How new EU legislations will transform medicines regulation

Opportunities across the medicines lifecycle

Faster, evidence-based R&D – identify unmet needs, refine target populations, accelerate clinical trials design

More efficient clinical trials – improved patient recruitment, continuous safety monitoring

Better regulatory decision-making: benefit-risk assessments, adaptive approvals, post-marketing evaluations

Optimised Market Access and Pricing – RWD supporting HTA and reimbursement decisions

→ But more is needed to make sure data can enable faster and better access to medicines

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Legislative ecosystem

Data Access and sharing

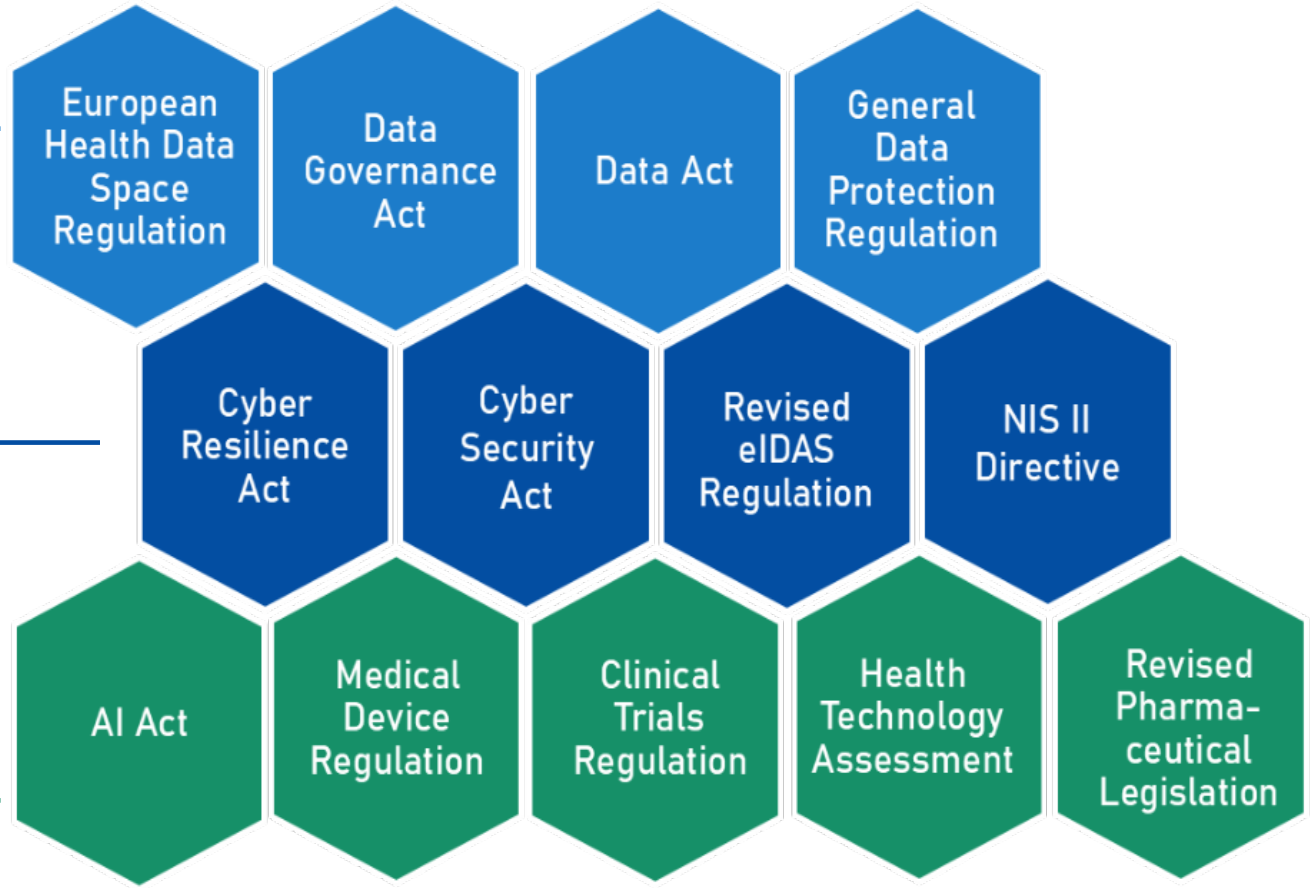
- Common rules and governance for the protection, access to, use, reuse and sharing of health data

