Coordinated Research Infrastructures Building Enduring Life-science services
- CORBEL -

Deliverable D3.4
4th MIUF Report

WP3 – Community-driven cross-infrastructure joint research - Medical

Lead Beneficiary: ECRIN-ERIC
WP leader: Jacques Demotes (ECRIN-ERIC)
Contributing partner(s): BBMRI, EATRIS, ELIXIR, Euro-BioImaging, INFRAFRONTIER, INSTRUCT

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Content

Executive Summary

The "Medical Infrastructure/Users Forum (MIUF)" combines the BMS ESFRI RIs with scientific expertise in different medical research areas, bringing together medical research communities corresponding to European priorities, including pan-European users' communities as well as patient associations. The MIUF is a key instrument for efficient development and use of biomedical research infrastructures in Europe, by promoting a culture of collaboration across the ESFRI BMS infrastructures and capturing needs and expectations of scientific communities and funders, to drive the development of tools and services and to promote a consistent development strategy, avoiding gaps and overlaps.

Project objectives

With this deliverable, the project has reached/this deliverable has contributed to the following objectives:

a) Establish a dialogue with funders and medical research communities to capture their expectations and needs
b) Implement strategic actions to encourage cross-collaboration at pan-European level

Detailed report on the deliverable

Background

The CORBEL Medical Infrastructure/ Users Forum (MIUF, WP3.1) is designed to promote close collaboration, at the pan-European level, between medical research communities, funding bodies, and medical research infrastructures. In particular, its mission is to

- promote the establishment of pan-European scientific communities, providing the scientific content and access to patients;
- define the respective roles of infrastructures vs. scientific communities, avoiding gaps, overlaps and fragmentation;
- capture the needs of the scientific communities and of the funders in terms of infrastructure services;
- ensure the appropriate development and deployment of these services by one or multiple research infrastructures.

Description of Work

Several face-to-face meetings were planned during the whole project, in order to gather input from various stakeholders (infrastructures, scientific communities, funding bodies) and to identify solutions for a long-lasting collaboration strategy.

Five meetings were organised and the respective outcomes are presented in deliverables D3.1/3.2/3.3.

During the period covered by the present report (deliverable), one final MIUF meeting was planned on December 6th, 2019, in Brussels. However, due to strikes in Paris affecting international travel, the

meeting was cancelled and re-scheduled during the CORBEL final event on March 2nd, 2020, in Brussels.

The part of the CORBEL meeting focussed on MIUF provided the opportunity to have an open discussion with RI end-users and representatives of funding agencies and the European Commission.

Discussions were focused on three main aspects:

1. How to use the MIUF as a template for stakeholder engagement activities across relevant initiatives and projects in the context of personalised medicine approaches and big data challenges

2. How to improve the involvement of Research Infrastructures in research projects

3. How to collaborate with Research Infrastructures to structure medical research communities at pan-European level

1. MIUF as a template for stakeholder engagement activities

Personalised medicine:
There are several ongoing initiatives to support personalised medicine worldwide, under the umbrella of the International Consortium for Personalised Medicine (ICPerMed), to promote membership with Latin American countries (EULAC-Permed), China (IC2PerMed) and African countries (under preparation). In addition, the PERMIT project (Personalised Medicine Trials) will develop methodological standards to optimise the design of clinical trials, taking into consideration some new essential components such as multimodal data management and machine learning processing. Finally, the EU-STANDS4PM project will identify data resources, standards, bottleneck and practices to promote data integration strategies for *in silico* methodologies in personalised medicine studies.

Data:
Secured and authorised access to health data (from research and healthcare practice), genomics, imaging data and biosamples is essential to optimise the use of research data. Policies for data sharing and reuse are generally lacking, which hampers the reuse of sensitive data at a larger scale across national borders. Technical and ethical/legal issues will be addressed by the projects EOSC-Life (life science data), B1MG (genomics), Synchros (cohorts), FAIRplus ("FAIRification" of datasets) that all plan a strong stakeholder engagement for a broad validation and adoption of data standards and workflows.

