



Co-funded by
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Consumers, Health and Food
Executive Agency



European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment

- Call: 4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

Key issues addressed by the Directive



Directive 2011/24/EU of patients' rights in cross-border healthcare



focussing on patients' rights & healthcare across the Union:

- Right to **choose and be reimbursed**, under certain circumstances for, **healthcare provided** by public or private providers located in the EU.
- More **transparency about their rights**, treatment options or, the quality and safety levels of healthcare providers
- Strong focus on **cooperation among Member States:**

Entry into force at National level 25 October 2013

Health and
Consumers

2

EUROPEAN
REFERENCE
NETWORKS

Background



□ Second Programme in the field of health (2008-2013)

- Adopted on 23 October 2007, by the European Parliament and the Council
- Intended to complement, support and add value to the policies of the Member States and to contribute to increased solidarity and prosperity in the EU.
- Objectives :
 - to improve citizens' health security;
 - to promote health, including the reduction of health inequalities and
 - to generate and disseminate health information and knowledge.

Cancer in Children and Adolescents

A Rare Disease



- **> 60 different diseases from newborns to teenagers**
(even more if biomarkers are considered!)
- **15 000 new cases each year in Europe!**
- **3000 will die each year**
- **1 out of 1000 adults aged 18 to 40 is a paediatric cancer survivor**

... a significant Public Health Issue

What is special about Paediatric Oncology in Europe ?

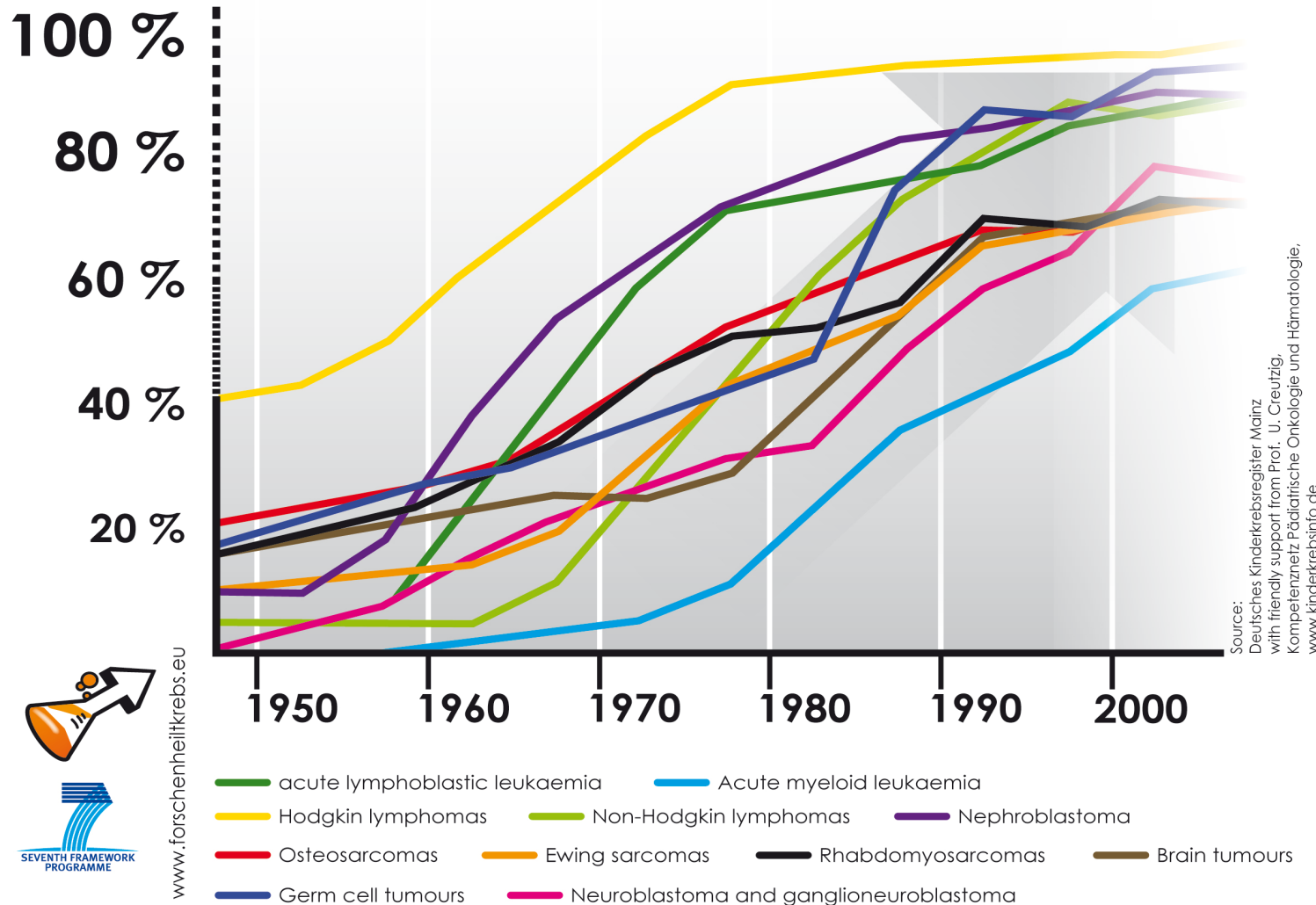


- EU public specialized centres
- Leukemia /Tumour specific Networking within clinical trial structures since late 60tes
 - **50% of patients treated within trials (phase I to III)**
 - **30% of patients treated according to standard within prospective studies**
 - **Less than 5% of pharma-sponsored trials**
- Many high-level research teams dedicated to paediatric tumour biology

A unique situation for an orphan disease !

