HORIZON EUROPE

# Investing to shape our future

## EU research & innovation activities on data sharing in health research

**HealthyCloud** public dissemination event
23 November 2022, hybrid event

**Christina Kyriakopoulou**, Ph.D.
Senior Policy officer – Research Programmes

Health Innovations & Ecosystems unit
Directorate General for Research and Innovation
European Commission

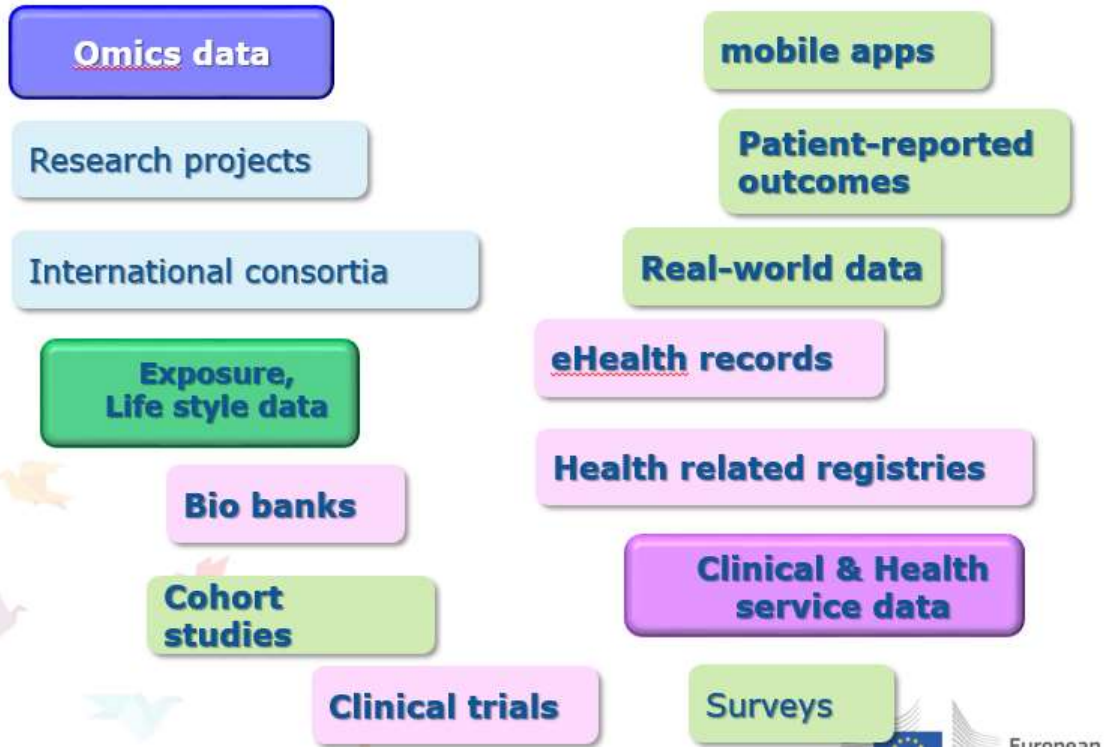
Christina.Kyriakopoulou@ec.europa.eu

European Commission


***"21st century is the century of complexity"***
***(source: Stephen W. Hawking)***

# Big data in health research

Auffray, C., Balling, R., Barroso, I. *et al.* Making sense of big data in health research: Towards an EU action plan. *Genome Med* **8**, 71 (2016).





Auffray et al. Genome Medicine (2016) 8:71
DOI 10.1186/s13073-016-0323-y

Genome Medicine

OPINION Open Access

## Making sense of big data in health research: Towards an EU action plan

Charles Auffray[1,2*], Rudi Balling[3*], Inês Barroso[4], László Bencze[5], Mikael Benson[6], Jay Bergeron[7], Enrique Bernal-Delgado[8], Niklas Blomberg[9], Christoph Bock[10,11,12], Ana Conesa[13,14], Susanna Del Signore[15], Christophe Delogne[16], Peter Devilee[17], Alberto Di Meglio[18], Marinus Eijkemans[19], Paul Flicek[20], Norbert Graf[21], Vera Grimm[22], Henk-Jan Guchelaar[23], Yi-Ke Guo[24], Ivo Glynne Gut[25], Allan Hanbury[26], Shahid Hanif[27], Ralf-Dieter Hilgers[28], Ángel Honrado[29], D. Rod Hose[30], Jeanine Houwing-Duistermaat[31], Tim Hubbard[32,33], Sophie Helen Janacek[20], Haralampos Karanikas[34], Tim Kievits[35], Manfred Kohler[36], Andreas Kremer[37], Jerry Lanfear[38], Thomas Lengauer[12], Edith Maes[39], Theo Meert[40], Werner Müller[41], Dörthe Nickel[42], Peter Oledzki[43], Bertrand Pedersen[44], Milan Petkovic[45], Konstantinos Pliakos[46], Magnus Rattray[41], Josep Redón i Màs[47], Reinhard Schneider[3], Thierry Sengstag[48], Xavier Serra-Picamal[49], Wouter Spek[50], Lea A. I. Vaas[36], Okker van Batenburg[50], Marc Vandelaer[51], Peter Varnai[52], Pablo Villoslada[53], Juan Antonio Vizcaíno[20], John Peter Mary Wubbe[54] and Gianluigi Zanetti[55,56]

