will be a final conference at the end of the action. The project also has a stakeholder distribution list. In addition, each participating institute disseminates the information through its own network, and keeps their respective ministry informed.

In terms of the success of the dissemination activities to date, the project leader stated that 2000 individual visitors have been reached through the NANOGENOTOX website so far (since its creation in September 2010). 60-80 people receive the newsletter directly. A further 20 people have been interviewed through consultation process.

Target groups

The JA proposes to target the following groups:

(i) **The general public**. An overview of nanomaterials (MNs) present in consumer products and available on the European market shows that MNs are used for a wide variety of applications (e.g. pharmaceuticals, food…) and technologies (e.g. ICT, energy, transport…). The most important product categories in Europe are: motor vehicles, electronics, computers, personal care, cosmetics and household. As for all newly developed substances or products, attention should be paid to potential health risks.
(ii) **The regulatory authorities and market surveillance bodies**. Implicitly, according to REACH, the use of MN is regulated by manufacturers (and importers) responsible for the safety of the chemicals or products they produce (or import), enabling the authorities to take action if products pose a health risk. It is, however, questionable if new risks arising from the presence of MN will be recognised through the current regulatory system. More knowledge is therefore needed to assess the extent to which the current legislations can identify potential new risks.
(iii) **The respective industries** which should apply the developed methodology before marketing their MN directly or in consumer products.
(iv) **The policy-making bodies**. Until there is an evidence base on which the nature of the risks posed by MN can be determined, it is not possible to assess the extent to which the implementation of current legislation addresses all potential risks posed by MNs.

9.13 Monitoring processes

As per proposal, the General Assembly (GA) is in charge of monitoring all activities towards the objectives (internal risks) of the Project in order to deliver what was promised, on time and on budget.

The Steering Committee (SC) controls the execution of the JA on a quarterly basis (in person or by phone conferences) with regards to the performance indicators and the description of work annexed to the Grant agreement, and monitors corrective action. The SC includes advisory capacity and shall help to address the external risks. The CO will provide dedicated tools to each participant to enable scientific and financial monitoring. It already has proven tools and relevant experience through the coordination of FP7 project ERA-ENVHEALTH, gathering 16 partners from 10 countries.

The project leader further stated that the successful development of a robust methodology for the assessment of the toxicity of nanomaterials will be the strongest indication for the success of the project.

9.14 EU Added Value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added NANOGENOTOX fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		NANOGENOTOX
1.	Implementing EU legislation:	1.3
2.	Economies of scale:	1.5
3.	Promotion of best practice:	2.7
4.	Benchmarking for decision making:	2.5
5.	Cross border threats:	1.8
6.	Free movement of persons:	0.0
7.	Networking:	0.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

9.15 Sustainability

According to the action leader, who was interviewed for the purpose of this case study, a database with the findings from the project will be accessible to relevant institutions and individuals. In addition, the scientific results will be published in a dedicated dossier of the OECD, which will be available on the OECD website in a few years. As the action leader stated, the raw data might not be widely available to the general public, but the results of the action will nevertheless be published.

It was also stated that many of the institutions from various member states who are involved in the Joint Action have now started working together and will hopefully still cooperate after funding has ended. The project leader noted that it is hoped that the work achieved through the project will be developed further, but that this also depends on how successful the project will be in terms of its research results.

9.16 Impact to be expected

The JA intends to improve citizens' health security and to complement, support and add value to the Member States' policies and to contribute to increasing the safe use of MNs in the European Union.

The action leader stated that the main impact expected is better knowledge regarding the toxicity of nanomaterials, i.e. if the materials are carcinogenic or not. This knowledge will help risk assessors to decide if further investigation of materials is needed, which will help to make progress in this area and hopefully improve the safety of citizens in the EU in the long term.

10. EURORDIS-FY-2010

10.1 Summary

A disease or disorder is defined as rare in Europe when it affects less than 1 in 2000. On the whole, rare diseases may affect 30 million European Union citizens. 80% of rare diseases are of genetic origin, and are often chronic and life-threatening.

EURORDIS is a non-governmental patient-driven alliance of patient organisations (PO) and individuals active in the field of rare diseases (RD), dedicated to improving the quality of life of all people living with rare diseases in Europe. It was founded in 1997, and is supported by its members and by the French Muscular Dystrophy Association (AFM), the European Commission, corporate foundations and the health industry.

EURORDIS was awarded an Operating Grant from the European Commission to support the successful execution of the organisation's work programme and activities in 2010. The proposed activities aimed at 1) gathering scattered knowledge; 2) developing expertise; and 3) establishing tools to allow building capacity for the development and implementation of effective public health policies in the area of RD.

Prior to the Operating Grant under assessment as part of this case study, EURORDIS was awarded an initial Operating Grant for Rare Disease Associations by the Commission in 2008 for nearly 0.5 million Euros, which was implemented throughout 2009 and was considered to show highly successful results.

In 2011, the Commission has renewed the Operating Grant to EURORDIS, though with a reduced budget. According to the final report submitted by EURORDIS for the 2010 grant, this reduction affected primarily two areas: the research policy activities (the planned hire of a Research Policy Manager was put on hold until after 2011) and the support & information services for patients, including Respite Care Services, Therapeutic Recreational Programmes and the European Network of Help Lines.

In terms of the rationale for funding this action, EURORDIS represents more than 469 rare disease organisations in 45 different countries (of which 25 are EU Member States), covering more than 1,200 rare diseases. EURORDIS has grown to be the voice of 30 million patients with RD throughout Europe. EURORDIS has also come to play a pivotal role in the definition and implementation of the EU strategy on RD.

According to the Final Report of the action, submitted to the Commission in 2011, the Operating Grant significantly contributed to the implementation of the organisation's

Strategy 2010-2015 and to the achievement of its Work Plan 2010. All the activities and

deliverables listed in the Grant Agreement were achieved in due time and according to the contract and its amendment.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
EURORDIS-FY-2010	+++	+++	+++	+++	+++	+++	+++	1	+++	1. Implementing EU legislation: 2.0 2. Economies of scale: 1.5 3. Promotion of best practice: 2.3 4. Benchmarking for decision making: 2.0 5. Cross border threats 0.3 6. Free movement of persons 0.0 7. Networking: 3.0
	The action meets the objectives of the HP and of the 2009 AWP. The evaluation report concludes that the action is relevant and will add value to actions already in place.	EURORDIS is dedicated to improve the quality of life of all people living with rare diseases in Europe. The action has a strong and justified rationale, and its work plan is appropriate and realistic.	EURORDIS is competent and experienced and has a clear capacity to organise and maintain sustainability of the project.	EURORDIS was awarded an initial Operating Grant for Rare Disease Associations by the Commission in 2008. The action also follows other projects that were awarded Commission co-funding.	Rare diseases as a whole had been ignored as a public health priority for some time, but the EU has taken measures in the last two decades to fight against rare diseases. To date, several initiatives and organisations on specific rare diseases at national and international levels exist.	Clear target audiences have been identified for the action, which make up the EURORDIS RD Community Database: - RD patients and their families; - relevant decision makers at EU and national levels; - health professionals, social workers etc.	The dissemination strategy indicates a clear use of channels: - Monthly newsletter in 6 languages - website available in 6 languages - campaigns through special Rare Disease Days - Awareness Videos and Photo contest - Online communities - Public contributions - Publications - Conferences - Representation in different fora	EURORDIS is an Operating Grant with a single beneficiary.	The evaluation of the outcomes resulting from the EC Operating grant for 2010 are under the direct responsibility of EURORDIS. The Steering Committee meets every two months and involves all relevant managers to ensure a regular evaluation of activity progress and budget implementation. Every activity of the work programme will be subject to indicators that have been recently developed and adopted, aiming at assessing the quantitative outcomes and success rate of the activities. The evaluation also includes satisfaction and evaluation questionnaires for event participants and subscribers of newsletters.	Particularly strong in: 1. Implementing EU legislation - The work plan in the proposal explicitly includes advocacy actions with decision makers and the empowerment of patient organisations to exercise a strong participation in specific committees and with decision makers at EU and national levels. The actions proposed can definitely contribute to implementing EU legislation. 3. Promotion of best practice - There are a number of detailed best practice elements in the proposal that EURORDIS proposes to implement with different stakeholder groups. 4. Benchmarking for decision making - Part of the work of this organisation is linked to providing member organisations, patients and decision makers with a strong body of scientific evidence as elements to contribute to the decision making process. 7. Networking - Given that the organisation's very own nature is that of networking, many of the elements in the work programme developed for 2010 are focused on this important aspect of EURORDIS' work.

10.2 Key Facts

Calls for proposals:	2009
Proposal title:	EURORDIS-FY2010
Acronym:	EURORDIS
Financing mechanism:	Operating Grant
Starting date:	1st January 2010
Duration (in months):	12 months
EC contribution:	€ 733,388.00
Overall score achieved in Consolidated Evaluation Report:	89
Total criteria block: A, B, C	A: 24; B: 36; C: 29
Main partner:	European Organisation for Rare Diseases (EURORDIS), France
Number of associated partners:	-
Number of collaborating partners:	-
Priority area:	3.3 PROMOTE HEALTH (HP-2009)

Action:	Prevention of major and rare diseases
Typology[36]:	Implementation action

10.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[37]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objectives to network and to produce/disseminate information:** EURORDIS is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe. The mission of this organisation is two-fold: – to build a strong pan-European community of patient organisations and people living with rare diseases (network) – to be their voice at the European level and - directly or indirectly - to fight against the impact of rare diseases on their lives (produce/disseminate information)
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Implementation grant**: As reflected in the evaluation report it is clear from the proposal that EURORDIS is highly competent and experienced and has a clear capacity to organise and maintain sustainability of the project. The work is well planned, with clear responsibilities and a step wise approach and it is well integrated into the organisation's work plan. The organisation is well networked with other key organisations in the area of patient rights and rare disease. However, in its Final Report of the Operating Grant EURORDIS highlights the great importance of the Grant in support of its recurring core activities and its direct impact on the operations of the organisation. The Report concludes that the Grant proved to be instrumental to reach the Core Values and General

[36] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[37] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
	Objectives of EURORDIS, and it allowed the organisation to continue to play its pivotal role in the definition and implementation of the EU strategy on rare diseases.
Clear target groups	Target groups defined in the proposal are those who make up the EURORDIS RD Community Database, namely: – RD patients and their families – relevant decision makers at EU and national levels – health professionals, social workers, etc.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	The dissemination strategy developed by EURORDIS is well documented in the proposal and features the following elements: – Dissemination of EURORDIS monthly newsletter in 6 languages to 4574 subscribers; – Revamped EURORDIS website available in 6 languages including online services for patients and new functions eg. RSS feed, tags, etc; – Large-scale awareness-raising campaign through the Rare Disease Day 2010, organised at both national and EU levels, including the establishment of a dedicated RDD website and broad media exposure (over 1200 articles in websites worldwide and 300 articles in printed media in 2009); – Rare Disease Awareness Video and Photo contest 2010; – Online patients and advocates communities operated by EURORDIS in order to provide a forum for information exchanges, feedback and knowledge sharing for and from patients, advocates and professionals – Public contributions, statements, comments, press releases, position papers, etc. widely circulated to relevant stakeholders, such as national and European decision-makers, industry representatives, regulators, patient communities, health professionals – Publications: Activity Report 2009, fact sheets, brochures; – ECRD 2010 Cracow: 600 participants expected + conference report (funded by POLKA project, DG SANCO); – Representation of EURORDIS in different fora

Criteria	Notes / Comments
	is also a valuable means of external dissemination of key messages (over 30 speeches and presentations expected)
Estimate the population reached (or targeted) by the action	According to the proposal EURORDIS has the potential to outreach over 600 patient organisations across the EU through its membership and the EU networks of national alliances and RD specific Federations. The universe that the organisation intends to reach are the 30 million patients affected with rare diseases throughout Europe and relevant decision makers and health professionals at EU and national levels.
Matching of project's deliverables (if any) with project's objectives	According to the Final Report, the Operating Grant significantly contributed to the implementation of the organisation's Strategy 2010-2015 and to the achievement of its Work Plan 2010. All the activities and deliverables listed in the Grant Agreement were achieved in due time and according to the contract and its amendment. That said, there are two specific conclusions that stand out from the Final Report, namely: – In 2010, the Operating Grant allowed for the development of areas which, compared to 2009, significantly expanded. This growth in recurrent core activities stems from EURORDIS' progressively increasing outreach to patient associations and communities, successful public awareness raising, as well as a growing number of technical activities in which to involve patient representatives so to turn the new EU and national rare disease policy frameworks into reality. This is the case of the communication activities revolving around the Rare Disease Day 2010; the outreach to patients and patient organisations and their empowerment; the support to the activities in the therapeutic area; support to the involvement of volunteers in EU and national policy working groups; support to international activities. – Notwithstanding, in 2010 EURORDIS was forced to restrain its activities in other sectors to take account of the reduction of the Operating Grant awarded in 2011 (EAHC decision communicated in July 2010). This reduction affected primarily two areas: the research policy activities (the planned hire of a Research Policy Manager was put on hold until after 2011) and the support & information services for patients, including Respite Care Services, Therapeutic Recreational Programmes and the European

Criteria	Notes / Comments
	Network of Help Lines (following the departure of the Health Policy Project Coordinator).
Use of multipliers	Even though not explicitly defined in the proposal, there are many multipliers of the work carried out by EURORDIS, including internal spokespersons, the member organisations, other relevant European and non-European networks, the patients themselves, the media, decision-makers, health professionals, etc.
Evaluation (provision of indicators)	Evaluation strategy: As highlighted in the evaluation report, the proposal describes internal evaluation of the actions, details the evaluation methodology and mentions the existence of a set of indicators, though they are not listed. An external financial audit by a consulting firm is also conducted. The main elements of the evaluation strategy (as per the proposal) include: – Regular meetings (every two months) of the EURORDIS Operating Grant Steering Committee to ensure a regular evaluation of activity progress and budget implementation. – Assessing the completion of each envisaged activity and deliverable in due time, as well as the good execution of the whole proposed work programme, bearing in mind the interests of patients affected by rare diseases and their families. – Every activity of the work programme will be subject to indicators that have been recently developed and adopted within EURORDIS and that aim at assessing the quantitative outcomes and success rate of the activities (indicators not listed) – Regular satisfaction questionnaires to members and subscribers to the newsletter – Event evaluation questionnaires distributed to all participants in conferences, workshops and training sessions. – EURORDIS financial accounts and statements are audited by Deloitte Touche Tohmatsu on an annual basis. – The General Assembly of members reviews the Activity and Financial Reports each year, and votes by secret ballot on these reporting documents, thereby endorsing or voting down the activities and their outcomes. – Other types of evaluation may also be performed

Criteria	Notes / Comments
	in collaboration with third parties
Sustainability plan	Even though not explicitly stated as part of the proposal, the work carried out by the organisation, its outreach capacity, its multiple funding sources, all speak in favour of continuity and sustainability of this project. According to the Final Report, the Commission's Grants have proved to be a very relevant resource in the last two years (2009; 2010). The reduction of the Commission's Operating Grant in 2011 has forced EURORDIS to restrain its activities in some sectors.

10.4 Introduction

EURORDIS represents more than 469 rare disease organisations in 45 different countries (of which 25 are EU Member States), covering more than 1,200 rare diseases. Its mission is to build a strong pan-European community of POs and people with RD (around 30 million patients throughout Europe), to be their voice at the European level and to fight against the impact of RD on their lives.

EURORDIS undertakes activities on behalf of its members, notably in favour of:

- Empowering RD patient groups
- Advocating RD as a public health priority
- Raising public awareness on RD (national and international levels)
- Improving access to information, treatment, care and support for people with RD, including support to families
- Improving quality of life
- Encouraging good practices in relation to these issues
- Promoting scientific and clinical research on RD
- Developing treatments and drugs for people with RD

EURORDIS plays a pivotal role in the definition and implementation of the EU strategy on RD.

10.5 Origins of HP grant

Through its various revenue sources, the Commission being one of the most important, EURORDIS is granted with financial support to play an essential role in the RD field throughout Europe: that of gathering, processing and disseminating relevant information, exchanging experience, building capacities of patient's representatives to increase patient participation in EMEA (European Medicines Agency), Commission and national activities.

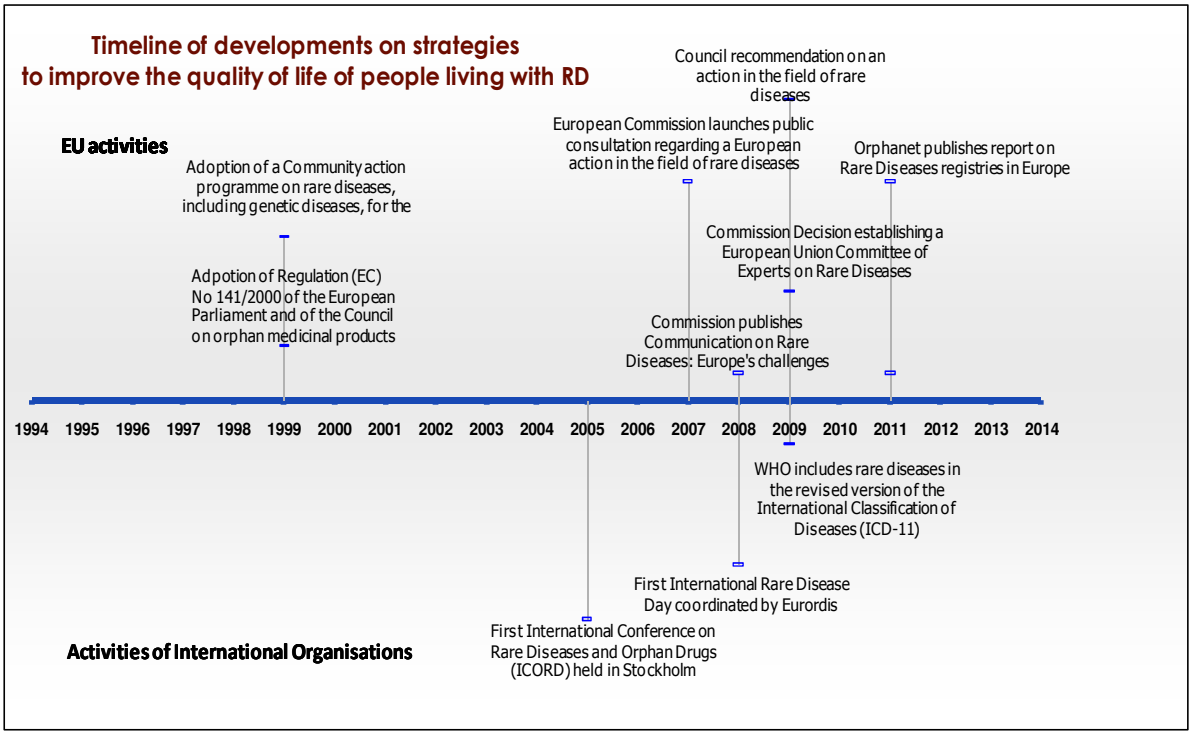
EURORDIS was awarded an initial Operating Grant for Rare Disease Associations by the Commission in 2008 for nearly 0.5 million Euros, which was implemented throughout 2009. Recent projects that were awarded Commission co-funding prior to EURORDIS FY-2010 include:

- Patients' Consensus on Preferred Policy Scenarios for Rare Diseases (POLKA, DG SANCO, 2008-2011)
- The European Project for Rare Diseases National Plans Development (EUROPLAN, DG SANCO, 2008-2011)
- The European Network of Reference for Rare Paediatric Neurological Diseases (nEUroped, DG SANCO, 2008-2011)

10.6 Background / Policy Context

The figure below provides an overview of the activities and public health interventions that have taken place and the organisations involved in developing strategies to improve the quality of life of all people living with rare diseases.

Figure 17 - Timeline of developments on strategies to improve the quality of life of people living with RD



In its founding document "Rare Diseases: Understanding this Public Health Priority" released in November 2005, EURORDIS acknowledged the reasons why rare diseases as a whole had been ignored as a public health priority for so long, the main problem being the impossibility to develop a national public health policy specific to each rare disease.

The document called however for a global approach that could give rise to suitable solutions and enable patients with rare diseases to escape isolation. It highlighted that appropriate public health policies could be developed in the areas of scientific and biomedical research, industry policy, drug research and development, information and training of all involved parties, social care and benefits, hospitalisation and outpatient treatment.

As reflected in the timeline above, since 1999 the European Union has taken measures to fight against rare diseases and their impact on patients' lives, and has made rare diseases a priority of its public health programmes. In recent years rare diseases have experienced an upsurge on the EU's agenda, with the Commission's Communication on Rare Diseases of 2008 and the Council Recommendation on an action in the field of rare diseases in 2009.

Both documents were very important steps in the fight for promoting the cause of rare diseases as a public health priority.

The text of the Council Recommendation highlights the need to establish national strategies and plans for rare diseases in order to provide patients with rare diseases universal access to high quality care, including diagnostics, treatments and orphan drugs throughout their national territory on the basis of equity and solidarity throughout the EU.

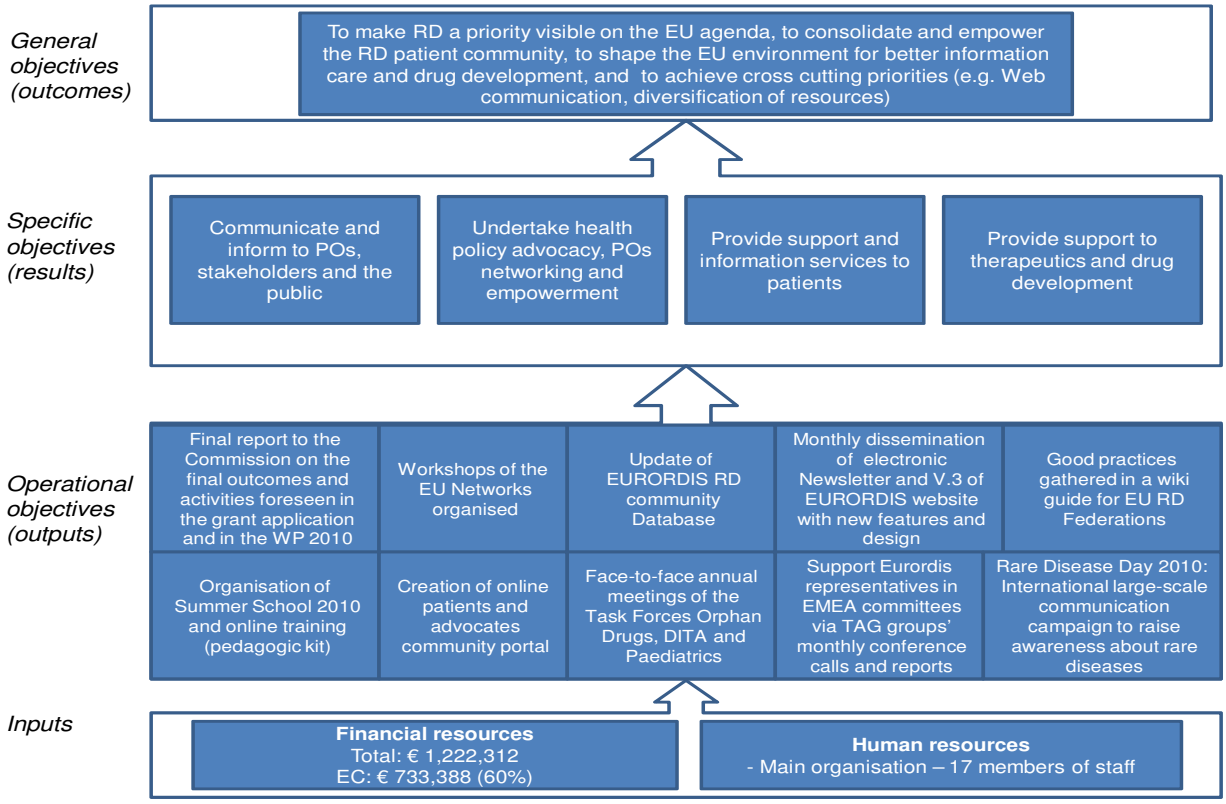
This gathering and disseminating exercise, also through capacity-building/sharing activities, is needed in the fields of care (medical and social), research (fundamental and clinical) and policy shaping in order to reduce postcode inequalities and promote an equal level of expertise and high quality care throughout the EU.

The work of EURORDIS, through its network of patient organisations and individuals with rare diseases, has been instrumental to raising awareness at EU and national levels and the main result is that rare diseases have in recent years gained unprecedented public attention and are becoming a health priority at EU level and in several Member States.

10.7 Overall objectives of the Operating Grant / Intervention logic

Based on an analysis of the proposal, the diagram below depicts the grant's complete intervention logic. It shows a clear sequence of the general and specific objectives the EURORDIS-FY2010 grant intended to achieve, the expected outputs, and the key inputs. More specific details on each of these aspects is presented below.

