

# PARENT – Joint Action cross-border PATient REGistries iNiTiative

**5th HTA Network meeting,  
Paris, 29 October 2015**

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# Context

The need for the EU activities on cross border registries:

- Health policy must be based on the best **scientific evidence** (EU Health Strategy 2008-2013)
- It is essential to systematically collect, process and analyse **comparable data** (2<sup>nd</sup> Health Programme)
- PARENT JA was a response to an explicit request for tackling major health challenges more effectively, through information sharing and exchange of expertise and best practice
- Added value to the existing knowledge of registries' development and enhancing its use

# Patient registries - definition

## Patient registries:

**“organized system** that collects, analyses, and disseminates the **data and information** on a group of people defined by a particular disease, condition, exposure, or health-related service, and that **serves a predetermined scientific, clinical or/and public health (policy) purposes”**.

*Source: "Methodological guidelines and recommendations...", page 14*  
*[http://parent-wiki.nijz.si/index.php?title=2\\_Patient\\_registries](http://parent-wiki.nijz.si/index.php?title=2_Patient_registries)*

# Registries – a tool to help the collection of HTA relevant data

- **Registries** could serve HTA as a source of data on:
  - Real life safety and clinical effectiveness
  - Rare events
  - Long term data
  - Help in collecting data for later assessments
- An absolute necessity for registry data used in HTA is that registries **publish studies** based on the use of their data

# Patient registries – the challenges

**Unstable funding** and therefore limited sustainability  
Differences in content, semantics (meaning) and quality  
Modes of data **collection** and **delays** in data availability



Poorly comparable and interoperable, **data access** for research purposes is **limited, insufficient data dissemination**



Data exchange or aggregation across organizations, regions and countries **for secondary purposes** difficult to perform

# Joint Action PARENT

**A joint effort by MS and the EC to provide MS guidelines on improving registry interoperability and use of data for secondary purposes in a cross-border setting**

05/2012 - 11/2015

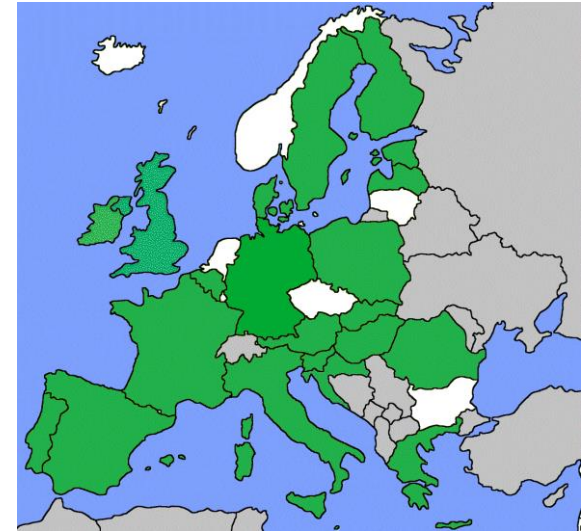
Budget: 3.4 Mio € (60% EC)

11 Associated partners

12+ Collaborating partners

**PARENT Associated Projects Group:**

EARN, EPIRARE (and RD-CONNECT), EUREMS, EUCERD JA, EUBIROD, EUROCISS, EPAAC, EuraHS, eHGI, epSOS, **EUnetHTA**, SHN, EHR4CR (and EMIF)