A Major Academic Effort !

Survival Rates of Children and Young Adults Suffering from Cancer



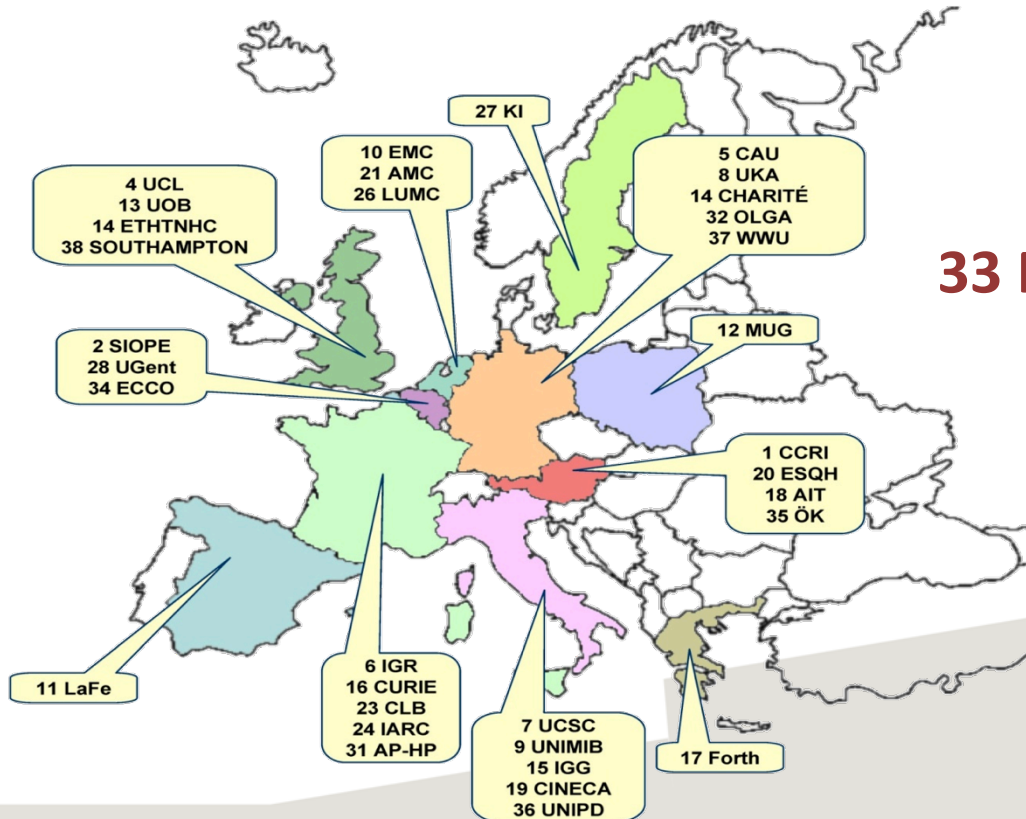
> 90% 2020

80% today

<10% < 1960



www.forscheneitkrebs.eu



FP7 “Network of Excellence”

Kick Off January 2011

33 Partners / 11 European Countries

18 WP: 80 Milestones

82 Deliverables



European Network for Cancer Research in Children and Adolescents

Objectives

- Improve both cure and quality of cure of children and adolescents suffering of cancer
- Facilitate access to:
 - Innovative therapies and tailored medicines
 - Standard care across Europe
- Develop biology-guided therapies
- Propose a European Virtual European Institute for Cancer Research in Children and Adolescents

WEBSITE: www.encca.eu



European Network for Cancer Research in Children and Adolescents

Home Project News & Events Team Community Education Dissemination and Deliverables Intranet

ENCCA

Tweets

Follow

 SIOPE @SIOPEurope 1h
#multidisciplinarity in Italy, le voci della ricerca a confronto @favo_it bit.ly/1brnpIW

 SIOPE @SIOPEurope 6 Dec
Lovely Vienna under the snow: #ENCCA & #ECRC meeting coming soon! siope.eu/?p=1176 bit.ly/1sHKF9

Tweet to @SIOPEurope



Important Announcement!

ENCCA General Assembly Meeting and ECRC meeting on 15 - 17 January 2014 in Vienna.

[REGISTER NOW](#)

Latest News

The TRANSCAN Call has been published: 'Translational research on tertiary prevention in cancer patients'



The ERA-NET TRANSCAN Third Joint Transnational Call for Proposals (JTC 2013) has been officially launched on the topic "Translational research on tertiary prevention in cancer patients". ... (more)

Search

Upcoming Events

JANUARY

ENCCA General Assembly Meeting and ECRC meeting
Location: Vienna
Time: 12:00 AM

15

www.encca.eu/

Joint 25th Annual Meeting of the I-BFM SG & 9th Biennial Childhood Leukemia Symposium



INTEGRATION: European Clinical Research Council

Chairs of European Paediatric Oncology Research Groups

CWS (Cooperative Weichteilsarkom Studiengruppe or Cooperative Soft Tissue Sarcoma Study Group)

I-BFM (The International BFM Study Group)

SIOPEL (SIOPE-Epithelial Liver Tumour Study Group)

EHL (European Hodgkins Consortium)

SIOPEN (SIOPE Europe Neuroblastoma Group)

EBMT (European Group for bone marrow and stem cell transplantation - Paediatric Working Party)

EpSSG (European Paediatric Soft Tissue Sarcoma Study Group)

ITCC (Innovative Therapies for Children with Cancer)

EICNHL (European Inter-group cooperation on childhood and adolescent Non Hodgkin Lymphoma)

EURAMOS (osteosarcoma)

EWOG-MDS (myelodysplasia)

Germ Cell Tumours

EURO-E.W.I.N.G.