2. How to improve the involvement of Research Infrastructures in research projects
European transnational research programmes such as ERA-Nets and Joint Programming Initiatives (JPIs) are implementing activities to encourage and foster the use of RIs (list/links of RIs and services offered are provided in the guidelines for applicants; joint transnational calls are disseminated through RIs; the current infrastructures are asked to include disease-specific sections, i.e. AMR). In addition, innovative strategies for i) alignment of infrastructures and tools, and ii) networking with European and international stakeholders are considered (in TRANSCAN3 and JPND programmes respectively).

However, these measures and the current bottom-up approach are insufficient. Overall, there is a lack of knowledge of RIs at all levels (funders, scientific community), in terms of national organisation, services provided and access. The ERIC member countries have a responsibility and a role to play in promoting the use of RIs, by establishing national strategies. As such, it is fundamental that the member countries fully understand the value of the RIs. Indeed, RIs are often asked to show how much research could not have been done without them; but the right approach should be to show how RIs could make research better: by making it faster, making data sets richer and more robust, and potentially enabling new capabilities. Examples of high-impact science could be used to show the value added by collaborating with RIs.

Moreover, the European Commission, for Horizon Europe, will implement actions to make RIs more visible, now that most of them are fully operational.

In addition, the medical Research Infrastructures BBMRI, EATRIS and ECRIN have recently set up a formal Alliance (AMRI) to establish a common strategy and provide the research communities with an integrated service pipeline for health innovation. In particular, the alliance will develop joint communication/outreach/training tools, data services (multimodal data management, secondary use of data, etc.) and quality policy/certification programmes.

3. Structuring medical research communities at pan-European level

The European Brain Research Area (EBRA) initiative was presented as an example of a coordinating action that plans collaboration between research communities and RIs. To support that collaboration EBRA will organise dedicated workshops to highlight tools and services available and to foster the development of use cases.

The core objective of CORBEL has been to increase the ability of Europe's life science infrastructures to collectively serve users - both individual scientists and large European projects.

Visibility and communication with users are extremely important to capture users' needs and to collect their feedback for continued improvement and development of a stable cooperation.

Again, it is important to show examples of how working together will multiply our capacities. For instance the experience of the CORBEL open calls shows that RIs provide access to facilities otherwise not available in most of the host institutions, as well as access to highly qualified and experienced staff.

Conclusions:

- **Select high-impact studies to show-case the value added by the RIs, targeting both researchers and national funders**
- **Improve communication and dissemination activities**
- **Implement national strategies to raise awareness and encourage the use of RI services**

Next steps

The final MIUF meeting provided the opportunity to ensure the transition into projects like EOSC-Life, B1MG, the future European Health Research and Innovation Cloud (to name a few), where

medical research stakeholders will be involved and invited to related meetings, building a solid forum for dialogue and joint strategy development.

Delivery and schedule

The delivery is delayed:

