

Joint controllers in large research consortia

Where are the limits?

RECAP Preterm – a federated model use case

Vasco Rosa Dias
DPO, Legal Counsel
INESC TEC, ISPUP

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Presentation - overall aims of the RECAP preterm Project

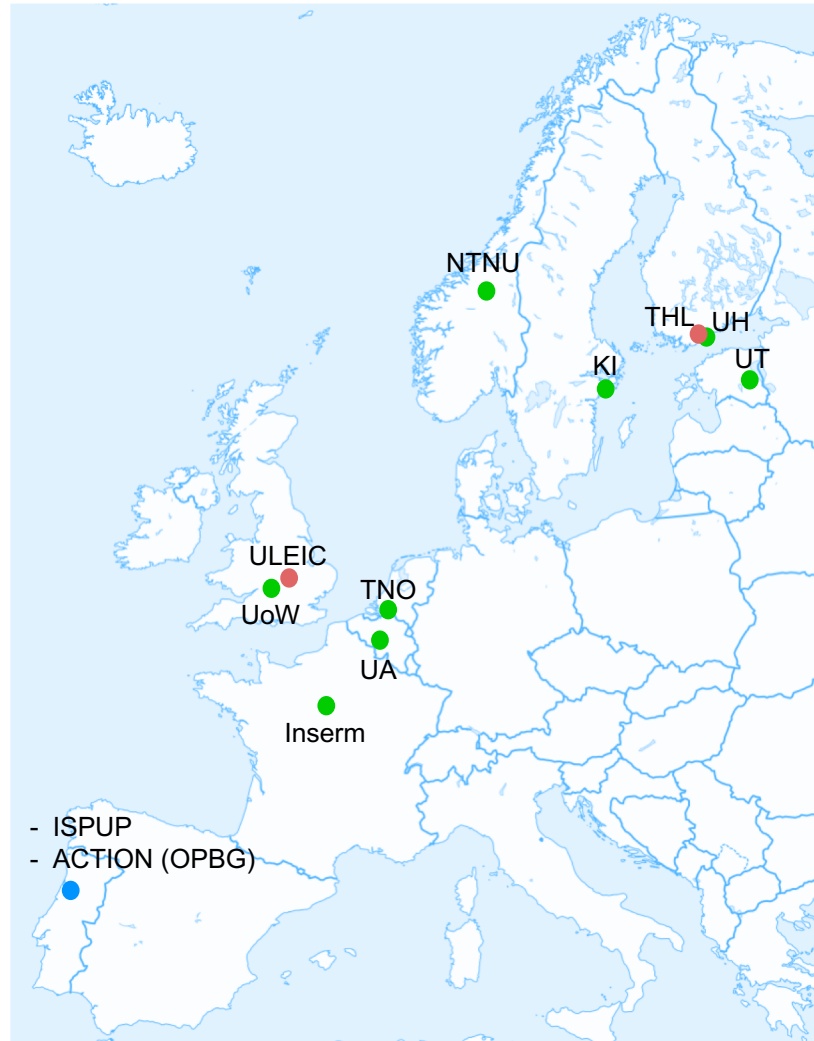


- To improve the health, development and quality of life of children and adults born very preterm (VPT) or with a very low birth weight (VLBW)
- Optimize the use of population data for research and innovation in healthcare, social and education policy, according to FAIR principles;
- Develop the [RECAP preterm Cohort Platform](#), a sustainable and geographically diverse network of national and European cohorts of babies born preterm, constituted over a 30 year time span;
- Develop novel methodologies and tools for data management, data collection (e-cohorts) and data analysis to strengthen research on current and future VPT/VLBW cohort



