

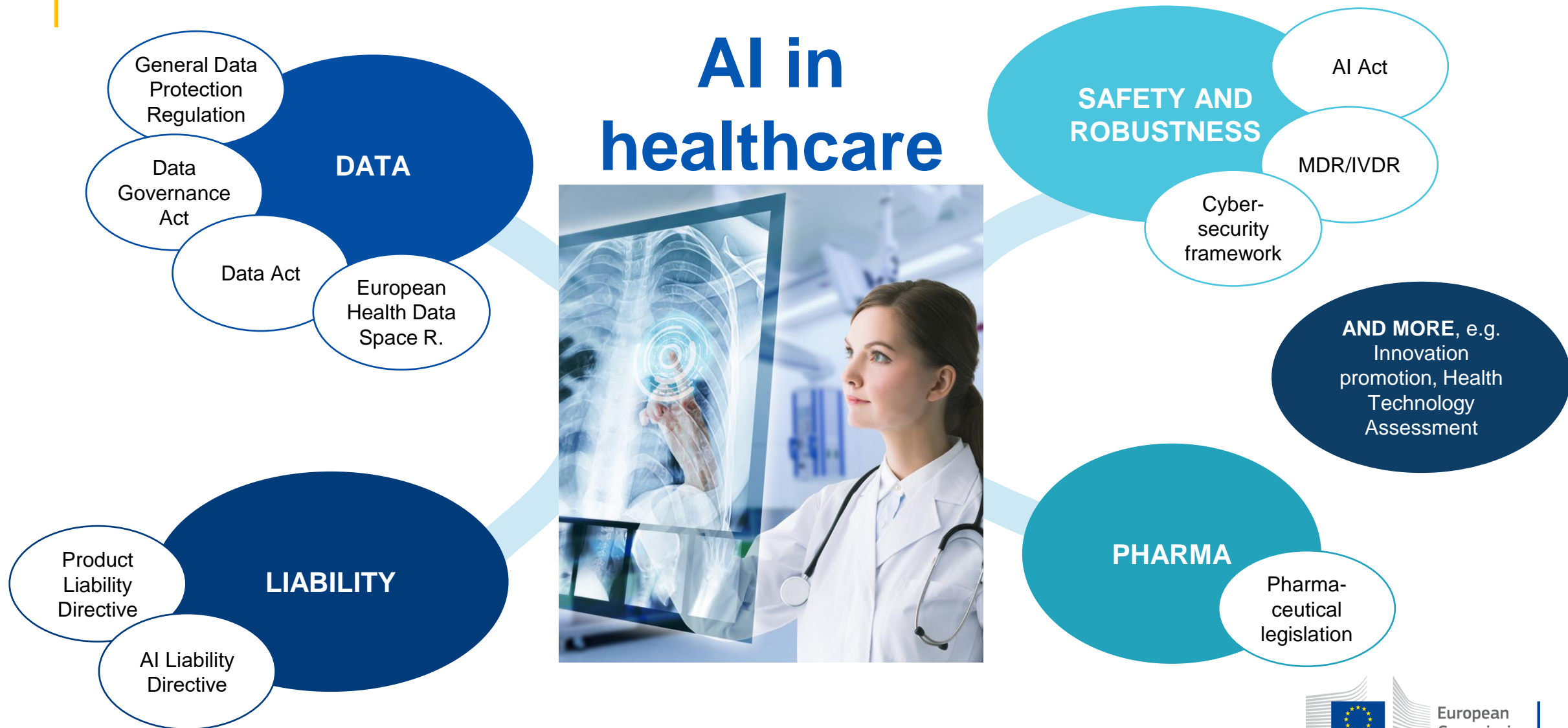


Promoting trustworthy AI in healthcare in Europe – European Commission initiatives

European Digital HealthTech Conference
15 May 2024
Luxembourg

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AI in healthcare – EU regulatory context overview