Security and Trust

- Common rules, standards and certifications for cybersecurity, and trust services ensuring the security of and trust in healthcare organisations' information systems

Safety and Robustness

- Common rules, for the development, validation of technologies, including AI systems, and their safe use across the medicine and medical device lifecycle



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Strategic ecosystem

Infrastructures

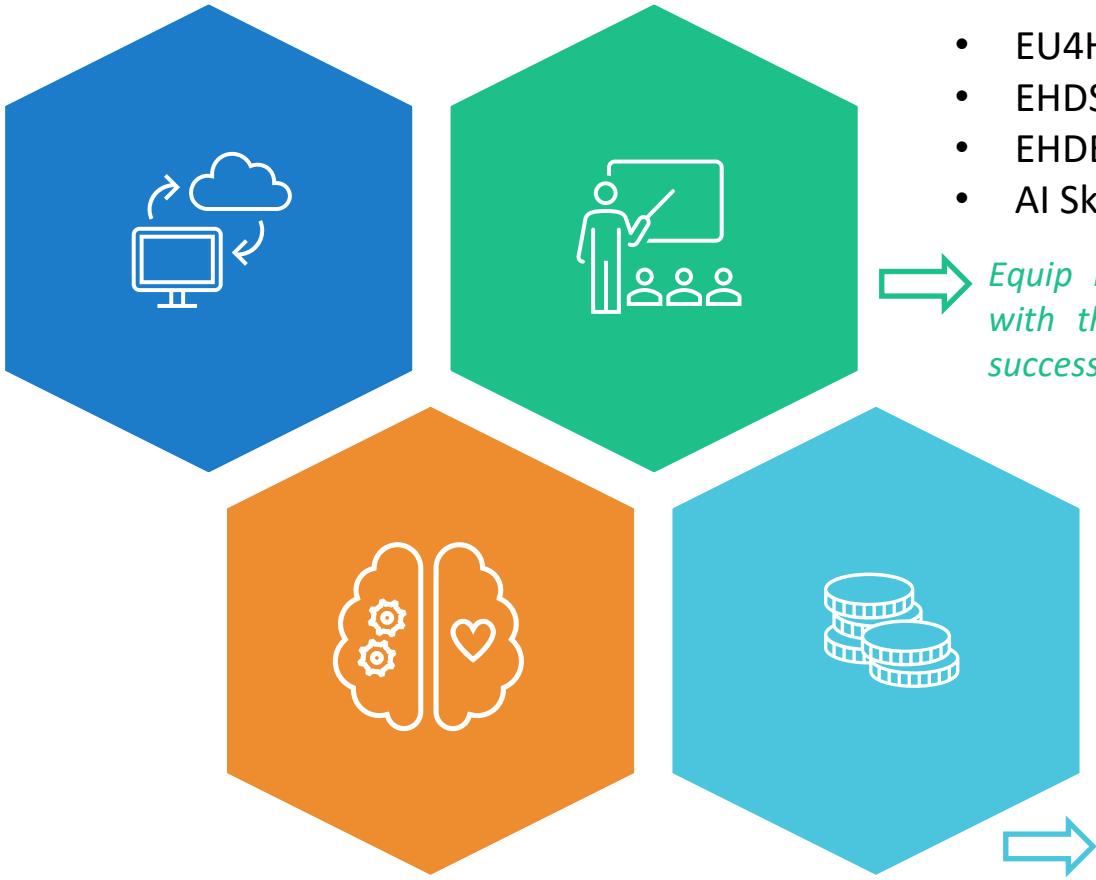
- DARWIN EU
- HealthData@EU
- AI Testing and Experiment Facilities / AI Factories

Providing researchers and innovators with the right infrastructures, support and settings to develop and validate their approaches

Development and Adoption

- Apply AI Strategy
- Life Science Strategy
- Biotech Act

Enhance the competitiveness of the EU by boosting data and AI adoption and innovation, including in life sciences



Skills

- EU4Health & Pact for Skills
- EHDS Capacity Building activities
- EHDEN Academy
- AI Skills Academy

Equip researchers and decision-makers with the right skills and resources to successfully leverage health data.