European Commission

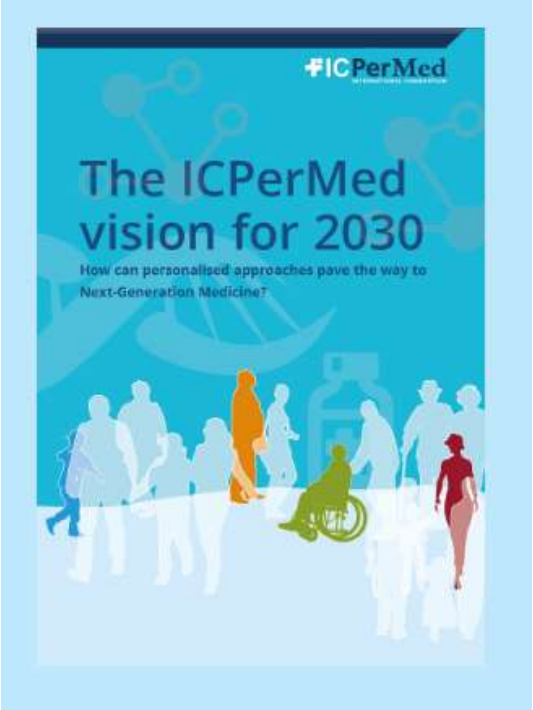
# European research on Personalised Medicine

ICPerMed
INTERNATIONAL CONSORTIUM

## The framework for Personalised Medicine

| R&D the basics | R&D stratifying tools | R&D test in human | Towards the market | Uptake in healthcare | In patients |
|---|---|---|---|---|---|
| "Omics"<br>Technologies<br>Data<br>Samples<br>Statistics | Biomarkers<br>Identification<br>Qualification<br>Validation<br>Data modelling tools<br>Technical aspects & challenges | Clinical trials<br>Methodologies<br>Ethics<br>Patient - recruitment | Diagnostics & Therapies<br>Approval processes<br>Regulatory aspects | Pricing & Reimbursement<br>Health economy<br>HTA<br>Novel models of healthcare organisation | Availability & usability in the clinic<br>Patient perspective<br>Equal treatment<br>Training of professionals |

Prediction - Prevention – Treatment - Cure




European Commission

# **GloPID-R** since 2016
# Global Research Collaboration for Infectious Diseases Prepardness

GloPID-R brings together funders investing in research related to new or re-emerging infectious diseases.

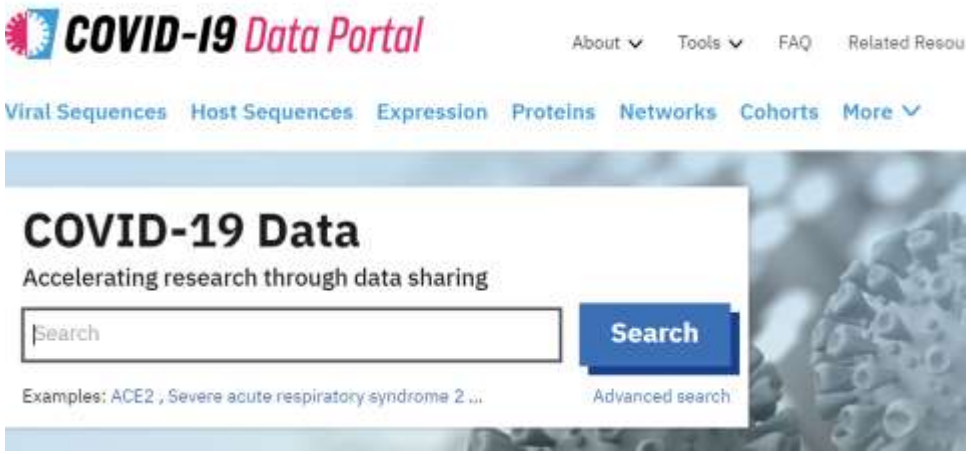
## Goals

- Supporting research preparedness & rapid response to outbreaks of emerging infectious diseases like COVID-19
- Promoting collaboration & information sharing among funders based on common goals and principles