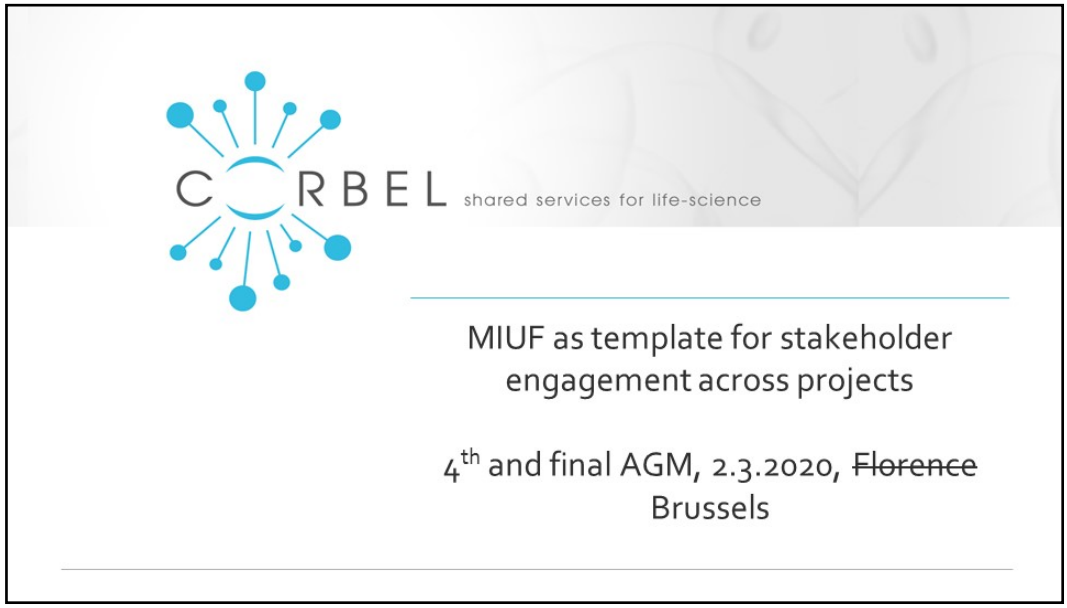
Yes

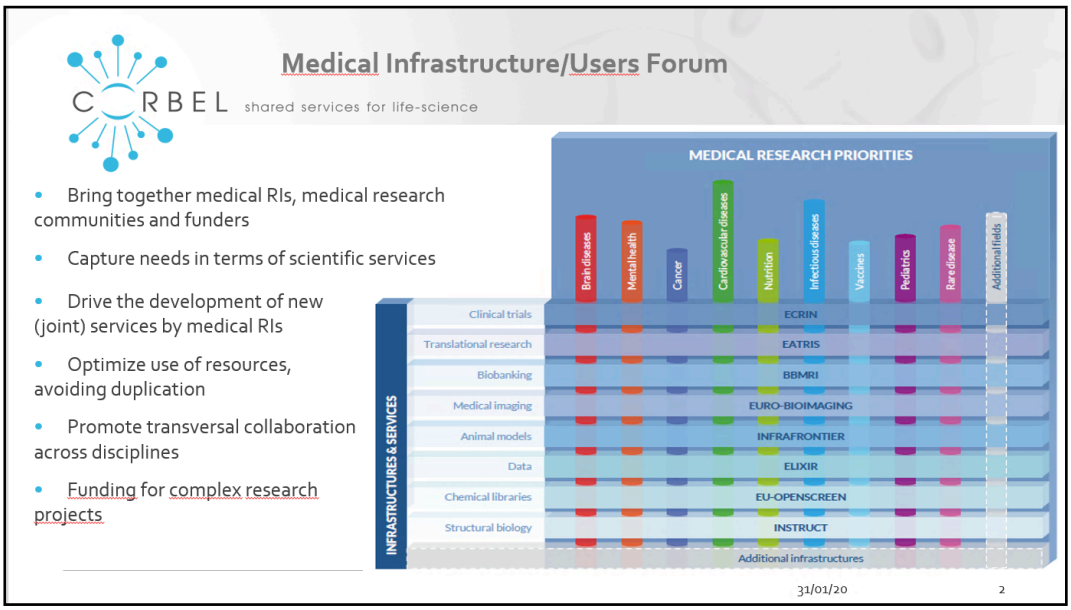
As the 6th MIUF originally planned in Spring 2019 was postponed to Winter 2019 in order to prepare the transition with the EOSC-Life project, it was agreed to postpone the corresponding deliverable D3.4 and milestone MS12.

The Deliverable D3.4 was further postponed as the meeting was eventually scheduled during the CORBEL final event, in March 2020.

Appendices

Appendix 1





Today's discussion

- Stakeholder engagement across projects/initiatives
  - Personalised Medicine
  - Data
- Involvement of RIs in research projects
  - Alliance of Medical Research Infrastructures
- Collaboration with RIs to structure medical research areas
  - European Brain Research Area (EBRA)

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PERSONALISED MEDICINE projects

Project	Purpose	Status/opportunities
PERMIT	Develop methodological standards	Work with major stakeholders (EMA, HMA, EUNetHTA, ethics committees, journal editors, funders)
EULAC-PerMed	Promote IC Permed Membership of Latin American countries	Conferences on data and on methodology
Other regional: Africa* China**	Promote IC Permed Membership of African countries and China	* Application April 2020 ** ECRIN partner
ERA-PerMed	Funding for multinational personalised medicine projects	3rd call in 2020

