PARENT Joint Action

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1st EUBIROD Network General Assembly
24th August 2015, University of Surrey, Guildford, Surrey, UK

PARENT (PAtient REgistries iNiTiative) - background

A Joint Action co-funded by the European Commission and some Member States (May 2012- November 2015).

- **Overall objective**:
  - to support the EU Member States in developing comparable and interoperable patient registries in clinical fields of identified importance (e.g. chronic diseases, medical technology).
- **Aim**:
  - to rationalize the development and governance of interoperable patient registries, thus enabling the use of secondary data for public health and research purposes in cross-organizational and cross-border setting
- **EUBIROD group** is a member of Associated Project Group (APG) of PARENT JA.

Key issues patient registries experience

- unstable funding and therefore limited sustainability
- many legal issues concerning registry set-up, data protection and re-use; legal backgrounds in MS differ a lot
- roles of registry stakeholders although very important, often not very clear
- various modes of data collection, access and sharing
- lack of alignment to standards (process, semantic)
- data quality and context
- transparency and information quality

PARENT Framework

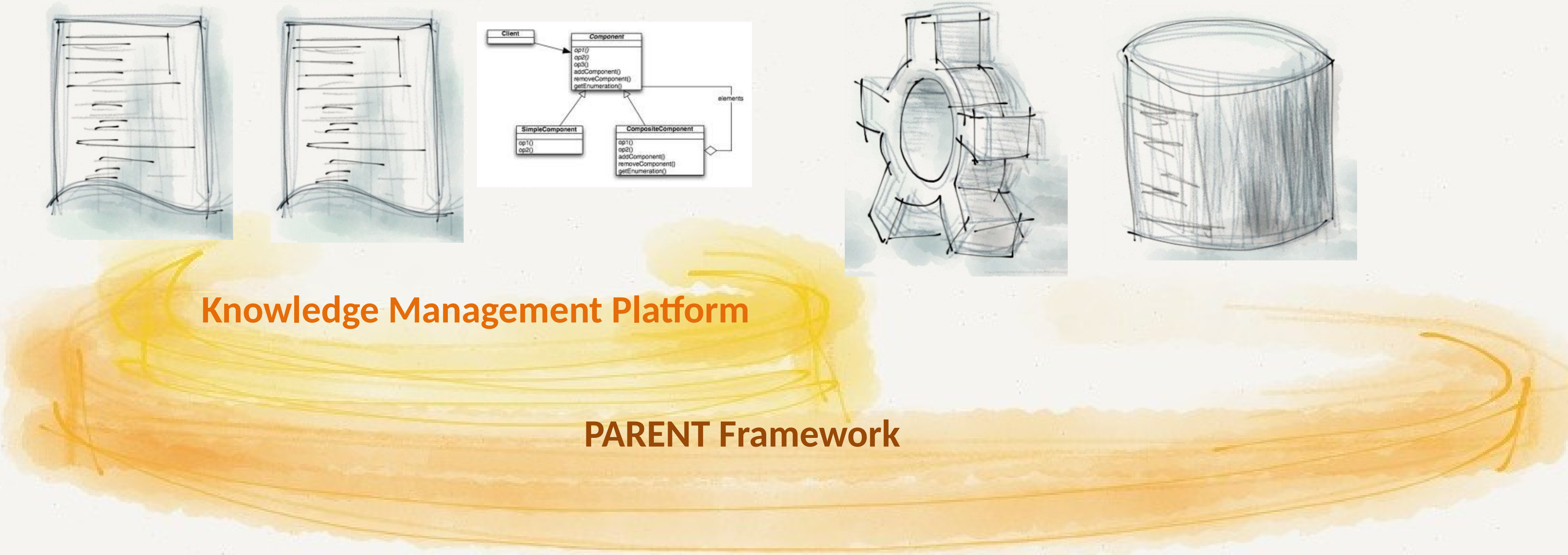
Guidelines,
Recommendations,
Methodologies