Figure 18 - Intervention logic for EURORDIS-FY-2010



Inputs:

The following table details the budget of EURORDIS providing costs for all inputs including staff, administrative expenditure and total expenditure linked to the beneficiary's normal operations:

PART A- Expenditure	
Title 1. Total Staff	728,080.00
Title 2. Total General Administrative Expenditure	54,302.00
Title 3. Total Expenditure Linked to the Beneficiary's Normal Operations	439,930.00
Total PART A– Expenditure	**1,222,312.00**

PART B- Income	
Title 1. Total Operating Income	0.00
Title 2. Total Beneficiary's Own Contribution	488,924.00
Title 3. Total EC Contribution in EUR	733,388.00
Title 4. Total Other External Contributions	0.00
Total PART B – Income	**1,222,312.00**

Commission funding %	**60,00%**

Source: Grant Agreement for EURORDIS-FY-2010 - 20093204

Expected outputs:

The table below describes the expected outputs that were outlined in the proposal, including the way each would be disseminated and the expected date of delivery of each output:

Title	Description	Date of delivery or achievement	Ways to disseminate
Activity Report Operating Grant	Final report to the European Commission on the final outcomes and activities foreseen in the grant application and in the WP 2010	M 12	Report
Workshops of the EU Networks	2 Workshops of the CNA, 1 Workshop of the CEF and 1 Workshop of the RD Helplines	M 11	Meetings
Update of EURORDIS RD community Database	Includes all POs/stakeholders linked with EURORDIS filing relevant information concerning membership, projects, events, diseases and drugs	M 12	Database

Title	Description	Date of delivery or achievement	Ways to disseminate
Electronic Newsletter and V.3 of EURORDIS website	Enhancing outreach with a monthly electronic newsletter in 6 languages for the rare disease community and revamping the website with new functions and design	M 12	Web communication
Wiki guide for EU RD Federations	Good practices gathered in a guide developed through wiki methods to help create and develop EU RD Federations	M 12	Web communication
Summer School 2010 and online training (pedagogic kit)	Capacity-building session for patients' representatives in drug development and regulatory processes and the e-learning tool	M 9	Training and web communication
Online patients and advocates community portal	Creation of patients online communities for specific RD as well as common symptoms and advocates communities focusing on common activities	M 12	Web communication
Meetings of the Task Forces Orphan Drugs, DITA and Paediatrics	At least 1 face-face meeting/year for each Task Force articulated with regular conference calls and email updates	M 12	Meetings
Participation in EMEA Committees (COMP, PDCO, CAT, PCWP) and update through the TAG	Support Eurordis representatives in EMEA committees via TAG groups' monthly conference calls and reports	M 12	Meetings
Rare Disease Day 2010	International large-scale communication campaign to raise awareness about rare diseases	M 3	Event, web and media communication

Expected aims/outcomes:

The table below contrasts the expected aims/outcomes that were outlined in the proposal with those documented in the Final Report of the Operating Grant. As can be seen, the outcomes of the Operating Grant – documented to a high level of detail – were successfully achieved, and in some cases they were more successful than the indicators that were agreed at the outset of the Grant:

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
1. Communicate and inform to POs, stakeholders and the public	• EURORDIS Website & electronic newsletter in 6 languages • Activity Report, brochures; update of main reference documents on RD; translation • European RD Day 2010 on 28/02 and Media Monitoring Services • Awareness video & photo contest • Maintenance of EURORDIS RD community databases: 1200 POs, 374 members, 150 volunteers; • Strengthening support to more volunteers representing EURORDIS in EU committees • Strengthening international dialogue with e.g. ICORD, NORD, CORD, DIA, etc	• New EURORDIS website developed further with a greater turnover of info, and new tailored sections created • Organisation of RD Day 2010: 46 participating countries (50% more than in 2009); campaign website 39,000 hits; strong media outreach (1800 press clippings); over 1000 events organised worldwide • 10 issues of electronic newsletter published in 6 languages with a revamped design and layout. Subscription rate went up 10% • Awareness video and photo contest implemented • Improved version of the Annual Activity Report was published and a new presentation brochure was also produced • EURORDIS RD community database reached 4870 contacts in 3920 organisations, including 1544 patient organisations, 447 of which are members of EURORDIS • Organisation put in place to support EURORDIS' volunteers representing EURORDIS in key EMEA and EC Committees, internal EURORDIS committees and task forces • Organisation put in place to support staff and volunteers in fulfilling obligations arising from partnerships with European and international organisations (NORD,

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
		EPPOSI, ICORD, DIA, EPF).
2. Undertake health policy advocacy, POs networking and empowerment	• Outreach to POs and members, dissemination of information, consultation of members, focus on new MS incl. fellowships • Support the EU Network of National Alliances; organisation of 2 Workshops of the Council of National Alliances (CNA); involvement in public awareness and empowerment on the development of strategies for RD at national level • Support and strengthen the Network of EU RD specific Federations; organisation of 1 Workshop for the Council of European Federations (CEF); support the creation of EU RD Federations through experience sharing and good practices on wiki tool(wiki guide); involvement in public awareness and empowerment on EU policies (e.g.: CoE, ERN) • Fact sheets on RD topics and policy aspects for capacity-building purposes.	• Growing number of patient representatives mobilised to participate to events, conferences, trainings and workshops organised • The European Network of 23 Rare Diseases National Alliances consolidated further • The European Network of 30 Rare Disease European Federations or Informal Networks held one European Workshop of its Council of European Federations • A pilot "EURORDIS Grant Programme for European Federations" funded 6 meetings of European Rare Disease Federations • Five Policy Fact Sheets on rare disease related topics were developed to provide member organisations and their representatives with advocacy tools to encourage them to implement the key recommendations of EU rare disease policy and facilitate their transposition into national plans on rare diseases
3. Provide support and information services to patients	• Stimulate development and improve access to 1) Respite Care Services 2)Therapeutic Recreation Programmes through fact sheets, site visits, promotional activities and maintenance of online information resources widely available to the public • Support and strengthen the EU Network of RD Help Lines through: - membership procedure - sharing tools and 6 visits or capacity building sessions for national help lines	• European Network of Rare Disease Help Lines received 11 applications for membership, organised a training session for help line respondents and one Workshop, analysed and disseminated the results of the 2nd Europe-wide Caller Profile Analysis finalised at the end of 2009. • Guidelines for Best Practices for Respite Care Services (RCS) and Therapeutic Recreation

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
	- 2 meetings of Steering Committee and 1 European Workshop • Support the development of Online Patients Communities services with web interactive tools; recruit, train and support moderators; promote the service and each community.	Programmes (TRP) were finalised in early 2010, • Two Policy Fact Sheets on RCS and TRP as well as two other Policy fact Sheets on National Help Lines and on the European Network of Help Lines were produced. • Online information was updated but unfortunately, these activities were put on hold due to the departure in July of the responsible Health Policy Project coordinator who could not replaced due to insufficient funds allocated under the Operating Grant 2011. • The web tool "Rare Disease Communities" was developed jointly with the US organisation NORD and was awarded the audience prize "Best Start-Up Idea of the conference" at the prestigious global Health 2.0 Conference, held in Paris in October 2010.
4. Provide support to therapeutics and drug development	• Patient involvement in EMEA activities: - Support the participation of patient representatives in the EMEA Committees (COMP, PDCO, CAT, PCWP) and in protocol assistance - Support the EURORDIS Therapeutic Advisory Group(TAG)composed of all RD patient representatives in EMEA activities to exchange information and coordinate activities; - Monthly report compiling feedback from each committee. • Review and validate public	• Continued support to the participation of patient representatives in the Committees (COMP, PDCO, CAT, PCWP) of the European Medicines Agency's, cumulating up to 104 days of meeting and 519 dossier examined • The therapeutic Action Group (TAG) held monthly conference calls and organised a face-to-face meeting in July prior to the Board of Directors meeting, discussing, amongst other, how to improve

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
	information on RD therapies disseminated by the EMEA at the time of designation (PSOs) and marketing authorisation (EPARs, Package Leaflet (PL)). • Support involvement of more RD patient representatives in the OD,PD, ATMP policies and in drug development through information dissemination and capacity building activities on clinical trials and EU regulatory affairs, using the following means: - Support EURORDIS Task Forces on Orphan Drugs, Paediatrics, Drug Information, Transparency & Access (DITA), each involving 10-15 trained volunteers; - Summer School 2010: build on previous training sessions(2008-2009) for the 2010 session (60 participants) based on experience exchange & case studies - Development of e-Learning on specific and advanced aspects of drug development, clinical trials and regulatory affairs • Support capacity building activities of patient advocates in HTA through a section on the website, dissemination of information, financing 10 fellows to participate in training for professionals (ex: DIA Forum on HTA) and initiation session on HTA in the Summer School 2010; • Support good practice relations between POs & Sponsors on RD CTs based on EURORDIS Charter on Clinical Trials (CCT): promote signature by	collaboration between committees and communication with EURORDIS Board • 11 monthly Therapeutic Activity Reports were produced on the activities of the EMA Committees and EURORDIS' patient representatives in these Committees • Further consolidation of the three Task Forces involving 34 patient representatives and volunteers, from different rare diseases and different EU Member states, trained and active in issues concerning Orphan Drugs, Paediatric Drugs and Drug Information & Transparency & Access (DITA) • EURORDIS is also extensively involved in the EMA's activities related to the provision of information to patients and the public about medicines authorised via the centralised procedure. A total of 123 Public Summaries of Opinion of Orphan Designations (PSOs), 5 European Public Assessment Reports (EPARs) and 7 Package Leaflets (PLs) were reviewed by EURORDIS staff members, in conjunction with relevant patient groups when appropriate • The EURORDIS Summer School is now a consolidated and consistently successful activity. • Continued engagement to implement the "Charter for Clinical Trials in Rare Diseases", which has been signed now by 6 pharmaceutical companies

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
	pharmaceutical Companies, and provide adequate staff and advisors to support the collaboration on specific CTs. • Promote RD research policy and patient involvement in research.	

10.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 1 as set out in the Health Strategy (2008-2013):

- Fostering good health in an ageing Europe - Healthy ageing is supported by taking action to promote healthy lifestyles and reduce harmful behaviours, and **to prevent and treat specific diseases, including genetic disorders**. The development of geriatric medicine needs to be actively promoted, with a focus on individualised care. Palliative care and better understanding of neurodegenerative diseases such as Alzheimer's are also important needs to address. There is also scope for further work on blood, tissues, cells and organs including transplant issues.

10.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

By its very own nature, EURORDIS is in constant interaction with other initiatives and organisations, mainly at EU level but also at both national and international levels. EURORDIS' mission is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level, and - directly or indirectly - to fight against the impact of rare diseases on their lives.

In accomplishing its mission, EURORDIS works closely with:

- Patient Organisations who are members of EURORDIS (there are more than 450 member organisations in 45 countries)
- The European Commission and the European Parliament, through advocacy efforts at EU level. Key DGs targeted by EURORDIS are DG SANCO, DG RTD and DG ENTR.
- Other alliances/organisations carrying out similar work to EURORDIS in other countries (NORD in the USA, CORD in Canada)
- National decision-makers throughout the EU, mainly through the work of national patient organisations who are members of EURORDIS
- Individual patients supported by EURORDIS' work
- The RD community at large

10.10 Rationale behind selection procedures (consistency with HP objectives)

According to the evaluation report, the action addresses the following objective of the 2009 AWP:

Objectives of Priority areas
Rare diseases (WP 2009, Annex – point 2.2.2): Developing European cooperation on rare diseases, in particular regarding their recognition, shared information on them, and cross-border cooperation in diagnosis and treatment through European reference networks.

The evaluation report also concluded the following points for the EURORDIS-FY-2010 proposal:

- The aim of the grant is relevant;
- The proposal is led by an experienced organisation;
- The work plan is appropriate and realistic, adding value to actions already in place;
- Recommended for funding with maximum EC contribution at the level requested;
- EAHC task with scrutinising the requested amount in view to avoid duplication of funding with the EC contributions allocated to the specific projects run by EURORDIS up until 2011.

10.11 Involvement of decision makers (design of project / exploitation of results):

As a patient-driven organisation, the legitimacy and independence of EURORDIS stem from its membership. The full members (more than 300 as of March 2009, when the application for the Operating Grant was submitted) vote at the General Assembly and present candidates to the Board. The Board is integrated by RD POs representing different countries and rare diseases and its members take part in strategic and political decisions. Part of the role of the Board includes taking part in discussions around the design of the Operating Grant and the exploitation of results. So even though the design, implementation and reporting of the Operating Grant is mainly run by EURORDIS management, the Board of Directors also has a voice.

10.12 Dissemination

As highlighted in the proposal to the Commission, EURORDIS has the potential to reach over 600 POs across the EU through its Membership and the EU Networks of national alliances and RD specific Federations. The main target audiences for EURORDIS are: RD patients and their families, relevant decision makers at EU and national levels, health professionals, social workers, etc. These audience groups are part of EURORDIS RD community Database.

The external dissemination strategy to be implemented as part of the 2010 work programme included the following main elements (all the figures below are taken from the proposal – the final report was not made available to the evaluation team):

- Dissemination of EURORDIS monthly Newsletter in 6 languages to 4574 subscribers;
- Revamped EURORDIS website available in 6 languages (website visitors/month: 53 558 from 183 countries) including online services for patients and new functions e.g. RSS feed, tags, etc;

- Large-scale awareness-raising campaign through the Rare Disease Day 2010, organised at both national and EU levels, including the establishment of a dedicated RDD website and broad media exposure (over 1,200 articles in websites worldwide and 300 articles in printed media in 2009);

- Rare Disease Awareness Video and Photo contest 2010;

- Online patients and advocates communities operated by EURORDIS in order to provide a forum for information exchanges, feedback and knowledge sharing for and from patients, advocates and professionals (Number of online communities/mailing lists: 25 - Number of registered users in online communities/mailing lists: 870 - Number of emails exchanged in mailing lists: 4,240);

- Public contributions, statements, comments, press releases, position papers, etc. widely circulated to relevant stakeholders, such as national and European decision-makers, industry representatives, regulators, patient communities, health professionals... (Number of documents downloaded from the website: 273,015);

- Publications: Activity Report 2009, fact sheets, brochures;

- European Conference on Rare Diseases (ECRD) 2010 Cracow: 600 participants expected + conference report (funded by POLKA project, DG SANCO);

- Representation of EURORDIS in different fora is also a valuable means of external dissemination of key messages (over 30 speeches and presentations expected).

According to the Commission's evaluation report on the proposal, the proposed dissemination strategy was detailed and suitable for the defined targets, and the adequacy of the actions and methods for communication and dissemination (based on running processes, via the web platform and adding on workshops and conferences) was sufficiently illustrated. The link and dissemination through other relevant European networks was prominent, reaching out to a variety of audiences.

The final status of the actions in the dissemination plan should be available in the Technical Implementation Report, which the evaluation team did not have access to when completing the case study.

10.13 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value Eurordis-FY-2010 fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		EURORDIS-FY-2010 Operating Grant
1.	Implementing EU legislation:	2.0
2.	Economies of scale:	1.5
3.	Promotion of best practice:	2.3
4.	Benchmarking for decision making:	2.0
5.	Cross border threats:	0.3
6.	Free movement of persons:	0.0
7.	Networking:	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

10.14 Sustainability

The fact that EURORDIS funding structure is diversified, with funding coming primarily from its members, but also from the European Commission, volunteers, corporate funding, national authorities, etc, is a signal of good financial health but also of transparency of the organisation.

EURORDIS differentiates between core activities and projects. Core activities are those considered to be essential to carry out the mission of the organisation. These include advocacy, information dissemination, capacity building, etc. Advocacy activities, which EURORDIS considers that need to be completely independent from industry, private donors, the Commission and national governments, are funded by members. The other core activities can be funded by other parties.

The objective of the Commission's Operating Grant is to support some of the core recurrent activities that allow the stability and the quality work of EURORDIS as a non-governmental organisation and as an actor in the field of RD across the EU. As such, the Commission's grant has come to play a very relevant role in terms of the sustainability of the organisation.

In the interview with the action leader for this grant, it was highlighted that the current annual nature of the grant is very difficult as it attempts again long term policy and stability. If the grant was pluri-annual (3 to 5 years' contract), decisions could be based on mid-term adjustments and there could be more time spent on the action itself as opposed to the application or reporting. The main issue affecting sustainability at present is the uncertainty

of not knowing if the organisation will continue with the grant from one year to the next or not. A pluri-annual grant scheme would minimise this risk.

The other issue that was raised during the interview as affecting sustainability is the rule that the Commission's contribution for Operating Grants has to decrease by 5% every year. A decreasing contribution, as argued by the interviewee, attempts not only against the stability of the organisation (which thanks to the grant experiences a growing activity with the development of the field and the action that needs to be addressed) but also against the stability of the EU health policy.

Another factor that was highlighted as negative for sustainability of the organisation were the changing rules and budget for Operating Grants from one year to the other. In particular, the 2011 Operating Grant for EURORDIS experienced a budget decrease which was a consequence of a cut down in the Commission's budget for Operating Grants.

10.15 Impact to be expected

The overall impact of the Operating Grant is hugely positive for the organisation. The fact that EURORDIS is being supported on a number of their core activities allows them to train people, to develop them as experts in the field, to support volunteers, to bring on board good professionals to work with the volunteers and PO. All of this is possible because of the existence of the grant, which contributes to a better return on the work of the organisation. As an instrument, it is considered to be a better investment than projects.

In terms of the measurement of the impacts, EURORDIS does a good identification of indicators at the design phase of the grant, and follows these on a regular basis. Indicators and metrics are now an important part of the organisation's culture and management. There are also external financial audits on the Operating Grant that are conducted annually, in addition to the Commission reviews of the application and final report of the grants, and individual evaluations that are carried out of different project undertaken. EURORDIS has not judged the need for an external evaluation of the organisation to be undertaken yet as all of the above elements have worked well for measuring impact so far.

11. CLUB HEALTH

11.1 Summary

Nightlife plays a major role in modern life, being a critical aspect of youth recreation and a major source of employment, economic development and tourism for towns and cities. However, nightlife activities also create a wide range of health and social problems including alcohol and drug use, anti-social behaviour and crime. The development of safe nightlife environments is a growing priority throughout Europe, where town and city authorities must manage not only the recreational habits of their own youth, but also those from other countries as international tourism increases. Effectively managing nightlife settings is critical both ***in protecting the health of young people*** and ***reducing the burdens that night time anti-social behaviour can place on public services and society***.

Most people over 45 die because of cancer and circulatory or respiratory diseases, whereas young people generally fall victim to external factors, such as suicide and intentional harm, transport accidents, drugs, AIDS, accidental poisoning and homicide / assault. In 2006, external causes accounted for a little more than 60 % (EuroStat) of deaths among young people aged 15 to 29. Considering external causes of death, it appears that about 30 % of deaths caused by transport accidents and 30 % of those caused by drug dependence involved young people aged between 15 and 29. These are some of the very factors that the CLUB HEALTH project is targeting.

Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved as associated partners	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
+++	+++	++	+++	+++	+++	++	16	++	1. Implementing EU legislation: 1.0 2. Economies of scale: 1.0 3. Promotion of best practice: 2.7 4. Benchmarking for decision making: 0.5 5. Cross border threats: 1.3 6. Free movement of persons: 0.0 7. Networking: 2.0
Action addresses EU HP Objectives and AWP by focusing on young people and their drinking of alcohol beverages and use of other drugs. Action underpins EU policies and activities regarding health promotion, especially in the field of alcohol (EU alcohol strategy) and illicit drugs (EU Drugs Strategy)	- Nightlife activities create a wide range of health and social problems for young people including alcohol and drug use, anti-social behaviour and crime. - CLUB HEALTH takes a systematic approach to addressing these problems through the creation of a well coordinated network.	Evidence was presented although section 3.2 in the proposal could have provided more extensive insights into the evidence on which the project had been based.	Builds on numerous EU funded projects: -Recreational Prev -Democracy, Cities & Drugs II	- Numerous complementary activities identified in EU MSs and in industrialised nations. - USA has Youth Risk Behaviour Surveillance System (YRBSS) monitoring priority health-Risk behaviours. - Also on WHO agenda.	Target groups: - Professionals in the field of youth risk behaviour prevention - Public officials in competent national, regional or local institutions - Politicians and policy/decision makers - Journalists, media owners and editors - Owners of night clubs and their staff. CLUB HEALTH aims to reach between 1000 to 1200 people among these target groups.	- Dissemination channels include: + Website + Club Health Conference - Dissemination strategy involves project partners in the major European and international networks in these fields (IREFREA, Prevnet, ProSkills etc.).	- 1 Lead Partner - 20 Associated Partners - 15 Collaborating Partners	- Internal: WP Leaders will evaluate their own WPS. - Specific events will also be evaluated. - External: The project will be also externally evaluated by sub-contractor (Hungarian Academy of Sciences) (summative and impact evaluation).	Particularly strong in: 2. Economies of Scale & 3. Promotion of Best Practice - Project expected to result in building capacity in public administrations at national and local level to facilitate more consistent implementation of strategies in the field of youth risk behaviour prevention (preparation of guidelines and recommendations), increasing safety and health standards in nightlife, raising awareness among discotheque and night club owners regarding their responsibility in protecting the health of young people, and finally education and training of staff working in discotheques and night clubs to enable them to help prevent different harms. 7. Networking - One of the objectives of the project is to consolidate and maintain a Club Health Network as an umbrella organisation in the field of nightlife prevention at European level;

11.2 Key Facts

Calls for proposals:	2008
Proposal title:	CLUB HEALTH - HEALTHY AND SAFER NIGHTLIFE OF YOUTH
Acronym:	CLUB HEALTH
Financing mechanism:	Project
Starting date:	January 1st 2009
Duration (in months):	36 months
EC contribution:	€700,000 (60%)
Total:	€1,166,667
Overall score achieved in Consolidated Evaluation Report:	79
Total criteria block: A, B, C	A: 34 B: 23 C: 22
Main partner:	Institute for Research and Development "Utrip"
Number of associated partners:	20
Number of collaborating partners:	15
Priority area:	2. PROMOTE HEALTH (HP-2008)
Action:	3.3 Priority actions for the second strand Promote health 3.3.4 Addiction prevention
Typology[38]:	Development Action

11.3 Overview of project success criteria

The following table of project success criteria has been developed based on a strategic document produced by the EAHC "EU Health Programme Evaluation"[39]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria. Please note that these criteria will be further refined for the Draft Final Report.

Project Success Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** - target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in	CLUB HEALTH objectives are broadly to: (i) to consolidate, maintain and broaden the Club Health network, bringing together a wide range of institutions, researchers, professionals and non-governmental organisations (NGO) in the field of youth risk behaviour; (ii) to undertake impact assessment of implementation of strategies and laws; (iii) to develop an inventory of effective evidence-based legislative and policy measures; and (iV) to build capacity at country, regional and local levels for effective implementation of legislative and policy measures through pilot trainings, workshops,

[38] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[39] The document was developed by Guy Dargent and Michel Pletschette.

Project Success Criteria	Notes / Comments
terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	seminar and conferences. Desk research suggests that CLUB HEALTH meets the objectives of the EU Health Programme and the 2008 AWP by focusing on young people and their drinking of alcohol beverage and use of other drugs. More specifically it addresses 3.3.4 Addiction prevention 3.3.4.1. Smoking prevention and tobacco control 3.3.4.2. Alcohol Strategy 3.3.4.3. Preventing drugs and drug related harm Regarding 1 b. A review of the Interim Report suggests that the outputs remain consistent with what was presented in the proposal. This should be examined carefully during the end-term evaluation when the majority of outputs will have taken place. The EAHC should also be monitoring project outputs to ensure that they adhere to HP objectives.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	CLUB HEALTH should be considered a Development Action. An extensive desk research exercise as part of this mid-term evaluation reveals that there is a robust evidence base for the Project. (See timeline, and example Eurostat data). While the proposal does highlight some relevant information and evidence, "Section 3.2 Relevant Evidence Base" in the proposal could have provided more extensive insights into the evidence on which the project had been based.
Clear target groups	Target groups are reasonably well-defined and quantified. Those mentioned in the proposal include: - professionals and researchers in the field of youth risk behaviour prevention, - public officials in competent national, regional or local institutions, - politicians or other policy/decision makers, - journalists, media owners and editors, - owners of night clubs and their staff.

Project Success Criteria	Notes / Comments
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination) Use of multipliers	- Dissemination strategy involves project partners in the major European and international networks in these fields (IREFREA, Prevnet, ProSkills etc.). - Website - Conference In many ways CLUB HEALTH can be considered a "capacity building project". A significant focus of the project is dedicated to producing and disseminating information and to a certain extent networking forms part of it. The project aims to reach between 1000 to 1200 persons among these target groups who will act as multipliers.
Estimate the population reached (or targeted) by the action	**Reducing Risk:** Potential target population = Young people in EU (15-29)
Matching of project's deliverables (if any) with project's objectives	Outputs appear to be consistent with what was presented in the proposal. The main products are going to be developed in the next few months and should be examined carefully during the end-term evaluation.
Evaluation (provision of indicators)	- Internal: WP Leaders will prepare evaluation plans, evaluation instruments (questionnaires) and methodology for their respective WPs. Specific events will also be evaluated. For example, training sessions, conferences and the seminars will be evaluated by questioning the participants for formative purposes and assessing the outcome. - External: The project will be also externally evaluated by sub-contractor (Hungarian Academy of Sciences) (summative and impact evaluation).
Sustainability plan	According to the Action Leader there are plans and commitments from those involved to continue with project activities in the future.