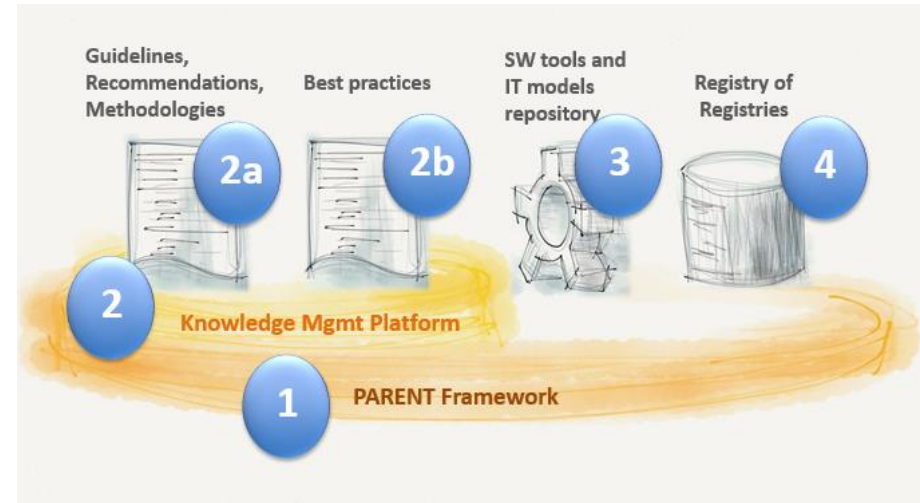


**PARENT collaboration:**

NICE UK, CPME, ESIP, EFPIA, EBE, EUREGHA, HIQA Ireland, etc

# Key PARENT JA deliverables

- IT tool: “**Registry of Registries**” with the Assessment Tool
- Methodological **Guidelines and Recommendations** for efficient and rational governance of patient registries
- **Sustainability** and support of Directive on Patient Rights in cross-border healthcare



“Policy paper with recommendations”

# Registry of Registries (RoR)

**PARENT RoR:**  
is a **web service** to  
ensure up-to-date  
information about  
**patient registry  
metadata**

The second version with included **assessment tool** will  
**have new functionalities like:**

- Registry benchmarking
- Registry quality assessment
- Registry interoperability readiness assessment

Available on: [www.parent-ror.eu](http://www.parent-ror.eu)



## BROWSE REGISTRIES

	Short registry name (English)	Country of operation	Primary purpose	Total number of cases	Total number of active cases	Primary observational unit	Governing board	Data linked from other sources	Part
<input type="checkbox"/>	TestReg13	Denmark	Surveillance	13000	13000	A person / patient, A hospital discharge or a	Yes	Yes	Yes
<input type="checkbox"/>	HU Database of the Hungarian Neonatal Int	Hungary	Statistics	40000	35000	A person / patient	No	No	
<input type="checkbox"/>	HU TBC Surveillance System	Hungary	Surveillance	8473	901	A person / patient	Yes	No	
<input type="checkbox"/>	ES Girona Heart Registry	Spain	Surveillance	5000	3000	A person / patient	Yes	Yes	
<input type="checkbox"/>	HU Hungarian Pediatric Cancer Registry	Hungary	Statistics	10750	5000	A person / patient	Yes	Yes	
<input type="checkbox"/>	HR Causes of death registry	Croatia	Statistics	581124	581124	A person / patient		Yes	
<input type="checkbox"/>	HR Vaccine Adverse Event Registry	Croatia	Surveillance	3612		An event (please specify), AEFI	Yes	No	
<input type="checkbox"/>	HR CroDiab	Croatia	Surveillance	150000	110000	A person / patient	Yes	Yes	
<input type="checkbox"/>	National Penile Cancer Registry	Sweden	Statistics	1997	1997	A person / patient	Yes	Yes	
<input type="checkbox"/>	WebRehab	Sweden	Outcome	18000	18000	A person / patient	Yes	Yes	
<input type="checkbox"/>	LV Register of the patients with cancer	Latvia	Statistics	312345	70860	A person / patient	No	Yes	
<input type="checkbox"/>	LV Register of the patients with multiple scler	Latvia	Statistics	1825	1624	A person / patient		Yes	
<input type="checkbox"/>	LV Register of the patients with congenital a	Latvia	Statistics	12140		A person / patient	No	Yes	
<input type="checkbox"/>	HU Drug-related mortality	Hungary	Statistics			A person / patient	No	No	
<input type="checkbox"/>	HU TDI Database	Hungary	Statistics			An event (please specify),	No	No	