Financing

- Horizon Europe
- Digital Europe
- Innovative Health Initiative (IHI) programme

Funding the research, development and deployment of data and AI in Europe.

European Health Data Space

Primary use

Empower individuals to access and control their personal health data + Ensuring seamless exchanges for continuity of healthcare.

Building on existing voluntary **MyHealth@EU** infrastructure not touching upon national rules on provision of care.

Promote International standards (i.e. EMA PMS, SNOMED CT, ISO)

Secondary use

Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Common European rules on who has to make which data available for which purposes and under which conditions.

Common infrastructure : **HealthData@EU**

Accelerated procedure for public bodies

EHR systems requirements

Creating a single market for electronic health records systems, supporting both primary and secondary use.

Product legislation for two components of EHR systems: interoperability and logging; Full harmonisation for those two components

All EHR systems providing standardised data (e-prescrption, patient summary)

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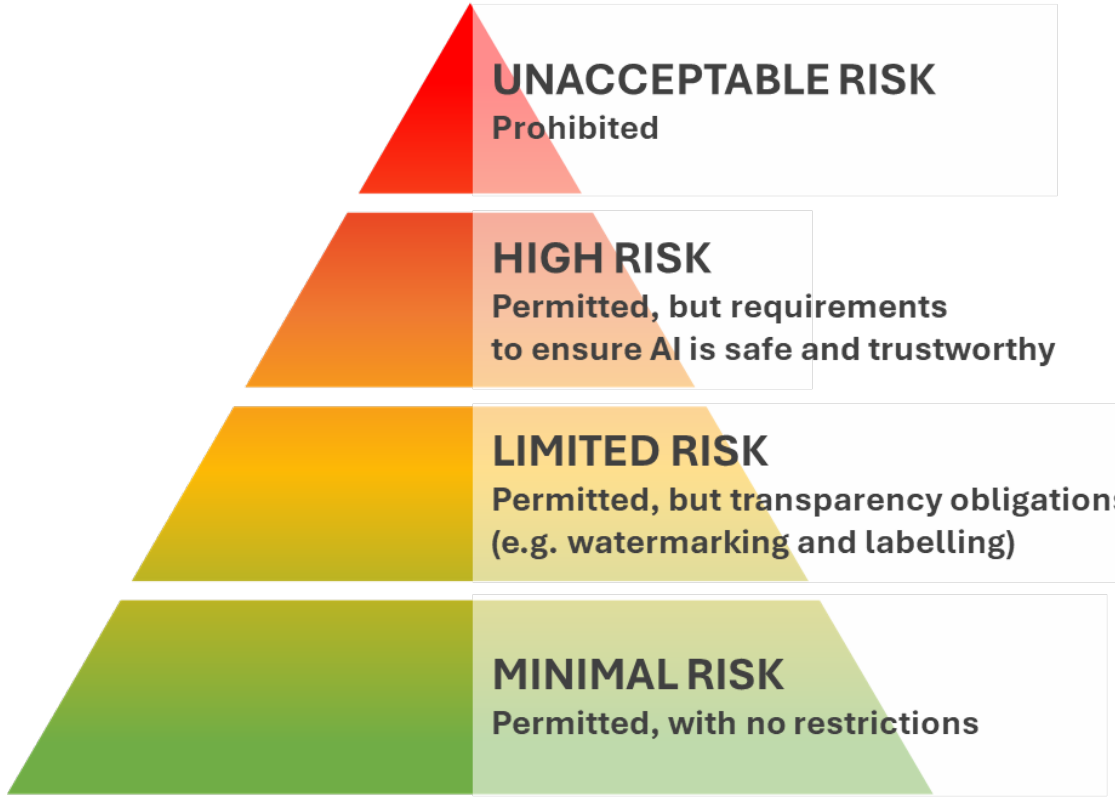
AI Act



First regulation on AI worldwide

Risk-based approach

Entered into force 1 August 2024

Complementary and coherent with the Union rulebook

Advancing the safe, effective, efficient and equitable deployment of AI in Healthcare (COMPASS AI project): Guidance, validation frameworks, and a dashboard for AI deployment monitoring across Member States

Making EHDS and AI work together (SHAIPED project): "regulatory sandboxes" for AI medical devices, assisting Health Data Access Bodies, developers, authorities, and data holders to seamlessly integrate AI solutions into