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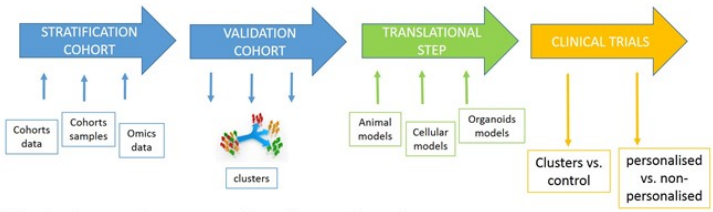
PERSONALISED MEDICINE : PERMIT project
methodological standards for personalised medicine



- High-throughput –omics / imaging data
- Cohort integration
- Multimodal data management
- Machine learning stratification
- Translational step
- Umbrella trials

31/01/20 6

Integrating China in the International Consortium for Personalised Medicine (IC2PerMed)

Starting date and duration: 01/01/2020 – 48 months

Topic: Actions in support of the International Consortium for Personalised Medicine

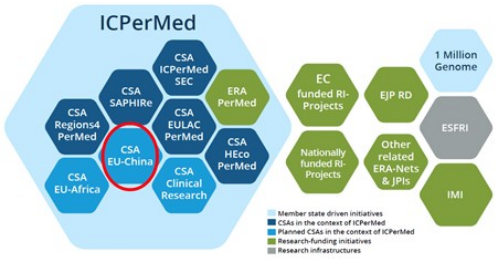
IC2PerMed project will provide key solutions for enabling the convergence under ICPerMed consortium of European and Chinese stakeholders.

The peculiarity of the project is its orientation towards a Public Health perspective and the utilization of a health services research approach to reach the aim of finding common methodologies and pathways for personalized medicine (PM) research, innovation, development and implementation, with implications for policy makers and healthcare beneficiaries.

BBMRI-ERIC is partner stakeholder, QM, some ELSI support (contact: andrea.wutte@bbmri-eric.eu)

China currently does not fund counterpart

ICPerMed "Family" and Related Initiatives



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Relevant data / data federation / data standardisation projects

Project	Purpose	Status / opportunity
EOSC-Life	Life science component of EOSC (data resources, provenance standards, policies)	Calls for partnerships/projects (2021)
EU-STANDS4PM	Data resources for PM (w bottlenecks for reuse); Standards	Stakeholder conference late 2020 - EU action plan
FAIRplus	"FAIRify" IMI datasets -> cookbook, ROI model	FAIR cookbook open source
CINECA/EUCanCan	Federated genomic + phenotype data infrastructure	Will inform B1MG
B1MG	Cross-border access to European genome collections	1+MG working groups established (not part of B1MG), awaiting evaluation of B1MG application
SYNCHROS	Develop methods for cohort integration	Expertise needed to support retrospective cohort integration (for stratification cohorts)

EOSC-Life: an open collaborative space for digital biology in Europe

Key expected outputs related to EOSC

- Establish EOSC-Life by publishing FAIR life science data resources in EOSC
- Create an ecosystem of innovative life-science tools in EOSC
- Enable groundbreaking data driven research in Europe by connecting life scientists to interoperable European clouds via open calls for participation

13 ESFRI Life Science Research Infrastructures

ELIXIR - Project Coordinator

46 Partners and 17 linked 3rd parties

Sourcing e-Infrastructure services from EOSC (Cloud, AAI, ...)

4-year project, 24M€, #824087

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824087

https://eosc-life.eu

EOSC-Life: Opportunities to engage

- ***Policies and Guidelines for sensitive data (WP4)***
  - Workshop on anonymisation good practice held in Paris on 22-23 January (report forthcoming)
  - Collection of information about national initiatives for health data hosting and reuse (landscape) – ongoing
  - Other thematic workshops in preparation (Data Workflows; IP/Nagoya: June 2020 in Brussels)
  - Guidelines for secure cloud provisioning (w WP7)
  - Priorities for further guidelines and policies will be driven by EOSC-Life use cases
- ***Open calls for projects / partnerships (WP3)***
  - EOSC-Life will launch first Open Call for external projects / partnerships in late 2020
- Stakeholder workshop at ESOF2020 for science policy stakeholders

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824087

https://EOSC-Life.eu

EU-STANDS 4PM

Mission: Establish a pan-European Expert Forum to tackle the complexity of big data integration for *in silico* methodologies in personalised medicine.