11.4 Introduction

Nightlife plays a major role in modern life, being a critical aspect of youth recreation and a major source of employment, economic development and tourism for towns and cities. However, nightlife activities also create a wide range of health and social problems including alcohol and drug use, anti-social behaviour and crime. The development of safe nightlife environments is a growing priority throughout Europe, where town and city authorities must manage not only the recreational habits of their own youth, but also those from other countries as international tourism increases.

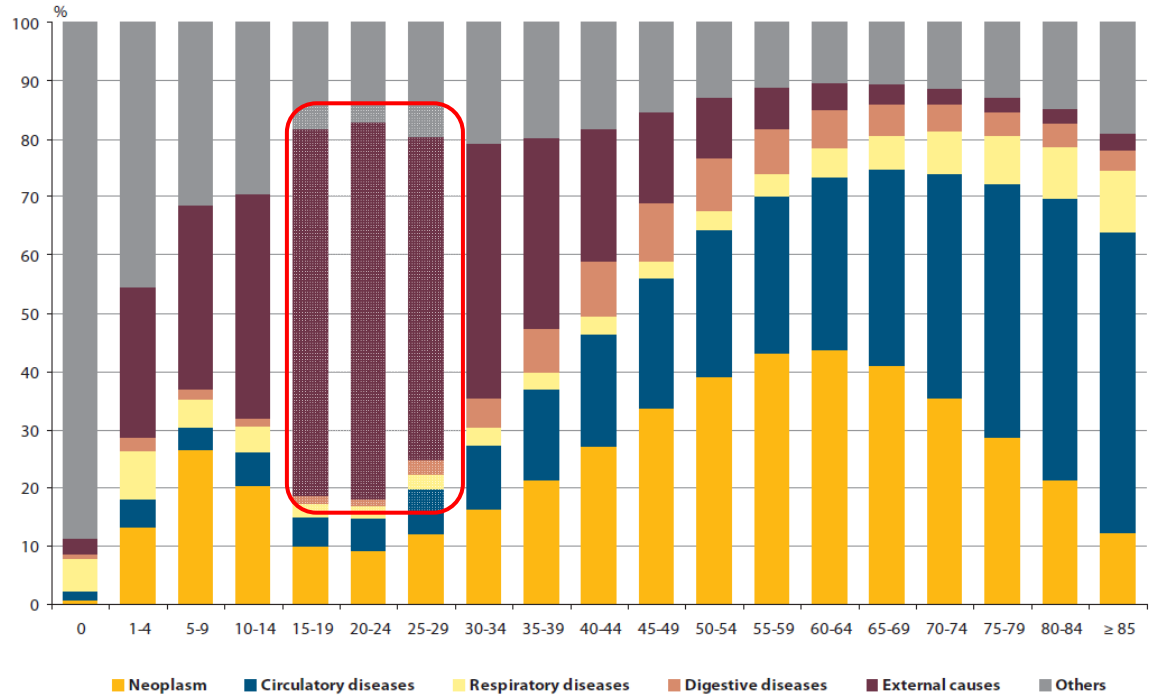
Effectively managing nightlife settings is critical both in protecting the health of young people and reducing the burdens that night time anti-social behaviour can place on public services and society.

Health and Social Problems:
Among the general population alcohol is the third (and first in the youth population) most likely cause of premature mortality and sickness in Europe. Approximately 8 % of illness in Europe can be attributed to alcohol. In monetary terms this burden costs €125 billion and accounts for 1.3% of European gross national product (Anderson and Baumberg, 2006). Alcohol is strongly related to violence. For example, in some countries a fifth of all violence takes place in or around pubs and clubs and 80 % of these incidents involve alcohol. Many people meet new sexual partners in nightlife settings; young people can be more than twice as likely to have unprotected sex when drunk than when alcohol has not been consumed. Across Europe and elsewhere, the proportion of young people that binge drink is increasing and there is a growing trend towards drinking specifically in order to get drunk.

Research in several countries (IREFREA, 2007 etc.) found levels of recreational drug use to be far more prevalent among clubbers than young people in the general population.

Noise levels in night clubs can be very high and two thirds of clubbers report having experienced hearing problems after a night out; in some cases hearing damage can be permanent. Clubbing has become an important part of young people's holiday activities. While on holiday, levels of alcohol consumption, illicit drug misuse and risky sexual behaviour are increased.

Figure 19 - Causes of death in the EU-27, by age group, 2006 (%)



Source: Eurostat, Health statistics (Causes of death)

The figure above shows that causes of death vary substantially according to the age group concerned. Most people over 45 die because of cancer and circulatory or respiratory diseases, whereas young people generally fall victim to external factors, such as suicide and intentional harm, transport accidents, drugs, AIDS, accidental poisoning and homicide / assault.

In 2006, external causes accounted for a little more than 60 % of deaths among young people aged 15 to 29. Considering external causes of death, it appears that about 30 % of deaths caused by

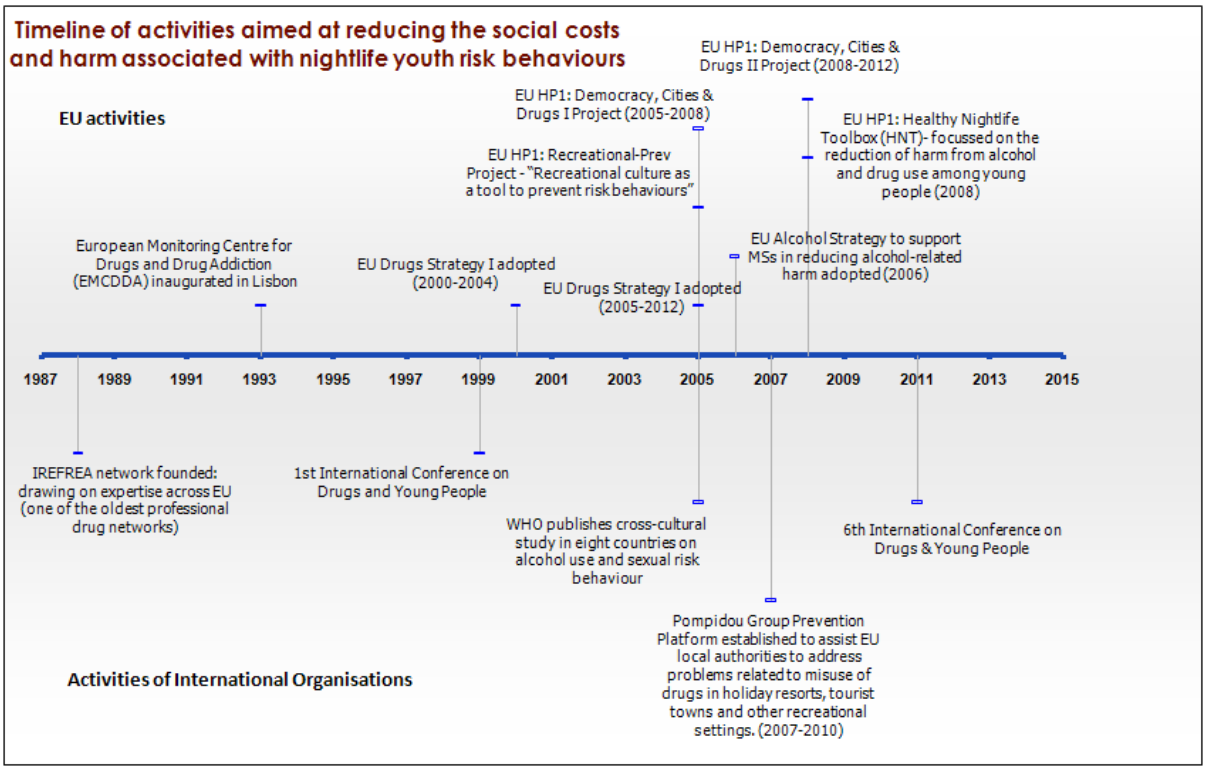
transport accidents and 30 % of those caused by drug dependence involved young people aged between 15 and 29.

These are some of the very factors that the CLUB HEALTH project is targeting.

11.5 Background / Policy Context

In order to gauge and make a judgement on the extent to which the CLUB HEALTH project is tackling a serious public health issue, an examination of related public health interventions / activities has been undertaken. The figure below provides a brief overview of how activities related to the public health effects of youth lifestyles have evolved over the last couple of decades.

Figure 20 – Timeline of activities aimed at reducing the social costs and harm associated with nightlife youth risk behaviours



Over the last decade, experts, research institutions and NGOs in countries all over Europe and internationally have initiated activities to increase health and safety standards in nightlife premises. The main purpose of such activities was and still is the reduction of risk and harm, caused by risk behaviour of young people in nightlife with the purpose of preventing addictions and long-term health consequences. Many studies have shown that activities in this area have improved the situation in addition to increasing awareness among the youth population about their own health and safety. There is also reported to be a greater awareness of those working in the entertainment industry.

It should be noted that the timeline presented above does not represent each and every activity in this area of public health that has taken place over the last 25 years. However it does go some way to demonstrating that there a significant amount of work being carried out in the area and that there is a widely held view among the public health community that it is a serious public health issue to be reconciled.

In line with this observation those responsible for the CLUB HEALTH project acknowledge that there is a significant body of expertise and experience in this field both in Europe and

internationally. The value in the CLUB HEALTH project is in continuing to bring all of this together in a systematic way through a well coordinated network.

11.6 Origins of HP project

It seems that the CLUB HEALTH project did not come about through any particular previous initiative or activity but a culmination of work in this area of public health. The proposal mentions that CLUB HEALTH builds upon conclusions of numerous completed projects and bridges the gaps between different existing project networks. More specifically, events such as the 4th international conference on nightlife, substance use and related health issues and complementary projects such as Democracy Recreational prev, Healthy Nightlife Toolbox and Democracy Cities & Drugs II are cited as being particularly important.

11.7 Project Partners

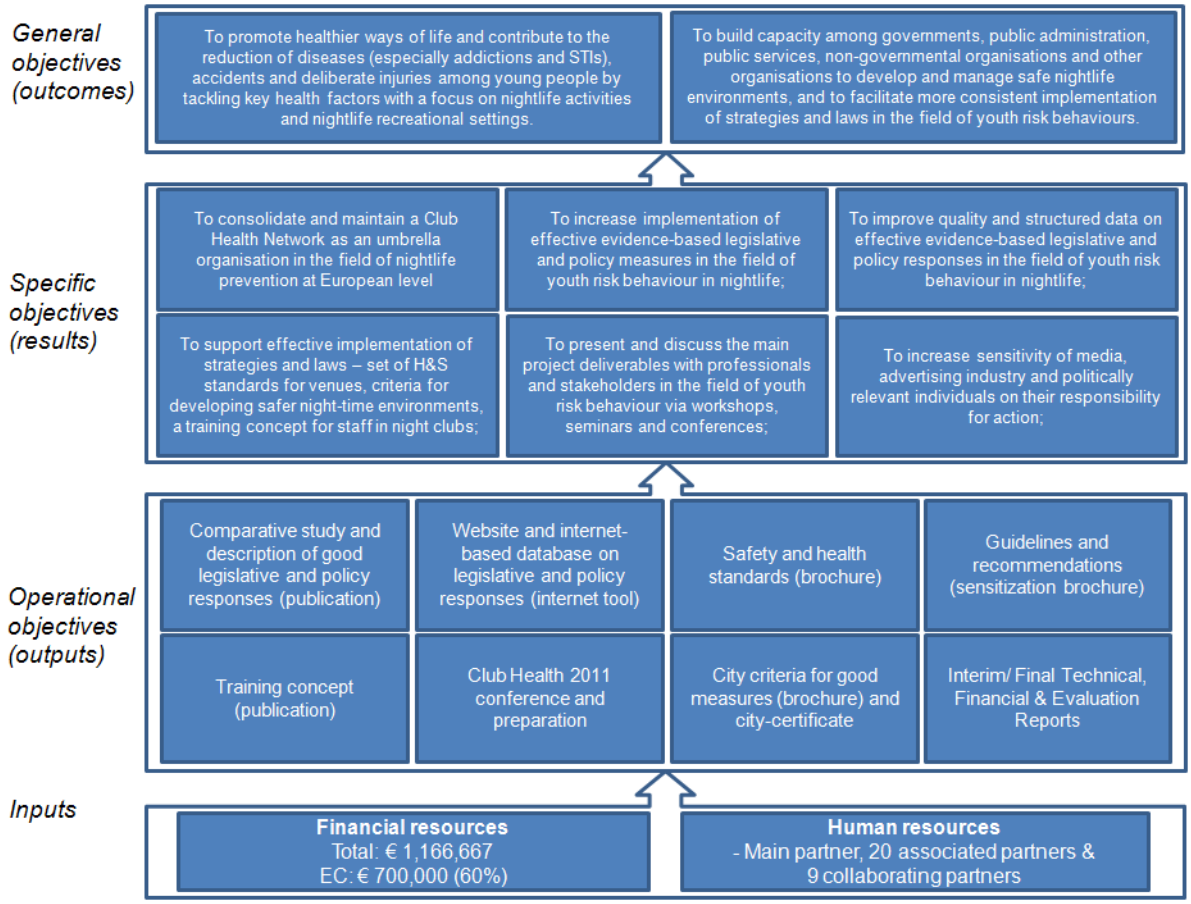
Main Partner	Country	Organisation Status
Institute for Research and Development "Utrip"	**Slovenia**	**Private - NfP**

Associated Partners	Country	Organisation Status
Centre for Public Health, Liverpool John Moores University	**UK**	**Public**
Zentrum für empirische pädagogische Forschung der Universität Koblenz-Landau	**DE**	**Public**
Centre de Prévention des Toxicomanies	**LUX**	**Private - NfP**
SANANIM o.s.	**CZ**	
Centre of Excellence on Applied Addiction ResearchKatholische Fachhochschule Nordrhein-Westfalen	**DE**	**Private – Academic Inst.**
Centre of Excellence on Applied Addiction Research University of Huddesfield	**UK**	**Public**
Faculty of Psychology Tibiscus University of Timişoara		**Private – Academic Inst.**
Scientific department Institut für Sozail- und Gesundheitspsychologie	**AU**	**Private - Company**
Health Promotion Department Health Service Executive (South)	**IE**	**Public**
Dipartimento per le Dipendenze Azienda Unità Locale Socio-Sanitaria n.1 Veneto	**IT**	**Public**
London Drug Policy Forum (LDPF) City of London	**UK**	**Public**
IDEC S.A.	**GR**	**Private – Company**
Blue Point Drug Counselling and Outpatient Centre Foundation	**HU**	**Public - NfP**
Megyei Egészség Kultúrát Koordináló Alapítvány	**HU**	**Public - NfP**
Faculty of Social Work and Social Welfare Studies Hogeschool Gent (University College Ghent)	**BE**	**Public - Academic**
Conversas de Rua – Associação	**PT**	**Private – NfP**
"PROTASI" Movement for another life style	**GR**	**Private – NfP**
Trimbos Institute - Netherlands Institute of Mental Health and Addiction	**NL**	**Public – NfP**

11.8 Overall project objectives / Intervention Logic

The CLUB HEALTH project covers several annual work plan priorities of the Health Programme 2008-2013. It supports key EU strategies on alcohol and illicit drugs adopted in recent years in purpose to reduce alcohol-related and drug-related harm. Based on an analysis of the proposal and interim report, the diagram below depicts the project's complete intervention logic. There is some confusion at the level of the general objectives as the second general objective seems to be included in the umbrella of the first general objective, hence it could be more appropriate as a specific objective.

Figure 21 - Intervention logic for CLUB HEALTH



Inputs:

Please find below a table detailing the EFHRAN budget providing costs for all inputs including staff, travel, equipment etc.:

Budget Overview	
E1a: Staff (public officials)	€ 62,283
E1b: Staff (non public officials)	€ 664,460
Total Staff (E1a + E1b)	**€ 726,743**
Total E2 - Travel Costs and subsistence allowances (E2a + E2b)	**€ 165,378**
Total E3 - Equipment	€ 0
Total E4 - Consumables & supplies linked to the project	€ 0
Total E5 - Subcontracting costs	€ 117,510
Total E6 - Other costs	€ 107,750

Budget Overview		
Total Direct Eligible Cost		**€ 1,117,381**
Total E7-Overheads	€ 49,286	
Total Indirect Eligible Cost		**€ 49,286**
TOTAL EXPENDITURE		**€ 1,166,667**

Expected outputs:

Expected outputs	Achieved outputs (as per Interim Report)
Website	Due date: Oct 2009 Actual date: Nov 2009
Comparative study and description of good legislative and policy responses (publication)	Later in project
Internet-based database on legislative and policy responses (internet tool)	Later in project
Safety and health standards (brochure)	Later in project
Conference (media)	Later in project
Training concept (publication)	Later in project
City criteria for good measures (brochure) and city-certificate	Later in project
Club Health 2011 conference	Year 3: Club Health 2011 will be held in Prague, Czech Republic, on 12th to 14th December 2011
Guidelines and recommendations (sensitization brochure)	Year 3: 2011
Final project report	Year 3: 2011

Expected aims/outcomes:

Aim	Indicators	Result (as per Interim Report)
To consolidate and maintain a Club Health Network[40] as an umbrella organisation in the field of nightlife prevention at European level;	(a) growing size of the network (membership); (b) activity of network; (c) commitment of the members to network	- 1st annual Club Health network meeting (December 2009 in Ljubljana, Slovenia) - Communication with national networks in Portugal
To increase implementation of effective evidence-based legislative and policy measures in the field of youth risk behaviour in nightlife;	(a) extent of European comparative study; (b) production of study; (c) dissemination of study; (d) dissemination of findings	- Research protocol drafted and discussed with EAHC
To improve quality and structured data on effective evidence-based legislative and policy responses in the field of youth risk behaviour in nightlife;	(a) development, maintenance and updating of the database; (b) completeness of content of database; (c) user friendliness of	- 36 policy reviews collected from 9 countries - Research protocol drafted and discussed with EAHC

[40] The project was initiated after an ad hoc group of participants regularly attended a conference that was held every two years. Informal "network" has been set up but the project will help to consolidate it and make it regular and formal.

Aim	Indicators	Result (as per Interim Report)
	database; (d) use of database; (e) dissemination of database entries	
To support effective implementation of strategies and laws by preparing a set of health and safety standards for night-time venues, a city criteria to demonstrate local commitment and progress in developing safer night-time environments, and a training concept for staff in discotheques and night clubs;	(a) development of health and safety standards for nightlife venues; (b) development of city criteria for good measures; (c) development of a training concept for staff in nightlife premises	- IREFREA España prepared article "Preventive interventions in nightlife: a review". - Research protocol drafted and discussed with EAHC
To present and discuss the main project deliverables with professionals and stakeholders in the field of youth risk behaviour via workshops, seminars and conferences;	(a) number of workshops; (b) participation in workshops and seminar; (c) professional development of participants; (d) attendance of the Club Health conference; (e) professional development and network experience of delegates; (f) dissemination of the activity; (g) production of sensitization brochure; (h) dissemination of sensitization brochure	- Research protocol drafted and discussed with EAHC
To increase sensitivity of media, advertising industry and politically relevant individuals on their responsibility for action;	(a) attendance of the conference on media; (b) professional development of delegates; (c) dissemination of activity	- Protocol drafted and discussed with EAHC - Contacts with policy makers and advisory bodies on communal and provincial level were made through a workshop - Several partners established contacts with specialised magazines, newspapers and media professionals in their countries to promote the project

11.9 Action compatible with the principle / objectives in the Health Strategy

The CLUB HEALTH action is compatible with Strategic Objective 1 of the Health Strategy (2008-2013). Objective 1: Fostering good health in an ageing Europe. Population ageing poses significant challenges for the European economy and welfare system as it is likely to increase the demand for

healthcare and reduce the size of the working population. This is considered to be one of the most important challenges facing the EU. However, DG ECFIN projections for 2006 showed that if the population remains healthy as they live longer, the rise in healthcare spending due to ageing can be halved. Thus, actions that promote health and prevent diseases through tackling issues such as nutrition, physical activity, **alcohol, drugs, tobacco**, environmental risks, genetic disorders, and traffic and home accidents can help **create a healthy and productive population that ages healthily**.

11.10 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified the following initiatives:

1. **Other EU / DG SANCO projects**

As mentioned above, the project also complements at least three related projects, co-financed by the European Commission under the first EU Health Programme:

a. Recreational prev (IREFREA España)
b. Healthy Nightlife Toolbox" (Trimbos)
c. Democracy, Cities & Drugs II" (EFUS)

2. **International Organisations / Activities involved in related activities:**

a. International Childhood and Youth Research Network (ICYRNet)
>> http://www.icyrnet.net/
b. International Association for Adolescent Health
>> http://www.iaah.org/
c. Society for Research on Adolesence
>> http://www.s-r-a.org/
d. WHO – Adolescent Health
>> http://www.who.int/topics/adolescent_health/en/

3. **Member State organisations involved in related activities:**

a. The European Institute of Studies on Prevention (IREFREA) network was founded in 1988 with experts from several European countries and it is one of the oldest professional drug networks. The areas covered by IREFREA include alcohol and drug prevention (research, evaluation and programme implementation) covering questions like risk factors, risky behaviours, related violence and programmes efficiency among others.
>> http://www.irefrea.org/

b. Irish National Youth Website
>> www.SpunOut.ie

c. Scottish Collaboration for Public Health Research and Policy
>> Adolescent and Young Adult Health in Scotland: Interventions that address multiple risk behaviours or take a generic approach to risk in youth

4. **3rd countries involved in related activities:**

a. **USA:** The Youth Risk Behaviour Surveillance System (YRBSS) monitors priority health-risk behaviours and the prevalence of obesity and asthma among youth and young adults. The YRBSS includes a national school-based survey conducted by the Centers for Disease Control and Prevention (CDC) and state, territorial, tribal, and district surveys conducted by state, territorial, and local education and health agencies and tribal governments.

   Youth Risk Behavior Survey (YRBS) is an American biannual survey of adolescent health risk and health protective behaviors such as smoking, drinking, drug use, diet, and physical activity conducted by the CDC. It is one of the major sources of information about these risk behaviours, and is used by federal agencies to track drug use, sexual behavior, and other risk behaviors.

   http://www.cdc.gov/HealthyYouth/yrbs/index.htm

   The YRBS was created in the early 1990s in order to monitor progress towards protecting youth from HIV infection. There are only two repeated nationally-representative surveys which give all the information in existence about youth risk behavior; YRBS and the University of Michigan's Monitoring the Future. Every academic research study which evaluates national US trends over time in adolescent smoking, drinking, drug use, sexual activity, or other health behaviors is based on these two studies. There are no other nationally-representative sources of information about these behaviors other than YRBS and MTF.

   The YRBS is the official source of information about adolescent risk behaviors used to evaluate federal, state, and local public health initiatives to decrease these risk behaviours.

b. **Australia:**
   >> Australian drug Foundation

c. **Canada:**
   >> Canadian Association for Adolescent Health

11.11 Rationale behind selection procedures (consistency with HP objectives)

The proposal evaluation report concluded that CLUB HEALTH meets the objectives of the EU Health Programme (2008-2013) and the Annual Work Plan by focusing on young people and their drinking of alcohol beverages and use of other drugs. While the proposal did not explicitly cite which sections of the AWP it was addressing it seems the following areas are most applicable:

3.3 Priority actions for the second strand Promote health
Activities under this section are designed to prevent major diseases and reduce health inequalities across the EU, by tackling key health determinants such as nutrition, alcohol, tobacco and drug consumption, as well as social and environmental determinants.
3.3.4 Addiction prevention
Actions to promote health through tackling addiction related health determinants will build on the activities funded in the first public health programme. Activities will be in line with the approach set out in the Commission communication on an EU strategy to support Member States in reducing alcohol-related harm, the EU Drugs Strategy and Action Plan, the Council Recommendation on Drugs, the Drug Prevention and Information Programme under the framework of the General

Programme 'Fundamental Rights and Justice' and the Green Paper 'Towards a Europe free from tobacco smoke — policy options at EU level' as well as the overall EU approach on tobacco control.
3.3.4.1. Smoking prevention and tobacco control
3.3.4.2. Alcohol Strategy
3.3.4.3. Preventing drugs and drug related harm

CLUB HEALTH activities are designed to support actions to provide and exchange best and promising legislative and policy measures and promote cross-cutting and integrative approaches across several health determinants and maximise countries efforts to prevent youth risk behaviour in nightlife. It should be noted that it is envisaged the results of the project will strongly underpin EU policies and activities regarding health promotion, especially in the field of alcohol (EU strategy was adopted by the European Commission in October 2006) and illicit drugs (EU strategy and action plans for the period of 2005-2012). The project focuses on healthier ways of life and reduction of accidents and injuries among youth by tackling different health determinants (alcohol, tobacco, drugs, sexual behaviour etc.).