Artificial Intelligence Act

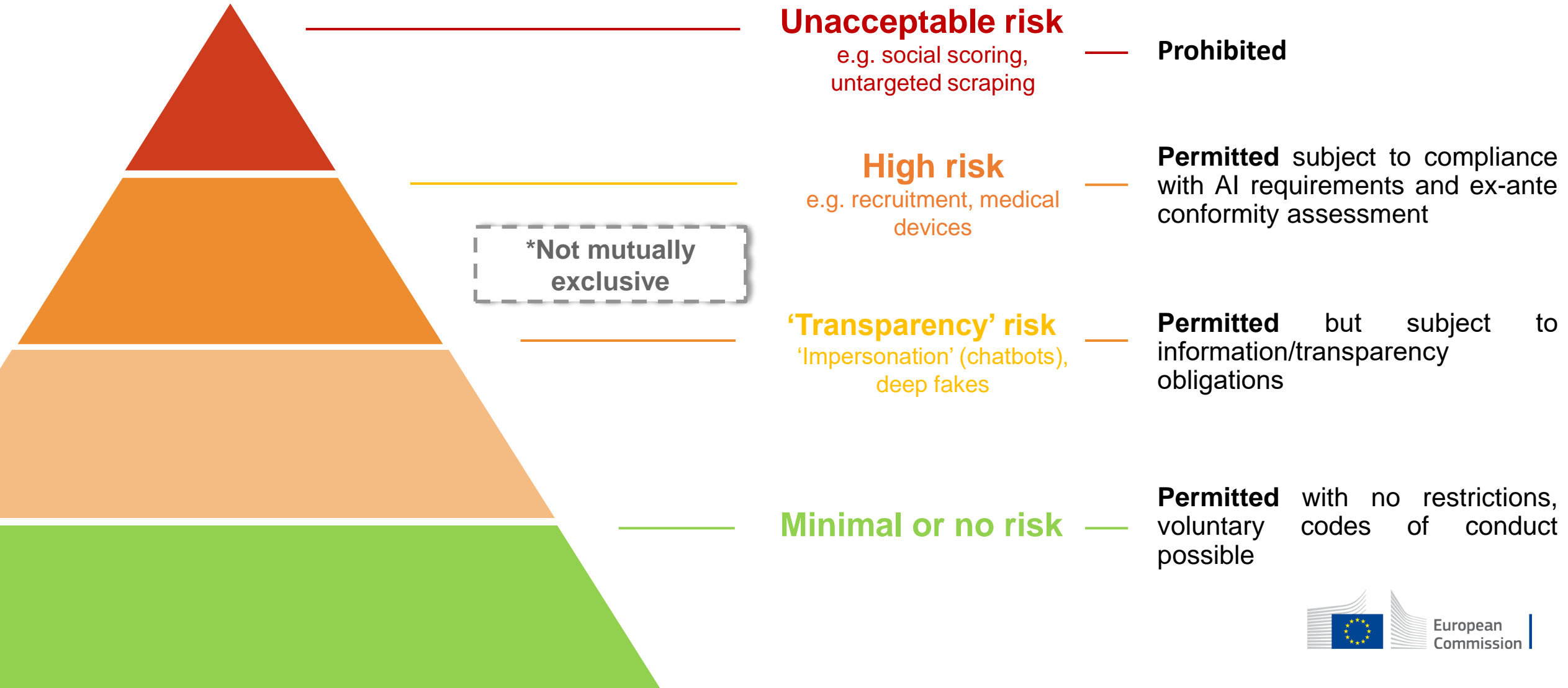
Aims to ensure that AI systems placed on the EU market are **safe** and respect **fundamental rights** and EU **values**, while significantly stimulating investment and innovation

Key elements

- Regulates AI systems based on their **risk** to cause harm to society
- Regulates only a **minimum**: High-risk applications
- Embedded and stand-alone systems
- Mandatory **fundamental rights** impact assessment for **high-risk** AI systems
- For General Purpose AI: Systemic risk approach
- Promotes **regulatory sandboxes** and **real-world testing** for AI innovation
- Establishes a light governance structure for successful implementation, including the **European AI Office**

AIA – Risk Based Approach

Potential harmful impact on the health, safety and fundamental rights of persons



Artificial Intelligence Act in Healthcare

Ensuring safety while stimulating innovation in the healthcare sector

Examples of applications

Examples of healthcare AI applications:

- Clinical decision support systems
- Patient monitoring systems
- AI for robotic surgery

Innovation promotion

Supporting innovation in healthcare through:

1. **Increased trust** of patients and professionals → increased demand of AI in healthcare
2. **Increased legal certainty** and harmonised rules across the EU → access to bigger markets, with products that users and consumers appreciate and purchase
3. **Enables regulatory sandboxes** → controlled environment for developers to test innovative technologies under real-world conditions, including healthcare applications

Regulatory synergies

European Health Data Space Regulation:

Makes available data to develop, test, train, and validate AI systems in the healthcare sector.

Medical Device Regulation / In-vitro Diagnostic Regulation:


AIA and MDR/IVDR **apply jointly** for AI-enabled medical devices (New Legislative Framework). The principle is clear and simple: AIA adds an “**additional layer**” of requirements that need to be proven under the conformity assessment. **AIA covers only what is not yet covered by MDR/IVDR, avoiding overlap and contradiction.**


Public webinar on the AI Act on 16 May 2024


On 16 May, 11.00 – 12.00 (CEST) the European AI Office will host a public webinar on the Artificial Intelligence Act


 Risk Management Approach in the #AIA: Must-Know Fundamentals for Regulatory Compliance

 Join the webinar on 16 May to learn:

 The AI Act's regulatory logic with insights into risk and quality management systems, compliance requirements for high-risk AI systems; #RiskManagement #Compliance

 Essential elements for developing risk assessments on general-purpose AI models with systemic risks; #AIRegulation #SystemicRisk

 How to be ahead of the curve and future-proof your regulatory compliance with the AI Act; #FutureProofing #RegulatoryCompliance

 Whether available international standards, such as recent ISO 42001, are sufficient for the regulatory compliance under the AI Act. #ISO42001 #InternationalStandards #CEN/CENELEC