European Commission

# EU research : COVID-19 response – Data sharing

https://www.covid19dataportal.org/




unCoVer

Unravelling Data for Rapid Evidence-Based Response to COVID-19

Rapid European SARS-CoV-2 Emergency research Response

ReCoDID

Reconciliation of Cohort data in infectious diseases

RCHESTRA

Connecting European Cohorts

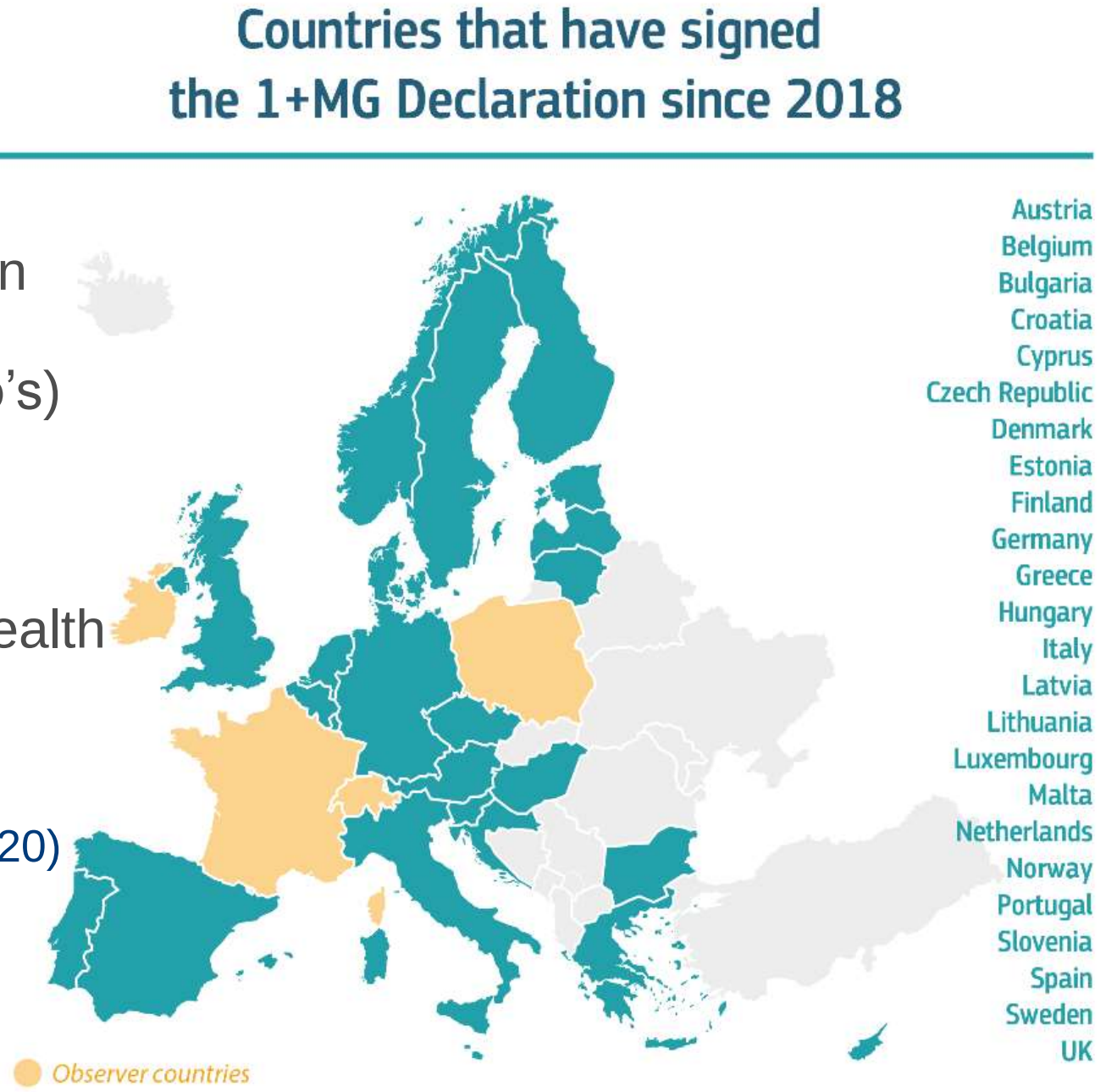
EUCARE

European Cohorts of Patients and Schools to Advance Response to Epidemics

European Commission

# 1+MG initiative

- 24 countries signed the declaration
- 1+MG Group (Member States' rep's)
- 12 Working Groups (experts)
- healthcare, research and public health
- supporting projects:
  - Coordination and support: B1MG (H2020)
  - Implementation: Genomic Data Infrastructure (DEP)



# ESFRI European Infrastructures

***Imaging facilities***

- **EUROBIOIMAGING – Imaging facilities**

***Biological Resource Centres***

- **BBMRI - Biobanks and Biomolecular Resources**
- **EMBRC - Marine biology resources**
- **EU-OPENSCREEN - Chemical libraries**
- **INFRAFRONTIER - Mouse archives and clinics**
- **MIRRI – Microbial resources**

***Genomics and proteomics facilities***

- **INSTRUCT - Structural biology facilities**

***Bioinformatics resources***

- **ELIXIR – Data repositories**
- **ISBE – Infrastructure for systems biology**

***Medical research facilities***

- **EATRIS - Translational research facilities**
- **ECRIN - Clinical trials support**
- **ERINHA - High-security labs**

***Wide spectrum of research, discovery and development on health challenges***


***Ecrin graph***

European Commission

# European Rare Disease Registry Infrastructure (ERDRI) developed by Joint Research Centre of the European Commission

This allows for GDPR-compliant access, search & sharing of interoperable patient data in rare diseases registries, including cohorts and clinical studies

**European Directory of Registries (ERDRI.dor)**

Overview of rare disease registries in Europe including their characteristics

List of participating RD registries with their main characteristics and description

**Descriptive metadata - eight sections with 38 data fields related to a registry of which 23 are obligatory**
- **specific rare disease addressed**
- **scope**
- **operating institution**
- **contact information**