11.12 Involvement of decision makers (design of project / exploitation of results):

While there is no specific mention of policy makers being directly involved in the design of the project it is evident that this is considered a serious public health issue at EU and MS level. The fact that there have been numerous interventions targeting the public health effects of radon demonstrates some level of commitment to tackling the issue. It is envisaged that the results of this project will certainly be examined closely and potentially used for determining future policy and decision making by the Commission and Member States.

11.13 Dissemination

As mentioned above, the backbone of the CLUB HEALTH resides in a comparative study and description of selected legislative and national policy responses. The results, synopsis and conclusion from this study will be published in English, both in a special publication and on the CLUB HEALTH website.

Target Audience

Target groups mentioned in the proposal include:
- professionals and researchers in the field of youth risk behaviour prevention,
- public officials in competent national, regional or local institutions,
- politicians or other policy/decision makers,
- journalists, media owners and editors,
- owners of night clubs and their staff.

CLUB HEALTH aims to reach between 1000 to 1200 people among these target groups who will act as multipliers.

Tools

Website
During the first year of the project the CLUB HEALTH website (www.club-health.eu) has been a key channel through which dissemination has taken place. The website contains information related to the project ranging from its objectives and the partners involved through to the latest project outputs including papers and presentations from recent conferences. There are also plans for the site to include a discussion forum for international discussions and exchanges on the products.

Project Partners / Networks
A significant part of the dissemination strategy involves project partners in the major European and international networks in these fields (IREFREA, Prevnet, ProSkills etc.). Based on the contacts and cooperation in these networks, products will be disseminated in other institutions, regions and countries.

Publications
To ensure the transferability and sustainability of the project, a series of publications containing practical information and action plans are planned. These publications include a manual presenting the training concept (training sessions, background information and training materials), the health and safety standards, and the city criteria. These products will be published in print and electronically. Additional to the English version, guaranteeing dissemination internationally, translations into all partner languages will facilitate a national, regional and local implementation of the proposed strategies in the countries of our project partners.

Conferences, workshops and meetings
Numerous partners have had the opportunity to present the CLUB HEALTH project at conferences and meetings involving entities that have a direct interest in this area of public health. It is envisaged that this type of activity will continue throughout the life of the project.

11.14 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the CLUB HEALTH project fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		CLUB HEALTH Project
1.	Implementing EU legislation:	1.0
2.	Economies of scale:	1.0
3.	Promotion of best practice:	2.7
4.	Benchmarking for decision making:	0.5
5.	Cross border threats:	1.3
6.	Free movement of persons:	0.0
7.	Networking:	2.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

11.15 Sustainability

According to the Action Leader there are serious plans and commitments to continue with project activities in the future. Outcome and impact evaluation will be used to demonstrate the worth of the project and future projects.

EU-funding is considered to have raised the profile of the project in this area of public health. Additionally, it increases references and all round reputation at international level. It provides those involved the opportunity to actively attend many conferences and present the project and the results. In the absence of EU funding it is likely that the Action would have taken place but with a less ambitious scope.

11.16 Impact

The CLUB HEALTH project is still an ongoing Action and many of the main outputs will be delivered in the coming months so it is too early to be able to make any comprehensive assessment of the impact of the project. However, it is the view of the Action Leader that CLUB HEALTH definitely complements other activities at Member State or EU level and goes a long way to promoting policy transfer and shared best practices between the Member States. To some extent, the project already has influenced the policies in the countries of the associated partners (for example, safety/security service legislation in Slovenia has improved significantly on the basis of Club Health recommendations).

12. VITO NV

12.1 Summary

The objective of this tender was to collect and evaluate European incidence data of respiratory and skin allergies, and to provide a first assessment of the issue. The background against which this tender was developed was the increasing incidence of respiratory and skin allergies in the EU, a phenomenon that according to the tenderers had been amplified as a result of exposure to specific chemicals in consumer products, environmental, occupational settings, leisure and sports.

According to the final evaluation of the project made by the Commission, the project made significant progress to 1) identify skin and respiratory sensitizers; 2) collect, report and critically evaluate published data on them; and 3) categorise them on a weight of evidence approach in terms of potency.

In addition, the Commission's final assessment highlighted that the study conducted careful analysis of the data and identified a number of data gaps in the collection and reporting of skin and respiratory allergies in Europe, potency evaluation (hazard characterisation) in conducting risk assessments of skin and respiratory sensitizers (establishing dose-response curves), effects of mixtures, and risk management. The study authors accompanied their findings with a number of recommendations to address the data gaps.

The project consisted of 3 work packages, each of them delivering on the strategic objectives which were:

- To systematically search, collect and report published data on the incidence of respiratory (asthma) and skin (contact dermatitis) allergies in the EU related to exposure to non food chemicals (consumer products, environment, occupational setting, etc).

- To critically evaluate the data in order to establish cause and effect relationships, to assess the severity of clinical picture, to estimate human behavioural trends which may affect incidence, and to identify time trends in the incidence of allergies in the EU.

- To identify gaps in the data and make recommendations to address them.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
VITO NV	+++	+++	+++	+++	++	o	N/A	1	N/A	1. Implementing EU legislation: 0.3 2. Economies of scale: 0.5 3. Promotion of best practice: 0.0 4. Benchmarking for decision making: 1.3 5. Cross border threats: 0.0 6. Free movement of persons: 0.0 7. Networking: 1.0
	The action addresses the objectives of the HP and of the 2008 AWP, aiming at collecting and evaluating European incidence data of respiratory and skin allergies.	According to the final evaluation of the action made by the EC, VITO NV made significant progress to - identify skin and respiratory sensitizers; - collect, report and critically evaluate published data on them; - categorise them on a weight of evidence approach in terms of potency.	Allergic diseases represent an important health issue. VITO VN takes a systematic approach to critically evaluate data to establish cause and effect relationships and to identify time trends in the incidence of allergies in the EU.	The action fed from various sources, including publications from EU projects / networks, national organisations, international organisations etc.	A number of strategies to assess the incidence and cause of skin and respiratory allergies exist.	No target groups were identified in the proposal.	No dissemination strategy or activities available for this action, apart from the comment in the Commission's final report that the results of the study would be submitted to the Scientific Committee on Consumer Safety.	- 1 Lead Partner	The proposal does not outline any evaluation strategy, though a final evaluation report by the European Commission exists.	The action does not score particularly high in of the EU added value criteria.

12.2 Key Facts

Calls for proposals:	2008
Proposal title:	Collection and Evaluation of data on incidence and severity of skin and respiratory allergy related to exposure to chemicals from non food sources
Acronym:	VITO NV
Financing mechanism:	Tender
Starting date:	12th November 2009 (as per signed contract)
Duration (in months):	10 months
EC contribution:	€ 100,000.00
Overall score achieved in Consolidated Evaluation Report:	n/a
Total criteria block: A, B, C	n/a
Main partner:	Flemish Institute for Technological Research (VITO), Belgium
Number of associated partners:	-
Number of collaborating partners:	Laboratory of Pneumology of the Katholieke Universiteit Leuven, Belgium (35% of the work subcontracted to them)
Priority area:	3.2 IMPROVE CITIZEN'S HEALTH SECURITY (HS-2008)

Action:	3.2.2.5 Assessment of incidence and causes of allergies
Typology[41]:	Research action

12.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[42]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to reduce risk:** The project was aimed at collecting and evaluating European incidence data of respiratory and skin allergies, and providing a first assessment of the issue.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Research action**: The action was tasked with a systematic search, collection and reporting of published data on the incidence of respiratory and skin allergies in the EU related to exposure to non food chemicals, the evaluation of the data and the identification of gapsin the data
Clear target groups	Target groups not identified in the proposal. However, the Commission's final evaluation report highlighted that the action's report would be submitted to the Scientific Committee on Consumer Safety for its intrinsic value in the Committee's

[41] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).
[42] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
	ongoing work on skin sensitisation.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	Not applicable
Estimate the population reached (or targeted) by the action	Not applicable.
Matching of project's deliverables (if any) with project's objectives	The Commission's final evaluation report on the results of the project concluded that it was a successful project which delivered value results in a quality, timely manner.
Use of multipliers	As per the interview with the action leader for this tender, there was an expectation that the Commission would assume a more active role as a multiplier in the dissemination of the results of the study. They understand that the results of the study did not receive any significant dissemination after it came to an end.
Evaluation (provision of indicators)	N/A
Sustainability plan	N/A

12.4 Introduction

The focus of this project was on the collection and evaluation of data on the incidence and severity of skin and respiratory allergies related to exposure to chemicals from non food sources.

The project was structured around three work packages that responded to three key objectives:

- **Objective / WP 1**: To systematically search, collect and report published data on the incidence of respiratory (asthma) and skin (contact dermatitis) allergies in the EU related to exposure to non food chemicals (consumer products, environment, occupational setting, etc).

- **Objective / WP 2**: To critically evaluate the data in order to establish cause and effect relationships, to assess the severity of clinical picture, to estimate human behavioural trends which may affect incidence, and to identify time trends in the incidence of allergies in the EU.

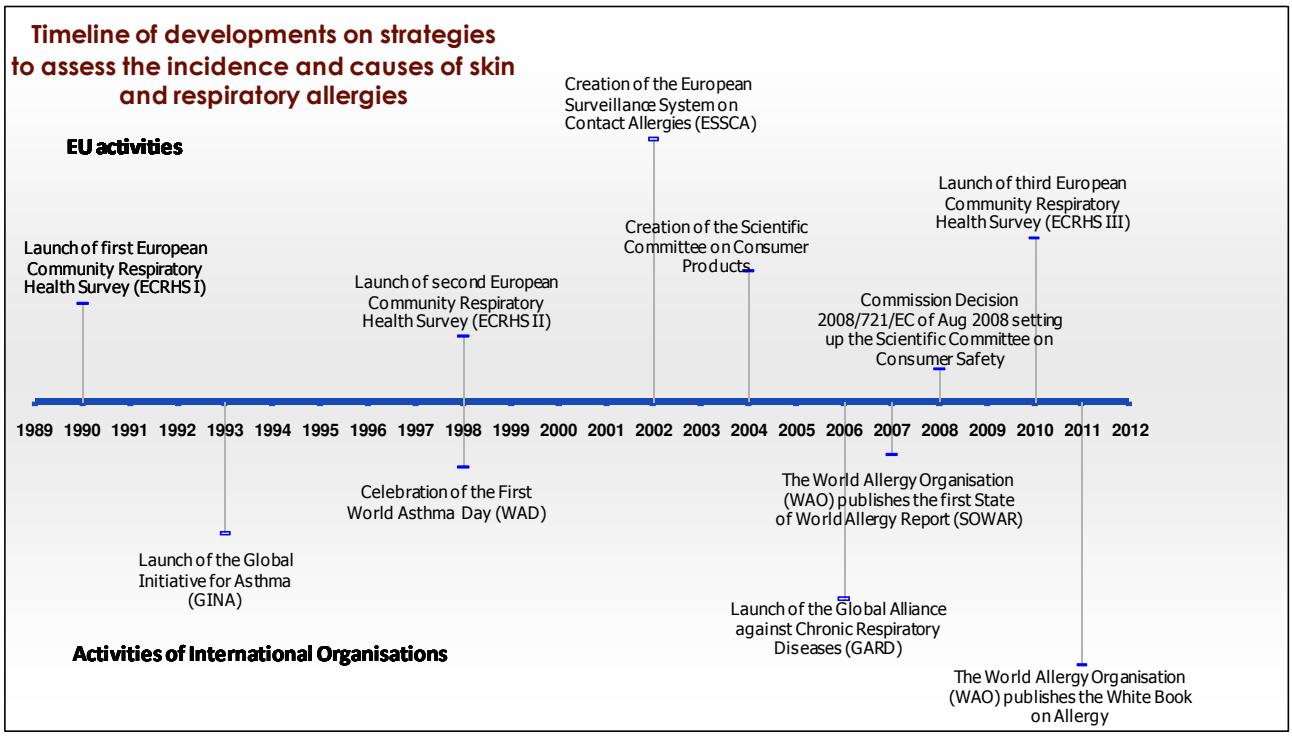
- **Objective / WP 3**: To identify gaps in the data and make recommendations to address them.

The project was considered by the Commission to have made significant progress in identifying skin and respiratory sensitizers; collecting, reporting and evaluating published data on them; and categorising them on a weight of evidence approach in terms of potency.

12.5 Background / Policy Context

The figure below provides an overview of the activities and public health interventions that have taken place and the organisations involved in developing strategies to assess the incidence and causes of skin and respiratory allergies.

Figure 22 - Timeline of developments on strategies to assess the incidence and causes of skin and respiratory allergies



The prevalence of allergic diseases is rising dramatically, not only at EU level but worldwide. This increase is especially problematic in children, who are bearing the greatest burden of the rising trend which has occurred over the last two decades. In spite of this increase, even in the developed world, services for patients with allergic diseases are fragmented and far from ideal. Very few countries have comprehensive services in this field of medicine.

Exposure to specific chemicals, such as in consumer products, environmental, occupational settings, leisure and sports, may contribute to the increased prevalence of allergy.

Chemicals in consumer products, such as deodorants, skin and hair care products are an increasing cause of skin allergy, according to various studies cited in the proposal.

Occupational allergic diseases represent an important public health issue due to their high prevalence and their socio-economic burden. Occupational asthma (OA) contributes significantly to the global burden of asthma, since the condition accounts for approximately 15% of asthma amongst adults. Occupational allergic diseases are associated with a

substantial adverse financial impact for affected workers, insurance or compensation schemes, health services, and employers. Occupational allergic diseases are, by definition, preventable diseases and their burden should be minimised by appropriate preventative strategies.

Close contact with sports equipment may increase the incidence of allergic contact dermatitis. Also exposure to air pollutants and environmental chemicals may cause allergy.

12.6 Origins of HP project

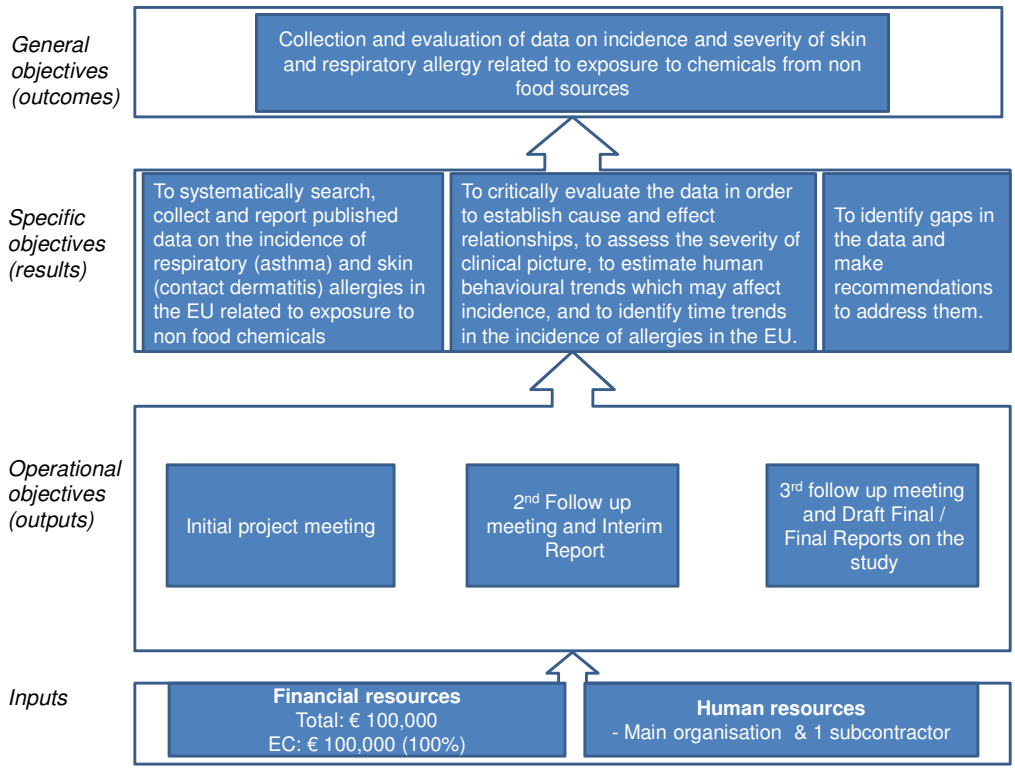
Even though this study did not directly follow up from previous studies conducted by VITO, it was very useful in helping them to bring the knowledge together for future work undertaken in the field.

The work of the Environmental Toxicology (ET) Centre of VITO, which was the unit involved in this study, had conducted numerous studies in the field of ecotoxicology and environmental health for clients at EU and national levels, and also in the industry. Other complementary disciplines where the ET was strongly positioned included in vitro toxicology, exposure assessment, human biomonitoring, epidemiological research biostatistics, environmental and human risk assessment.

12.7 Overall project objectives / Intervention logic

The overall objective of the project was to collect and evaluate European incidence data of respiratory and skin allergies, and to provide a first assessment of the issue. Based on an analysis of the proposal, the diagram below depicts the project's intervention logic. It shows a clear sequence of the general and specific objectives that VITO proposed to achieve, the expected outputs, and the key inputs. More specific details on each of these aspects is presented below.

Figure 23 - Intervention logic of the VITO tender



Inputs:

Please find below a table detailing the VITO budget providing costs for all inputs:

VITO Budget Overview	
Staff Expenditure	64,719.00
Operational Costs (subcontracting)	35,000.00
Travel and subsistence	281.00
Total PART A– Expenditure	**100,000.00**

Source: VITO proposal – Annex V

Expected outputs:

The table below lists the expected outputs of the study, namely a number of meetings and reports to assess progress and inform on the results:

Expected outputs (as per proposal)	**Nature**	**Achieved outputs (as per Technical Implementation Report)**
Initial project meeting	Meeting	Yes
2nd follow up meeting and Interim Report	Meeting and Report	Yes
3rd follow up meeting and Draft Final / Final Report	Meeting and Report	Yes

Expected aims/outcomes:

As reflected in the table below, the expected outcomes listed in the proposal have not been assessed against achieved outputs as the Interim and Final Reports for this project are still not available:

Aim (as per proposal)	**Indicator**	**Outcomes (as per Technical Implementation Report)**
7. To systematically search, collect and report published data on the incidence of respiratory (asthma) and skin (contact dermatitis) allergies in the EU related to exposure to non food chemicals	• Collection of epidemiological data on the incidence of respiratory allergy caused by low-molecular weight chemicals that cause the allergy • Information on respiratory and skin allergies searched and classified according to ICD (international classification of disease) codes.	• Published literature, internet, data bases searches were carried out and data was collected on respiratory and skin allergies for the years 1960-2008 • Contacted a number of European organisations with data bases on the subject to acquire the data • Identified 252 suspect skin sensitizers and 152 respiratory sensitizers on which additional in-depth searches were carried out • Developed a reporting structure for each chemical which contains relevant information on its physical/chemical sensitisation

Aim (as per proposal)	Indicator	Outcomes (as per Technical Implementation Report)
		properties and human related data (incidence, severity, source of data, etc). Developed core HTA handbook.
8. To critically evaluate the data in order to establish cause and effect relationships, to assess the severity of clinical picture, to estimate human behavioural trends which may affect incidence, and to identify time trends in the incidence of allergies in the EU	• Incidence data evaluated and checked for completeness • Development of a weight of evidence approach to rank the strength of evidence that is available on the ability of chemicals to cause skin and respiratory allergies	• Critically evaluated the data from the literature and data bases • Developed a weight approach to account for the variability in the data based on both the hazard characterisation data (animal test, human data, classification and labelling) and on morbidity (incidence, prevalence, severity, sources, etc.) to establish cause and effect relationships. • Conducted meta analysis when sufficient epidemiological data allowed its processing to establish time trends • Identified occupational, behavioural, regional and time trends in the incidence and prevalence of skin and respiratory sensitisation
9. To identify gaps in the data and make recommendations to address them	• The information collected will be evaluated for completeness of the database • Gaps will be identified and described in the report • Recommendations will be formulated	• Identified data gaps in the human data in terms of comparability (non harmonised schemes of reporting, not all EU MS), access to data, surveillance schemes, exposure and diagnosis) • Identified issues that need to be addressed in hazard characterisation (potency mechanistic studies), in the effect of mixtures (adjuvant effect), in susceptibility (genetic polymorphisms may play a role), and in risk assessment (no means to establish dose response curves and from them 'safe exposure thresholds') • Made recommendations to address the identified data gaps in particular stressing the need for harmonised reporting schemes across the EU.

12.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 2 as set out in the Health Strategy (2008-2013):

- Protecting citizens against health threats

12.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

This study fed from various sources, including:

- Publications from EU projects/networks about asthma and allergy, such as:

    - ECRHS: (European Community Respiratory Health Survey www.ecrhs.org), now undergoing its third edition (ECRHS III) the project received funding from the European Commission, DG RTD

    - ESSCA: European Surveillance System of Contact Allergies (www.essca-dc.org), project funded by the European Commission, DG RTD, under FP5 (2002-2004). The aim was to provide scientific information necessary for primary prevention

    - ISAAC (www.respirar.org): worldwide investigation project on the prevalence and risk factors associated to asthma and allergic diseases. ISAAC developed from a merging of two multinational collaborative projects each investigating variations in childhood asthma at the population level. These were an initiative from Auckland, New Zealand to conduct an international comparative study of asthma severity, and an initiative from Bochum, Germany to conduct an international study to monitor time trends and determinants of the prevalence of asthma and allergies in children.

    - PDCAAE: Prevalence and determinants of childhood asthma and allergies across Europe (www.iras.uu.nl), project funded by the European Commission, DG RTD, under FP5. The objective was to estimate the variance of childhood asthma and allergies across Europe and to assess the relation with known and suspected risk factors for these diseases within and between study centres

- National allergy/asthma centres, such as:
    - www.astma-en-allergiekoepel.be, Belgium
    - www.astmafonds.nl, The Netherlands
    - www.asthma.org.uk, United Kingdom
    - www.ahaswiss.ch, Swiss Center for Allergy

- National organisations, such as:
    - WIV, Belgium (www.iph.fgov.be)

- International organisations, such as:
    - EAACI: European Academy of Allergology and Clinical Immunology (www.eaaci.net), the European umbrella allergy organisation of EU Member State allergy organisations
    - EDEN: European Dermato-Epidemiology network (www.org.dermis.net)
    - ESCD: European Society of Contact Dermatitis (www.escd.org)
    - EFA: European network of patient organisations (www.efanet.org)
    - FAO: Food and Agriculture Organisation (www.fao.org)
    - GINA: The Global Initiative for Asthma (www.ginasthma.com)
    - The British Institute for Allergy and Environmental Therapy (www.allergy.org.uk)
    - The UCB Institute of Allergy (www.theucbinstituteofallergy.com)
    - WAO: World Allergy Organisation (www.worldallergy.org)
    - WHO: World Health Organisation (www.who.int)

Other related EU-funded projects in the fields include:

- Allergy and asthma research projects:
    - **GABRIEL (2006-2010)**, funded by the European Commission, DG RTD, under FP6. This was a multidisciplinary study to identify the genetic an environmental causes of asthma in the European community
    - **PARSIFAL (2000-2004),** funded by the European Commission, DG RTD, under FP5. The study focused on the prevention of allergy – risk factors for sensitisation in children related to farming and anthroposophic life style.
    - **AIRALLERG (2001-2005),** funded by the European Commission, DG RTD, under FP5. Focused on the effects of outdoor and indoor air pollution on the development of allergic disease in children.
    - **E21 - 4AYC (2000-2003),** funded by the European Commission, DG RTD, under FP5. Focused on the environmental influences and infection as aetiological agencies in atopy and asthma in young children.
    - **PLUTOCRACY (2001-2004),** funded by the European Commission, DG RTD, under FP5. Focused on placental uptake and transfer of environmental chemicals relating to allergy in childhood years.
    - **ALLERGY FLORA (2001-2005),** funded by the European Commission, DG RTD, under FP5. Focused on the impact of intestinal microflora on allergy development

- **RAIAP (2001-2004),** funded by the European Commission, DG RTD, under FP5. A European-wide assessment on respiratory allergy and inflammation due to ambient particles
- **PASTURE (2002-2006),** funded by the European Commission, DG RTD, under FP5. A study in rural environments on the protection against allergy.
- **MOCALEX (2002-2005),** funded by the European Commission, DG RTD, under FP5. Study focused on the measurement of occupational allergen exposure.

- Skin allergy research projects:

  - **Chemokines-Atopy (2002-2005),** funded by the European Commission, DG RTD, under FP5. Focused on the role of chemokines in the pathogenesis of atopic eczema.
  - **FRAGRANCE ALLERGY (2003-2006),** funded by the European Commission, DG RTD, under FP5. Study on the fragrance chemical allergy: a major environmental and consumer health problem in Europe.

12.10 Rationale behind selection procedures (consistency with HP objectives)

According to the final evaluation of the project made by the Commission, the project made significant progress to 1) identify skin and respiratory sensitizers; 2) collect, report and critically evaluate published data on them; and 3) categorise them on a weight of evidence approach in terms of potency.

In addition, the Commission's final assessment highlighted that the study conducted careful analysis of the data and identified a number of data gaps in the collection and reporting of skin and respiratory allergies in Europe, potency evaluation (hazard characterisation) in conducting risk assessments of skin and respiratory sensitizers (establishing dose-response curves), effects of mixtures, and risk management. The study authors accompanied their findings with a number of recommendations to address the data gaps.