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Health Technology Assessment Regulation

In application since **12 January 2025**

Common **framework and procedures** for cooperation of Member States on health technologies at Union level

Strengthens data requirements for Joint Clinical Assessments (JCAs) by promoting standardized, high-quality clinical and real-world evidence

Encourages efficient cross-border data sharing and reuse, aligning methodologies for evidence generation (including RWD/RWE)

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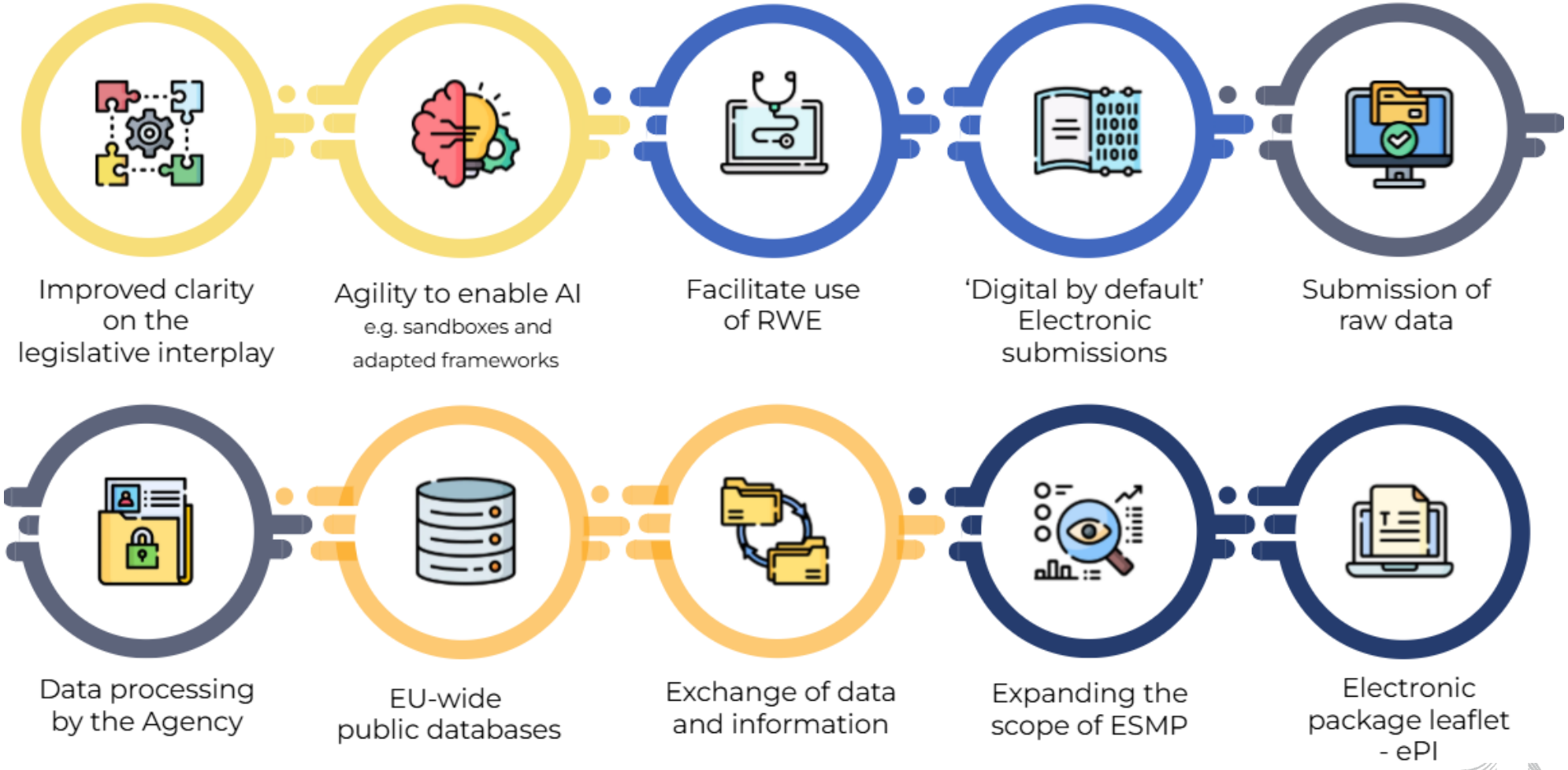
The new EU pharmaceutical legislation: Driving digital transformation in medicines