### Views

- List
- Compare
- Advanced search
- Compare by survey topic

- All registries in RoR
- Selected registries

### Choose comparison fields

- Country of operation
- Primary purpose
- Other purpose(s)
- Type of holder
- Current funding source
- Registry started in
- Currently collecting data
- Total number of cases
- Total number of active cases
- Average no. of new cases (yr)
- Sources of registry data
- Geographical coverage
- Registry type
- Primary observational unit
- Governing board
- Minimum data set
- Data security policies, and procedures
- Data linked from other sources
- Participation in a network of registries
- Sharing data with interested parties
- Registry metadata standards

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HR Causes of death registry 🔗 ✕

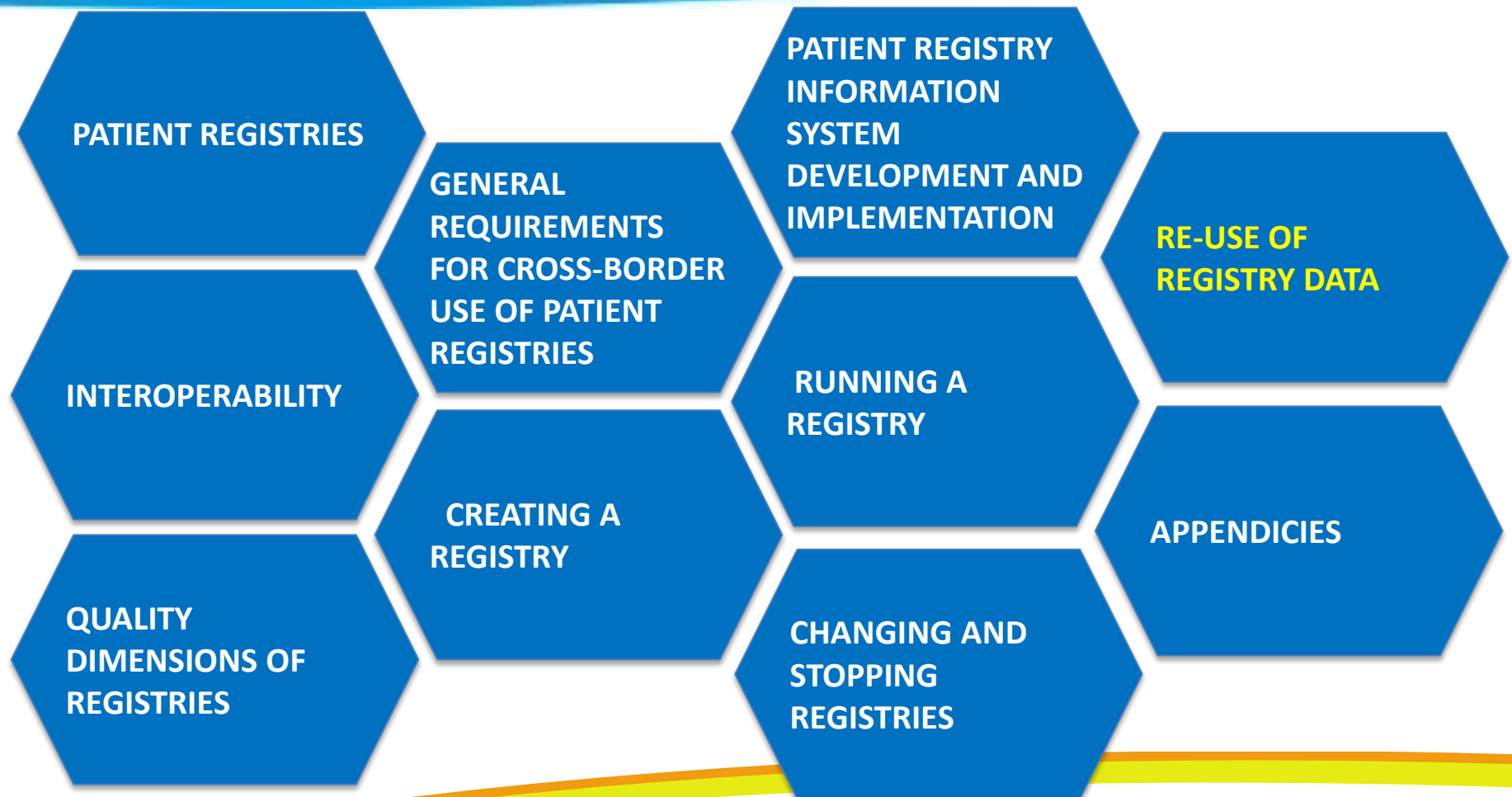
<b>Country of operation</b>	Croatia	<b>Registry started in</b>	
<b>Currently collecting data</b>	Yes	<b>Geographical coverage</b>	National
<b>Primary observational unit</b>	A person / patient	<b>Governing board</b>	
<b>Sharing data with interested parties</b>	No	<b>Data model documented</b>	