12.11 Involvement of decision makers (design of project / exploitation of results):

There is no data available on the involvement of decision makers in the design of the project. In terms of the exploitation of the results of the study, the Commission's final evaluation report concluded that the report of the study would be submitted to the Scientific Committee on Consumer Safety as it was judged to be of value in their ongoing work on skin sensitisation. According to the interview with the action leader for this study, they would have expected the Commission to undertake a more active role in disseminating the results of the study in relevant networks, but they never received any feedback on the final report or on the exploitation of the results.

12.12 Dissemination

No dissemination strategy or activities available for this study, apart from the comment on the Commission's final report that the results of the study would be submitted to the Scientific Committee on Consumer Safety.

12.13 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the action VITO fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and the final evaluation report prepared by the Commission. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		VITO Tender
1.	Implementing EU legislation:	0.3
2.	Economies of scale:	0.5
3.	Promotion of best practice:	0.0
4.	Benchmarking for decision making:	1.3
5.	Cross border threats:	0.0
6.	Free movement of persons:	0.0
7.	Networking:	1.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

12.14 Sustainability

N/A

12.15 Impact to be expected

The main positive impact of the study was of an internal nature, in that it helped VITO to bring the knowledge in this field together and it fed other work undertaken by the organisation.

There is however no indication on the impact that this study had at EU level, and whether its results were disseminated. The only indicator available in this line was the intention stated in the Commission's final evaluation report to submit the report of the study to the Scientific Committee on Consumer Safety. In the interview that the evaluation team had with the action leader for this study, there was a concern manifested on the lack of feedback and communication from the Commission on what had happened with the results of the project,

and there was the view that the Commission could have done more to promote the visibility of the results of the study.

13. UNAIDS

13.1 Summary

The general objective of the conference was to strengthen community action and mobilization in the response to AIDS in the European Union and its neighbouring countries through support to the participation of civil society in the 2010 International AIDS Conference in Vienna.

The EU Member States and the European neighbouring countries face a high number of new HIV and associated infections and the resulting medical, social and economic consequences. While the epidemiological situation differs widely among the Member States of the European Union and the neighbouring countries, the overall situation makes combating HIV/AIDS an important public health concern and a political priority for the European Union and its neighbouring countries. This is reflected by the myriad of initiatives and events in the field of HIV/Aids taking place at national, European and international levels.

The International AIDS Conference in Vienna in July 2010 represented a great opportunity to raise awareness, strengthen European leadership, review the European situation and examine options to control it better. It was anticipated that European authorities and activists will use the conference as a landmark event for renewed efforts towards better awareness and improved prevention of HIV infections. The conference was also expected to give civil society organizations a unique opportunity to confirm their central role in the fight against the epidemic and raise concerns of their constituencies about the state of national response to AIDS in Europe.

The overall purpose of the HP action was to maximize participation in the Vienna conference to support the overall reach of the conference in Europe, make maximal use of its conclusions and use the momentum created by the conference to trigger a joint European review of the Universal Access to prevention and care in the region by the end of 2010. As per proposal, support to an increased reach of the Conference was going to be achieved through the provision of translation services for conferences, speakers, media, etc. and simultaneous interpretation whenever technically possible.

The conference took place in July 2010 and went according to plan, based on the statement of the action leader and the information released on the conference website. The final report for this project has not been made available yet however the action leader stated that all activities of the action have been carried out successfully. According to the action leader, the main challenge was the lack of involvement of Eastern European countries, e.g. Russia, in the conference.

Based on the information above, it can be said that the action has added further value to the conference by maximising accessibility and promoting the involvement of a wide range of stakeholders with a particular emphasis on civil society groups. Funding this action through the EU Health Programme 2008-13 can therefore be seen as a successful effort to support what is a unique platform for collaboration, knowledge sharing and establishing best practice in the fight against HIV/Aids as a major health threat in Europe and worldwide.

The figure below provides a summary of this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
UNAIDS	+++	+++	+++	+++	+++	++	++	1	o	1. Implementing EU legislation: 2.0 2. Economies of scale: 1.5 3. Promotion of best practice: 3.0 4. Benchmarking for decision making: 2.0 5. Cross border threats: 2.5 6. Free movement of persons: 1.0 7. Networking: 3.0
	The action addresses the objectives of the HP and of the 2009 AWP by strengthening community action and mobilisation in the response to AIDS in the EU and its neighbouring countries.	The action can be seen to be based in the best available evidence, as it is the premier gathering for people working in the field of HIV aids.	Combating HIV/AIDS remains an important public health concern and a political priority for the EU. UNIAIDS takes a systematic approach to maximise participation in the Vienna Conference on HIV/AIDS to support its overall reach, to make maximal use of its conclusions and use the momentum created by the conference to trigger a joint EU review of the Universal Access to prevention and care in the region by the end of 2010.	The action ties well in with other HIV/AIDS related projects funded by the EU.	HIV/AIDS has been on the international and national health agenda since the early 1980s. The International Aids Conference is an annual event chaired by the International Aids Society, and the largest regular conference on any health or development issues.	The proposal specifies civil society groups active in the field of HIV/AIDS as the intended target groups of the action, together with other stakeholder groups attending the conference. The reason why the target audiences are not broken down more might be that the conference targets a large number of different groups with the only common aspect of working in the field of HIV/Aids, while different sessions of the conference might target individual groups specifically. However the action serves to support the conference as a whole.	Dissemination was planned in the form of conference press releases, as well as programme and promotional material, a report on key discussion points as well as a conference report.	- 1 Project leader; The available documentation does not provide any information on the number of different countries involved in the conference.	No monitoring activities/evaluation strategy were foreseen for the action itself, however, one of the objectives of the action was to carry out an evaluation of the International Aids Conference, and an evaluation report has been published on the conference website.	Scores particularly high in: 3. Promotion of best practice - All aspects of the action are geared towards facilitating participation, networking, discussions and debate, and accessibility / dissemination of information. The action can therefore be seen to promote best practice. 5. Cross border threats - The EU Member States and the European neighbouring countries face a high number of new HIV and associated infections and the resulting medical, social and economic consequences. 7. Networking - The Aids Conference is an annual event and chaired by the International Aids Society, the world's leading independent association of HIV professionals. The action can therefore be seen to support existing networking activities (i.e. The IAS) as well as new networking activities (i.e. the 18th International Aids Conference).

13.2 Key Facts

Calls for proposals:	2009
Proposal title:	UNAIDS Awareness rising on HIV/AIDS
Acronym:	UNAIDS
Financing mechanism:	Conference
Start date:	18 – 23 July 2010 (date of the conference)
Duration (in months):	N/A
EC contribution:	400,00.00
Total:	690,500.00
Overall score achieved in Consolidated Evaluation Report:	N/A
Total criteria block: A, B, C	N/A
Main partner:	UNAIDS
Number of associated partners:	0
Number of collaborating partners:	0
Strand:	3.3.2. Promote healthier ways of life and reduce major diseases and injuries by tackling health determinants
Action:	3.3.2.5 Sexual health and HIV- AIDS
Typology[43]:	Implementation action

13.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[44]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system**	**Objective to network:** One specific aim of the action was to facilitate discussions and debates among European stakeholders to help strengthen the response to HIV/AIDS in the European Union and its neighbouring countries, with the potential to contextualise the outcomes and prepare a comprehensive plan for future actions at local or regional level. **Objective to produce / disseminate**

[43] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).
[44] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
– target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**information:** Another specific aim of the action was to disseminate the debates and proceedings of the Conference to media and stakeholders as well as general public to ensure a wide and relevant sharing of data and knowledge in the European region.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	**Implementation action** The general objective of the project was to strengthen community action and mobilisation in the response to AIDS in the European Union and its neighbouring countries through support to the participation of civil society in the 2010 International AIDS Conference in Vienna. The project can be seen to be based on the best available evidence, as the conference is the premier gathering for people working in the field of HIV, as well as researchers, policy makers, persons living with HIV and other individuals committed to ending the pandemic, and the most widely followed AIDS event in the world.
Clear target groups	The action's main target groups were civil society groups active in the field of HIV/Aids, with other stakeholder groups attending the conference (e.g. policy-makers, health professionals, academics, scientists) as secondary target groups.
Clear dissemination plan – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	As per proposal, dissemination was planned in the form of conference press releases, as well as programme, and other communication/promotional materials. A report on key discussion points and recommendations for action from the Community Dialogue Space, as well as a conference report (with key evaluation data, including participation statistics) was anticipated as per proposal. The latter is publicly available on the conference website. Information on the conference overall was disseminated via the conference website, which is still up and running, containing webcasts, a conference report and an evaluation report. Information was also disseminated on Facebook, Twitter, and through blog posts. More than 1000 online articles related to the conference have been published. In addition, a number of related events such as fundraising events took place at the time of the conference, raising additional

Criteria	Notes / Comments
	awareness.
Estimate the population reached (or targeted) by the action	The action leader stated that a total of 19300 participants attended the conference, with 30% of attendees from the EU (4800). 197 countries around the world were represented. It was further stated that more than 70000 visits to the website have been recorded after the conference took place.
Matching of project's deliverables (if any) with project's objectives	The project had six deliverables (e.g. dissemination of information, translation at conference) that were all in line with the action's objectives.
Use of multipliers	One of the specific aims of the action was to disseminate the debates and proceedings of the Conference to media and stakeholders as well as the general public to ensure a wide and relevant sharing of data and knowledge in the European region.
Evaluation (provision of indicators)	Indicators for all specific objectives have been provided. No monitoring activities were foreseen for the project itself, however, one of the objectives of the project was to carry out an evaluation of the International Aids Conference, and an evaluation report has been published on the conference website.
Sustainability plan	As stated by the action leader, the HP funding was only a small part of the budget of the conference, which is a large biennial event. The next conference in two years will be in Washington and will probably not be funded through the HP. However funding from other sources will be available. A website of the conference is still up and running, containing webcasts, a conference report and an evaluation report.

13.4 Introduction

The Europe Union and its neighbouring countries have an estimated 2.4 million people living with HIV. Among these, more than 800,000 live in Member States of the European Union; nearly 1 million live in Russia and about 450,000 in Ukraine. In some of the new Member States and neighbouring countries of the European Union, Russian speaking minorities are more exposed to risks of HIV transmission, notably through injecting drug use, and have a higher rate of prevalence than the rest of the population. This is for example the case in Estonia, Latvia, Moldova and Ukraine.

Effectively combating HIV/AIDS in the European Union and its neighbouring countries requires increased coordination, collaboration as well as transfer of skills and knowledge.

Some countries are yet to adopt evidence-based prevention and support policies that have proved effective and there is a need for stronger exchanges and policy dialogue. In this context it is of significant importance that the XVIII International AIDS Conference took place in Vienna, Austria.

The biennial International AIDS Conference is the premier gathering for people working in the field of HIV, as well as researchers, policy makers, persons living with HIV and other individuals committed to ending the pandemic. It is a chance for stakeholders to take stock of where the epidemic is; evaluate recent scientific developments and lessons learnt; hold leaders to account on commitments; and collectively chart a course forward. It also serves as a barometer of the global response. The International AIDS Conference is the most widely followed AIDS event in the world. At the 2010 conference, 19,300 participants, including 1,218 participants from Eastern Europe and Central Asia represented 197 countries. News coverage of the conference is a very important source of public awareness and education, and 1,276 media representatives attended the event.

13.5 Background / policy context

HIV/Aids has been on the international and national health agenda since the early 1980s, when the Acquired Immune Deficiency Syndrome has first been discovered (1981) and HIV (initially called HTLV-III or LAV) has been identified as the cause of AIDS (1984). The subsequent years saw a rapid spread of the disease: in 1990, around 8 million people were living with HIV worldwide. This number increased to 22 million people worldwide by 1997, and to 33.3 million people by the end of 2009.

Each year around 2.6 million more people become infected with HIV and 1.8 million die of AIDS. Although HIV and AIDS are found in all parts of the world, some areas are more afflicted than others. The worst affected region is sub-Saharan Africa, where in a few countries more than one in five adults is infected with HIV. The epidemic is spreading most rapidly in Eastern Europe and Central Asia, where the number of people living with HIV increased by 54.2% between 2001 and 2009.

The first International Aids Conference took place in 1985 in Atlanta, USA. The conference has taken place annually since until 1994 when it became biennial. Following this, the WHO held the first World Aids Day in 1987. The IAS was officially established after the fourth International Aids Conference in Stockholm, Sweden in 1988. UNAIDS was established in 1995 by a resolution of the UN Economic and Social Council, and in 2000 the UN Millennium Development Goals (MDGs) were developed. The goal to “combat HIV/Aids, Malaria and other diseases” was included as the sixth MDG. Finally, the Global Fund to Fight Aids, Tuberculosis and Malaria was established in 2002. The figure below presents an overview of the development of large scale initiatives and events in the area of HIV/Aids and the spread of the disease.

Important European declarations in the area of HIV/Aids include the “Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia”, the “Vilnius Declaration on Measures to strengthen Responses to HIV/AIDS in the European Union and in Neighbouring Countries” and the “Bremen Declaration on Responsibility and Partnership - Together Against HIV/AIDS”.

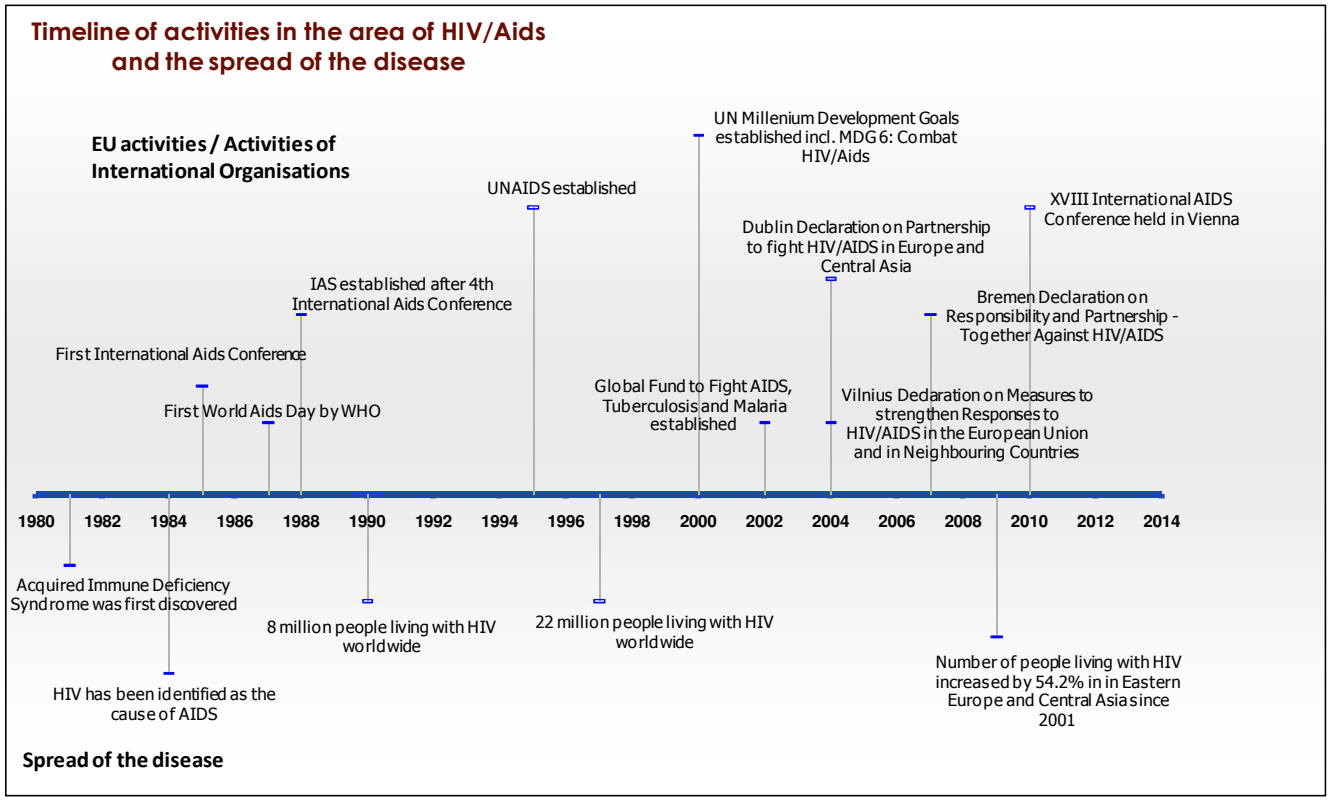
The “Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia”, signed in February 2004, is a key European document on HIV/AIDS. It sets out 33 actions for

governments to undertake as related to leadership, prevention, living with HIV (including treatment and care) and partnership in the 53 countries of the WHO European Region.

The Dublin Declaration was followed by the "Vilnius Declaration on Measures to strengthen Responses to HIV/AIDS in the European Union and in Neighbouring Countries" in September 2004.

The "Bremen Declaration on Responsibility and Partnership - Together Against HIV/AIDS" was issued in 2007 by the German EU Presidency.

Figure 23 – Timeline of activities in the area of HIV/Aids and the spread of the disease



13.6 Origins of HP project

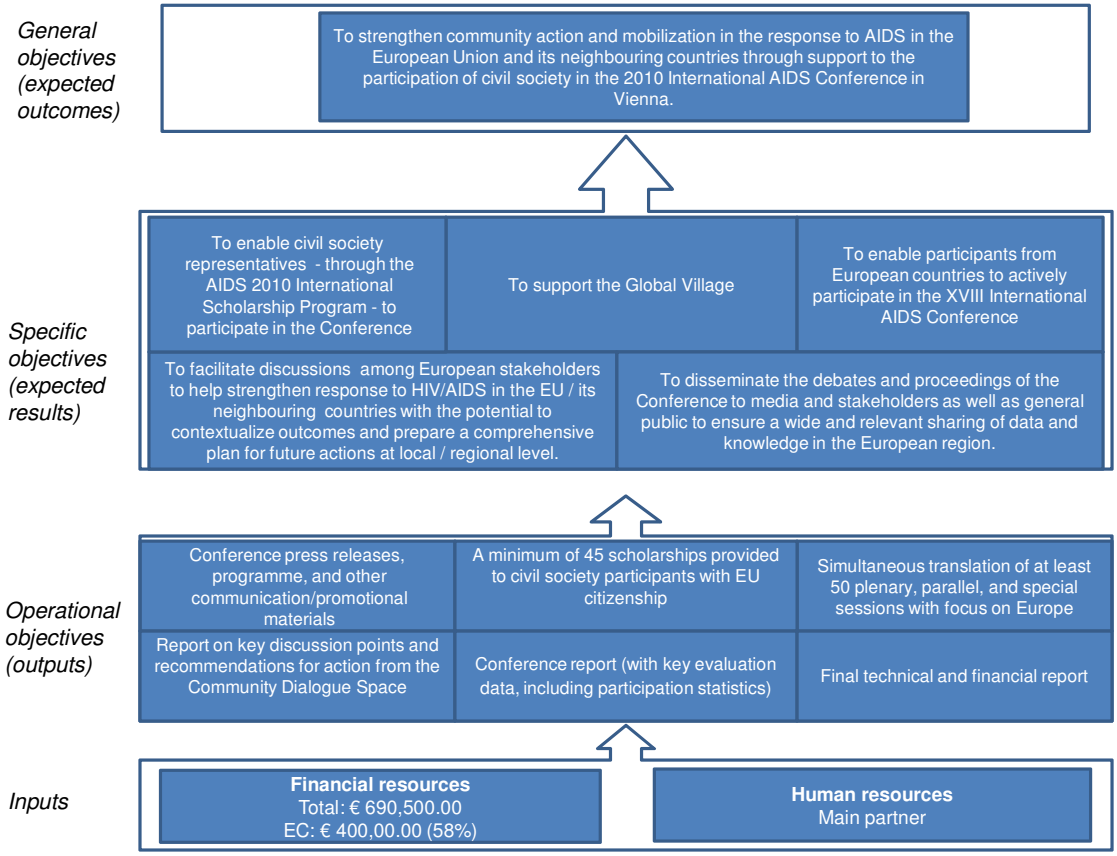
The International Aids Conference is a biennial event chaired by the International Aids Society (IAS - the world's leading independent association of HIV professionals), and the largest regular conference on any health or development issue. These conferences provide a unique forum for the interaction of science, community and leadership, and strengthen an evidence-based policy and programmatic response to the epidemic. The conferences also provide an opportunity to intensify political and financial commitments to AIDS, and include the largest international conference scholarship programme in HIV/AIDS. The IAS was launched in 1988 and has chaired the International Aids Conference.

A range of other events in the field of HIV/Aids are being undertaken at Member State, European and international level, as described in section 1.10.

13.7 Overall project objectives / intervention logic

The overall objective of the conference was to strengthen community action and mobilization in the response to AIDS in the European Union and its neighbouring countries through support to the participation of civil society in the 2010 International AIDS Conference in Vienna. Based on an analysis of the proposal, the diagram below depicts the action's intervention logic. Even though the overall logic seems to be clear, there is a certain degree of confusion between some of the specific objectives and outputs, in particular as there are some specific objectives that qualify more as outputs. More specific details on each of these aspects is presented below.

Figure 25 - Intervention logic for UNAIDS



Based on an analysis of the proposal and supporting documents, the diagram above depicts the action's complete intervention logic (final report was not available at the time of analysis). It shows the general and specific objectives the action intends to achieve, the expected outputs, and the key inputs. More specific details on each of these aspects are presented below.

Inputs:

Please find below a table detailing the budget providing costs for all inputs including coordination, dissemination, evaluation etc. as per grant agreement:

Item	Total amount in €	EC contribution in	Contribution from

		€	UNAIDS and other donors
Coordination	85,000	56,000	29,000
Dissemination	63,500	50,000	13,500
Evaluation	30,000	30,000	
International Scholarship Programme	100,000	100,000	
Global Village including Red Ribbon Award and Community Dialogue Space	324,000	164,000	160,000
Core Activities including, translation, monitoring & evaluation	88,000		88,000
Total	**690,500**	**400,000**	**290,500**

Expected outputs:

Expected outputs	Achieved outputs (as per Final Report)
Conference press releases, programme, and other communication/promotional materials	N/A as no Final Report available yet
A minimum of 45 scholarships provided to civil society participants with EU citizenship	See above
Simultaneous translation of at least 50 plenary, parallel, and special sessions with focus on Europe	See above
Report on key discussion points and recommendations for action from the Community Dialogue Space	See above
Conference report (with key evaluation data, including participation statistics)	See above
Final technical and financial report	See above

Expected specific aims of the action:

Aim	Indicators	Result (as per Final Report)
To enable civil society representatives - through the AIDS 2010 International Scholarship Program - to	Number of participants from European Civil Society supported through the proposed programme	N/A as no Final Report available yet

Aim	Indicators	Result (as per Final Report)
participate in the Conference		
To support the Global Village element of the conference	Number of sessions for which translation and interpretation services are provided	See above
To enable participants from European countries to actively participate in the XVIII International AIDS Conference by providing translation, including when possible simultaneous interpretation into European languages.	Community dialogue space is organized within the Global Village	See above
To facilitate discussions and debates among European stakeholders to help strengthen the response to HIV/AIDS in the European Union and its neighbouring countries, with the potential to contextualize the outcomes and prepare a comprehensive plan for future actions at local or regional level.	Number of presentations, open discussions and media interactions organized within the community dialogue space of the Global Village	See above
To disseminate the debates and proceedings of the Conference to media and stakeholders as well as general public to ensure a wide and relevant sharing of data and knowledge in the European region.	Media can access communication about the Conference in European languages	See above

Wider expected outcomes of the conference:

Aim	Indicators	Result (as per Final Report)
To ensure the interaction of AIDS policy-makers, professionals, and civil-society activists from the European Union and its neighbouring countries and a combined contribution to	Indicators have not been provided. Interim and final reports are not available yet.	N/A as no Final Report available yet

Aim	Indicators	Result (as per Final Report)
global discussions on research, policy and practice to support an efficient AIDS response.		
To increase the awareness of HIV of the general population in the European Union and neighbouring countries through wide mass media coverage of the conference in at least two languages.	See above	See above
To strengthen the global response to HIV and AIDS, as well as having a positive impact on the response in the European Union and its neighbouring countries.	See above	See above
To increase the capacity of delegates to introduce, implement, and advocate for effective, evidence-based HIV & AIDS interventions in the European Union and its neighbouring countries	See above	See above
To influence leaders, including key policy makers and donors, to increase their commitment to gender sensitive, evidence- and human-rights based HIV & AIDS interventions in the European Union and its neighbouring countries	See above	See above
To serve as an accountability and feedback mechanism for those engaged at various levels of the response to HIV & AIDS, including policy makers and other leaders in the European Union and its neighbouring countries	See above	See above
To increase public awareness of the continued impact of HIV & AIDS and the need for responses to the epidemic through the media and other means in the European Union	See above	See above

Aim	Indicators	Result (as per Final Report)
and its neighbouring countries		
To increase understanding of the connection between human rights and an effective response to HIV & AIDS in the European Union and its neighbouring countries.	See above	See above
To increase understanding of the synergistic relationship between the scale up of the HIV & AIDS response and other global health, human rights and development priorities among key stakeholders involved in these distinct fields.	See above	See above
To provide opportunities for multi-stakeholder dialogue to develop creative solutions to unresolved challenges in research and implementation of HIV & AIDS policies and programmes.	See above	See above

13.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Health Strategy objective 2: Protecting citizens from health threats. Health threats include infectious diseases (e.g. **HIV/AIDS**, tuberculosis, Creutzfeldt Jacob Disease, etc.) and threats emerging from physical, chemical or biological sources, including those relating to terrorist acts and environmental agents (e.g. ionising and non-ionising radiation and noise).