SIOPEL-RTSG (SIOPE Wilms Tumour)

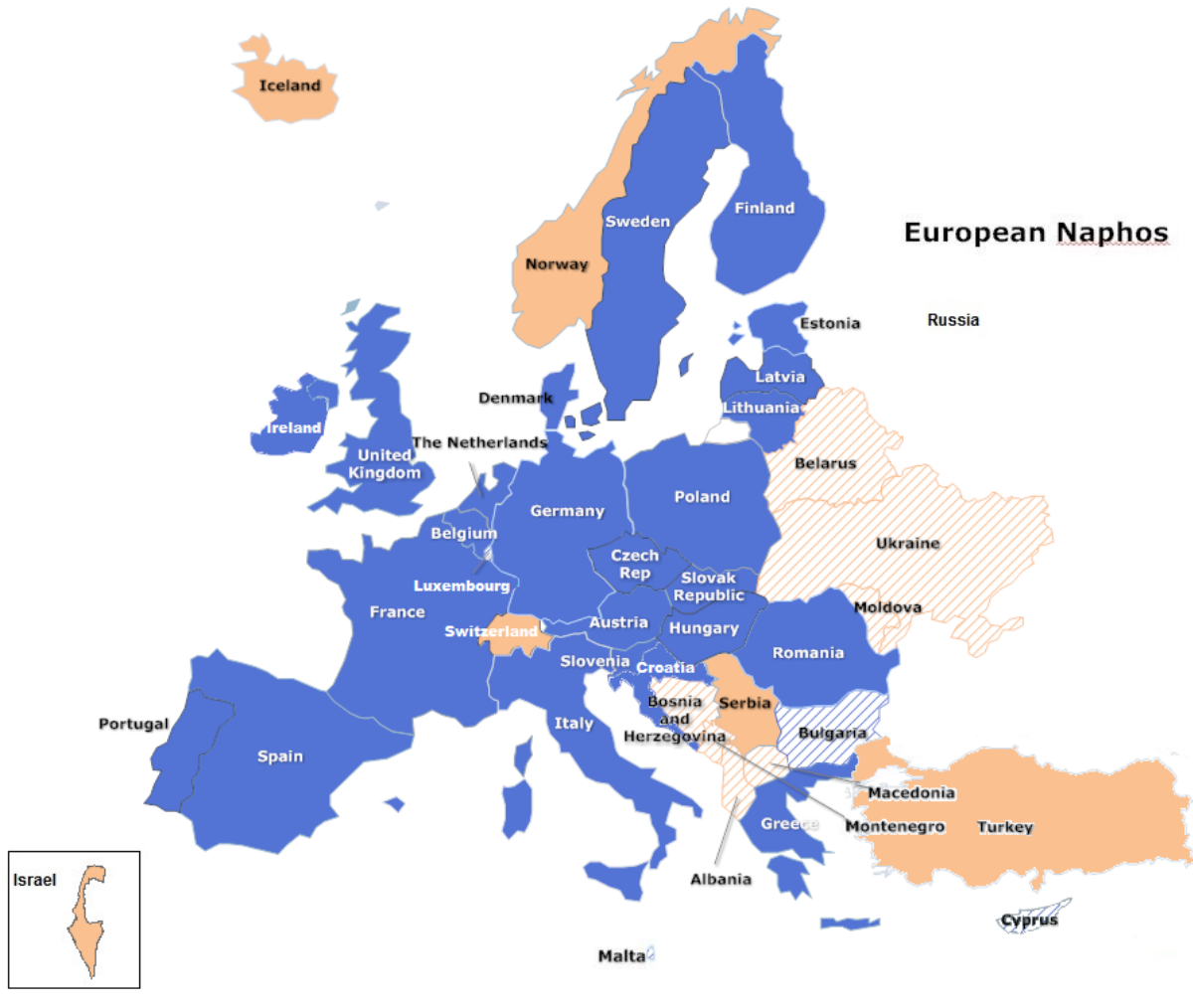
Histiocyte Society

UK Novel Agents Subgroup

SIOPEL Brain tumour group



INTEGRATION: European Clinical Research Council Chairs of the National Societies of Paediatric Haemato-Oncology in Europe



- **Blue or pink:** European countries with NaPHOS (blue: in EU / pink: non-EU)
- **Dashed countries:** European countries without a NaPHOS





***NEXT LEVEL:
European Reference Networks (ERN):
Aim of Article 12:
(Directive Patient's Rights to Cross border Healthcare)***

- ✓ Support the development of European Reference Networks
- ✓ Improving access to highly specialised healthcare for patients suffering of diseases and conditions:
 - low prevalence/rare
 - complex and cost-intensive
 - requiring a particular concentration of expertise

The Call



4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

- European reference networks will link health care providers and centres of expertise in the Member States.
 - to improve access to diagnosis and provide high-quality health care to patients who have conditions that require a particular concentration of resources or expertise, especially where the expertise is rare and case volume low.
 - concentration of low-frequency or high complexity diagnostic and therapeutic procedures in services that have an adequate caseload and audited results.
 - It also covers an evaluation of outcomes.