Data input is performed by registry owners

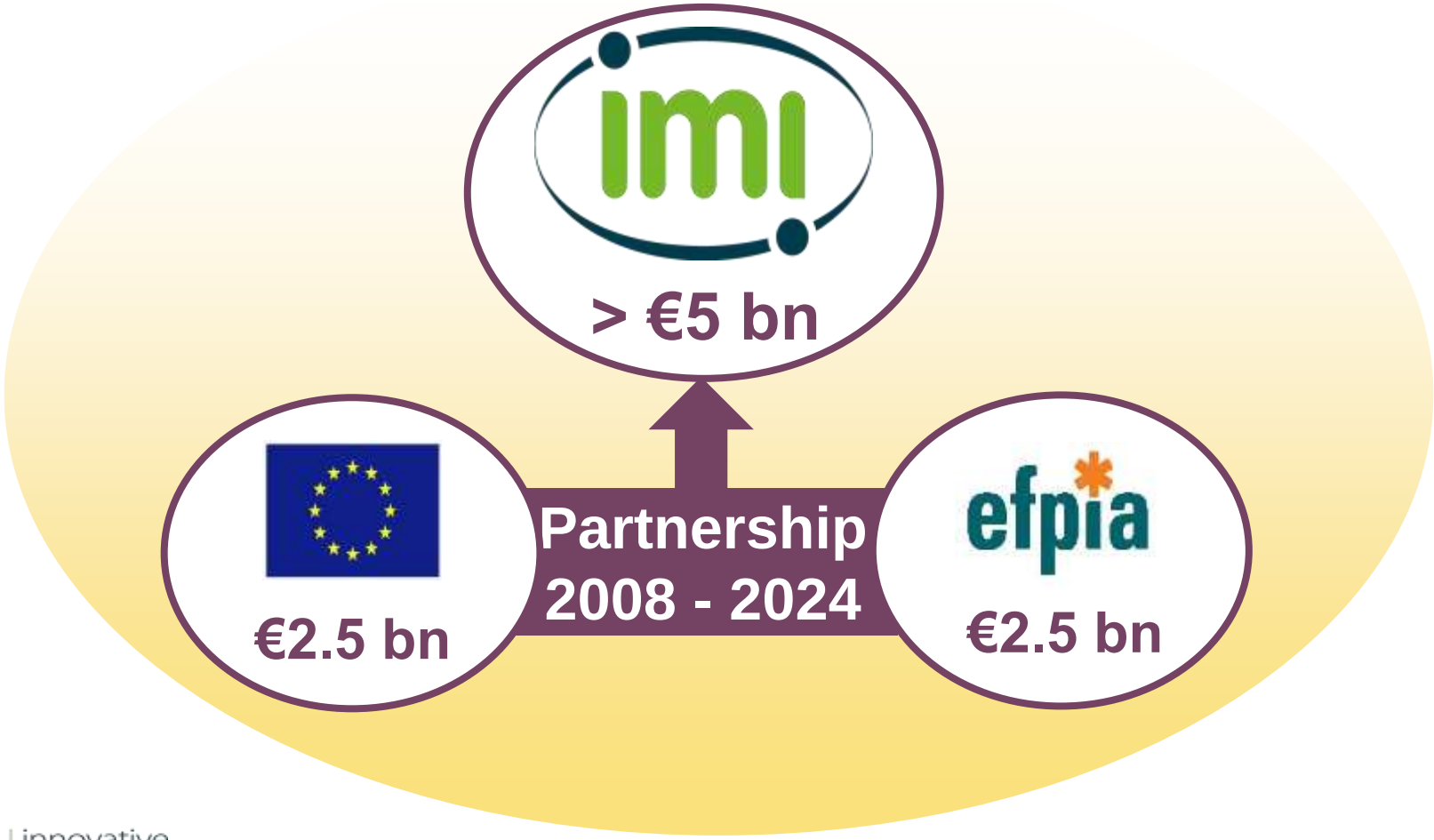
List of the data elements collected by the registries according to the ERDRI.mdr:

registry-specific data scheme

https://eu-rd-platform.jrc.ec.europa.eu

European Commission

# Innovative Medicines Initiative




innovative medicines initiative

# Use Real World Data (RWD) for rapid decision making

- **EHR4CR** (Electronic Health Records Systems for Clinical Research)
- **EMIF** (emif-catalogue.eu) laid the foundation for a number of subsequent IMI projects through facilitating access to RWD at scale to answer research questions. A key output is the EMIF data catalogue.
- **EHDEN** (ehden.eu) has put in place a network of over 160 European RWD sources which can be mobilised in a short time-frame to provide rapid answers to research questions. Already used for safety of potential COVID-19 treatments & vaccines.

# EOSC implementation: a two-stage approach

| EOSC phase 1: preparatory | EOSC phase 2: continuous EOSC roll-out |
|---|---|
| 2018 - 2020 | 2021 - 2030 |
| **H2020 calls/grants approach** | **Partnership approach in Horizon Europe** |
| **EOSC roadmap** 2018-2020 by the European Commission | EOSC Strategic Research and Innovation Agenda (**EOSC SRIA**) 2021-2027 by the EOSC community |
| **Initial EOSC Governance** (Member States and the Commission to steer and oversee initial EOSC development) | **New EOSC Governance** (Increasingly stakeholder-driven, high-level steering role maintained for the European Commission and the Member States) |

# European Commission workshop – March 2018

Expert opinion paper: ‘
Towards a European health research and innovation cloud (HRIC)’
*Genome Med* **12**, 18 (2020).


