PARENT – Joint Action
cross-border PAtient REgistries iNiTiative

5th HTA Network meeting,
Paris, 29 October 2015

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With the contribution of Persephone Doupi, Haralampos Karanikas and Ivan Pristaš

www.patientregistries.eu
Context

The need for the EU activities on cross border registries:

• Health policy must be based on the best \textit{scientific evidence} (EU Health Strategy 2008-2013)

• It is essential to systematically collect, process and analyse \textit{comparable data} (2\textsuperscript{nd} 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:

“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
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
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”
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
<table>
<thead>
<tr>
<th>Short registry name (English)</th>
<th>Country of operation</th>
<th>Primary purpose</th>
<th>Total number of cases</th>
<th>Total number of active cases</th>
<th>Primary observational unit</th>
<th>Governing board</th>
<th>Data linked from other sources</th>
<th>Part</th>
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</thead>
<tbody>
<tr>
<td>TestReg13</td>
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<td>Surveillance</td>
<td>13000</td>
<td>13000</td>
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<td>Hungary</td>
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<td>Hungary</td>
<td>Surveillance</td>
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<td>901</td>
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<td>No</td>
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<td>5000</td>
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<td>Yes</td>
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<td>581124</td>
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<td>Yes</td>
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<tr>
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<td>Croatia</td>
<td>Surveillance</td>
<td>150000</td>
<td>110000</td>
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<td>Yes</td>
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<td>1997</td>
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<td>Sweden</td>
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<td>18000</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
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<td>Statistics</td>
<td>312345</td>
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<td>No</td>
<td>Yes</td>
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<td>LV Register of the patients with multiple sclerosis</td>
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<td>Statistics</td>
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<td>1524</td>
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<td>LV Register of the patients with congenital anomalies</td>
<td>Latvia</td>
<td>Statistics</td>
<td>12140</td>
<td>A person / patient</td>
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<td>HR Drug-related mortality</td>
<td>Hungary</td>
<td>Statistics</td>
<td>12140</td>
<td>A person / patient</td>
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</table>

**HR Causes of death registry**

- **Country of operation**: Croatia
- **Currently collecting data**: Yes
- **Primary observational unit**: A person / patient
- **Sharing data with interested parties**: No

**Registry started in**

- **Geographical coverage**: National
- **Governing board**: Yes
- **Data model documented**: Yes
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

- Patient Registries
- General Requirements for Cross-Border Use of Patient Registries
- Creating a Registry
- Patient Registry Information System Development and Implementation
- Running a Registry
- Changing and Stopping Registries
- Interoperability
- Quality Dimensions of Registries
- Appendices
- Re-Use of Registry Data
Cloud representation of the Guidelines
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-assesments? (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":

<table>
<thead>
<tr>
<th>JRC</th>
<th>EMA</th>
<th>HTA community</th>
<th>eHealth</th>
<th>European Reference Networks</th>
<th>CEF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registries' platform (for rare diseases and cancer)</td>
<td>Framework on Registries: pilots</td>
<td>JA III on HTA, WP5 on Evidence Generation</td>
<td>National Contact Points for eHealth to include registries (?)</td>
<td>Guidelines and methodologies needed and to be used by all Networks</td>
<td>Sustainability of the PARENT tool &quot;Registry of Registries&quot; (?)</td>
</tr>
</tbody>
</table>
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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WEB: www.patientregistries.eu
Twitter: @ParentJA