ExPO-r-Net Consortium



18 Associated Partners	Name	Country
CCRI (<i>Coordinator</i>)	St. Anna Kinderkrebsforschung e.V.	Austria
SIOPE	European Society of Paediatric Oncology	Belgium
IGR	Institut Gustave-Roussy	France
MUL	Medical University of Lublin	Poland
HULAFE	Fundación para la Investigación Hospital Universitario La Fe	Spain
ULUND	Lund University	Sweden
AOPD	Azienda Ospedaliera di Padova	Italy
IGG	Istituto Giannina Gaslini	Italy
CAU	Christian-Albrechts-Universitaet zu Kiel	Germany
AIT	Austrian Institute of Technology	Austria
CINECA	Consorzio Interuniversitario	Italy
INT	Istituto Nazionale dei Tumori	Italy
KlinikumDo	Klinikum Dortmund GmbH	Germany
UCL	University College London	United Kingdom
UOB	Lund University	United Kingdom
ECRMF	European Cancer Research Managers Foundation	United Kingdom
Charité	Universitätsmedizin Berlin: Charité	Germany
ÖKKH	Österreichische Kinder-Krebs-Hilfe	Austria

Collaborating partners

Number	42	includes PARENTS& PATIENTS ADVISORY COMMITTEE (SIOPE/encca – PAC)
Eastern European	17%	
Western European	83%	

Parent Patient Advocacy Committee (PPAC)

Created at the 3rd European Member Meeting of ICCCPO in April 2012 in Schengen.



List of members (ICCCPO- Eurpean branch)

- **France:** **ARNOLD Frederic**, UNAPECLE,
- **Spain:** **BASSET Luisa** , Federacion Española de padres de Niños con Cáncer
- **Luxembourg,:** **COSTELLOE Jacqueline** , Een Häerz fir kriibskrank Kanner,
- **Bosnia and Hercegovina,** **KAMERIĆ Lejla**, The heart for the kids with cancer in FBiH, **KAMERIĆ Neira**, Cancer Survivor Network,
- **Greece:** **TSIROU Aimilia**, Kyttaro/Greek Survivors Association,

Expert advisors

- **Germany,** **BODE Gerlind**,
- **The Netherlands** **NAAFS-WILSTRA Marianne**

European Network for Cancer Research in Children and Adolescents



OVERALL AIM:



To reduce the current inequalities in survival by improving the quality of the current healthcare provided accross Europe , in particular European countries with lower healthcare.

Link pre-existing reference centres of excellence, seeking mechanism to facilitate provision of information and knowledge (ICT tools, e-Health) and offer patients cross-border best practice health interventions to patients and families when really indicated



Project goals

- ❑ **The ExPO-r-Net project will build a Paediatric Oncology (PO) European Reference Network (ERN) providing paramount requirements for 'Cross-border healthcare'**
 - **Provision of healthcare** to children and young people with cancer in a Member State other than the Member State of affiliation.
 - **Identification of the target groups** , i.e. **children with special diagnostic and therapeutic needs with conditions** requiring a particular concentration of resources or expertise, especially when the expertise with certain cancer conditions is rare and case volume low.
 - **Reduction of current inequalities** in childhood cancer survival and healthcare capabilities in different member states.
 - Establish a PO-ERN **linking pre-existing leukaemia & tumour reference centres with tumour boards** to provide cross border expertise. The latter is inherent to the Cooperative PO-Clinical Trial tumour and Leukaemia Groups which may contribute high-level diagnostic and medical expertise to rare childhood cancer populations.
 - **Improving access to high-quality health care for children with cancer** whose conditions require specialised resources or expertise not widely available due to low case volumes and lack of local resource.

Objectives



Nb	Title
1	Identifying the needs of rare childhood and young people cancer types and entity subgroups with experts of the ECTG (ECRC) by addressing also the challenges (costs, resources, psychological burden and ethical aspects).
2	Build a Paediatric Oncology ERN–roadmap to identified and certified reference sites and tumour boards.
3	Establishment of a Paediatric Oncology tumour board ERN working to common standards and using IT tools based on E-Health concepts for sharing and providing expertise and advise.
4	Defining the criteria for a common process for identification and certification of paediatric oncology expert centres in Europe .
5	The cross-border dimension of long-term follow-up of childhood cancer survivors in Europe: the survivorship passport as an instrument for crucial treatment and follow-up data.
6	Integrating very rare tumors and soft tissue sarcomas into an European reference network.

THEMES

Project Coordinator Ruth Ladenstein



Coordination

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Dissemination

Evaluation

WP4

WP5

WP6

WP7

WP8

Structure



3 Horizontal Work Packages		Leader
1	Coordination of the project	CCRI
2	Dissemination of the project	SIOPE
3	Evaluation of the project	UOB
5 Core Work Packages		Leader
4	Addressing needs and challenges of cross-border healthcare co-operations and current expert fragmentation.	CCRI
5	Paediatric Oncology tumour board ERN based on E -Health and ICT concepts for sharing and providing expert advice.	HULAFE
6	Defining criteria for a common process for identification and certification of PO expert centres in Europe.	MUL
7	Cross-border dimension of long-term follow-up: survivorship passport with crucial treatment & follow up data.	ULUND
8	Integrating children with very rare tumours in a European Reference Network.	AOPD



WP 4: CCRI



Addressing needs and challenges of cross-border healthcare co-operations and current expert fragmentation.