13.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified numerous initiatives:

5. Other EU / DG SANCO projects

The projects listed below are HIV and AIDS related projects that are funded within the 1st or 2nd EU Public Health Programme:

- Aids & Mobility Europe (HP 1, 2007)
- BORDERNETwork. Highly active prevention: scale up HIV/AIDS/STI prevention, diagnostic and therapy across sectors and borders in CEE and SEE (HP 2, 2009)
- CONNECTIONS - Integrated responses to drugs and related infections across the European criminal justice systems (HP 1, 2006)

- Correlation - European Network Social Inclusion & Health (HP 1, 2004)
- ENCAP - Expanding Network for Coordinated and Comprehensive Actions on HIV/AIDS Prevention among IDUs and Bridging Population (HP 1, 2005)
- Eurosupport 6: Developing a training and resource package to improve the sexual and reproductive health of people living with HIV (HP 2, 2008)
- Everywhere Project (HP 1, 2007)
- H-CUBE. HBV-HCV-HIV: Three different and serious threats for European young people. A Network to study and face these challenges in the EU. (HP2, 2008)
- Sialon: capacity building in HIV/Syphilis prevalence estimation using non-invasive methods among msm in southern and eastern Europe (HP 1, 2007)
- TAMPEP 8: European Network for HIV/STI Prevention and Health Promotion among Migrant Sex Workers (HP 1, 2006)

The projects listed below are HIV and Aids related projects funded under DG Research's Framework Programmes (FP6 / FP7):

- NEAT European AIDS treatment Network (FP6, 2007)
- AVIP AIDS VACCINE INTEGRATED PROJECT (FP6, 2004)
- HIVEVO Intra-patient evolution of HIV (FP7, 2011)
- SILENT HIV Paving the way toward HIV eradication/control (FP7, 2010)

6. International organizations involved in HIV/Aids related initiatives

- International Aids Society
- The European AIDS Clinical Society (EACS) will hold the 13th European AIDS
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Conference (Serbia, October 2011)
- International HIV/AIDS Alliance
- International Aids Vaccine Initiative
- International HIV Fund

7. Forthcoming initiatives in Member States

- The National Aids Trust (UK) runs an annual World Aids Day
- European Conference "HIV in European Region - Unity and Diversity" (Estonia, May 2011) will cover the key issues related to HIV epidemic, prevention, and care in European Region, with a special focus on Eastern European countries.
- 7th International Workshop on HIV & Hepatitis Co-infection (Italy, June 2011)
- FEMP 2011: 'The Future of European Prevention among MSM' will take place in Stockholm, Sweden in November 2011

8. Forthcoming initiatives in third countries

- 5th South African Aids Conference (June 2011)
- 10th International Congress on AIDS in Asia and the Pacific (South Korea, August 2011)
- 2nd International Workshop on HIV & Aging (USA, October 2011)

13.10 Rationale behind selection procedures (consistency with HP objectives)

N/A

13.11 Involvement of decision makers (design of project / exploitation of results):

During the interview, the action leader stated that the conference was organised by a committee with representatives from the EC and regional representations from the EU (government and civil society). Scientific review committees were also involved in the organisation of the conference. In addition it was stated that the International Aids conferences are unusual, as they bring together policy makers, scientists, civil society and media (more than 1200 representatives). According to the action leader the conference led to a renewed commitment for the fight against HIV/Aids from the EU (in form of a policy document). This was a concrete outcome.

13.12 Level to which outputs / results contribute to / are in line with the HP objectives:

The outputs as specified above (Objective 1: To enable civil society representatives - through the AIDS 2010 International Scholarship Program - to participate in the Conference; Objective 2: To support the Global Village; Objective 3: To enable participants from European countries to actively participate in the XVIII International AIDS Conference by providing translation; Objective 4: To facilitate discussions and debates among European stakeholders to help strengthen the response to HIV/AIDS in the European Union and its neighbouring countries; Objective 5: To disseminate the debates and proceedings of the Conference to media and stakeholders as well as general public to ensure a wide and relevant sharing of data and knowledge in the European region) are in line with HP objective 3: Generate and disseminate health information and knowledge.

13.13 Dissemination

As per proposal, dissemination was planned in the form of conference press releases, as well as programme, and other communication/promotional materials. A report on key discussion points and recommendations for action from the Community Dialogue Space, as well as a conference report (with key evaluation data, including participation statistics) was anticipated as per proposal. The latter is publicly available on the conference website.

As stated by the action leader there is a website of the conference, which is still up and running, containing webcasts, a conference report and an evaluation report. It was stated that more than 70,000 visits to the website have been recorded after the conference took place. Information was also disseminated on Facebook, Twitter, and through blog posts. More than 1000 online articles related to the conference have been published. In addition, a number of related events such as fundraising events took place at the time of the conference, raising additional awareness.

Target groups

The general objective of the action was to strengthen community action and mobilisation in the response to AIDS in the European Union and its neighbouring countries through support to the participation of civil society in the 2010 International AIDS Conference in Vienna. The main target group of the project was therefore civil society groups active in the field of HIV/Aids, with other stakeholder groups attending the conference (e.g. policy-makers, health professionals, academics, scientists) as secondary target groups.

13.14 Monitoring processes

No monitoring activities were foreseen for the action itself, however, one of the objectives of the action was to carry out an evaluation of the International Aids Conference, and an evaluation report has been published on the conference website.

13.15 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the action VITO fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and the final evaluation report prepared by the Commission. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		UNAIDS Conference
1.	Implementing EU legislation:	2.0
2.	Economies of scale:	1.5
3.	Promotion of best practice:	3.0
4.	Benchmarking for decision making:	2.0
5.	Cross border threats:	2.5
6.	Free movement of persons:	1.0
7.	Networking:	3.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

13.16 Sustainability

As stated by the action leader, the HP funding was only a small part of the budget of the conference, which is a large biennial event. The next conference in two years will be in Washington and will probably not be funded through the HP. However funding from other sources will be available.

13.17 Impact to be expected

The action leader stated that the findings presented by the conference are guiding the global response to HIV/Aids. In addition, the Vienna Declaration, a policy document arguing for legalisation of drugs for certain groups, was one of the outcomes of this conference. The United Nations General Assembly High Level Meeting on AIDS in New York from 8-10 June 2011 will also take up many of the issues raised at the conference in Vienna. It is anticipated that this High Level Meeting will be a milestone in the global response to HIV. It was also stated that at the local level, the EC organises the HIV/Aids Think Tank every 6 months, and the results from the conference in Vienna will also be discussed there.

14. OECD Health Data

14.1 Summary

The aim of the action is to improve the data and evidence base regarding health indicators and health care quality indicators across Europe in order better to inform evidence-based policymaking. The action included two different work packages:

The first work package, the European edition of *Health at a glance* (EHaG), has the objective to produce a publication of health indicators covering European countries, including non-OECD member countries (in order to compare indicators in different situations) and, necessarily, all the EU countries. The publication was released, as planned, in December 2010. The purpose of this part of the project was to indicate areas where policy action is likely to be needed in different countries, and to push policy learning between countries. A range of other related activities are taking place at national, European and international levels, reflecting the recognition of health indicators as a relevant and important tool for policy making in the field of public health.

The second work package "Health Care Quality Indicators: moving to the next level", had the objective to move work on health care quality indicators to the centre stage of health system analysis by producing a high profile publication on achievements and barriers, and producing analysis showing its analytic strength. There are two strands to this work. The first is analysis showing the strength of the Health Care Quality Indicators (HCQI) by looking in particular at differences in the quality of care across countries, with a focus on the quality of cancer care performance. A final report will be published in June 2011. The second strand was to produce a high profile publication on what we know about the quality of health care, and what we need to do to know more. The publication was issued in October 2011.

The importance of measuring the quality of health care has grown significantly in recent years, as many innovative health policies depend on the ability to measure the quality of care accurately. This element of the project can therefore also be seen to make a useful contribution in the area of public health.

Based on the interim report and statement of the action leader, most of the objectives of the two work packages set out above have already been met since the beginning of the action and it is anticipated that all outstanding objectives, most importantly the publication of the report on explaining differences in cancer outcome indicators across countries, will be met over the forthcoming months.

On completion of the action, the three deliverables, i.e. the EHaG publication, the Publication of 'state-of-the-art in HCQI' and the Report on explaining differences in cancer outcome indicators across countries, represent a strong body of evidence and high EU added value as they will allow countries to compare health care quality indicators, measures of cancer outcomes and evidence of policy effectiveness across different countries to promote policy learning and, ultimately, improve the health of European citizens. Funding through the EU Health Programme 2008-13 can therefore be seen to have facilitated the generation and dissemination of valuable knowledge and best practice at a large, EU-wide scale.

In terms of unexpected / expected difficulties, the action leader stated that some unfortunate clashes in timetabling the launch of EHaG with other European events probably slightly reduced impact. He further stated that the main problem regarding the OECD's work on cancer has been a greater than expected demand for inclusion in the project by countries (they anticipated no more than half of EU countries would want to participate, whereas in fact

nearly every country did), putting severe strains on the resources available.

The figure below provides a summary for this case study:

Action	Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved	Extent to which Action has an effective evaluation strategy	Extent of EU Added Value (based on EU added value analysis)
OECD Health Data	+++	+++	++	+++	++	+	+	1	o	1. Implementing EU legislation: 3.0 2. Economies of scale: 1.5 3. Promotion of best practice: 3.0 4. Benchmarking for decision making: 2.8 5. Cross border threats: 1.8 6. Free movement of persons: 0.0 7. Networking: 1.0
	The action meets the objectives of the HP and of the 2009 AWP by improving the data and evidence base regarding health indicators and health care quality indicators across Europe in order to better inform evidence-based policymakeing.	The importance of measuring health and the quality of health care has grown significantly in recent years. The action can therefore be seen to make a useful contribution in the area of public health.	Evidence base presented in proposal, though background could have been more tied in with developments at international level.	The action ties well in with previously EU funded research and actions, including other actions funded by DG SANCO.	While the action seems to address an issue of concern in MSs, not many similar initiatives seem to be undertaken at national level, but has been taken up by International Organisations.	The proposal / action leader states that the results of the action are meant to be used by policy makers, but this is not clearly lined out in the documentation.	No clear dissemination plan seems to be in place, and no clear use of channels is outlined in the proposal, though there is some information regarding the dissemination of information, e.g. the EHaG report has been published on the website. .	The action is a Direct Grant between the OECD and DG SANCO.	The proposal outlines no specific evaluation strategy other than that the OECD and the EC commit themselves to regular visits to update each other on action achievements.	Scores particularly high in: - Implementing EU legislation - The aim of the action is to improve the data and evidence base in order to better inform evidence-based policymaking. 3. Promotion of best practice - The expected results of the action, i.e. the publications mentioned above are directly linked to the identification and selection of best practices. 4. Benchmarking for decision making - The data and evidence produced as a result of the Action specifically aims to inform evidence-based policymaking. Data will be available in all EU MSs.

14.2 Key Facts

Calls for proposals:	2009
Proposal title:	OECD Health Data
Acronym:	OECD
Financing mechanism:	DA
Start date:	1/11/2009
Duration (in months):	26
EC contribution:	€400,000
Total:	€674.092
Overall score achieved in Consolidated Evaluation Report:	N/A
Total criteria block: A, B, C	N/A
Main partner:	OECD
Number of associated partners:	None
Number of collaborating partners:	None
Priority area:	3.2.2
Action:	3.2.2.2. Improving patient safety through high-quality and safe health care
Typology[45]:	Development project

[45] Based on the strategic document "EU Health Programme evaluation" by the EAHC, actions can be categories by the following typolgies: 1) Research action (for actions where there is little or no pre-existing evidence); 2) Development/Demonstration actions (small-scale pilot and further large-scale demonstration actions for which a

14.3 Overview of project success criteria

The following table of project success criteria has been developed taking into account the strategic document by the EAHC "EU Health Programme Evaluation"[46]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** – target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to produce/disseminate information** – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	**Objective to produce / disseminate information:** The aim of the action is to improve the data and evidence base in order better to inform evidence-based policymaking through two different work packages. The first package has the objective to produce a European edition of Health at a Glance (EHaG), a publication of health indicators covering European countries. The second work package has the objective to move work on health care quality indicators to the centre stage of health system analysis by producing a high profile publication on achievements and barriers.
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best available evidence;	Development action Strong evidence in the field of health care quality indicators already exists, but more research and analysis is needed.
Clear target groups	Target groups: • National policy makers and experts
Clear dissemination plan – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	As stated by the action leader, EHaG has already been launched using a website, press release, launch event at the European Commission, many press interviews and much coverage. The publication is regularly cited in the press. EHaG has reached a mass audience in countries where it hit a nerve (Ireland) or on particular messages (e.g. child obesity). The action leader also stated that the Cancer work (part 2) needs to be

strong evidence exists, but the larger, external validity – application to other population groups or broader groups – had yet to be established; 3) Implementation actions (strong body of evidence exists).

[46] The document was written by Guy Dargent and provided to the evaluation team by Michel Pletschette.

Criteria	Notes / Comments
	reviewed by national policymakers/experts before the best strategy for dissemination is considered. So far, has reached a significant number of experts and various meetings are in preparation on this. The publication 'State-of-the-art in HCQI' is accessible online. To improve dissemination, a summary document was produced for the high-level forum on quality of care. A dissemination plan will be prepared prior to the final report being released which will identify priority countries to be targeted where the message is particularly clear and strong.
Estimate the population reached (or targeted) by the action	As stated above, EHaG has reached a mass audience in countries where it hit a nerve (Ireland) or on particular messages (e.g. child obesity). As for the publication 'State-of-the-art in HCQI' it is not clear what the population reached is.
Matching of project's deliverables (if any) with project's objectives	The project has six deliverables (e.g. the EHaG and the 'State-of-the-art in HCQI' publication) which are all in line with the project's objective to improve the data and evidence base in order better to inform evidence-based policymaking.
Use of multipliers	The project is mainly directed at policy makers and experts. It is not clear if any multipliers have been used.
Evaluation (provision of indicators)	The action leader stated that all OECD activities are rated by countries on two dimensions – quality, and impact. This happens in the two years after completion of projects. High level policymakers in health departments rate each project on a scale of 0 (very poor quality, or no impact) to 5 (very high quality, immediate and strong policy impact). There is no other evaluation strategy in place.
Sustainability plan	The action leader stated that the measures of cancer outcomes developed by the action are likely to feed directly into the international effort to measure cancer survival rates by 'stage' of cancer at diagnosis e.g. via the 'Concord' process, which is closely involved as a collaborator in the outcome. The policy analysis is likely to be used in conjunction with other efforts to explain differences in cancer outcomes, e.g. that

Criteria	Notes / Comments
	of McKinsey consulting for the UK government. It would be surprising were this not to become a main area of academic discussion over the coming years, based on the data and approach developed for the action. Regarding the EHaG, a major effort of data co-ordination is underway between OECD, ESTAT and WHO Europe. The EHaG experience will feed into this ongoing effort (it has already influenced the childhood obesity data collection, for example).

14.4 Introduction

This section provides an introduction to the two different work packages of the OECD Health Data action, (1) European edition of Health at a Glance and (2) Health Care Quality Indicators: moving to the next level.

European edition of Health at a Glance: *Health at a Glance* is a publication by the OECD which has so far been published every two years since 2001. The publication provides information around a series of indicators, including health outcomes, non-medical determinants of health, health resources, health expenditures, and quality of care. The publication is designed to present comparisons of health outcomes and health systems in an easily accessible way. The purpose is not to analyse why some countries perform better in some respects than others, but rather to indicate areas where further analytic investigation might be warranted. The publication will allow countries to compare evidence of policy effectiveness across jurisdictions, thereby promoting policy learning and, ultimately, improving the health of European citizens.

Health Care Quality Indicators: moving to the next level: Much media coverage of health care focuses on the quality of care. Are breast cancer survival rates higher in the United States than in the United Kingdom and France? Are a patient's chances of dying within 30 days after admission to a hospital with a heart attack lower in Denmark than in Germany? Are surgeons in some countries more likely to leave "foreign bodies" behind after operations or make accidental punctures or lacerations rates when performing surgery? The importance of such measuring of quality has grown significantly in recent years. Many innovative health policies depend on the ability to measure the quality of care accurately. Governments want to increase "patient-centeredness", improve co-ordination of care, and pay providers of high-quality care more than those who underperform. However, measuring the quality of health care is challenging.

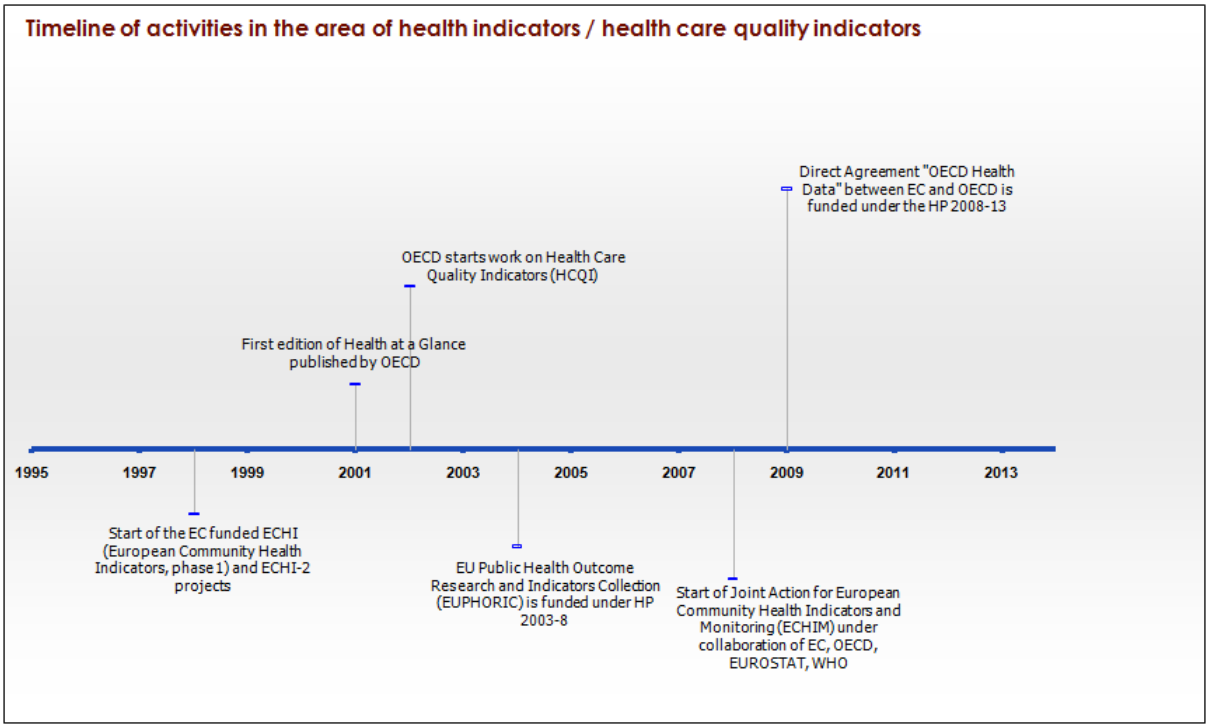
The aim of this work package is to identify what policy direction countries (particularly countries with poor outcomes) should be going in, and then to publicize these conclusions to persuade countries to make the change.

14.5 Background / policy context

In order to gauge and make a judgement on the extent to which the project is tackling a serious public health issue, the case study examines what other public health interventions

have taken place and the organisations involved in coordinating/funding these activities. The figure below provides a brief overview of how activities in the area of health indicators have evolved:

Figure 26 – Timeline of activities in the area of health indicators / health care quality indicators



As stated in section 1.4 above, the OECD has been publishing information on health indicators such as health outcomes, non-medical determinants of health, health resources, health expenditures, and quality of care since 2001.

Similarly, the OECD has been working on Health Care Quality Indicators (HCQI) since 2002, with EC support, through the systematic development, testing and analysing of outcome and process based quality indicators on areas such as care for acute conditions (AMI and Stroke), care for cancer (breast, cervical and colon cancer), care for chronic conditions (asthma, diabetes, CHF) and care for communicable diseases. At present, around 30 countries are participating in the work, and in November 2009 for the second time a chapter on quality of care was published in OECD's *Health at a Glance*. Recent additions are indicators on avoidable hospital admissions for chronic conditions, mental health care and patient safety indicators. In 2009/10, developing and testing of new indicators is focussing on primary care and prevention, patients' safety indicators and international comparability of patient experience measurements.

The European Community Health Indicators programme (ECHI) is also relevant in this field. The main objective of the ECHI projects (ECHI, ECHI-2, ECHIM) is to establish a European wide system of health information standards (e.g. health indicators) that enable national health information providers to incrementally adopt these standards for national and international public health monitoring and reporting. The ultimate objective of these efforts is the gathering of comparable health data in the European Union that allow for international comparisons and benchmarking.

The current ECHIM project, the JA on European Community Health Indicators Monitoring is also funded under the EU Health Programme. ECHIM is a three-year project to develop and

implement health indicators and health monitoring in the EU. It continues the work of the previous ECHI and ECHIM projects, and ends on 31.12.2011. Its general objective is to consolidate and expand the ECHI Indicator system towards a sustainable health monitoring system in Europe.

As set out in section below, the WHO, the United Nations, as well as national initiatives also lead on activities in the area of health indicators.

14.6 Origins of HP project

The OECD has produced *Health at a Glance* for several years. The European edition of the publication is to produce a publication of health indicators covering European countries, including non-OECD member countries and, necessarily, all the EU countries, in order to provide better, more timely information on health outcomes across Europe and in comparison with the rest of the developed world.

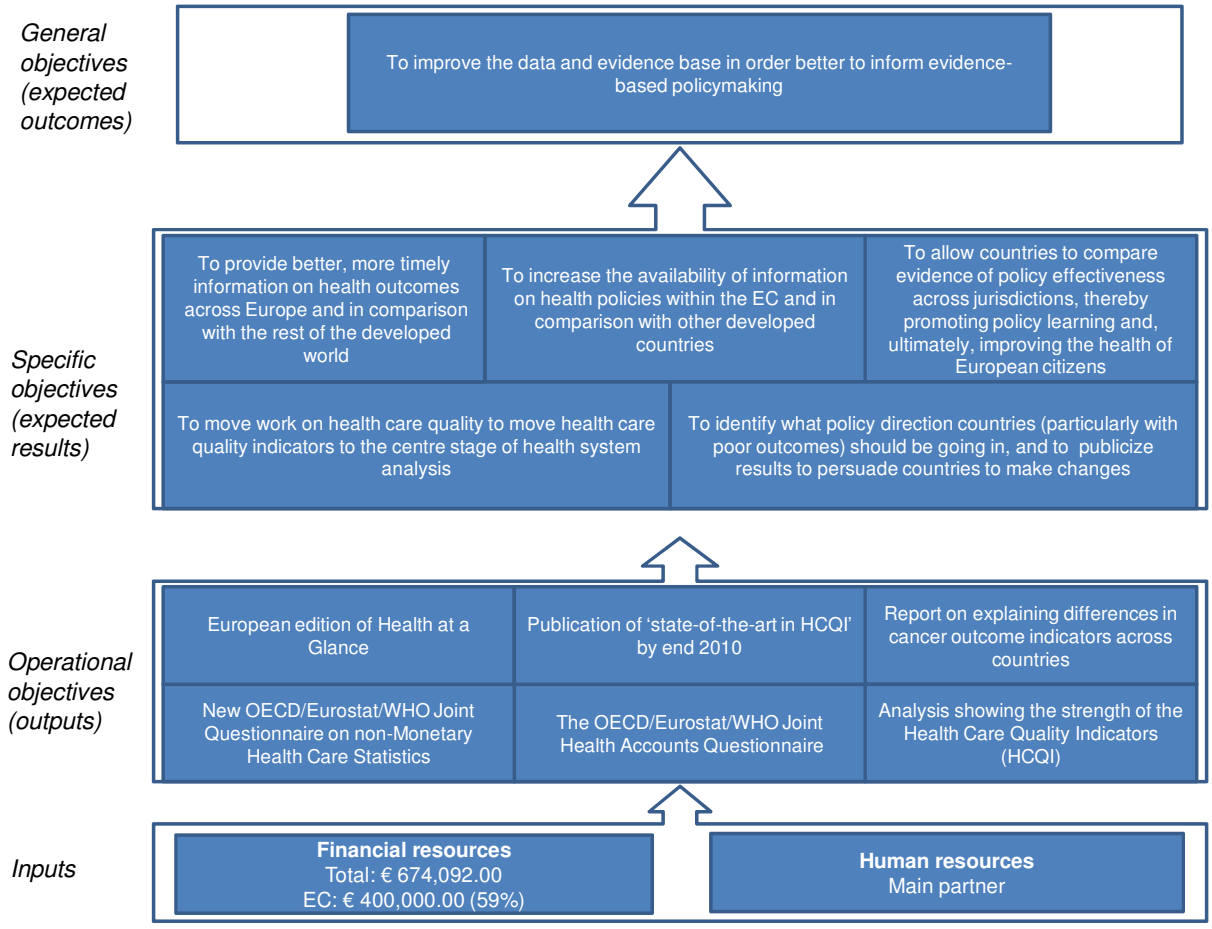
Similarly, the OECD has been working on Health Care Quality Indicators (HCQI) with EC support since 2002. One of the areas where greatest progress has been made in developing quality indicators has been in cancer. The Direct Agreement therefore aims to move beyond the collection of data to make a first attempt at explaining the differences in internationally comparable health care quality indicators by reference to key policy settings.