Best
practices

Information models,
ontologies,
vocabularies

Services, SW
tools repository

Registry of
Registries,
Assessment Tool

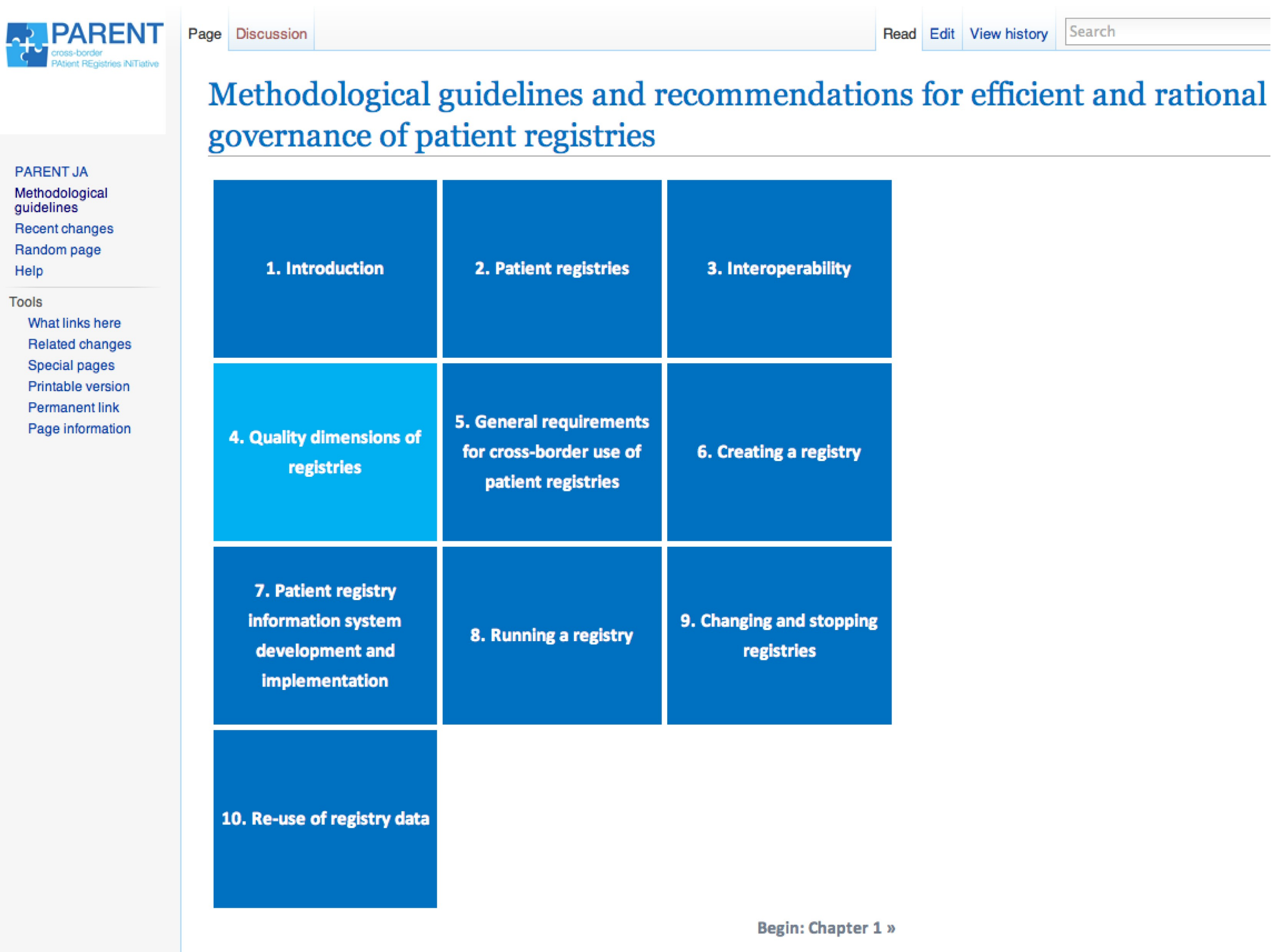


Knowledge Management Platform

PARENT Framework

1. Methodological guidelines

- Target group: registry holders, researchers, healthcare providers, developers, competent authorities responsible for registries
- Prepared by PARENT JA partners - Croatia, Finland, Greece, Hungary, Slovenia, Spain and some experts; approximately 40 authors
- PDF and Wiki tool
- Available in October 2015
- Future: potential implementation/pilot testing within EMA, EUnetHTA