Aims:

Big data in health
Promote the broad and safe use of health data to benefit predictive *in silico* approaches in personalised medicine.

Data integration
Harmonise health & disease data integration strategies to drive *in silico* approaches.

Standardisation
Catalogue current practices & recommend standardised interoperable approaches & data integration strategies to develop in silico approaches.

Harmonisation needs
Adoption of standards, practices, & harmonisation strategies to benefit *in silico* approaches.

EU-STANDS4PM standards for in silico models for personalised medicine

elixir

FAIRplus – fairplus-project.eu

Key expected outputs related to EOSC

- Value-based model to select and prioritise datasets for FAIRification
- FAIRification toolkit for life-science data used by industry and academia
- SME engagement ("associate partners") and *Innovation and SME* events to foster an innovation ecosystem for FAIR open data that power future reuse, knowledge generation and societal value

Grant ID #: 802750
ELIXIR - Project Coordinator
Janssen - Project Leader

22 participants
12 academic, 7 EFPIA, 3 SME

€8.23M budget
€4M H2020 EC funding + €4.23M EFPIA in-kind

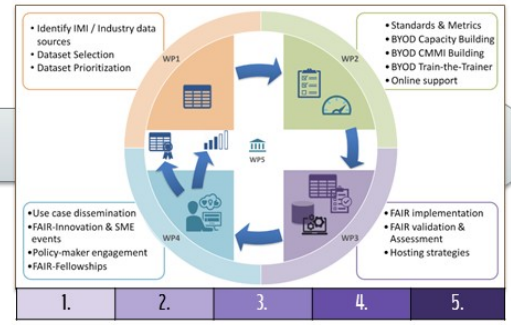
42 months

FAIRplus imi innovative medicines initiative efpia

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No. 802750. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation and EFPIA companies.

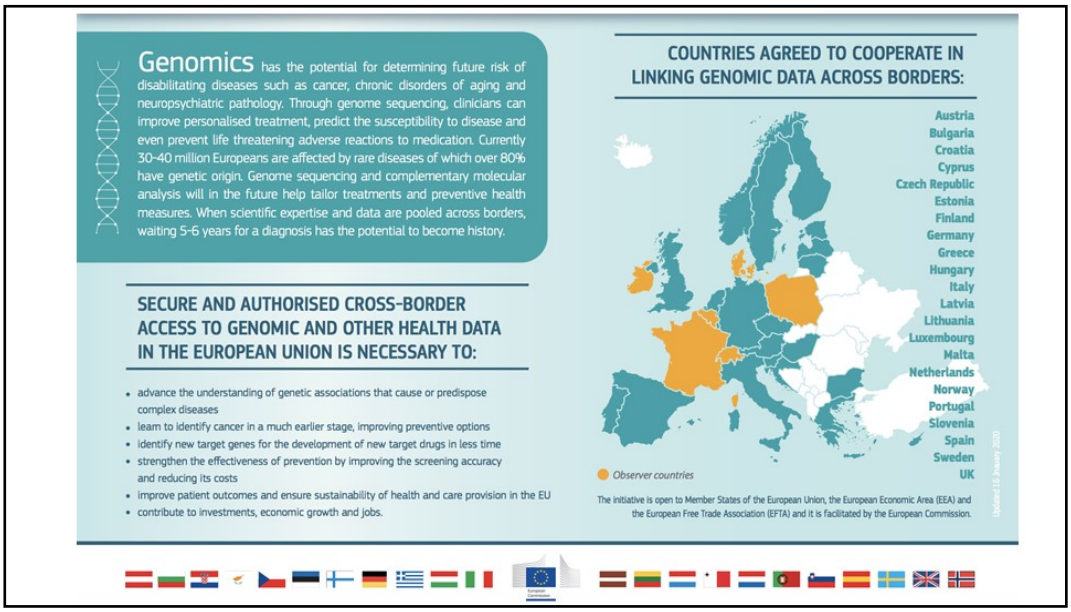
FAIRplus

IMI Project Portfolio
> 100 translational research projects in public-private partnerships