# The Methodological Guidelines - background

- **Target group:** registry holders, researchers, healthcare providers, developers, competent authorities responsible for registries
- **Prepared** by PARENT JA partners and few individual experts; approximately 40 authors
- **The process** of the preparation quite complex with a lot of coordination; several workshops/presentations organized to support the writing process
- **External review** by three appointed reviewers and several other experts
- **Final version:** version 1.0; 231 pages



# Methodological guidelines – content capture





# Re-use of registry data – key principles

- Re-use of information: some information collected for a given purpose is to be used for another one
- Registries are realisations of information re-use
- Cross-border use of data:
  - for **public health** (surveillance, alerts, bioterrorism threat, identification of best and cost-effective practices...),
  - for **research** purposes (risk factor studies, genetic research, clinical and therapeutic research),
  - **HTA** purposes
- Issues: compatibility, comparability and interoperability

# How PARENT deliverables can contribute to HTA?

- Do relevant registries exist already? (RoR)
- Is there a need to upgrade/change existing registries to facilitate HTA re-assessments? (RoR, Guidelines)
- Generate new evidence (Guidelines)
- Development of the quality standards (Guidelines)

# How PARENT can contribute to HTA?

- Address the issues of availability of data to support **HTA**
- **Investigate and enhance the linkage between registries and planned HTA work**
- Establish a **process of notification** of registries with regard to **emerging/new technologies (RoR)**
- Upgrade/improve guidelines with necessary elements for **HTA core model**

***The advantage of PARENT: link the HTA needs with the registry holders and improve data quality and limit procedural barriers.***

# Re-use of PARENT instruments

## JA PARENT deliverables and the potential "customers":

JRC	EMA	HTA community	eHealth	European Reference Networks	CEF
Registries' platform (for rare diseases and cancer)	Framework on Registries: pilots	JA III on HTA, WP5 on Evidence Generation	National Contact Points for eHealth to include registries  (?)	Guidelines and methodologies needed and to be used by all Networks	Sustainability of the PARENT tool "Registry of Registries"  (?)



# PARENT Recommendations: HTA feedback

- **Encourage collaboration** between the registries and other stakeholders;
- Set up a **permanent mechanism** for regular updating of the Guidelines and monitoring the implementation;
- Strengthen the **collaboration** and integrate PARENT JA deliverables with the work in which the **JRC** (Joint Research Centre) is currently engaged in the area of cancer registries and rare disease registries;
- Strengthen the collaboration with **EMA** ("EMA Registry Framework") and **EUnetHTA 3**.
- **Pilot** the PARENT deliverables on some test cases
- Explore the concept of **National Contact Points** and the **CEF (Connecting Europe Facility) funding**

Thank you for your attention



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