Regulatory science research – EU perspective

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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

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

Horizon Europe call 2025: “Boosting the translation of biotech research into innovative health therapies” (closed 16 September 2025)

The scope

- Speed up the development of innovative biotech-based therapies by supporting the initial phases of clinical research
- The topic targets collaborative multidisciplinary consortia of SMEs, academics, clinicians and research organisations… to launch the clinical development of novel biotech-derived therapeutics (vaccines, recombinant molecules, ATMPs, nano-based drugs, RNA therapies etc)
- Proposals should include a clinical study phase I, II or I/II
- Proposals should include a clearly defined exploitation plan, with a detailed proposed route to commercialisation, description of the intellectual property ownership and benefit for the SME(s). The plan should include an anti-shelving strategy, commercial forecasts for the product sales & revenue, and strategies for follow-up financing as well as market authorisation. The exploitation strategy should envisage a first deployment in the EU.

Call number: HORIZON-HLTH-2025-01-TOOL-05

Horizon Europe call 2025: “Facilitating the conduct of multinational clinical studies of orphan devices and/or of highly innovative (“breakthrough”) devices” (closed 16 September 2025)

The scope

- Design and conduct multinational clinical studies in a minimum of two different countries in the EU or Associated Countries, with a focus on orphan devices and/or highly innovative (“breakthrough”) devices, with a view to demonstrate the safety and clinical performance of the device(s) subject to the study

- …

- For multinational clinical studies, authorisation for the study approval by more than one national competent authority may be necessary. Develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with regulators and other relevant bodies (e.g., European Medicines Agency (EMA), EMA expert panels, national regulators, Health Technology Assessment bodies, etc.) in a timely manner. Consider also the potential for future regulatory impact of the results.

Call number: HORIZON-HLTH-2025-03-IND-03-two-stage

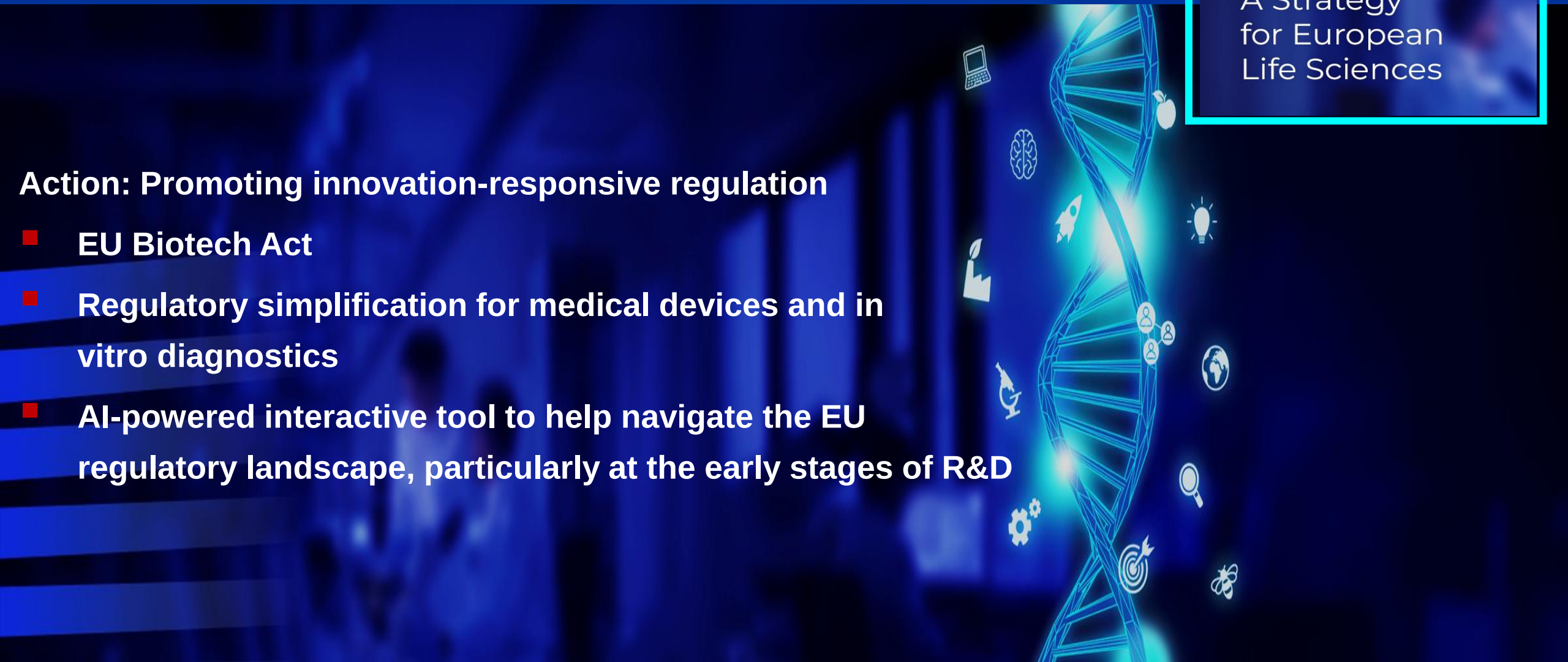
Regulatory steps are part of the “life science innovation journey”

- Increasing emphasis on translation of basic research into clinical practice
- Awareness of regulatory aspects among researchers is of growing importance
- Certain call topics require a regulatory strategy at the proposal stage
- Interaction with regulators can be indispensable to the success of the project, and mandated in call topics
- Regulatory acceptance/qualification may take time and effort
- Conscious adherence to regulatory pathways shortens time to patient and to market
- Particularly crucial for novel technologies

The Life Sciences Strategy: position the EU as the world's most attractive place for life sciences by 2030

FOR LIFE SCIENCES

A Strategy for European Life Sciences



Action: Promoting innovation-responsive regulation

- **EU Biotech Act**
- **Regulatory simplification for medical devices and in vitro diagnostics**
- **AI-powered interactive tool to help navigate the EU regulatory landscape, particularly at the early stages of R&D**

Thank you

European Commission