PARENT JA
Methodological guidelines
Recent changes
Random page
Help

Tools
- What links here
- Related changes
- Special pages
- Printable version
- Permanent link
- Page information

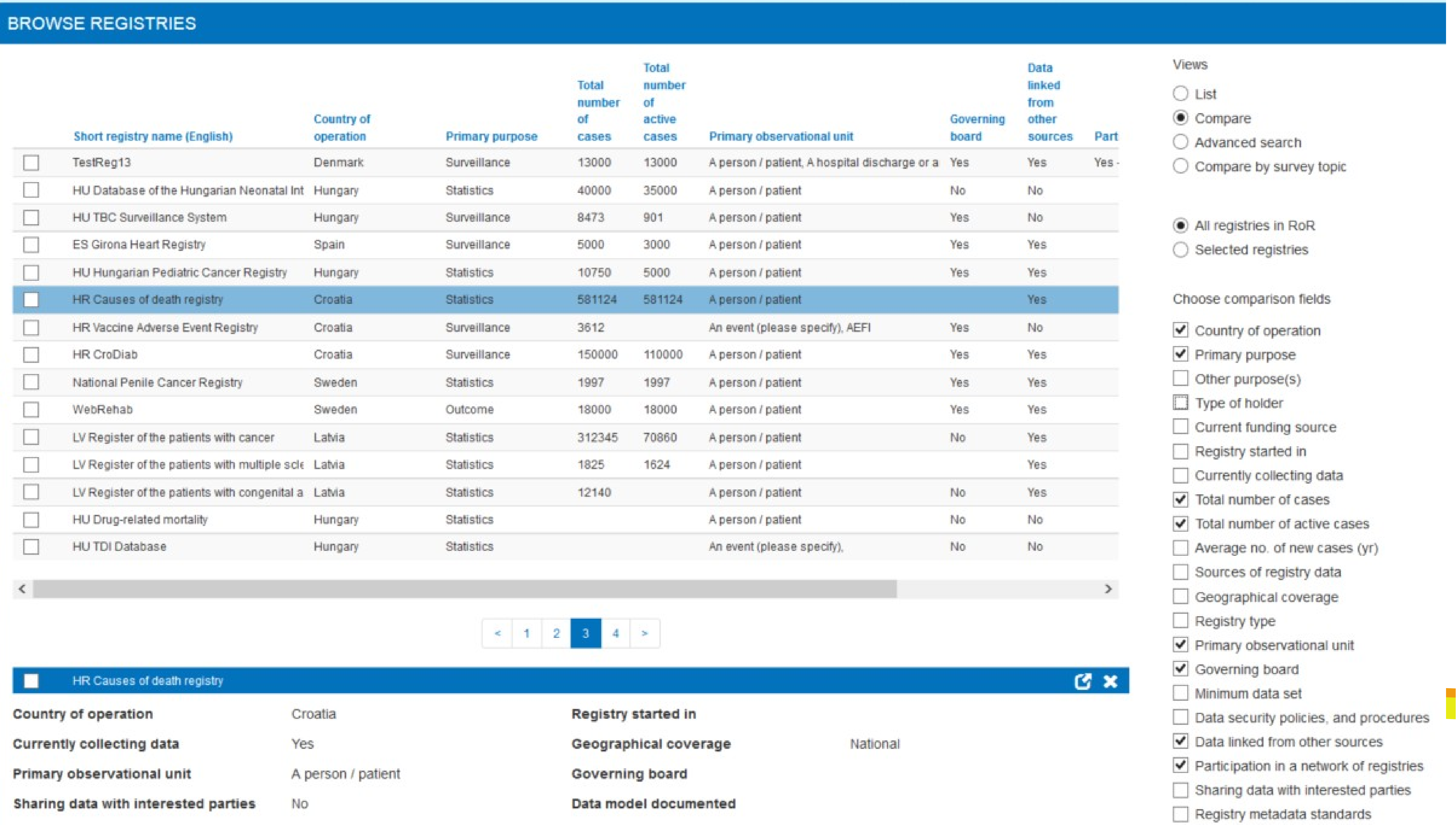
Methodological guidelines and recommendations for efficient and rational governance of patient registries