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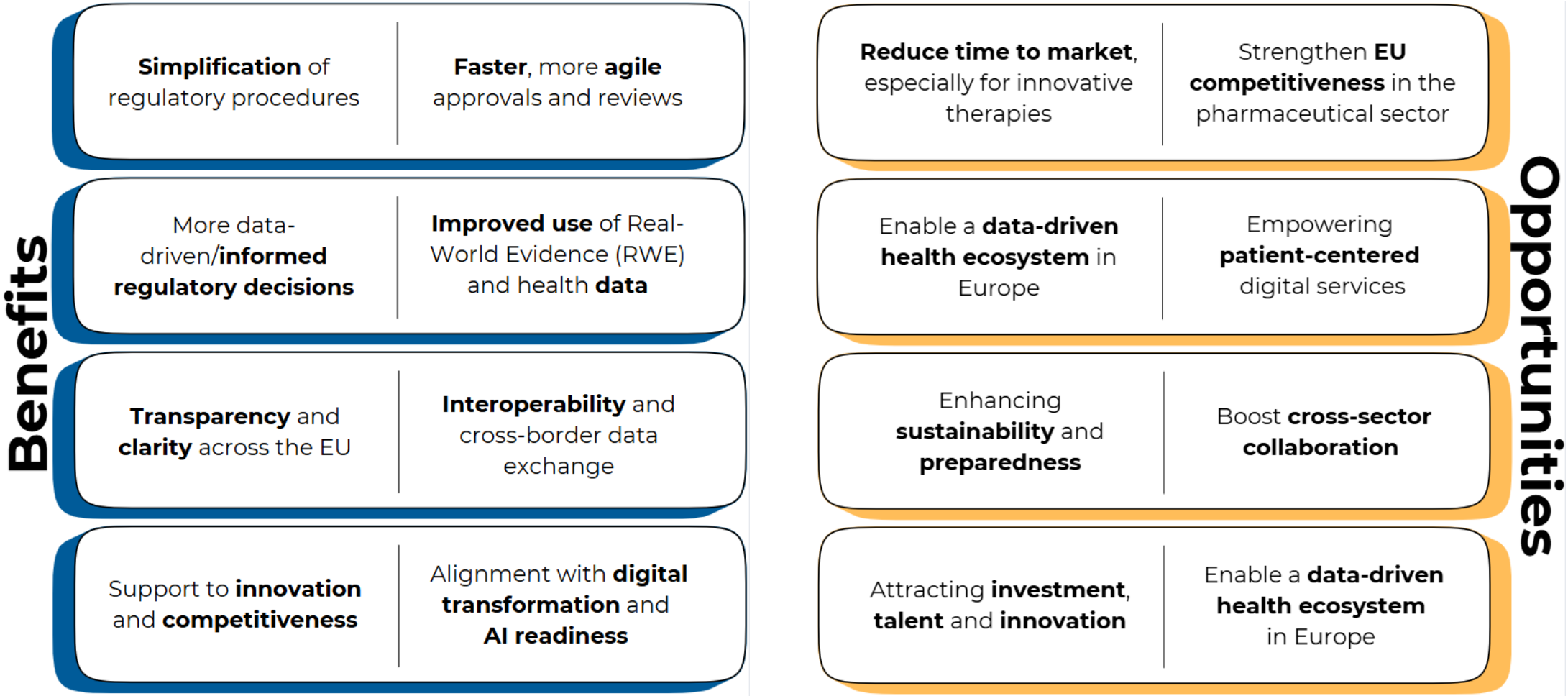
MDR’s contribution to the shift to data-driven legislation

- Strong emphasis on data quality, traceability and transparency, overall reinforcing the trends towards **ongoing evidence generation**
- MDR introduced:
  - **EUDAMED** for centralised device and safety data – mandatory use of 4 modules from 28 May 2026
  - **UDI system** improving traceability and recall readiness
  - **Monitoring availability of devices**
  - **Strengthened Post Market Surveillance** → constant safety/performance monitoring
  - **Robust clinical data expectations** pre-market and post-market
  - **Reinforced requirements for medical devices software** including cybersecurity

Benefits and Opportunities



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Thank you