- ✓ Identifying special therapeutic needs of young people with cancer with experts of the ECTG (ECRC) requiring high expertise interventions (i.e. special surgery, radiotherapy (proton therapy), stem cell transplants).
- ✓ Addressing also the challenges (costs, resources, psychological burden and ethical aspects).
- ✓ Identify European institution ready to engage as reference centers by establishing a/o rolling out tumor boards .
- ✓ Identify European Institutions /hospitals offering top level expertise for special therapeutic interventions

Roadmap for public health care providers and patients



WP 5: La Fe



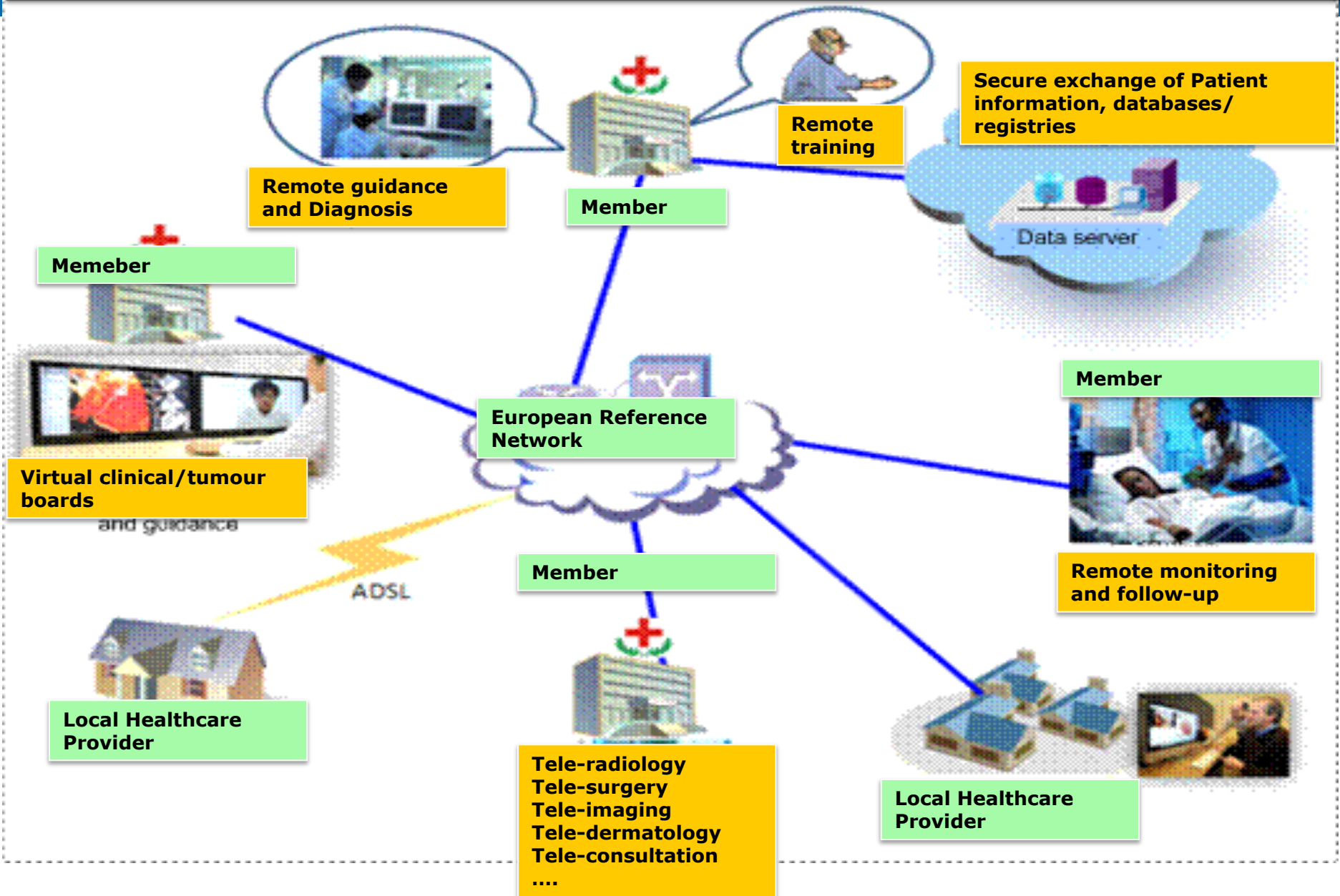
Paediatric Oncology tumour board ERN based on eHealth/ICT concepts for sharing and providing expert advice.

- ✓ To develop a strategy to build Expo-r-net TB as tools for providing access to expert care to all European children with cancer in a cross-border setting.
- ✓ Implementation of modern IT tool across borders will allow TB to share expert opinions for European children with cancer in need of special cross-border settings..