Overview of the RECAP preterm Platform

Current Deployment Status



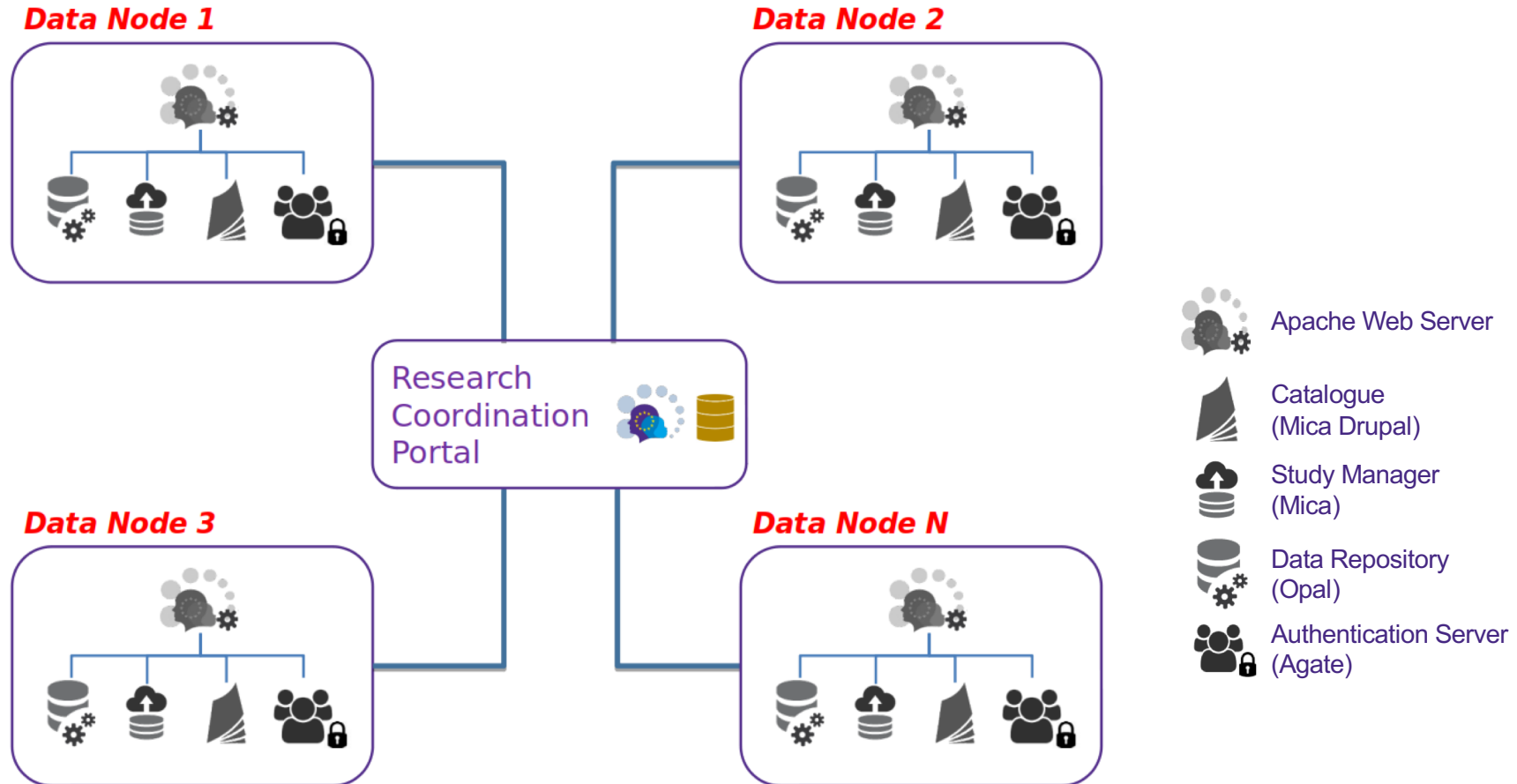
● Data Node hosted
at INESC TEC



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Overview of the RECAP preterm Platform

Distributed Architecture



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RECAP Preterm Catalogue

The RECAP Preterm Data Platform allows researchers to find and use data from participating very preterm (VPT) and very low birth weight (VLBW) cohorts to answer research questions using novel tools and methodologies. Cohort variable summaries can be accessed in the [catalogue](#) and data access requests can be made via the [central researcher portal](#).

Find out more about the [RECAP Preterm project](#).

Networks

2

[More info ➔](#)

Studies

23

[More info ➔](#)

Datasets

45

[More info ➔](#)

Variables

5,884

[More info ➔](#)

Authentication Server



Create and manage user accounts and groups.

Data Repository



Store data and data summary statistics. Define data dictionaries and harmonisation algorithms.

Study Manager



Create and publish Networks, Studies, Datasets.



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There are two types of studies presented here:

- An **individual study** - any epidemiological study (e.g. cohort, case control, cross sectional, etc.) conducted to better understand the distribution and determinants of health and disease.
- A **harmonisation study** - a research project harmonizing data across individual studies to answer specific research questions.

Studies



All Individual Harmonisation

Show 25 entries

Search:

Acronym	Name	Description	Type
ACTION	Accesso alle Cure e Terapie Intensive Ostetrico Neonatali (Access to Obstetrical and Neonatal Intensive Care)	The ACTION cohort is a prospective area-based cohort started in 2003 in six Italian regions, ...	Individual
AYLS	Arvo Ylppö Longitudinal Study	The AYLS is the Finnish arm of the Bavarian-Finnish Longitudinal Study. The original ...	Individual
BEST/BLS	Bavarian Longitudinal Study Cohort	Phase I (1984-1990) Four assessments (1985-1990) were carried out daily during the neonatal ...	Individual
EFGR in very preterm infants	Extreme Fetal Growth Restriction in very preterm infants	- Describe the prevalence and risk factors of infants with extremely severe fetal growth ...	Harmonisation
EPICE	Effective Perinatal Intensive Care In Europe	The EPICE project explored the use of evidence based practices for the care of very preterm ...	Individual
EPICE-PT	Effective Perinatal Intensive Care in Europe	The EPICE project explored the use of evidence based practices for the care of very preterm ...	Individual
EPIcure	EPIcure	The aim of the EPIcure Study is to determine survival rates and long term health, developmental, ...	Individual
EPIcure 2	EPIcure 2	EPIcure 2 is a population study of health and development after birth before 27 weeks of ...	Individual
EPIPAGE 1	Étude épidémiologique sur les petits âges gestationnels	The EPIPAGE 1 study aimed to assess the outcome of very preterm (VPT) babies, to identify early ...	Individual
EPIPAGE 2	Étude épidémiologique sur les petits âges gestationnels	The EPIPAGE 2 study aims:	Individual