1. Introduction	2. Patient registries	3. Interoperability
4. Quality dimensions of registries	5. General requirements for cross-border use of patient registries	6. Creating a registry
7. Patient registry information system development and implementation	8. Running a registry	9. Changing and stopping registries
10. Re-use of registry data		

Begin: Chapter 1 »

2. Registry of Registries (RoR)

(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
☐	TestReg13	Denmark	Surveillance	13000	13000	A person / patient, A hospital discharge or a	Yes	Yes	Yes -
☐	HU Database of the Hungarian Neonatal Int	Hungary	Statistics	40000	35000	A person / patient	No	No	
☐	HU TBC Surveillance System	Hungary	Surveillance	8473	901	A person / patient	Yes	No	
☐	ES Girona Heart Registry	Spain	Surveillance	5000	3000	A person / patient	Yes	Yes	
☐	HU Hungarian Pediatric Cancer Registry	Hungary	Statistics	10750	5000	A person / patient	Yes	Yes	
☐	HR Causes of death registry	Croatia	Statistics	581124	581124	A person / patient		Yes	
☐	HR Vaccine Adverse Event Registry	Croatia	Surveillance	3612		An event (please specify), AEFI	Yes	No	
☐	HR CroDiab	Croatia	Surveillance	150000	110000	A person / patient	Yes	Yes	
☐	National Penile Cancer Registry	Sweden	Statistics	1997	1997	A person / patient	Yes	Yes	
☐	WebRehab	Sweden	Outcome	18000	18000	A person / patient	Yes	Yes	
☐	LV Register of the patients with cancer	Latvia	Statistics	312345	70860	A person / patient	No	Yes	
☐	LV Register of the patients with multiple scle	Latvia	Statistics	1825	1624	A person / patient		Yes	
☐	LV Register of the patients with congenital a	Latvia	Statistics	12140		A person / patient	No	Yes	
☐	HU Drug-related mortality	Hungary	Statistics			A person / patient	No	No	
☐	HU TDI Database	Hungary	Statistics			An event (please specify),	No	No	