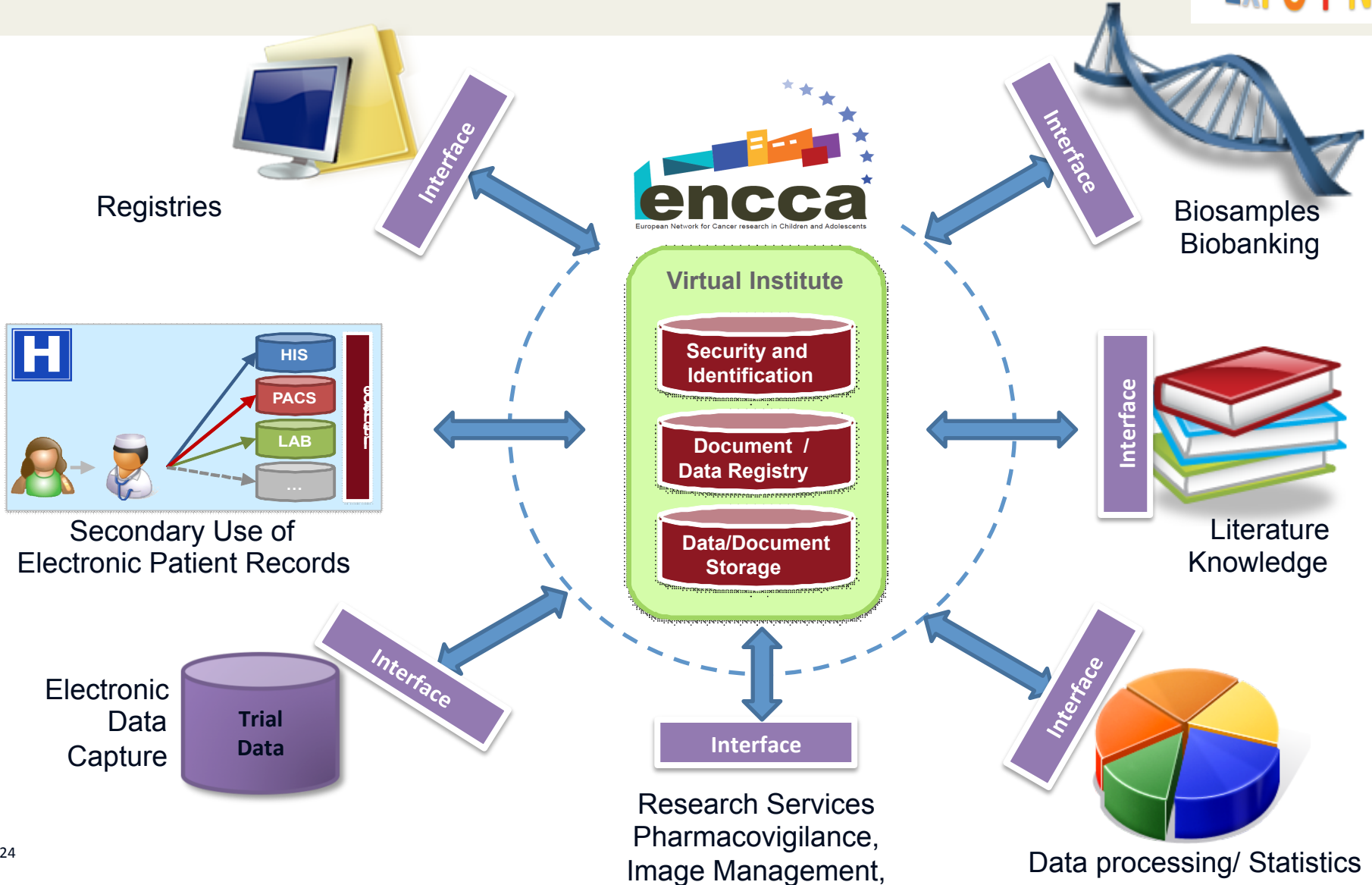
Expo-r-net Tumor Boards= Hubs of expertise

Telemedicine and other IT solutions and tools are the basis for this project





Elements of a Biomedical Research Infrastructure



What could be a solution for ERN requirements ?



This situation is similar to healthcare ...

→ Adoption of a solution based on the

Integrating the **Healthcare Enterprise (IHE)**

IHE Integrating
the Healthcare
Enterprise

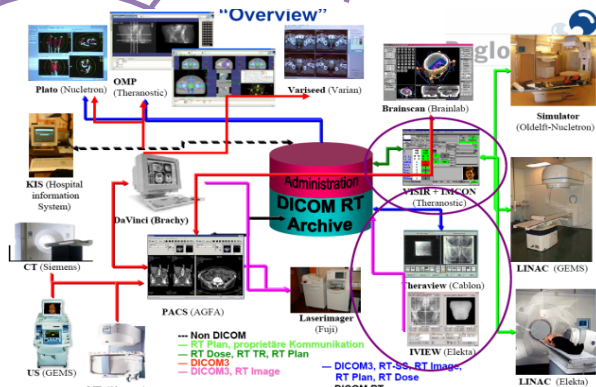
www.ihe.net

Integrating the Healthcare Enterprise

- IHE is designed for **interoperability**
- IHE is already **established and approved** in healthcare
- IHE is based on **standards commonly used** in healthcare and biomedical research
- IHE represents a **fully open approach**

- Integration of data
 - document based repository
 - no complete database model needed upfront
 - Takes care of the diversity of data, processes and research questions
 - Well poised for secondary use of data

