Data-driven approaches in health research & innovation

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The European Health Data Space (EHDS)

- The EHDS will **empower individuals to take control of their health data** and **facilitate the exchange of data** for the delivery of healthcare across the EU (primary use of data)
- It will also foster a **genuine single market for electronic health record systems**
- The EHDS will provide a **consistent, trustworthy and efficient system for reusing health data** for research, innovation, policy-making and regulatory activities (secondary use of health data)
- In April 2024**, the European Parliament and the Council reached a political agreement on the Commission proposal for the EHDS**
- **Final adoption** and publication expected in **autumn 2024**

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

European Commission

Horizon Europe call 2022: “New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment”

The challenge

- Harness RWD and synthetic data for regulatory decision-making and for health technology assessment (HTA)

Research & innovation needs

- Develop evidentiary standards in the analysis of real-word data (RWD) and/or synthetic data for regulatory decision making and/or HTA
- Define methodological standards for the regulatory acceptability of RWD and/or synthetic data
- Develop machine learning methods to help process and analyse RWD and/or synthetic data for regulatory decision making and HTA

EU research & innovation policies

- Synergise with the European Health Data Space and the DARWIN Initiative

Call number: HORIZON-HLTH-2022-TOOL-11-02

European Commission

The MetReal project cluster

MORE EUROPA
(01/2023 - 12/2027)

oncovalue
(12/2022 - 11/2026)

Real4Reg
(01/2023 - 12/2026)

REALM
(01/2023 - 12/2026)

REDDIE
(01/2023 - 12/2026)

INSAFEDARE
(11/2023 - 10/2026)

More-EUROPA: More Effectively Using Registries to suppOrt PAtient-centered Regulatory and HTA decision-making

ONCOVALUE: Implementing value-based oncology care at European cancer hospitals: An AI-based framework for assessing real life effectiveness of novel cancer therapies in real-time

Real4Reg: Development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making and health technology assessment along the product lifecycle

REALM: Real-world-data Enabled Assessment for heaLth regulatory decision-Making

REDDIE: Real-world evidence for decisions in diabetes

INSAFEDARE: Innovative applications of assessment and assurance of data and synthetic data for regulatory decision support

European Commission

Real4Reg: Unlocking Real-World Data with AI

- **Develop AI/ML-based methods & tools** for the effective analyses of RWD in regulatory decision-making & HTA for medicines

- **Conduct a retrospective observational cohort study**, based on national healthcare registers and claims data

- **Use-cases aligned with regulatory decision-making**: pre-authorisation, evaluation and post-authorization:

  - description of the study population (breast cancer, ALS)
  - historical controls & synthetic data (breast cancer, ALS)
  - safety assessment (fluoroquinolones)
  - effectiveness + drug repurposing (SGLT2 Inhibitors)

7 million EUR

2023-2026

10 partners

HORIZON EUROPE

www.real4reg.eu

The Innovative Health Initiative

- Focus: cross-sectoral approaches to facilitate creation of new products and services to prevent, intercept, diagnose, treat and manage diseases and foster recovery more efficiently.

- Goal: lay foundations for development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be implemented into healthcare systems.

Total budget: 2.4 billion EUR over 7 years

(half provided by the EU, half provided by member industry associations and contributing partners)

https://www.ihi.europa.eu/

EHDEN: European Health Data and Evidence Network

- Standardising health data across Europe, enhancing interoperability and accelerating evidence generation.
- RWD network: 187 data partners in 29 countries
- Over 850 million anonymous health records being harmonised to OMOP common data model
- Strong research impact with several use cases
- Infrastrucure used by DARWIN-EU
- Training: EHDEN Academy
- Sustainability: the EHDEN Foundation

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

imi innovative medicines initiative

DARWIN EU

31m EUR budget, 14.1m from EC

2018-2024

25 partners

www.ehden.eu

Improving clinical decision-making through better use of health data

Aim: Establish and **open platform that integrates and analyses diverse health data** to enable **better research, patient care and health outcomes**.