☐ HR Causes of death registry

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

Views

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

- ● All registries in RoR
- ○ Selected registries

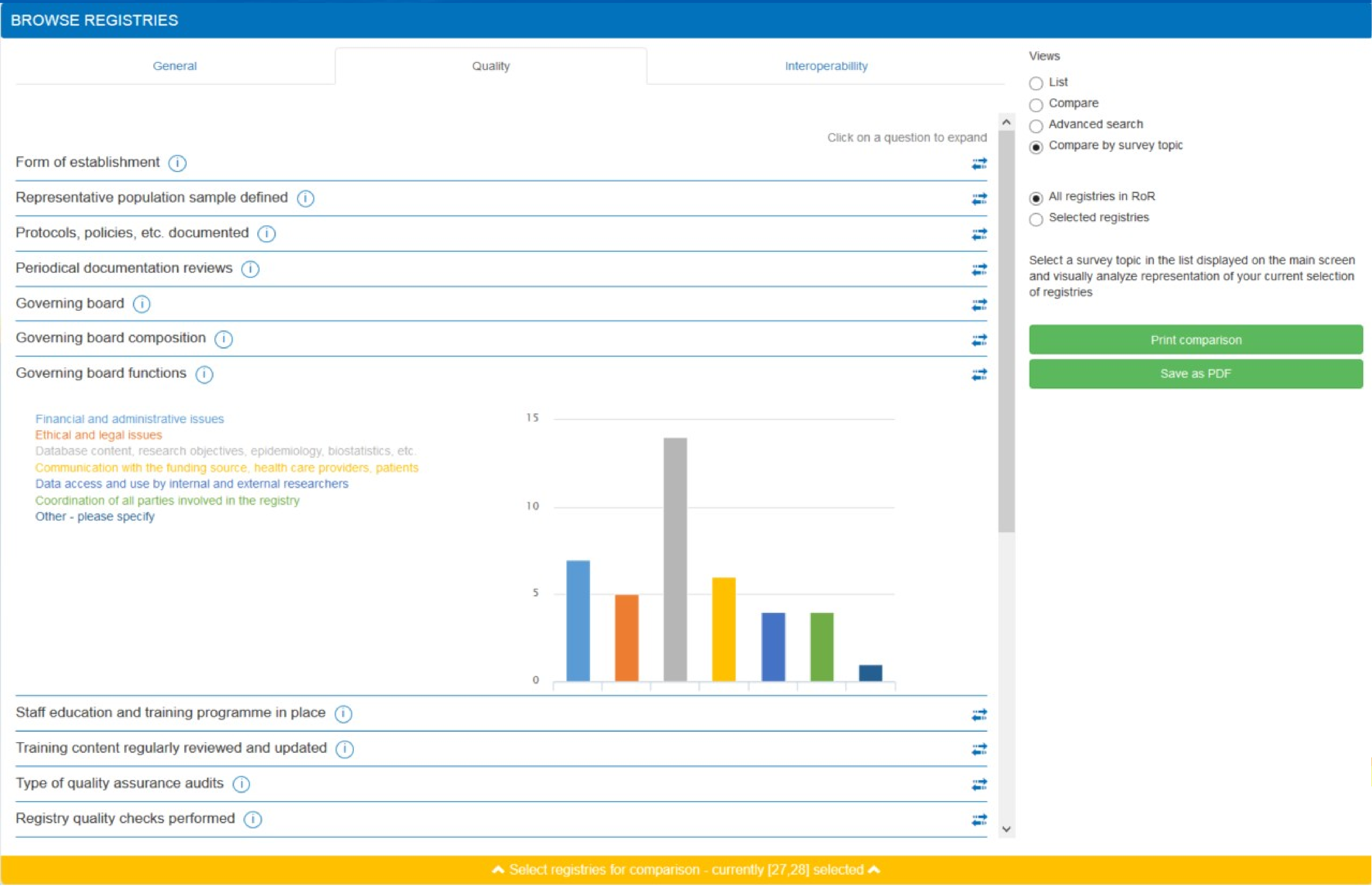
Choose comparison fields

- ☑ 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

RoR 2 - Core services

- **Registry browsing:** search, registry details, registry metadata, customizable comparison tool
- **Services:**
  - registry quality and interoperability readiness assessment
  - data dictionary access
  - registry benchmarking
  - alignment with PARENT Guidelines
  - repository of archetypes (clinical models in openEHR) that can be reused

Descriptive statistics



BROWSE REGISTRIES

General | Quality | Interoperabillity

Click on a question to expand

Form of establishment ⓘ

Representative population sample defined ⓘ

Protocols, policies, etc. documented ⓘ

Periodical documentation reviews ⓘ

Governing board ⓘ

Governing board composition ⓘ

Governing board functions ⓘ

- Financial and administrative issues
- Ethical and legal issues
- Database content, research objectives, epidemiology, biostatistics, etc.
- Communication with the funding source, health care providers, patients
- Data access and use by internal and external researchers
- Coordination of all parties involved in the registry
- Other - please specify