ICT Landscape



Institutional IT Systems



IHE Integrating the Healthcare Enterprise

Interoperability Initiatives

Directive 95/46/EC

ELGA-G

Directive 2011/24/EU

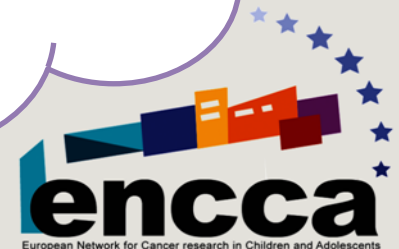
National and international Regulations



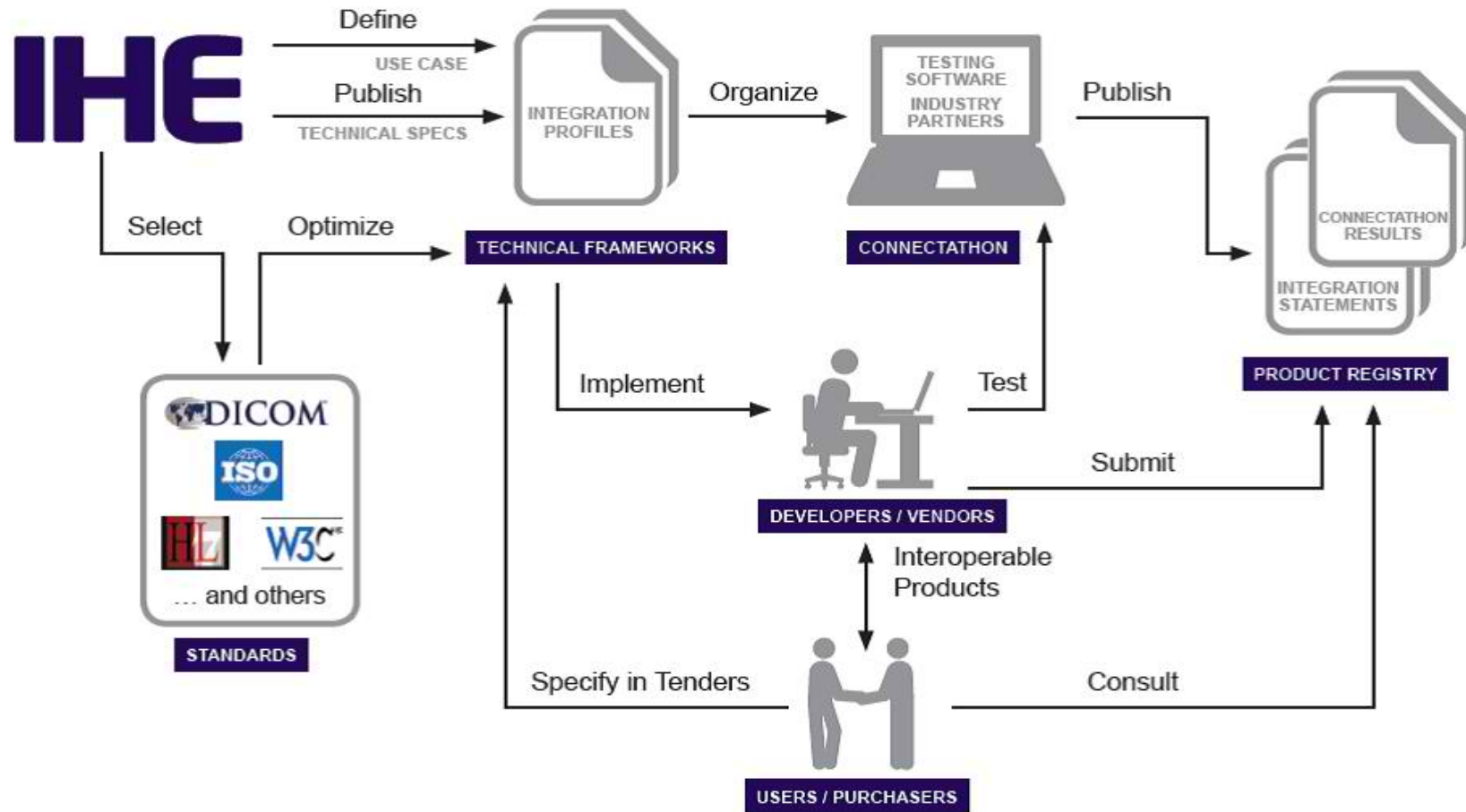
Meine elektronische Gesundheitsakte



Health Information Exchange Systems



IHE - Integrating the Healthcare Enterprise



WP 6: Lublin



To promote high quality patient care in paediatric oncology centres through a recognised system of assessment and to reduce inequalities in care among centres and countries

- ✓ Build a Ped O ERN-roadmap to identify reference centers and tumor boards.
- ✓ Define relevant PO eligibility criteria and conditions for assessment
- ✓ .



Outcome: A European PO ERN expert reference manual.



WP 7: ULund



Cross-border dimension of long-term follow-up: survivorship passport with crucial treatment & follow-up data.

- ✓ To build a virtual paediatric oncology expert reference network for late effects after treatment for cancer in childhood and adolescence
- ✓ To translate the Survivorship passport and relevant Guidelines into multiple European languages

The Survivorship Passport



- Riccardo Haupt
- Silvia Caruso
- Francesca Bagnasco

IGG

- Giulia Stabile
- Maurizio Ortali
- Davide Saraceno
- Roberta Amato

CINECA

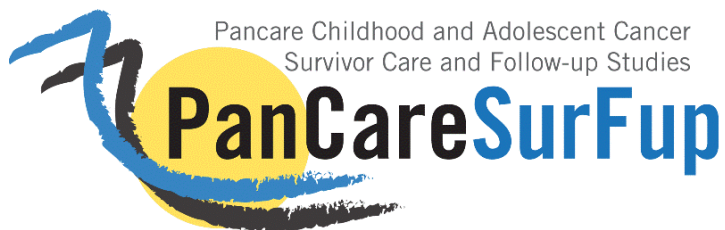
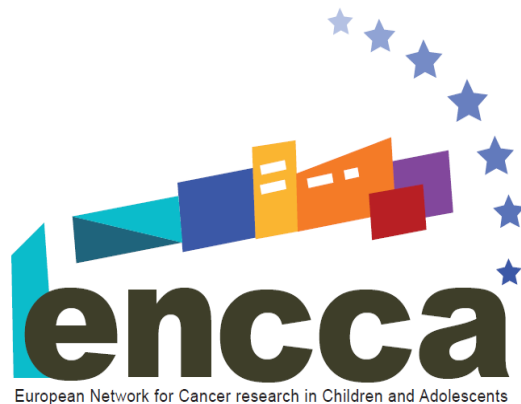
- Sabine Karner
- Anita Kienesberger