OPINION Open Access

Towards a European health research and innovation cloud (HRIC)

F. M. Aarestrup[1], A. Albeyatti[2,3], W. J. Armitage[4], C. Auffray[5*], L. Augello[6], R. Balling[7], N. Benhabiles[8*], G. Bertolini[9], J. G. Bjaalie[10], M. Black[11], N. Blomberg[12*], P. Bogaert[13], M. Bubak[14], B. Claerhout[15], L. Clarke[16], B. De Meulder[5], G. D'Errico[17], A. Di Meglio[18], N. Forgo[19], C. Gans-Combe[20], A. E. Gray[21], I. Gut[22], A. Gyllenberg[23], G. Hemmrich-Stanisak[24], L. Hjorth[25], Y. Ioannidis[26], S. Jarmalaite[27], A. Kel[28], F. Kherif[29], J. O. Korbel[30*], C. Larue[31], M. Laszlo[32], A. Maas[33], L. Magalhaes[34], I. Manneh-Vangramberen[35], E. Morley-Fletcher[36,37], C. Ohmann[38], P. Oksvold[39], N. P. Oxtoby[40], I. Perseil[41], V. Pezoulas[42], O. Riess[43], H. Riper[44], J. Roca[45], P. Rosenstiel[24], P. Sabatier[46], F. Sanz[47], M. Tayeb[2,3], G. Thomassen[48], J. Van Bussel[49], M. Van den Bulcke[49] and H. Van Oyen[14,50]

## Recommendations

- Provide and foster standards, good practices, and guidelines necessary to establish the European HRIC
- Develop and certify the infrastructure and services required for operation of the HRIC
- Enable the HRIC to operate within an ethical and legal framework that is adequate for health systems
- Establish a proper environment for the training of a new generation of data and medical scientist
- Fund public and private initiatives for the development of the HRIC through EU Framework Programmes (e.g. Horizon 2020 and Horizon Europe).

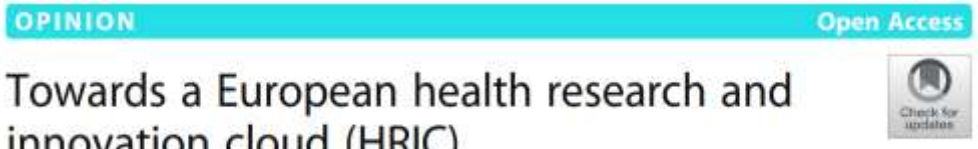
European Commission

# HORIZONSC1-HCC-10-2020: **Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research**

**The challenge:**

- Need to make **EU health research data FAIR (i.e., Findable, Accessible, Interoperable and Re-usable)** becomes more pressing than ever before if European health research is to reap the full benefits of Big data opportunities
- Need to integrate and analyse health data coming from different sources and different health sub-disciplines, individual research institutes and/or hospitals would need a potent IT infrastructure and interoperability solutions as well as powerful data analytics tools.
- Address the security and privacy of health research data, and the compliance with EU legislations

# HealthyCloud CSA:  – Health Research & Innovation Cloud
(01-03-2021 to 31-07-2023)



OPINION Open Access

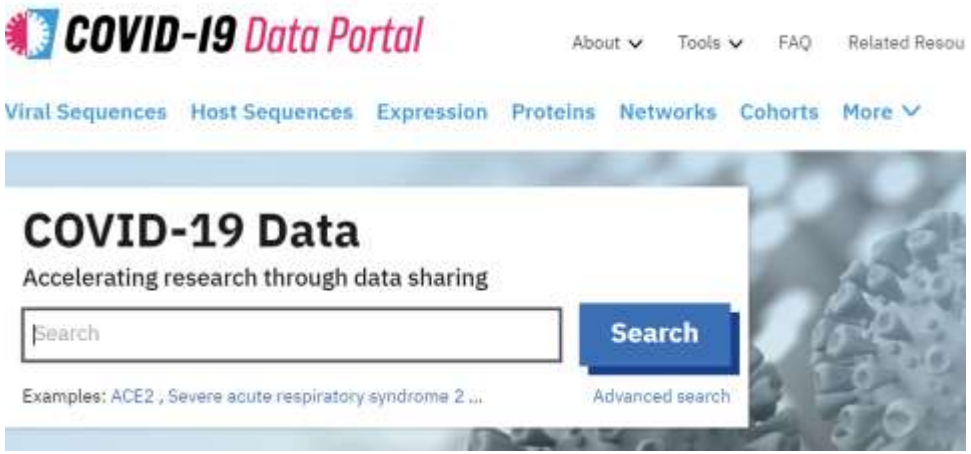
Towards a European health research and innovation cloud (HRIC)