Staff education and training programme in place ⓘ

Training content regularly reviewed and updated ⓘ

Type of quality assurance audits ⓘ

Registry quality checks performed ⓘ

Views

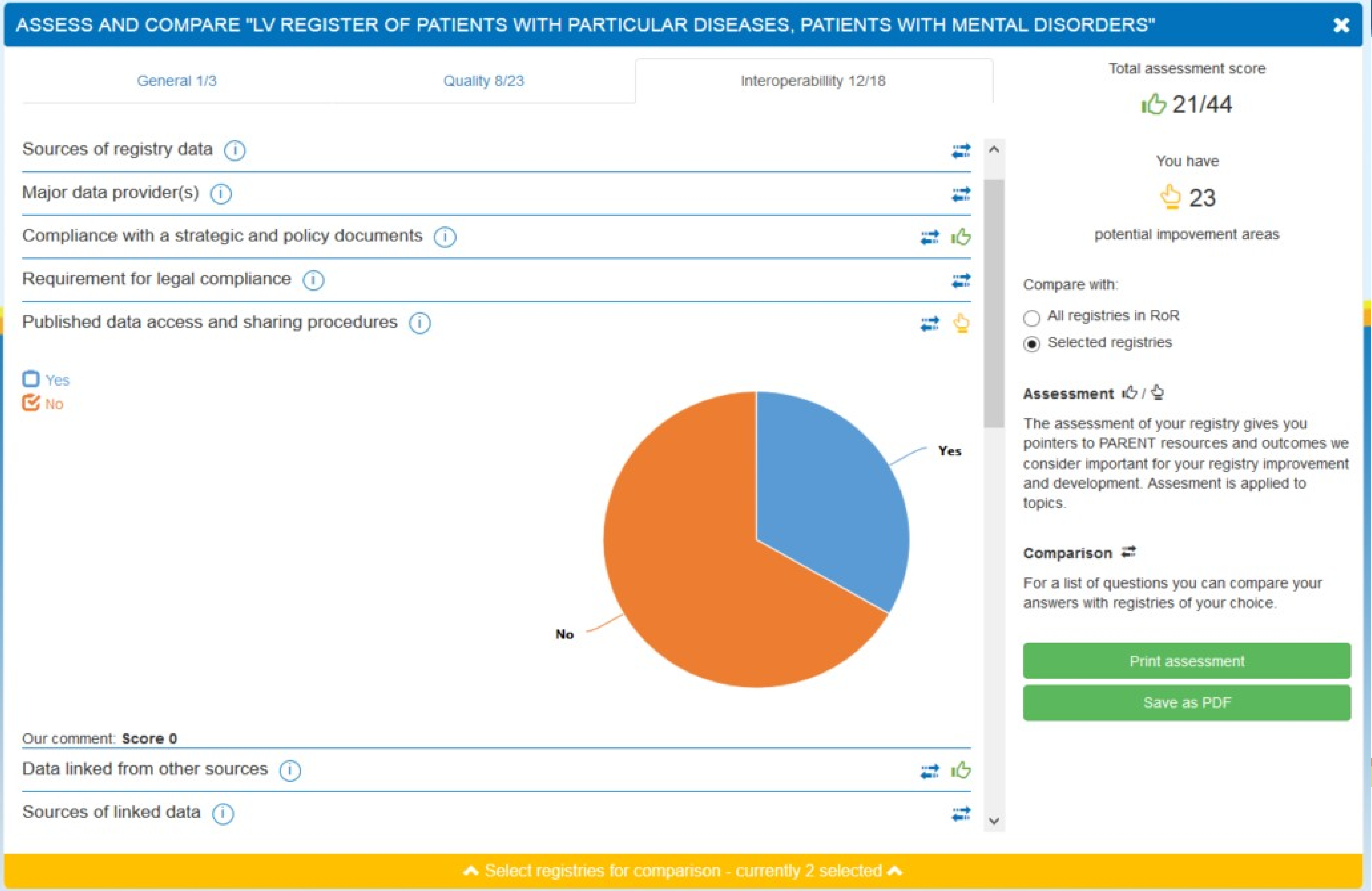
○ List
○ Compare
○ Advanced search
● Compare by survey topic