ICCCPO

All partners of:

ENCCA: WP 13

PanCareSurFup: WP6



Diagnosis



The survivorship passport

DE | EN | IT
Ospedale Gaslini - Genova
User: Riccardo Haupt

Log out

Home >> Passports list >> Passport's View >> Diagnosis

N. passport	Initials	Date of Birth	Date of Registration	Diagnosis
IT001201304121011	DOE JHON	21/03/1999	12/04/2013	-

DIAGNOSIS FORM

Fields containing * are mandatory.

Date of diagnosis* dd/mm/yyyy

Primary treatment Center* ▼

DIAGNOSIS

Cancer category*

Diagnosis*

Diagnosis description

Cancer category according to ICCC-3 diagnostic group/division

SITE

Site description

Laterality

DETAILS

Summary and Events after elective end of therapy

N. passport	Initials	Date of Birth	Date of Registration	Diagnosis
IT00120130227997	MARK SMITH	18/01/2009	27/02/2013	

Demographics



Demographic data

Diagnosis



Diagnosis

Clinical course



Front line treatment



Chemotherapy (from 05/02/2011 to 06/04/2012)



Stem Cell transplantation n.1 (03/09/2011)



New: Stem Cell transplantation



Radiation Therapy



New: Radiation Therapy



Surgery



New: Surgery



Relapse/Progression n.1 (01/11/2011)



New: Relapse/Progression



New: Other relevant clinical events



Medical suggestions

Relapse after first elective end of treatment



Relapse/Progression

Second malignant tumor



Second malignant tumor

In case of relapse/progression after first elective end of treatment) a separate form is available





The survivorship passport

Data integration options

- Integration with existing data flows through **standard format files**
- Automatic or on-demand **data import** from local databases to Passport central database
- **Integration** with Clinical Trials databases
- **DB download** for hospitals according to data access rules
- Possibility to develop specific web services for seamless data integration

Clinical Recommendations for Follow- Up



STRONG recommendation “*is recommended*”

MODERATE recommendation “*is reasonable*”

WEAK recommendation “*may be reasonable*”

NOT TO DO recommendation “*is not recommended*”

The Survivorship Passport

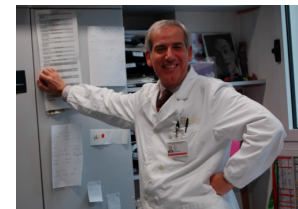
Present status and future vision?



- A template for the individual patient at the moment of the elective end of therapies containing standardized and condensed cancer history and relevant therapy information
- Paper and electronic based, potentially including images and other relevant medical source documents.
- To provide advice and guidance on patient-specific long-term follow-up of possible late effects
- **All languages of the EU ⇒ ExPO-r-Net**
- **Integration into future eHealth based platforms & tools for the survivor population allowing life long best possible care based on accurate information and paying tribute to Europe mobility**



WP 8: Padova



Integrating children with very rare tumours in a European Reference Network

through the identification and connection of Pediatric Oncology Centres and
Cooperative Groups with the necessary expertise

with the aim

to provide accurate diagnosis and evidence-based treatment to children with
VRT in Europe (and worldwide)

Creation of a European Cooperative Group devoted to VRT

VISION: OVERCOME INEQUALITIES IN EUROPE



**A huge task and role
for Information Technologies
to treat Childhood Cancer and to improve outcomes!**

Special thanks to IT partner
in Clinical Trial Management and
European Framework Projects
for more than a decade



Summary

Project expected impact

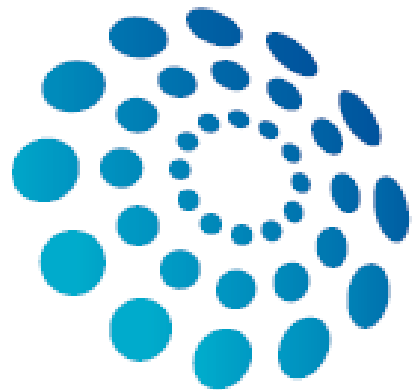


□ The strategic relevance

- Generation of information and provision of a framework for the PO-ERN to improve standards of care for children and young people with cancer.
- Next level of integration within Pediatric Oncology
- Follow up and advise for childhood cancer survivors allowing integration of outcomes research

□ The innovative contribution

- A clear **roadmap** to approved expert referral sites and tumour advisory boards for healthcare providers = **Pediatric Oncology ERN Network**
- **Fostering eHealth solutions based on interoperability and standardisation to allow well functioning tumour boards**



European Reference Networks



European Reference Networks

- ❖ **Network**
Rare neuromuscular
diseases
(Malattie
neuromuscolari
rare)
- **Member**
Azienda Ospedaliera
Universitaria di Pisa
— Italy