F. M. Aarestrup[1], A. Albeyatti[2,3], W. J. Armitage[4], C. Auffray[5*], L. Augello[6], R. Balling[7], N. Benhabiles[8*], G. Bertolini[9], J. G. Bjaalie[10], M. Black[11], N. Blomberg[12*], P. Bogaert[13], M. Bubak[14], B. Claerhout[15], L. Clarke[16], B. De Meulder[5], G. D'Errico[17], A. Di Meglio[18], N. Forgo[19], C. Gans-Combe[20], A. E. Gray[21], I. Gut[22], A. Gyllenberg[23], G. Hemmrich-Stanisak[24], L. Hjorth[25], Y. Ioannidis[26], S. Jarmalaite[27], A. Kel[28], F. Kherif[29], J. O. Korbel[30*], C. Larue[31], M. Laszlo[32], A. Maas[33], L. Magalhaes[34], I. Manneh-Vangramberen[35], E. Morley-Fletcher[36,37], C. Ohmann[38], P. Oksvold[39], N. P. Oxtoby[40], I. Perseil[41], V. Pezoulas[42], O. Riess[43], H. Riper[44], J. Roca[45], P. Rosenstiel[24], P. Sabatier[46], F. Sanz[47], M. Tayeb[2,3], G. Thomassen[48], J. Van Bussel[49], M. Van den Bulcke[49] and H. Van Oyen[14,50]

European Commission

# EU research : COVID-19 response – Data sharing

https://www.covid19dataportal.org/




unCoVer

Unravelling Data for Rapid Evidence-Based Response to COVID-19

Rapid European SARS-CoV-2 Emergency research Response

ReCoDID

Reconciliation of Cohort data in infectious diseases

RCHESTRA

Connecting European Cohorts

EUCARE

European Cohorts of Patients and Schools to Advance Response to Epidemics

European Commission

# Maximising investments in health research: FAIR* data for a coordinated COVID-19 response

**Need:** The interoperability of participant-level data and descriptive metadata, including the need to move from retrospective harmonisation to prospective adoption of data capture standards, i.e., FAIR by design, were highlighted as both the most important and challenging aspects of FAIR data for COVID-19 response

**Key recommendations** by EU-funded research consortia and infrastructures, and the Open Science and policy communities:

- Improve and coordinate the implementation of FAIR
- Promote quality participant-level data and metadata
- Support connections between data types at the participant level
- Develop transparent, ethical, and responsive governance for data reuse

* **Report March 2022**

European Commission

# EOSC implementation: a two-stage approach

| EOSC phase 1: preparatory | EOSC phase 2: continuous EOSC roll-out |
|---|---|
| 2018 - 2020 | 2021 - 2030 |
| **H2020 calls/grants approach** | **Partnership approach in Horizon Europe** |
| **EOSC roadmap** 2018-2020 by the European Commission | EOSC Strategic Research and Innovation Agenda (**EOSC SRIA**) 2021-2027 by the EOSC community |
| **Initial EOSC Governance** (Member States and the Commission to steer and oversee initial EOSC development) | **New EOSC Governance** (Increasingly stakeholder-driven, high-level steering role maintained for the European Commission and the Member States) |

**Findable, Accessible, Interoperable, Re-usable (FAIR) research data/resources**

# EOSC as part of the European Research Area

ERA Priority Area: "*Deepening a truly functioning internal market for knowledge*"

ERA Policy Agenda priority action: **"*Enable the open sharing of knowledge and the re-use of research outputs, including through the development of the European Open Science Cloud*"**