As stated in the section above, a range of other initiatives are taking place in the field of health quality indicators. In particular the ECHI projects (ECHI, ECHI-2, ECHIM), also funded under the HP, are of relevance and the work for the current ECHI project (ECHIM) is carried out in close collaboration with Member States, the European Commission, Eurostat, WHO, OECD and other international organisations with the aim of supporting the EU Health Strategy.

14.7 Overall project objectives / intervention logic

Based on an analysis of the proposal and interim report, the diagram below depicts the action's complete intervention logic. It shows a clear sequence of the general and specific objectives the action intends to achieve, the expected outputs, and the key inputs. The objectives stated in the proposal are in line with the objectives referred to by the interim report, and the ongoing project is working towards the operational, specific and general objectives as presented in the diagram above. More specific detail on each of these aspects is presented in this section.

Figure 247 – Intervention logic diagram for OECD Health Data



Inputs:

OECD Health Data Budget Overview			
Direct eligible costs			
1.1 Management and professional staff 1.1 Technical / administrative support staff Total Staff (E1a + E1b)	 € 330,328.00 € 283,461.00	 €613,789.00	
2.1 Staff missions *Total – Travel Costs*	 € 11,000.00	 € 11,000.00	
3.1 Office costs		€ 31,302.00	
Total Direct Eligible Cost		**€ 18,000.00**	
Indirect eligible costs Total-Overheads *Total Indirect Eligible Cost*			€ 656,092.00 € 18,000.00
TOTAL EXPENDITURE			**€ 674,092.00**

Expected outputs:

Expected outputs	Achieved outputs (as per Interim Report)
The OECD/Eurostat/WHO Joint Health Accounts Questionnaire (the source of data on health expenditure)	circulated between December 2009 and March 2010
The new OECD/Eurostat/WHO Joint Questionnaire on non-Monetary Health Care Statistics (the source of data on health care resources)	circulated between January 2010 and April 2010
Analysis showing the strength of the Health Care Quality Indicators (HCQI)	Completed
European edition of Health at a Glance	The publication was released, as planned, in December 2010 as per interim report
Publication of 'state-of-the-art in HCQI' by end 2010	Publication was issued in October 2010 as per interim report
Report on explaining differences in cancer outcome indicators across countries by end June 2011	The findings from the performed analyses will be discussed at the HCQI Expert Group meeting in May 2011. The final report will be produced shortly after, concordant with the planning described in the action

Expected aims/outcomes:

Aim	Indicators	Result (as per Interim Report)
Overall aim is to improve the data and evidence base in order better to inform evidence-based policymaking.	Publication of data and dissemination to relevant policy makers	Achieved (see expected outputs above).
European edition of Health at a Glance will seek to provide better, more timely information on health outcomes across Europe and in comparison with the rest of the developed world.	Publication of European edition of Health at a Glance	Achieved (see expected outputs above).
European edition of Health at a Glance will increase the availability of information on health policies within the EC and in comparison with other developed countries.	Publication of European edition of Health at a Glance	Achieved (see expected outputs above).
European edition of Health at	Publication of European	Achieved (see expected

Aim	Indicators	Result (as per Interim Report)
a Glance will allow countries to compare evidence of policy effectiveness across jurisdictions, thereby promoting policy learning and, ultimately, improving the health of European citizens.	edition of Health at a Glance	outputs above).
Health Care Quality Indicators: moving to the next level: The aim is to move work on health care quality indicators to the centre stage of health system analysis by producing a high profile publication on achievements and barriers, and producing analysis showing its analytic strength.	Publication of 'state-of-the-art in HCQI'	Achieved (see expected outputs above).
Health Care Quality Indicators: moving to the next level: The aim is to identify what policy direction countries (particularly countries with poor outcomes) should be going in, and then to publicize these conclusions to persuade countries to make the change.	Improvement of outcomes	So far, has reached a significant number of experts and various meetings are in preparation on this.

Based on the interim report and statement of the action leader, most of the objectives set out above have already been met since the during the lifetime of the action and it is anticipated that all outstanding objectives, most importantly the publication of the report on explaining differences in cancer outcome indicators across countries, will be met over the forthcoming months.

14.8 Action compatible with the principle / objectives in the Health Strategy

The action is compatible with Strategic Objective 1 as set out in the Health Strategy (2008-2013). Objective 3: Supporting dynamic health systems and new technologies.

14.9 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified the following initiatives:

5. **Other EU / DG SANCO projects**

   - Under the current Health Programme, the EU is funding the Joint Action (JA) on European Community Health Indicators Monitoring (ECHIM)

The following projects were funded under the previous Public Health Programme 2003 – 2008:

- Preparation of the Global Report on the Health of the European Union - EUGLOREH (2005)
- European Cancer Health Indicator Project (Phase 2) - EUROCHIP 2 (2003)
- Health indicators in Europe's regions (Phase 3) / Indicateurs de santé dans les regions d'Europe (Phase 3) - ISARE 3 (2003)
- EU Public Health Outcome Research and Indicators Collection - EUPHORIC (2004)

The following projects were funded under DG Research's 7th Framework Programme (FP7):

- European Consortium in Healthcare Outcomes and cost-benefit research - ECHOUTCOME (2010)
- EuroHOPE European *Health* Care Outcomes, Performance and Efficiency - EUROHOPE (2010)

6. **International Organisations**

   - The WHO publishes information on health indicators through the WHO Core Health Indicators database and the WHO Statistical Information System on an ongoing basis
   - The United Nations Statistics Division publishes health indicators covering all countries on an ongoing basis

7. **Member State organisations**

   - The NHS information centre for health and social care, England's central, authoritative source of health and social care information for frontline decision makers, has established indicators of health, performance, quality and efficiency and publishes information on these on an ongoing basis

8. **3rd countries involved**

   - The Canadian Institute for Health Information (CIHI) has established more than 80 indicators to measure the health of the Canadian population and the performance of the health system, and publishes information on an ongoing basis
   - The US Centre for Disease Control and Prevention (CDC) carries out and publishes surveys on national health care, including information on the quality of health care on an ongoing basis

14.10 Rationale behind selection procedures (consistency with HP objectives)

For Direct Agreements, no evaluation reports of proposals are produced.

The aim of the action is to improve the data and evidence base regarding health indicators and health care quality indicators across Europe in order better to inform evidence-based policymaking. The action therefore meets objective 3 of the EU Health Programme 2008-13:

To generate and disseminate health information and knowledge, exchanging knowledge and best practice on health issues.

14.11 Involvement of decision makers (design of project / exploitation of results):

During the interview carried out with the action leader, it was explained that the action's work on cancer has drawn on an extensive network of cancer specialists in Europe and in other developed countries. There are two types of experts: those involved in national policymaking and those who are more involved in the implementation of policy, including academics and practicing oncologists. The national policymakers were already identified through a pre-existing group in the OECD Health Care Quality Indicators network. The secretariat to this group (which involves the main researchers in the action) also participates in the European Union networks and interacts with the academic networks (e.g. Eurocare). As stated by the action leader, the 'implementer' group was identified by reference to the network of policymakers, who indicated people who had specific expertise in policy implementation – at least for those countries where suitable such 'implementers' were not well-known figures.

The work on the European edition of *Health at a Glance* drew on two networks indirectly. The first was via the OECD-EUROSTAT-WHO Joint Health Questionnaire network. The three organisations have taken steps to harmonise questions asked to countries. This has involved a relatively intensive exchange of views with experts as to what is important to them, as well as what is feasible. The second network was the European Communities Health Indicators (ECHI) network, which has, over a number of years, identified the most important indicators that it feels are necessary to compare health system performance. The publication drew mainly on the ECHI list of indicators as a guide to what should be included.

14.12 Dissemination

Strategy

During the interview, the action leader stated that EHaG has already been launched using a website, press release, launch event at the European Commission, many press interviews and much coverage. The publication is regularly cited in the press. EHaG has reached a mass audience in countries where it hit a nerve (Ireland) or on particular messages (e.g. child obesity).

The publication has been made available by the OECD in English only, except for an introductory abstract, which is available in French as well. Additional translations will be funded and managed by the European Commission.

The action leader also stated that the OECD's work on cancer (part 2) needs to be reviewed by national policymakers/experts before the best strategy for dissemination is considered. It is likely to vary from country to country. A possible policy message is that very poor performance in the field of cancer care is due to lack of resources, in which case the principle activity will be to publicise the poor performance to a wider audience to incite and, more importantly, enable a policy response. However, when more resources are provided, a point is reached when further resources have little effect, and the principle message needs to be better governance of cancer systems. This is not a message amenable to a mass audience, so this will be a case of presenting and persuading policymakers directly. So far, the results of the work the OECD has undertaken in this area as part of the action has reached a significant number of experts and various meetings are in preparation on this.

The publication 'State-of-the-art in HCQI' is online and can be accessed at: http://www.oecd.org/document/42/0,3746,en_2649_37407_46144874_1_1_1_37407,00.html

To improve dissemination, a summary document was produced for the high-level forum on quality of care. This can be accessed at: http://www.oecd.org/dataoecd/14/27/46098506.pdf

A dissemination plan will be prepared prior to the final report of the action being released which will identify priority countries to be targeted where the message is particularly clear and strong.

Target groups

The action leader stated that national policy makers and experts are targeted primarily and are expected to be the main group making use of the action's results. European policymakers do not have a mandate to make policy proposals in most areas of health.

Monitoring processes

The action leader stated that all OECD activities are rated by countries on two dimensions – quality, and impact. This happens in the two years after completion of projects. High level policymakers in health departments rate each project on a scale of 0 (very poor quality, or no impact) to 5 (very high quality, immediate and strong policy impact). As the OECD Health Data action has not been finalised yet, the rating of this stating is still outstanding.

No other monitoring provisions have been mentioned.

14.13 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the action VITO fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and the final evaluation report prepared by the Commission. This summary table has been taken from a fuller analysis of the EU added value contained in an Annex.

EU Added Value Criteria		OECD HealthData Direct Agreement
1.	Implementing EU legislation:	3.0
2.	Economies of scale:	1.5
3.	Promotion of best practice:	3.0
4.	Benchmarking for decision making:	2.8
5.	Cross border threats:	1.8
6.	Free movement of persons:	0.0
7.	Networking:	1.0

0. **No EU Added value foreseen**	
1. EU added value **potentially**	(i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely**	(i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain**	(i.e. A **key objective** of the Action outlined in proposal)

14.14 Sustainability

The action leader stated that the measures of cancer outcomes developed by the action are likely to feed directly into the international effort to measure cancer survival rates by 'stage' of cancer at diagnosis e.g. via the 'Concord' process, which is closely involved as a collaborator in the outcome. The policy analysis is likely to be used in conjunction with other efforts to explain differences in cancer outcomes, e.g. that of McKinsey consulting for the UK government. As the action leader stated, it would be surprising were this not to become a main area of academic discussion over the coming years, based on the data and approach developed for the action.

Regarding the EHaG, it was stated that a major effort of data co-ordination is underway between OECD, ESTAT and WHO Europe. The EHaG experience will feed into this ongoing effort (it has already influenced the childhood obesity data collection, for example).

As previously stated, the EHaG will continue to be publicly available on the OECD website. The other two deliverables, i.e. the publication of 'state-of-the-art in HCQI' by end 2010 and the report on explaining differences in cancer outcome indicators across countries will be available to policy makers, health professionals and other relevant stakeholder groups. As the funding was made available specifically to support the OECD in the production of these three deliverables, which represent a robust body of evidence on which to base decision making in public health policy, the cease of funding after the action has been completed will not impact negatively on the outcomes of the action.

The possibility of further funding through the EU Health Programme has not been mentioned by the action leader.

14.15 Impact to be expected

European edition of Health at a Glance

As stated by the action leader, the first work package (the EHaG) will mainly have an impact at the National level, though EU policy makers may take note of 'gaps' in the information base on which the publication draws. According to him, this element of the action has achieved its main objective, which was to indicate areas where policy action is likely to be needed in different countries, and to push policy learning between countries. An improved knowledge of health indicators across the EU and better access to expertise and best practice in a broad range of public health issues is the main impact of this package.

As regards the second work package, the action leader stated that the impact of the work on cancer will be (a) to encourage greater resources to be devoted to cancer screening, diagnosis and treatment, depending on the country, and (b) to encourage a greater understanding of the 'governance' of the cancer system. In each case the main impact will be at the national level, though it is possible that EU policymakers may wish to follow through on these messages.The impact is expected to be achieved through the presentation of the reports, primarily directly to policymakers via the various OECD and EU networks, but also to a wider academic audience via presentations in conference.

15. EFRETOS

15.1 Summary

It has been commonly accepted in the transplant community that organ transplantation is the preferred treatment option for patients with end-stage organ failure. Progress in transplantation medicine is hampered by the shortage of donor organs. Maximizing the potential of available donors and redefining the borders of acceptability of extended criteria donors was the aim of a former EU Framework Programme 6 funded project - Improving the Knowledge and Practice of Organ Donation (commonly known as the DOPKI project).

Another approach to be taken in order to deal with the challenge of organ shortage, quality and safety is to describe the outcome of the organ after transplantation. Providing comprehensive information will help in drafting guidelines for listing for transplantation. The objectives of these guidelines are to define patient groups that benefit from transplantation and to define patient subgroups that benefit from transplantation with extended criteria donor organs. Wider European collaboration is necessary for creating a common post-transplant registry. It is the intention of the EFRETOS project to enable committees throughout Europe to gain the same in depth knowledge of post-transplant outcome results as counterparts in the US. The general objective of the EFRETOS project is to evaluate the results of transplantation, by promoting a registry of registries on the follow-up of organ recipients. It is envisaged that this framework will be the foundation for a future European registry.

Extent to which Action Objectives align with HP Objectives (based on intentions in proposal)	Intervention Logic / Rationale	Extent to which Action builds on a robust evidence base (based on proposal)	Extent to which Action follows on from previous EU funded research / actions	Extent to which Public Health issue addressed by Action is a cause of concern in MSs, and internationally (based on proposal and desk research)	Extent to which clear target audience has been identified	Extent to which an effective dissemination plan is in place - Clear use of channels	Extent to which different MSs are involved as associated & collaborating partners	Extent to Action has an effective evaluation strategy / approach	Extent of EU Added Value (based on EU added value analysis)
+++	++	+++	++	+++	+++	++	13	+	1. Implementing EU legislation: 3.0 2. Economies of scale: 1.0 3. Promotion of best practice: 3.0 4. Benchmarking for decision making: 2.8 5. Cross border threats: 2.0 6. Free movement of persons: 1.0 7. Networking: 2.0
Project meets the AWP 2008 fully. It covers the following which are explicitly mentioned in AWP: Evaluation of post transplant results on organ transplantation: Promote common definitions of terms and methodology to evaluate the results of transplantation. Promote register or network of registers to follow-up on organ recipients, monitor their health and evaluate results.	There appears to be solid rationale for Action. Based on how the Action directly addresses a recommendation in EU Directive on standards of quality and safety of human organs intended for transplantation. However this is not particularly well described in project documentation. For example, there is no clear distinction / and overlap between Specific Objectives and Outputs.	Existing evidence from: - Numerous small national registries and the not-consecutive large international registries. - The Netherlands Organ Transplant Registry has extended data on donors, recipients, and adverse events during transplant follow-up, but only covers transplants within the Netherlands. - The Collaborative Transplant Study (CTS), covering a large part of Europe, has extensive data on follow-up after transplantation, but minimal data on the donors that were used for the transplant.	Follows on from EU funded interventions: - Alliance-O (FP6) - DOPKI project (FP6) (Improving the Knowledge and Practice of Organ Donation)	- Complementary activities identified including Global Observatory & Observatory on Donation & Transplantation (Spanish National Transplant Organization ONT in collaboration with WHO) - European Transplant Coordinators Organisation - Active OEOs in all MSs	Four clear target groups: - National governments; - Organ Exchange Organisations (OEO); - Physicians in the field of organ transplantation; - Patients with end-stage organ disease. N.b. All European OEO's as well as the European scientific society (ESOT) participate in EFRETOS. As a group they represent all physicians, researchers and a body of policy makers in Europe.	- No evidence of dissemination approach or strategy detailed in proposal or Interim Report. - However, much of project dissemination will take place through internal communication channels that are already in place. For example, European OEO's meet once a year to share knowledge and information. - Dissemination channels include: EFRETOS website EFRETOS newsletters EFRETOS symposium	- 1 Lead Partner - 6 Associated Partners - 10 Collaborating Partners	Little on evaluation approach or strategy detailed in proposal or Interim Report. - Management team to focus on the following outputs: - Deliverables (planning versus realisation) - Person months per partner (allocated/ realised) - Cost (prognoses/ realised)	Overall a strong assessment in terms of EU added value. In particular: - Implementing EU Legislation & Benchmarking for decision making: The Action directly addresses a recommendation in an EU Directive (Rec(2006)15 of the Committee of Ministers of the Council of Europe to MSs) on it being *preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability.* - Promotion of Best Practice: The proposed registry will combine state-of-the-art technology and research with access for all European countries. Greatest asset of this project lies in it potential to combine evidence contained in small national registries and allow it to be of use for the cooperating countries.

15.2 Key Facts

Calls for proposals:	2008
Proposal title:	European Framework for Evaluation of Organ Transplants
Acronym:	EFRETOS
Financing mechanism:	Project
Starting date:	January 1st 2009
Duration (in months):	24 months
EC contribution:	€700,000 (56%)
Total:	€1,250,000
Overall score achieved in Consolidated Evaluation Report:	89
Total criteria block: A, B, C	A: 37 B: 26 C: 26
Main partner:	Stichting Eurotransplant International Foundation, The Netherlands
Number of associated partners:	6
Number of collaborating partners:	10
Priority area:	1. IMPROVE CITIZEN'S HEALTH SECURITY (HS-2008)
Action:	1.2 Improve citizens' safety

15.3 Overview of project success criteria

The following table of project success criteria has been developed based on a strategic document produced by the EAHC "EU Health Programme Programme Evaluation"[47]. The table contains elements that make the success of a funded action and its positive outcome likely, and provide an assessment of the action funded against these criteria.

Project Success Criteria	Notes / Comments
Well-defined and SMART objectives - **Objective to reduce risk** - target could be expressed in terms of target population (then compare target population in EU based on HP priority with target population based on project's objective and based on project's results) - **Objective to**	**EFRETOS objectives mainly relate to 1. Improving the performance of a health system and 2. producing/disseminating information:** The general objective of the EFHROS project is to evaluate the results of transplantation, by promoting a registry of registries on the follow-up of organ recipients. This framework will be the foundation for a future European registry. Based on the desk research exercise the EFRETOS objectives appear to be fully aligned to the HP objectives and the Priorities specified in the 2008 AWP.

[47] The document was developed by Guy Dargent and Michel Pletschette.

Project Success Criteria	Notes / Comments
produce/disseminate information – target could be expressed in terms of global impact vs. impact on the decision making project - **Objective to improve the performance of the health system** – target is the quality - **Objective to network** – target could be related to management, translation, exchange of knowledge, diffusion of innovations…	
Evidence base (depending on type of action): - **Research action** (gaining new knowledge) – action must be based on a strong intrinsic validity, elements should not contradict each other, methods used for research need to be validated and appropriate to the domain; - **Pilot/development actions** (pilot and demonstration projects) – strong evidence does exist, but the larger, external validity (application to other population groups or broader groups) has yet to be established; - **Implementation actions –** check in the action outcomes that the intervention remains based on the best	**Development Action**: Existing evidence from: - Numerous small national registries and the not-consecutive large international registries. - The Netherlands Organ Transplant Registry - The Collaborative Transplant Study (CTS), covering a large part of Europe, has extensive data on follow-up after transplantation, but only has minimal data on the donors that were used for the transplant. EFRETOS Builds on numerous EU funded interventions: - Alliance-O (FP6) - DOPKI project (Improving the Knowledge and Practice of Organ Donation)

Project Success Criteria	Notes / Comments
available evidence;	
Clear target groups	EFRETOS project defines four quite clear target groups. - National governments, the body that decides on organ allocation rules and donor acceptance criteria; - Organ Exchange Organisations (OEO), whose tasks is to advise the government on allocation rules and donor acceptance criteria; - Physicians in the field of organ transplantation, who decide on donor acceptance and patient referral - Patients with end-stage organ disease, who need to be informed on the risks and benefits of organ transplantation All European OEO's as well as the European scientific society (ESOT) participate in EFRETOS. As a group they represent all physicians, researchers and a body of policy makers in Europe.
Clear dissemination plan (concerns **implementation projects only**) – check if all settings likely to benefit from or to use the intervention have been reached and effectively have been used/benefited from the intervention (Note: if the target population has not been fully reached by the action results, it could be due to a weak or absent dissemination)	- No evidence of dissemination approach or strategy detailed in proposal or Interim Report. - Dissemination is most importantly done via the National Competent Authorities, which are multipliers in respective Member States - Additionally, much of project dissemination will take place through internal communication channels that are already in place. For example, European OEO's meet once a year to share knowledge and information. - Dissemination channels: EFRETOS website EFRETOS newsletters EFRETOS symposium (17th May 2011)
Estimate the population reached (or targeted) by the action	EU Data: 9152 Deceased Organ Donors Kidney Transplants: 17886 Liver Transplants: 6687 Heart Transplants: 2090 Lung Transplants: 1418

Project Success Criteria	Notes / Comments
	Pancreas transplants: 779 Source: http://www.ont.es/publicaciones/Documents/Newsletter2010.pdf
Matching of project's deliverables (if any) with project's objectives	In general, outputs appear to be consistent with proposal. However, responsibility for the coordination and part of one WP has changed from one partner (NHSBT) to another (ET) with EAHC's agreement. Additionally, the objective of WP6 concerning organ vigilance has been modified, also in agreement with the EAHC.
Use of multipliers	- OEO's in MSs reached as potential multipliers
Evaluation (provision of indicators)	Little on evaluation approach or strategy detailed in proposal or Interim Report. EFRETOS Management team to focus on the following outputs: - Deliverables (planning versus realisation) - Person months per partner (allocated/ realised) - Cost (prognoses/ realised)
Sustainability plan	It is envisaged that while the project will come to end, the results of the project will be carefully considered by the EC and competent authorities in the MSs. Additionally, the results of the project will live on through those individuals and organisations involved in the Action.

15.4 Introduction

It has been commonly accepted in the transplant community that organ transplantation is the preferred treatment option for patients with end-stage organ failure. Whether this paradigm still holds in the framework of a globally changing pattern in organ donation is a matter of debate for organ allocation decision makers and a matter of concern for any particular treating physician. Progress in transplantation medicine is hampered by the shortage of donor organs. Maximizing the potential of available donors and redefining the borders of acceptability of extended criteria donors was the aim of a former EU Framework Programme 6 funded project - Improving the Knowledge and Practice of Organ Donation (commonly known as the DOPKI project).