Promoting trustworthy AI in Europe: AI Innovation Package from January 2024



Communication on boosting startups and innovation in trustworthy artificial intelligence (January 2024)

- To foster an innovative European AI ecosystem for startups and innovators, including in health
- Strategic investment framework for **trustworthy AI**
- Financial support for **GenAI** through Horizon Europe and Digital Europe Programme
- Initiatives to boost up **skills** on GenAI

GENAI4EU Initiative

- EUR 500 million initiative to stimulate the uptake of **GENAI** in key sectors including healthcare
- Development of **novel use cases** and emerging **applications**
- **Collaboration** between AI startups, industry, public sector

AI Factories

- **One-stop-shops** to test and validate large-scale AI models and solutions
- Privileged access to **supercomputers** to AI startups – including in healthcare
- Linked to **TEF-Health** for pre-market validation

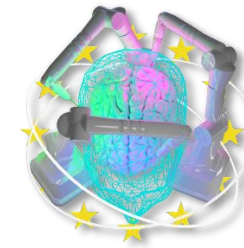
Promoting AI innovation: Regulatory sandboxes supported by AI Act

- **AI innovators** can **test** their solutions in a controlled environment, in **compliance** with the **AI Act**
- **Priority** access to **SMEs**
- At least one **sandbox** in each EU Member State
- Leverage **TEF-Health** facilities



AI Testing & Experimentation Facility for Health (TEF-Health)

- Launched January 2023, co-funded under DIGITAL (EUR **60 million** over 5 years)
- Support developers in healthcare AI and robotics **bring their solutions to the market**
- Assisted **validation** and **certification** of AI and robotics in medical devices
- **Regulatory sandboxes** to test AI solutions in controlled real-world environments



TEF-Health

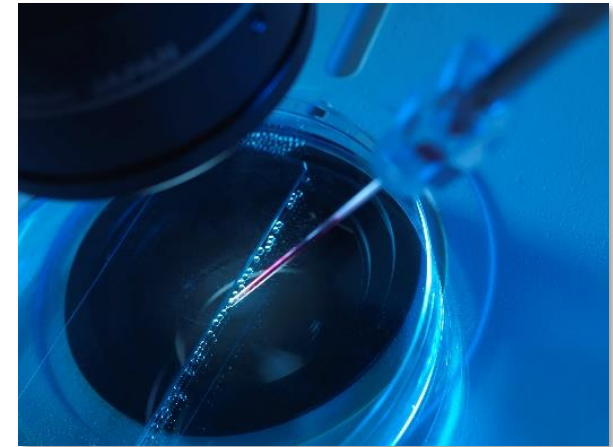
Testing and Experimentation Facility
for Health AI and Robotics



Communication on boosting Biotechnology and Biomanufacturing in the EU (March 2024)

➤ Push the application of AI, in particular GenAI, in health biotech and biomanufacturing

- Targeted actions to support innovation in biotechnology and biomanufacturing, including application of AI in these sectors
- Biotech and biomanufacturing companies applying AI benefit from the **AI Innovation Package**
- Support the development of advanced **GenAI models**, through health data **infrastructures** & **Euro HPC supercomputing**



EU funding on digital health including AI: an overview

Horizon Europe (2021-2024)

€549m



Digital Europe (2021-2024)

€129m



EU4Health (2021-2022)

€115m



Innovative Health Initiative (IHI) 2021-2027

€351m under Horizon
Europe to date



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EU Spotify

Research & Innovation support – Horizon Europe

Destination 1: tackling demographic change

- Digital innovation for **active and healthy living**
 - EUR 100m

Destination 3: reducing disease burden

- **AI solutions** for treatment & care
 - EUR 60m

Destination 4: access to sustainable & high-quality care

- **Decision-support tools** for better health care delivery
 - EUR 40m

Destination 5. Unlocking new health technologies and digital solutions

- New methods for **data integration & real-time data analysis** for personalised care
- Computational **models, Virtual Human Twins**
 - EUR 286m

Destination 6. Innovative, sustainable & competitive health industry

- **EHDS** implementation
- Quality & reliability of **wellness apps**
- Harmonised methodologies for **health technology assessment**
 - EUR 63m

Innovative Health Initiative (IHI)

EU public-private partnership funding health research and innovation

Funding 2021-2027: €2.4 billion in total, of which €1.2 billion from Horizon Europe



Past calls

- **IHI call 1** (2022): cancer, neurodegenerative diseases, and health data
- **IHI call 2** (2022): cardiovascular disease and early feasibility studies
- **IHI call 3** (2022): diseases of unmet public health need, rare diseases, mental health, hospital efficiencies, and patient-generated evidence
- **IHI call 4** (2023): 3Rs, patient-centric blood sample collection, clinical trials, and the environmental impacts of healthcare
- **IHI call 5** (2023): 3Rs, theranostics, stroke management and synthetic data
- **IHI call 6** (2024): treatment persistency and use of real-world data and evidence

Open calls

- **IHI call 7:** heart disease, the healthcare workforce, and biomarker validation (Deadline to apply: **22 May 2024**, 17.00 CEST)