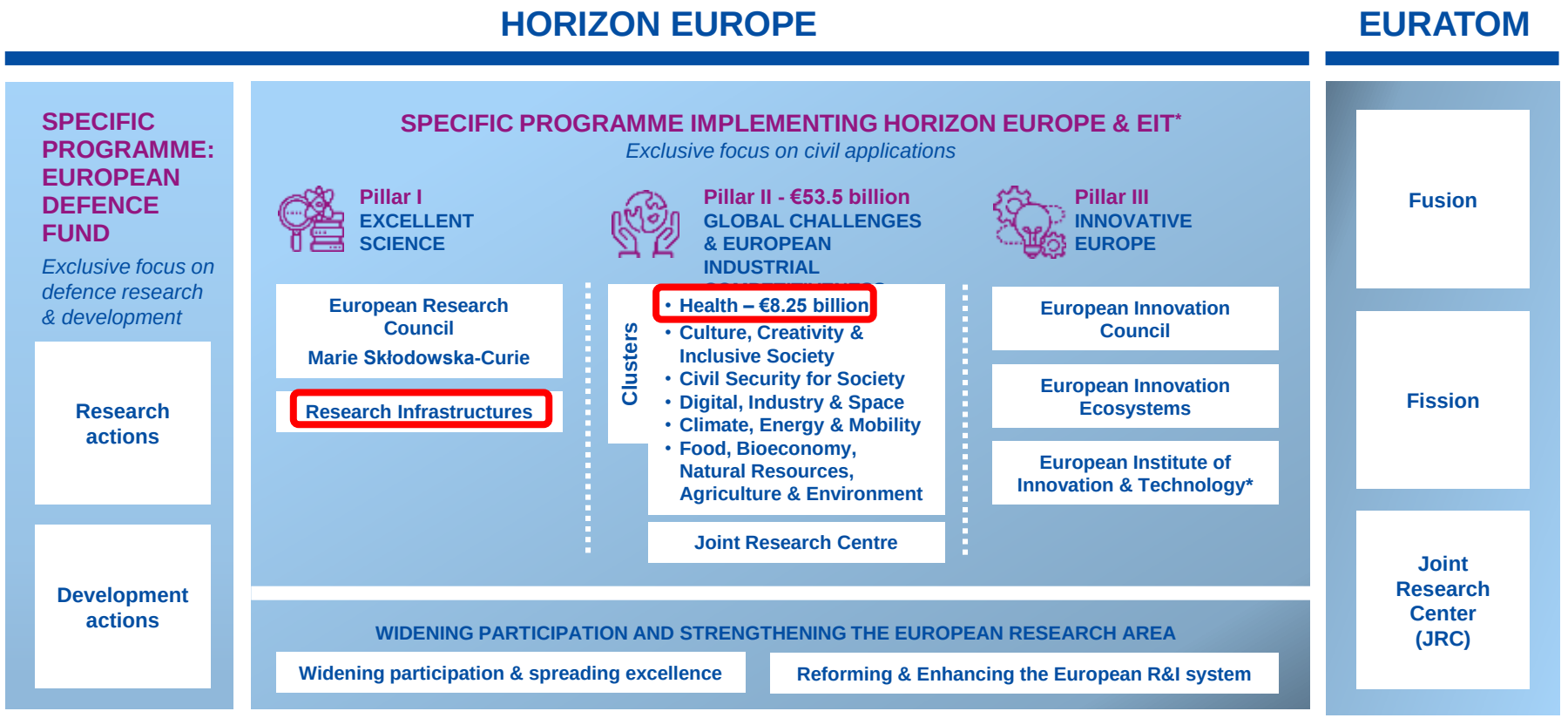
Synergies with other ERA priority actions:

- Data legislative framework for research
- Research Infrastructures
- Green/digital transition
- Reform of Research Assessment
- International cooperation
- etc.

European Commission

# European Health Data Space

## Harnessing the power of health data for people, patients and innovation




* The European Institute of Innovation & Technology (EIT) is not part of the Specific Programme

European Commission

# Horizon Europe – Cluster 1: Health

Aims:

- to contribute to the promotion of social cohesion and inclusiveness and the health and well-being of people.
- to help develop “an economy that works for people” by supporting research (and coordination) in order to make innovative, high-quality health technologies and health care both available and affordable for citizens;
- and to make health care systems more accessible and sustainable, including through the digital transformation of health and care.

# ESFRI European Infrastructures

***Imaging facilities***

- **EUROBIOIMAGING – Imaging facilities**

***Biological Resource Centres***

- **BBMRI - Biobanks and Biomolecular Resources**
- **EMBRC - Marine biology resources**
- **EU-OPENSCREEN - Chemical libraries**
- **INFRAFRONTIER - Mouse archives and clinics**
- **MIRRI – Microbial resources**

***Genomics and proteomics facilities***

- **INSTRUCT - Structural biology facilities**

***Bioinformatics resources***

- **ELIXIR – Data repositories**
- **ISBE – Infrastructure for systems biology**

***Medical research facilities***

- **EATRIS - Translational research facilities**
- **ECRIN - Clinical trials support**
- **ERINHA - High-security labs**

***Wide spectrum of research, discovery and development on health challenges***


*Ecrin graph*

European Commission

# Horizon Europe – Cluster 1: Health

**Strategic Plan 2021-24** (link) → **6 Expected Impacts**

**Work Programme 2021-22** (link) → **6 "Destinations"**

1. Staying healthy in a rapidly changing society
2. Living and working in a health-promoting environment
3. Tackling diseases & reducing disease burden
4. Ensuring access to innovative, sustainable & high-quality healthcare
5. **Unlocking the full potential of new tools, technologies and digital solutions for a healthy society**
6. Maintaining an innovative, sustainable & globally competitive health industry

European Commission

# Health cluster: WP 2021 & 2022 topics relevant to health data innovations

## Destination 5: Unlocking the full potential of new tools, technologies and digital solutions for a healthy society

HORIZON-HLTH-2021-TOOL-06-03: **Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries**
Closure: 21.09.2021
Instrument: RIA
Indicative budget: €30M
Project size: €8M

**InToEHR Cluster**

AIDAVA

DataTools4Heart

eCREAM

IDEA4RC

RES-Q+

European Commission

# HORIZON-HLTH-2021-TOOL-06-03-single-stage
# **Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries)**

**The challenge:**

- Health data in diverse forms and fragmented in multiple local repositories
- Sharing and analysing data from multiple countries in a safe and legally compliant manner