- IDERHA addresses the challenge of **accessing, integrating and health data from various sources**, including digital technologies, patient-reported outcome measures, clinical trials and routine care.
- A platform will be designed with **lung cancer as a use case**, with the goal of **improving diagnosis, treatment and research**, utilising remote technologies, such as wearables and digital applications, to monitor patients' conditions and **provide real-time data for informed decision-making**.
- The project will ensure **compliance with current and forthcoming health data legislation**, including the European Health Data Space (EHDS), and **prioritise patient empowerment and data sharing recommendations.**


42.7m EUR budget, 23m from EC


2023-2028


37 public and private partners

https://www.ihi.europa.eu/projects-results/project-factsheets/iderha
https://www.iderha.org/

Framework to improve the integration of patient generated health data to facilitate value based healthcare

Aim: Develop an evidence-based, real-time framework to integrate patient-generated health data to facilitate value-based healthcare.

- IMPROVE addresses the challenge of **scattered patient data** across different platforms and systems, hindering its effective use in improving patient care.
- The framework will **integrate data from patient-reported outcomes, experiences and preferences**, as well as **real-world data** from remote technologies like wearables and mobile apps.
- The platform will be tested trough **ten use cases across five disease areas** (ophthalmology, oncology, cardiovascular disease, chronic inflammation, and neurology) in different European countries.
- The project aims to put **patients at the centre**, advancing the use of patient preferences and experiences in treatment decisions and medical device design, enabling cost-effective care.


18.7m EUR budget, 10.3m from EC


2023-2028


27 public and private partners

https://www.ihi.europa.eu/projects-results/project-factsheets/improve

IHI: data-intensive projects

- SOPHIA Obesity. 800 000 patient records
- ConcePTION Pregnancy & breastfeeding. 21 data access providers
- BIGPICTURE Whole slide pathology images. 3 million slides
- EPND Alzheimer's Disease. >160,000 cohort records
- RHAPSODY Type 2 diabetes. > 70,000 cohort records
- DRIVE Flu vaccine effectiveness. 21 hospitals, >1000 GPs
- BigData@Heart Cardiovascular diseases. >5 million records
- HARMONY Haematological malignancies. 163 000 records
- PIONEER Prostate cancer. >3 million records
- OPTIMA Prostate, breast and lung cancers. >100 million records
- IDERHA Lung cancer. ~1.5 million records
- EHDEN EHR, registry, claims. >850 million patient records

www.imisophia.eu; www.imi-conception.eu; www.bigpicture.eu; www.epnd.org; www.imi-rhapsody.eu; www.drive-eu.org; www.bigdata-heart.eu; www.harmony-alliance.eu; www.prostate-pioneer.eu; www.optima-oncology.eu; www.iderha.org; www.portal.ehden.eu

IHI Regulatory Science Summit 27-28 Feb 2024, Brussels

Forum for discussion and exchange of views to help identify research needs and specific IHI topics, with the following objectives:

- discuss regulatory science **challenges and opportunities** that would be game changers in enabling the development of healthcare solutions;
- understand the needs of all stakeholders and identify **research gaps that could be addressed in IHI** as a cross-sectoral, public-private partnership and contribute to advance regulatory science;
- discuss how to **maximise regulatory impact** of IHI projects, **optimise regulatory engagement** and the regulatory acceptance framework.

RWD supporting evidence generation for regulatory purposes

- Generation of evidence that meets diverse information needs and requirements, including alignment on **common methodologies**, integration of different sources of evidence, including registries and agreement on core data fields
- Use of **non-randomised control trial designs**
- Create greater **predictability and understanding** of the use of RWE by all stakeholders to support decision making, also considering the proliferation of RWE frameworks

IHI – future opportunities

Call 8 – Topic 4: Patient-centred clinical-study endpoints derived using digital health technologies

- New methods for analysing patient preference information, clinical outcome assessments and digital health technology-derived measures, to quantify the patient-centred benefits of therapies.
- Tentative call opening: end June 2024
- Tentative call deadline: October 2024 (for Stage 1 proposals)

Call 6 – Topic 2: Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence

- The scope includes new methods for analysing patient preference information and digital health technology-derived measures to quantify the patient-centred benefits of therapies
- Call closed (second-stage deadline in October 2024)

https://www.ihi.europa.eu/

European Commission

Thank you!

HorizonEU

http://ec.europa.eu/horizon-europe

EU Funding & Tenders Portal (europa.eu)