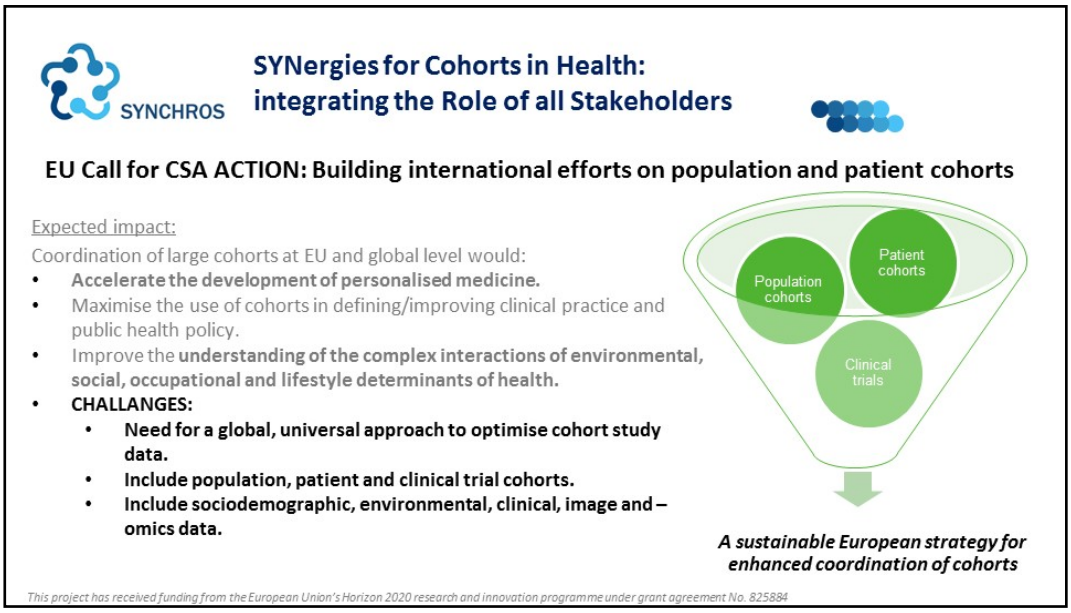


- FAIR maturity assessment
  - ROI of 'FAIRification'
  - Dataset selection
- FAIR 'cookbook'
  - Standards, metrics
  - Capacity building
  - Support
- Publish FAIR datasets from >20 projects for access and reuse
- FAIRified internal EFPIA datasets
- SME engagements, hackathons and fellowships

imi efpia This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 802750. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA companies.


Genomics has the potential for determining future risk of disabilitating diseases such as cancer, chronic disorders of aging and neuropsychiatric pathology. Through genome sequencing, clinicians can improve personalised treatment, predict the susceptibility to disease and even prevent life threatening adverse reactions to medication. Currently 30-40 million Europeans are affected by rare diseases of which over 80% have genetic origin. Genome sequencing and complementary molecular analysis will in the future help tailor treatments and preventive health measures. When scientific expertise and data are pooled across borders, waiting 5-6 years for a diagnosis has the potential to become history.
SECURE AND AUTHORISED CROSS-BORDER ACCESS TO GENOMIC AND OTHER HEALTH DATA IN THE EUROPEAN UNION IS NECESSARY TO:
advance the understanding of genetic associations that cause or predispose complex diseases
learn to identify cancer in a much earlier stage, improving preventive options
identify new target genes for the development of new target drugs in less time
strengthen the effectiveness of prevention by improving the screening accuracy and reducing its costs
improve patient outcomes and ensure sustainability of health and care provision in the EU
contribute to investments, economic growth and jobs.
COUNTRIES AGREED TO COOPERATE IN LINKING GENOMIC DATA ACROSS BORDERS:
Austria
Bulgaria
Croatia
Cyprus
Czech Republic
Estonia
Finland
Germany
Greece
Hungary
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Norway
Portugal
Slovenia
Spain
Sweden
UK
Observer countries
The initiative is open to Member States of the European Union, the European Economic Area (EEA) and the European Free Trade Association (EFTA) and it is facilitated by the European Commission.