Another approach to be taken in order to deal with the challenge of organ shortage, quality and safety is to describe the outcome of the organ after transplantation. Providing comprehensive information will help in drafting guidelines for listing for transplantation. The objectives of these guidelines are to define patient groups that benefit from transplantation

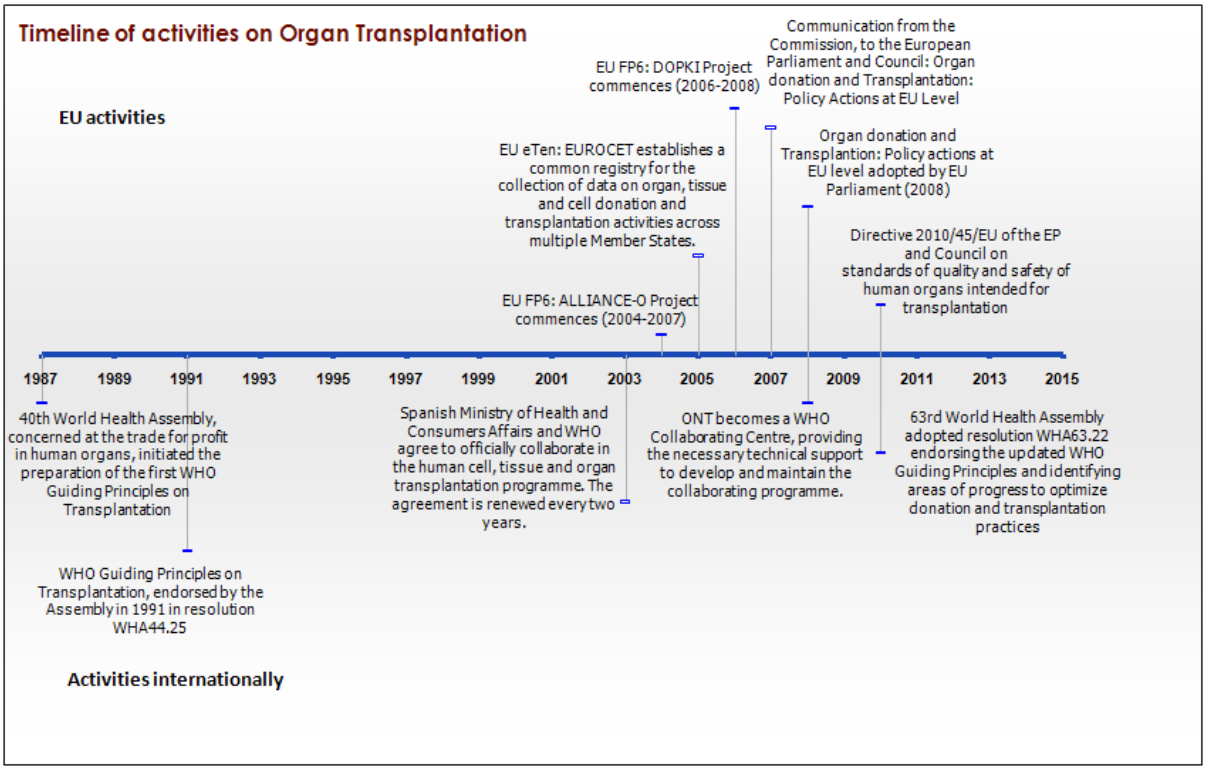
and to define patient subgroups that benefit from transplantation with extended criteria donor organs. Wider European collaboration is necessary for creating a common post-transplant registry. European end-stage disease patients are not comparable to US patients, differences in co-morbidity patterns and differences in access to immunosuppressive medicine do not allow a correct inference from US data to the European population. Organisational structures are also different in Europe and the US. Most ECD kidneys are judged for their suitability for transplantation based on a biopsy, in Europe professional procurement standards do not routinely include a biopsy in their protocol. As a consequence discard rates between the US and Europe differ vastly. It is the intention of the EHFROS project to enable these committees throughout Europe to gain the same in depth knowledge of post-transplant outcome results.

The general objective of the EFHROS project is to evaluate the results of transplantation, by promoting a registry of registries on the follow-up of organ recipients. It is envisaged that this framework will be the foundation for a future European registry.

15.5 Background / Policy Context

In order to gauge and make a judgement on the extent to which the EFRETOS project is tackling a serious public health issue, an examination of related public health interventions / activities has been undertaken. The figure below provides a brief overview of how activities related to the public health effects of youth lifestyles have evolved over the last couple of decades.

Figure 28– Timeline of activities on organ transplantation



The concept of the EFRETOS project was initially conceived at an expert conference in Venice (17-18/9/2003). The expert meeting recognised the shortage of organs and the problem of organ trafficking as the main priorities and underlined that the quality and safety aspects would have to be considered fully within the framework of supply and demand for

organs. The EFRETOS project partners were fully aware of the following reports and guidelines produced by the European Commission and the European Parliament:

1) REPORT on organ donation and transplantation: Policy actions at EU level (2007/2210(INI)) Committee on the Environment, Public Health and Food Safety Rapporteur: Adamos Adamou (RR\398666EN.doc) (adopted by EU-parliament 26/3/2008)

2) Organ Donation and transplantation policy options at EU level consultation document 27 June 2007)

3) Communication from the Commission to the European Parliament and the Council Organ donation and transplantation: Policy Actions at EU Level {SEC(2007) 704} {SEC(2007) 705} (30/5/2007)

4) COMMISSION STAFF WORKING DOCUMENT: Accompanying document to the Communication from the Commission to the European Parliament and the Council Organ donation and transplantation: Policy Actions at EU Level: Summary of the Impact Assessment {COM(2007) 275 final} {SEC(2007) 704}

5) Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

It should be noted that the following points from the Communication and the Directive are addressed through the EFRETOS project:

- *Traceability and vigilance of events and reactions. It is important to ensure that* ***all transplanted organs can be traced forward to the recipient and back to the donor****.*

- *The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions,* ***the collection of relevant post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation.*** *Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union. As emphasised by the Recommendation Rec(2006)15 of the Committee of Ministers of the Council of Europe to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO),* ***it is preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability.*** *However, depending especially on the division of competences within the Member States,* ***a combination of local, regional, national and/or international bodies may work together to coordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, cooperation and efficiency****.*

15.6 Origins of HP project

As detailed in the timeline above, the EFRETOS project can be considered as the follow up to the ALLIANCE-O project (Alliance-O was a coordination action of the ERA-Net scheme of the 6th framework programme) and another FP6 project, DOPKI (DOPKI = Improving the Knowledge and Practice of Organ Donation). As mentioned above, the Action Plan and preparations for the Directive should be seen as the origin of the project as well.

15.7 Project Partners

Main Partner	Country	Organisation Status
Stichting Eurotransplant International Foundation	**The Netherlands**	**Private**

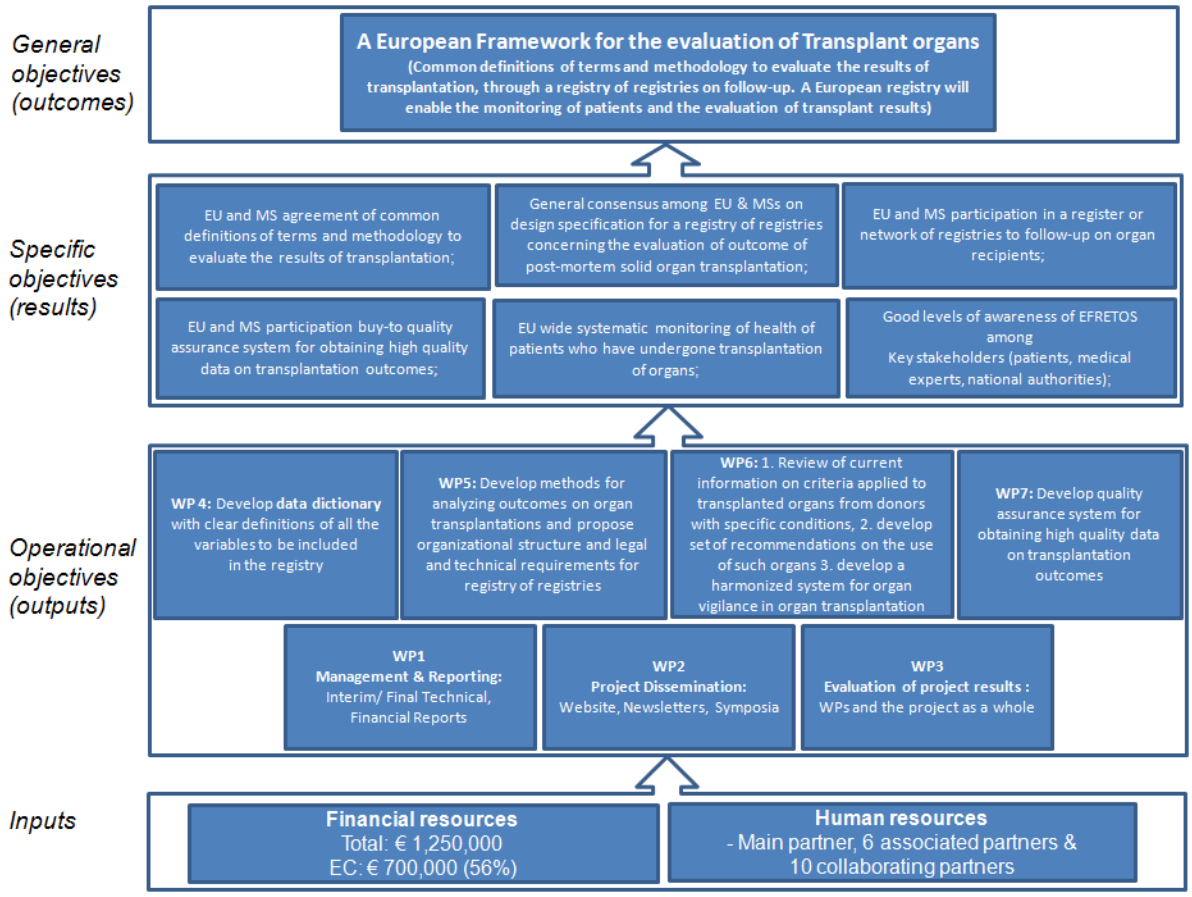
Associated Partners	Country	Organisation Status
Agence de la Biomédecine	**France**	**Public**
European Society for Organ Transplantation	**The Netherlands**	**Private**
NHS blood and Transplant (Statistics and Audit)	**UK**	**Public**
Organización Nacional de Trasplantes	**Spain**	**Public**
Istituto Superiore di Sanità	**Italy**	**Public**
Scandiatransplant	**Denmark**	**Public**

15.8 Overall project objectives / Intervention Logic

The EFRETOS project covers the annual work plan priorities of the Health Programme 2008-2013 very well. This is described more fully in a section below.

It should be noted that the specific objectives and outputs could have been considerably clearer in all the project documentation from the proposal to the interim report and the website. A specific objective is different to an output or deliverable but there appears to be no clear distinction made and a significant amount of overlap between specific objectives and outputs, particularly in the proposal. Based on an analysis of the documentation the diagram below is an attempt to depict the project's intervention logic. It shows the general and specific objectives the EFRETOS project intends to achieve, the expected outputs, and the key inputs.

Figure 25 – Intervention logic for EFRETOS



15.9 Inputs, Outputs and Outcomes:

Inputs:

Please find below a table detailing the EFRETOS budget providing costs for all inputs including staff, travel, equipment etc.:

Expenditures	
Direct eligible costs	
E1. Staff	731,542.00
a. Costs pertaining to public officials	*300,790.00*
b. Costs not pertaining to public officials	*430,752.00*
E2. Travel costs and subsistence allowances	116,358.00
E3. Equipment	0.00
E4. Consumables and supplies directly linked to the project	0.00
E5. Subcontracting costs	150,183.00
E6. Other costs	208,744.00
Total direct eligible costs	1,206,827.00
Indirect eligible costs	
E7. Overheads	43,173.00
Total indirect eligible costs	43,173.00
Total - Expenditures	**1,250,000.00**

Incomes	
I1. Commission funding	749,999.00
I2. Contribution pertaining to public officials	300,790.00
I3. Applicant's financial contribution	111,194.00
I4. Income generated by the project	88,017.00
I5. Other external resources	0.00
Total - Incomes	**1,250,000.00**

I1. Commission funding %	**60.00%**

Expected outputs:

WP	Expected outputs	Achieved outputs (as per Interim Report)
1	Financial and Technical Interim Reports	June 2010
1	Financial and Technical Final Reports	TBD
2	EFRETOS Website	Jan 2010
2	Project brochure and promotion material	Oct 2010
2	Dissemination plan	Feb 2010
4	Report on set of common data	June 2010
4	Report on a dedicated data dictionary	Oct 2010
5	Pilot study in order to develop methods for analysis	April 2010
	Preliminary report on the use of a registry of registries	June 2010
	General requirements for a European registry: requirements for participating countries	Oct 2010
	Report on the use of a registry of registries	March 2010
	Developed surveys on functional, technical and legal requirements	April 2010
6	First outline report on safety and vigilance	June 2010
	Recommendation for the development of an	December 2010

WP	Expected outputs	Achieved outputs (as per Interim Report)
	Organ Vigilance system	
7	Report on quality assurance	March 2011

Expected aims/outcomes:

Aim	Indicators	Result (as per Interim Report)
to prepare the specifications of a registry of registries concerning the evaluation of outcome of post-mortem solid organ transplantation	First outline of the report on the use of a registry of registries	**The information in the first two columns is taken from the Interim Report. The indicators for each of the aims take the form of outputs and not indicators. The Action would benefit from a set of indicators that could provide an insight into the extent to which the outcomes are being / have been achieved. Without these it is difficult to determine how effective the Action has been and the extent of its impact at this point.**
to promote common definitions of terms and methodology to evaluate the results of transplantation	A list of variables and definitions	
to promote a register or network of registries to follow-up on organ recipients	A project website, newsletters on the progress, a project brochure and promotion material for congresses.	
to monitor health of patients who have undergone transplantation of organs	A set of functional, technical and legal requirements to build up a registry of registries Recommendations on safety, with focus on non-standard risk donors	
to evaluate the results of the project in strong cooperation with the European Commission (EAHC) using the European Network of Competent Authorities	Methodology on how to combine and merge data from different registries in a pilot study	
to disseminate the results of this innovative project, especially concentrating on the main stakeholders (patients, medical experts, national authorities)	A dissemination plan	
to describe a quality assurance system for obtaining high quality data on transplantation outcomes	A report on a quality assurance system	

15.10 Action compatible with the principle / objectives in the Health Strategy

The EFRETOS proposal does not specify which principle it addresses in the EU Health Strategy. The Action appears to be most compatible with Strategic Objective 1 of the Health Strategy (2008-2013).

Objective 1: OBJECTIVE 1: FOSTERING GOOD HEALTH IN AN AGEING EUROPE …There is also scope for further work on blood, tissues, cells and organs including transplant issues.

Action : Follow up of the Communication on organ donation and transplantation (Commission)

… and the Treaty of the European Union

TITLE XIV PUBLIC HEALTH

Article 168 (ex Article 152 TEC)

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

15.11 Relationship of funded action with other Initiatives (international, EU, national, regional)

In terms of how the project ties in with other work in the same area the evaluation has identified the following initiatives:

1. **Other EU / DG SANCO projects / organisations:**

    a. **ALLIANCE-O Project (EU FP6):**
    European Group for Coordination of National Research Programmes on Organ Donation and Transplantation: The ERA-NET ALLIANCE-O coordination action was established to coordinate the efforts of countries on organ transplantation, each of them having different approaches and programmes to tackle organ transplant (OT) issues. The project is coordinated by the Agence de la biomédecine, France, and involved partners from six other countries: Germany, Hungary, Italy, Portugal, Spain and United Kingdom. They were represented by national public bodies involved in the organisation of OT. ALLIANCE-O project lasted three years and was granted € 2 million by the European Commission. The objective was to identify existing organisations and programmes and propose strategies for improving coordination including joint activities between several countries with a national public body in charge of organ transplantation. Research programmes for improving OT efficiency concern many activities from donor to the follow-up of the patient.

b. DOPKI project (EU FP6): http://www.dopki.eu/

DOPKI is an EU funded project that deals with the problem of organ shortage for transplantation. It specifically addresses "Public health issues including epidemiology contributing to disease prevention and responses to emerging rare and communicable diseases, allergies, procedures for secure blood and organ donations, non-animal test methods". DOPKI is developed by a consortium of partners, from participating countries (Spain, France, Italy, Germany, UK, Slovenia, Hungary, Poland, Czech Republic, Portugal, Croatia and Switzerland) as well as Eurotransplant International Foundation (ET) on behalf of Austria, Luxembourg, Belgium and the Netherlands. DOPKI project aims to develop an applicable methodology that could be used to determine both, the potential for organ donation and its outcome, as well as to define the limits for an organ's safety and quality

c. ETPOD, EU LIVING DONOR, ODEQUS, COORENOR, JA MODE, ELIPSY

d. European Transplant Coordinators Organization

>> www.etco.org

Coordination of organ and tissue procurement and subsequent transplantation requires the commitment of a dedicated professional group. Transplant coordinators are employed worldwide and form an essential component of this complex process which requires technical, organizational and communication skills. *The European Transplant Coordinators Organization* (**ETCO**) was set up in 1983 to represent all those working as *Transplant Coordinators* in Europe and around the world to promote *organ and tissue donation* in all member countries. ETCO organises congresses and annual meetings, international and national workshops and collaborates with Organs, Tissues and Cells Journal to publish and disseminate research in this field and produces a web to promote and inform about relevant issues and provide members with information about ETCO and the field of organ procurement, donation and transplantation. **ETCO** provides a forum in which members can share skills and experience and work towards a comprehensive strategy to ensure that all families are offered the option of donation and that maximum organ retrieval rates are maintained to support the *transplant programmes.* ETCO also manages the International Registry of Organ Donation and Transplantation (IRODaT).

2. International Organisations / Activities involved in related activities:

a. Global Observatory & Observatory on Donation & Transplantation
Spanish National Transplant Organization ONT in collaboration with WHO.
>> http://www.transplant-observatory.org/

b. WHO and Transplantation
>>www.who.int/transplantation
Following the World Health Assembly Resolution WHA57.18, transplantation became an area of work at WHO. The mission of WHO in transplantation is carried out by the Clinical Procedures unit in the Department of Essential

Health Technologies (EHT/CPR). This unit is responsible for promoting the ethics of donation and transplantation and the appropriate effective and safe use of cells, tissues and organs for transplantation. The objectives are summarized as follows:

1. To work with Member States and to provide assistance at their request to ensure effective national oversight of allogeneic and xenogeneic transplantation activities. This would ensure accountability, traceability and appropriate surveillance of adverse events.
2. To increase access of citizens to safe and effective transplantation of cells, tissues and organs. Additionally, to ensure ethical and technical practices from procurement of human material for transplantation to the follow-up of recipients and live donors.
3. To promote international cooperation to encourage the global harmonization of technical and ethical practices in transplantation. This would include the prevention of the exploitation of the disadvantaged through transplant tourism, and the sale of human material for transplantation.
4. To encourage the donation of human material for transplantation, in particular promoting deceased donor donations.

3. Member State organisations involved in related activities:

a. Spanish National Transplant Organization ONT
>>www.ont.es
The Spanish National Transplant Organization, Organización Nacional de Trasplantes (ONT), is the technical coordinating institution that belongs to the Spanish Ministry of Health, Social Policy and Equality. It is in charge of coordinating donations and transplantations performed on a national scale, assuring the best use of organs, tissues and cells. According to the principles of cooperation, efficacy and solidarity, ONT coordinates and facilitates the activities of donation, extraction, preservation, distribution, exchange and transplantation of organs, tissues and cells across the Spanish health system.

Since the creation of ONT in 1989, Spain has progressively reached the highest rate of organ donation thanks to the implementation of the well-known Spanish Model. The model takes into consideration organizational measures to improve organ donation which are considered key issues for the success of the transplant system. Thus, the Spanish Model has become the international reference when facing the problem of scarcity of organ donors.

15.12 Rationale behind selection procedures (consistency with HP objectives)

The proposal evaluation report concluded that EFRETOS fully meets with the objectives of the EU Health Programme (2008-2013) and the Annual Work Plan. Extracts from the 2008 AWP are presented below. EFRETROS is directly aligned with the text highlighted in bold.

3.2 Priority actions for the first strand 'Improve citizen's health security'
3.2.2. Improve citizens' safety
Activities at European level in this area aim to identify risks to health and evaluate their

possible impact, in addition to complementing national measures in tackling avoidable incidents and patient safety by increasing awareness and fostering knowledge exchange. Furthermore, the **EU has a Treaty obligation to set standards of quality and safety of organs** and substances of human origin for medical use. Actions under the Programme will support the implementation of Community legislation on blood, tissues and cells.

3.2.2.2. Safety of blood, tissues, cells, organs (Annex – Point 1.2.2)
Specific questions related to blood, tissues, cells and organs remain on the promotion of voluntary unpaid donations, inspections, electronic exchange of data and optimal use. For the implementation of the tissues and cells directives traceability, coding and reporting systems for adverse events should be established at community level. There is a need to support projects that help in managing import and export, registers and reporting obligations of the directives. Stem cells, reproductive cells and new human derivatives are special cases that will require specific attention. **On organs, improving quality and safety, increasing organ availability and making transplantation systems more efficient and accessible will require further work following the Commission Communication on organ donation and transplantation.**

In 2008, the following projects will be prioritised:
- **Evaluation of post transplant results on organ transplantation: Promote common definitions of terms and methodology to evaluate the results of transplantation. Promote register or network of registers to follow-up on organ recipients, monitor their health and evaluate results. [Financing mechanism: Call for proposals]**

15.13 Involvement of decision makers (design of project / exploitation of results):

As mentioned above, those involved in the EFRETOS project appear to be fully aware of the EU's policy on organ transplantation and in this sense the project has been designed with this in mind. Once the project results are ready for dissemination, it is envisaged that the European Commission will be discussing the subject of Organ Vigilance, using the EFRETOS results, with the competent authorities in the Member States.

15.14 Dissemination

Target Audience

The EFRETOS project defines four quite clear target groups.

- National governments, the body that decides on organ allocation rules and donor acceptance criteria;
- Organ Exchange Organisations (OEO), whose tasks is to advise the government on allocation rules and donor acceptance criteria;
- Physicians in the field of organ transplantation, who decide on donor acceptance and patient referral
- Patients with end-stage organ disease, who need to be informed on the risks and benefits of organ transplantation

All European OEO's as well as the European scientific society (ESOT) participate in EFRETOS. As a group they represent all physicians, researchers and a body of policy makers in Europe.

Tools

In general much of the project dissemination will take place through internal communication channels that are already in place. For example, European OEO's meet once a year to share knowledge and information. Additionally there are regular scientific meetings in this area and it is in such fora that results of the project can be shared with clinicians.

The Interim Report does not provide a significant amount of detail on dissemination. At this stage a list of stakeholders had been put together and was being used for disseminating Newsletters and a Project brochure. A dissemination plan had been constructed but this was not detailed in the Interim Report. It is envisaged that much of the dissemination will come at the end of the project. In terms of specific channels, the website and the symposium constitute two key dissemination tools:

Website: A project website (www.efretos.org) was launched in December 2009. The website was enhanced with RSS functionality in January 2010. The EFRETOS consortium considers the website crucial for keeping all stakeholders up to date and informed on the project.

Presentations at Conferences: The EFRETOS project report circa 100 presentations at conferences.

EFRETOS Symposium: On May 17th 2011 the EFRETOS project board organised symposium 'Unifying data collection - creating new knowledge'. One of the main purposes of the symposium was to present the most important results of EFRETOS and offer an insight into the future of post-transplant data collection in Europe. The EFRETOS symposium was not only aimed at scientists, researchers and medical professionals, but also for politicians and policy makers, patients and representatives of organizations in the field of organ transplantation.

15.15 EU added value

Seven criteria defining EU Added Value have been developed by the EAHC. The table below provides an overview of which areas of EU added value the EFRETOS project fulfils and the extent to which it does this. These judgements have been made on based on a thorough review of the proposal and interim report. This summary table has been taken from a fuller analysis of the EU added value provided in an Annex.

EU Added Value Criteria		EFRETOS Project
1.	Implementing EU legislation:	3.0
2.	Economies of scale:	1.0
3.	Promotion of best practice:	3.0
4.	Benchmarking for decision making:	2.8
5.	Cross border threats:	2.0
6.	Free movement of persons:	1.0
7.	Networking:	2.0

0. **No EU Added value foreseen**
1. EU added value **potentially** (i.e. **Some** reference made to such an outcome in proposal)
2. EU added value **likely** (i.e. **Strong** reference made to such an outcome in proposal)
3. EU added value **almost certain** (i.e. A **key objective** of the Action outlined in proposal)

Based on this analysis it appears that the Action scores well in terms of its EU added value. In particular:

- Implementing EU Legislation & Benchmarking for decision making: The Action directly addresses a recommendation in an EU Directive (Rec(2006)15 of the Committee of Ministers of the Council of Europe to MSs) on it being preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability. In addition it features in the Treaty of the European Union:

TITLE XIV PUBLIC HEALTH

Article 168 (ex Article 152 TEC)

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

- Promotion of Best Practice: The proposed registry will combine state-of the-art technology and research with access for all European countries. Greatest asset of this project lies in it potential to combine evidence contained in small national registries and allow it to be of use for the cooperating countries.

- **Networking** (mainly in the support of an existing network) and to some extent in addressing cross-border threats. In this context, the EFRETOS proposal outlines the fact that international cooperation between OEOs will ensure that consecutive transplants are registered. This information is mandatory to identify missing records. Putting a system (EFRETOS) in place allows the linkage with different national transplant registries as well as other registries so that proper risk benefit analyses can be performed.

15.16 Sustainability

There is a strong view from the Project Coordinator that Actions of this type could be more effectively implemented and benefit from sustained funding over a longer period of time. It is very unlikely that the project would have taken place without Health Programme support. In this context, the EFRETOS project is considered to complement (and not overlap) activities being undertaken at Member States level.

15.17 Impact to be expected

As yet, the results of the EFRETOS project have not been fully disseminated. Therefore it is too early to gauge any impact. As mentioned above, it is expected that the European Commission will discuss the subject of Organ Vigilance, using the results from the EFRETOS project, with the competent authorities in the Member States.