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Exact gestational age

❗ Exact gestational age of infant at delivery (weeks).

Overview

Value type	Decimal
Nature	Continuous
Entity type	Participant
Unit	week

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Definition

Dataset	EPICE-PT Perinatal Dataset
Study	EPICE-PT
Population	EPICE Portugal Cohort
Data Collection Event	Perinatal Assessment

Summary Statistics

Contingency Table

N	974
N with values	974
N missings	0

**Statistics retrieved from
distributed node**

Frequencies

Value	Frequency	%	Missing
NOT_NULL	974	100.00	

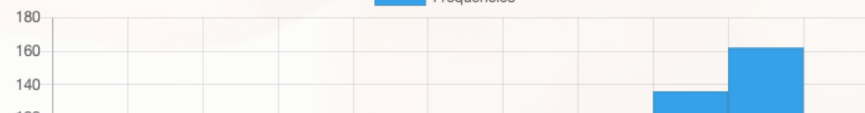
NOT_NULL



Mean	27.94
Standard deviation	2.89
Sum	27217.60
Sum of squares	768686.50

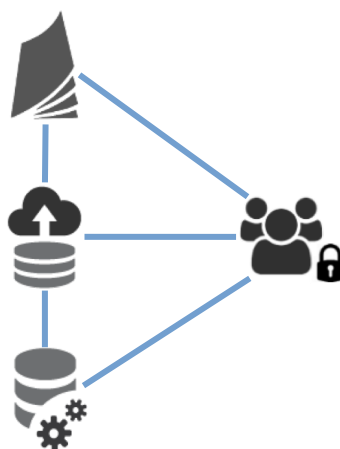
Histogram

Frequencies



Overview of the RECAP preterm Platform

Node Components



The **Data Repository** (Opal) is the data warehouse component that provides data storage, harmonisation and analysis.



The **Study Manager** (Mica) is used for defining metadata pertaining to the studies hosted at the node.



The **Catalogue** (Mica Drupal) is the top layer of a node, providing browsing and querying capabilities over the metadata published in the Study Manager.



The **Authentication Server** (Agate) is the authentication component for each RECAP node. A local user is able to use the same account to access all the other applications.

RECAP Preterm Harmonisation Workflow

Cohorts harmonise the variables

- The platform is based on a federated network system, so each cohort is responsible for harmonising their own data in their own node.
- The data repository in each node provides tools to harmonise variables to a specific harmonisation dictionary, as well as to curate, describe and store data.



RECAP Preterm Harmonisation Workflow

Cohorts grant research topic leads access to the harmonised variables

- At any point during harmonisation on a node, the cohort should grant research topic leads access to the harmonised dataset.
- The level of access will depend on the type of analysis that the research topic leads intend to perform:
 - analysis of individual-level data
 - non-disclosive analysis via DataSHIELD



Non-Disclosive federated analysis via Data Shield

Data Analysis at each data node

Arguably only anonymous/ aggregated data are exchanged



Analysis of individual-level data

- Roles within the consortium:

Researchers

Software Developers

Local Nodes Managers

Central Node - Consortium

Data Subjects

Data Recipients

- Relevant criteria*: Joint vs individual determination of the purpose (close/ complementary processing purposes); Joint vs individual determination of essential means (storage periods; categories of data; TOM;
- Secondly: common interest; involvement in data processing (data access); ToU

*GDPR; ECJ Case law; EDPB / WP29 Guidelines



Preliminary conclusions (how to avoid the Devil)

- Mere facilitating roles: legal or technical advise, maintenance services; etc - Not (joint) controllers. Possibly processor regarding data operations/ processing involving the central node / PaaS, maintenance
 - SW development: how decisive are the choices made?
 - Local Nodes (cohorts data) Data controllers
 - Data Recipients – Data Controllers
 - Joint Controllership will occur typically in the ambit of individual research partnerships: either within or beyond the consortium, otherwise:
 - DC – DC relationship
- Contractual implications: 1- DC-DP; 2- JCA; 3- DC-DC



Preliminary conclusions (how to avoid the Devil)

- Contractual implications: Platform management
 - GA
 - CA
 - ToU
 - Future use/ exploitation



Questions & Discussion

Thank You

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