FEDERATED SECURE CROSS-BORDER ACCESS TO PERSONALISED MEDICINE DATA BOOSTS EU RESEARCH AND INNOVATION
WP5 Personalised Medicine Delivery, Scientific and Societal Impact
WPLs: Astrid Vicente (INSA), Serena Scollen (ELIXIR Hub)
CITIZENS
WP1 Stakeholders Engagement
Currently 140 members from 20 countries in stakeholder coordination group
WPLs: Denis Horgan (EAPM), Ruben Kok (DTL-Projects), Jan Korbel (EMBL), Toni Andreu (EATRIS)
WP4 Federated Secure Cross-border Technical Infrastructure
WPLs: Tommi Nyrönen (CSC), Ilkka Lappalainen (CSC), Bengt Persson (UU), Sergi Beltran (CRG)
WP2 ELSI
WPLs: Regina Becker (UNILU), Jasper Bovenberg (Legal Pathways)
WP3 Standards and Quality Guidelines
WPLs: Ivo Gut (CRG), Jeroen Belien (VUmc)
WP6 (Project Management, Communication, Governance and Sustainability
WPLs: Juan Arenas (ELIXIR Hub), Esther Rodriguez (ISCIII)


SYNCHROS
SYNergies for Cohorts in Health: integrating the Role of all Stakeholders
EU Call for CSA ACTION: Building international efforts on population and patient cohorts
Expected impact:
Coordination of large cohorts at EU and global level would:
Accelerate the development of personalised medicine.
Maximise the use of cohorts in defining/improving clinical practice and public health policy.
Improve the understanding of the complex interactions of environmental, social, occupational and lifestyle determinants of health.
CHALLANGES:
Need for a global, universal approach to optimise cohort study data.
Include population, patient and clinical trial cohorts.
Include sociodemographic, environmental, clinical, image and –omics data.
Population cohorts
Patient cohorts
Clinical trials
A sustainable European strategy for enhanced coordination of cohorts
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825884

SYNergies for Cohorts in Health: integrating the Role of all Stakeholders

SYNCHROS

"To establish a **sustainable European strategy** for the development of the next generation of integrated cohorts, thereby **contributing to an international strategic agenda for enhanced coordination of cohorts globally**, in order to **address the practical, ethical and legal, and the methodological challenge** to optimising the exploitation of current and future cohort data, towards the **development of stratified and personalised medicine as well as facilitating health policy**".

www.synchros.eu

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825884

Methodology

SYNCHROS

Our approach can be divided into **three phases**:

Phase 1
Collecting & analysing evidence

- **Mapping exercise** of the landscape of cohort studies in Europe based on an extensive systematic reviews and **Technical metadata documented in a matrix format.**
- Systematic reviews, scoping exercises, key informant interviews, stakeholders meetings and Delphi methods.
- Thorough survey and analysis of the **future of data generation technologies.**

Phase 2
Coordination methodology

Stakeholder dialogues:

- To **review, evaluate and recommend appropriate harmonisation and integration techniques for the strategy**, appropriate both for existing cohort data sources and future innovations in kinds of data and varieties of data collection platforms.
- To **investigate and resolve the practical, ethical and legal issues** that need to be resolved for a strategy for optimising cohort information.