● All registries in RoR
○ Selected registries

Select a survey topic in the list displayed on the main screen and visually analyze representation of your current selection of registries

Select registries for comparison - currently [27,28] selected

Assessment and comparison



ASSESS AND COMPARE "LV REGISTER OF PATIENTS WITH PARTICULAR DISEASES, PATIENTS WITH MENTAL DISORDERS"

Sources of registry data

Major data provider(s)

Compliance with a strategic and policy documents

Requirement for legal compliance

Published data access and sharing procedures

☐ Yes
☑ No

Our comment: **Score 0**

Data linked from other sources

Sources of linked data

Total assessment score

21/44

You have

23

potential impovement areas

Compare with:

○ All registries in RoR
● Selected registries

Assessment

The assessment of your registry gives you pointers to PARENT resources and outcomes we consider important for your registry improvement and development. Assesment is applied to topics.

Comparison

For a list of questions you can compare your answers with registries of your choice.

Select registries for comparison - currently 2 selected

Description of the EUBIROD Activity in PARENT JA

- EUBIROD representatives (M.Massi Benedetti, F.Carinci, I. Štotl) have participated in regular meetings of PARENT project, that were open for APG.
- EUBIROD project/initiative is mentioned and explained in guidelines as a good example and model to be re-used for other chronic diseases as well.
- EUBIROD PIA initiative has been identified and included in the guidelines as very useful and related with the goals of the PARENT project.
- I. Štotl presented a presentation about EUBIROD group approach regarding business models in platforms for cross-border use of patient data.

Description of the EUBIROD Activity in PARENT JA (2)

- EUBIROD member registries have participated in **series of structured interviews** conducted for the purposes of the Cross-border patient registries initiative:
  - Cyprus - Diabetes Registry
  - Slovenia - Child Diabetes Registry
  - Latvia - Register of Patients with Particular Diseases, Patients with Diabetes Mellitus
- Final report and results of interviews will be available as a result of PARENT WP4 (October 2015)

Questions

Core services

Component	Service	Available now	Available by the end of 2015	For future development
RoR v1.0	List of registries	+		
	Registries metadata	+		
	Questionnaire for registry holders	+		
	Customized (by selection) or full (complete list) registry browsing	+		
	Customizable search function (search filters)	+		
	Customizable comparison tool	+		
	Patient registry submission – PARENT editor published	+		
	Access to registry contact details	+		
RoR v2.0	User registration		+	
	User authorization		+	+
	Cross-content and user linking (tagging)			+
	Questionnaire-profile with criteria for quality and interoperability dimensions assessment		+	
	Patient registry submission – user published		+	
	Integrated access to registry guidelines		+	
	Data dictionary access		+	+
	Customizable user profile		+	+
	Customizable registry profile		+	+
	Access to registry Assessment tool		+	+
	Advanced and customized search filters		+	

Core services (continued)

Component	**Service**	**Available now**	**Available by the end of 2015**	**For future development**
Assessment tool	Profile completeness assessment		+	
	Registry benchmarking		+	+
	Alignment with PARENT Guidelines		+	+
	Registry quality assessment		+	+
	Registry interoperability readiness assessment		+	+
	Coding sandbox (modular site, reusability assurance)		+	+
	Pilots (EAR...)		+	+
Guidelines v1.0 Static		+	+	+
Guidelines v2.0 Wiki			+	+
	Case study (Arthroplasty register)	+		
OpenEHR	Repository of archetypes (clinical models) that can be reused	+		+
	Creation and verification of new archetypes	+		+
…	Creation of new templates based on archetypes	+		+
OpenEHR server	Implementation of registries (data structures, forms) based on OpenEHR	+		+