Funding programmes and regulatory science research

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European Commission

Application of regulatory science: win-win for research consortia and regulators

- Early engagement of regulators is key for innovation planning and development in the context of understanding regulatory requirements
- Enabling faster translation of health technology innovation into practice

- Regulators are informed about ongoing research, including methodology
- Awareness of opportunities and bottlenecks, e.g. innovative pathways of earlier access; need for better regulatory evaluation methodology of AI

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

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

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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

SUSTAIN-HTA

- **Understand the needs** of European HTA bodies for new innovative HTA methods and tools
- Take stock of the innovative HTA methods and tools developed so far, e.g. in recent EU-funded projects
- **Support HTA bodies in the uptake** of innovative methods and tools, tailored to their needs.

→ Bridge the gap between HTA method development and implementation

4.5 million EUR

2024-2027

15 partners

www.sustain-hta.org

Trends

- Increasing emphasis on translation of basic research into clinical practice
- The regulatory step is a necessary step
- Awareness of regulatory aspects among researchers is of growing importance
- Interaction with regulators can be mandated in call topics
- Funding opportunities for new methods useful in regulatory or HTA decision making: NAMs, RWE, clinical trials methodologies, new statistical methods…

Thank you

European Commission