Phase 3
Sustainable strategy & dissemination

- **Completion of a sustainable strategy for cohort data optimization** providing an approach for next generation of cohort studies and their integration to optimise the full exploitation of data resources.
- **Dissemination** of a sustainable strategic agenda **across Europe and globally.**

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825884

CORBEL

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Alliance of medical research infrastructures (AMRI)

Integrated service pipeline for health innovation

- Joint partnerships with
  - medical specialties / users communities - MIUF
  - industry
  - international cooperation
- Communication, outreach, training
- Access, joint oversight of project development, joint support / services ?
- Development of tools, databases and procedures
- Data services (data management, multimodal data management, secondary use, machine learning)
- Quality policy, certification programmes

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EBRA
European Brain Research Area

Hella Lichtenberg
DLR, Bonn, Germany

CORBEL final meeting 03/2020

EBRA - Partners

EBC	European Brain Council
HBP	Human Brain Project
JPND	Joint Programme – Neurodegenerative Disease
ERA NET NEURON	Network of European Funding for Neuroscience Research

Coordinator: Brain Research Council (Prof. Monica di Luca)

Project runtime: 11/2018 – 10/2021



CORBEL final meeting 03/2020

EBRA

CSA (Coordination and Support Actions) 'Coordinating brain research and developing global initiatives'

Scope:

- To coordinate and develop synergies in brain research
- To improve efficiency
- To integrate EU funded initiatives and help create thematic clusters
- To align brain research strategies and initiate new ones
- To develop international collaboration
- To optimize research investments and efforts



CORBEL final meeting 03/2020

EBRA

WP1: Management

WP2: Analyse research portfolio and identify projects to call together in active clusters

- Mapping of the European brain research area
- Foster the emergence of research clusters in critical areas; generation of a list of projects to call together in active clusters and collection of coordination requirements : **EpiCluster, Prevention of severe mental disorders (PSMD)** cluster

WP3: Shared European Brain Research Agenda and Global Initiatives

- Development of the European Brain research agenda



CORBEL final meeting 03/2020

EBRA

WP4: Accelerate excellence, innovation and translation, and foster exchange by promoting Open Science

- Promote the links to and use of infrastructures among researchers

  Subtask: Promote the link to the European Research Infrastructure via the CORBEL project (NEURON-linked, by DLR)

  Subtask Promote the link to other relevant infrastructures within EBRA consortium

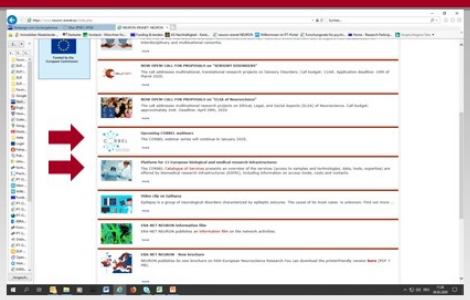
- Promoting quality assurance in research (QUEST, EQIPD-IMI, NEURON-linked, by DLR)

WP5: Patient involvement and dissemination

- Developing a patient involvement strategy
- Support and enhance communication, dissemination activities of the active clusters
- Design and implementation of EBRA communication and dissemination strategy

CORBEL final meeting 03/2020

Promote the link to the European RIs: Activities so far……



NEURON promotes the Catalogue of Services which are offered by biomedical research infrastructures on the website, and encourages applicants to explore RI participation in the JTC call texts.

Organization of a pilot workshop in January 2019, 220 attendees, very well received, ECRIN presented

CORBEL final meeting 03/2020

Planned collaboration with Medical Infrastructure/ Users Forum (MIUF)

Work program: *'EBRA and CORBEL project will organize face-to-face workshops dedicated to the active clusters and institutional multipliers to highlight tools and services available and to foster the development of use cases.'*

1. **Biomedical RI workshop in January 2021**, embedded in the NEURON MidTerm symposium on JTC 2018 on **Mental Health** in Berlin, Germany.
   - Half day workshop, 2-3 keynotes, break-out sessions or individual consortia consultations; curriculum to be discussed; suggested RIs ELIXIR, ECRIN, BBMRI, EATRIS……

2. **Stand-alone workshop in November 2020**, target audience NEURON/JPND researchers, and EBRA-cluster PIs in Bonn, Germany.
   - Half day workshop, 2-3 keynotes, break-out sessions or individual consortia consultations; curriculum to be discussed; suggested RIs ELIXIR, ECRIN, BBMRI, EATRIS……

CORBEL final meeting 03/2020