**Research & innovation needs:**

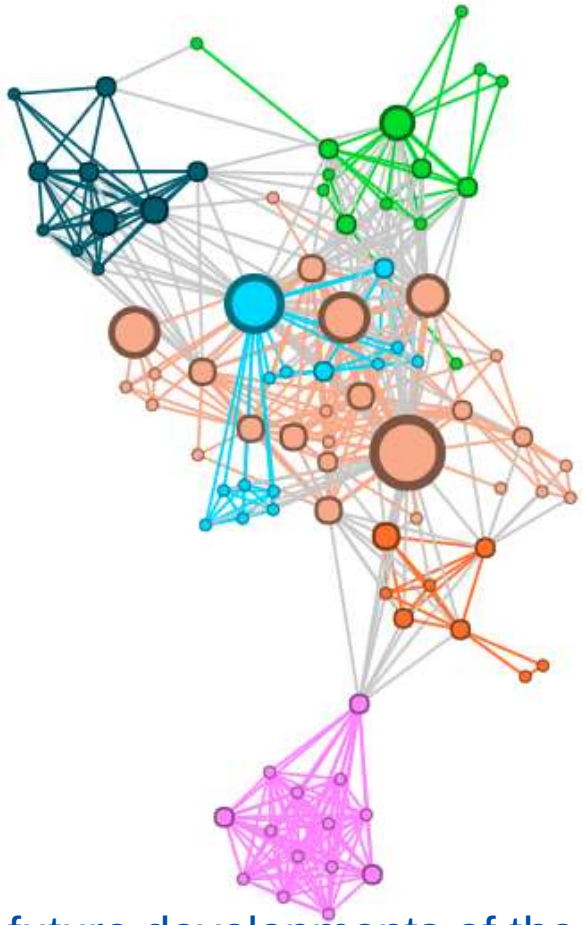
- Improve the ways structured and unstructured health data is stored, analysed and interpreted
- Develop innovative tools and standards to improve the quality, interoperability, machine-readability and re-use of structured/unstructured health data and metadata

**EU research & innovation policies**:

- Contribute to the work on the creation of the **European Health Data Space**
- Contribute to existing European and international standards and specifications for health data.
- Synergise with relevant ongoing research infrastructures

European Commission

# Why clustering of EU-funded projects?



- **Increased impact**
  - Synergies across projects to enable faster progress
  - Maximise outcomes/impact of EU-funded research
  - Knowledge sharing & communication

- **Feedback to EU policies**
  - Health cluster research policy monitoring Input to support the future developments of the Health cluster work programme
  - EC legislative work (e.g. EHDS regulatory proposal)

# 1st InToEHR cluster meeting- November 2022

## Data & Metadata

- Data quality
  - FAIR metrics, data quality metrics and data privacy compliance
- Data models & semantic interoperability
  - Building on existing standards ontologies & terminologies
- Metadata driven automated FAIRification process
  - Contextual information such as structure and language
  - Orchestration of data curation tools

# European Commission workshop – March 2018

Expert opinion paper: ‘
Towards a European health research and innovation cloud (HRIC)’
*Genome Med* **12**, 18 (2020).


OPINION Open Access

Towards a European health research and innovation cloud (HRIC)

F. M. Aarestrup[1], A. Albeyatti[2,3], W. J. Armitage[4], C. Auffray[5*], L. Augello[6], R. Balling[7], N. Benhabiles[8*], G. Bertolini[9], J. G. Bjaalie[10], M. Black[11], N. Blomberg[12*], P. Bogaert[13], M. Bubak[14], B. Claerhout[15], L. Clarke[16], B. De Meulder[5], G. D'Errico[17], A. Di Meglio[18], N. Forgo[19], C. Gans-Combe[20], A. E. Gray[21], I. Gut[22], A. Gyllenberg[23], G. Hemmrich-Stanisak[24], L. Hjorth[25], Y. Ioannidis[26], S. Jarmalaite[27], A. Kel[28], F. Kherif[29], J. O. Korbel[30*], C. Larue[31], M. Laszlo[32], A. Maas[33], L. Magalhaes[34], I. Manneh-Vangramberen[35], E. Morley-Fletcher[36,37], C. Ohmann[38], P. Oksvold[39], N. P. Oxtoby[40], I. Perseil[41], V. Pezoulas[42], O. Riess[43], H. Riper[44], J. Roca[45], P. Rosenstiel[24], P. Sabatier[46], F. Sanz[47], M. Tayeb[2,3], G. Thomassen[48], J. Van Bussel[49], M. Van den Bulcke[49] and H. Van Oyen[14,50]

## Recommendations

- Provide and foster standards, good practices, and guidelines necessary to establish the European HRIC
- Develop and certify the infrastructure and services required for operation of the HRIC
- Enable the HRIC to operate within an ethical and legal framework that is adequate for health systems
- Establish a proper environment for the training of a new generation of data and medical scientist
- Fund public and private initiatives for the development of the HRIC through EU Framework Programmes (e.g. Horizon 2020 and Horizon Europe).

European Commission

# Horizon Europe – Cluster 1: Health

**Strategic Plan 2021-24** (link) → **6 Expected Impacts**

↳ **Work Programme 2023-24** (*to be published soon - end November 2022*)

**6 "Destinations"** → **Topics (Calls)**

1. Staying healthy in a rapidly changing society
2. Living and working in a health-promoting environment
3. Tackling diseases & reducing disease burden
4. Ensuring access to innovative, sustainable & high-quality healthcare
5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society
6. Maintaining an innovative, sustainable & globally competitive health industry

Focus on outcomes contributing to the impacts specified per Destination

# Thank you for your attention