AI & Data in Healthcare

Healthcare Data Innovation Council

26 September 2024

#DATASAVESLIVES

Welcoming remarks

Benjamin Baelus
Director Government Affairs Belgium and Luxembourg, Microsoft

Introduction and presentation of the Healthcare Data Innovation Council

Stefano Sedola
Co-founder and partner, Stratejai

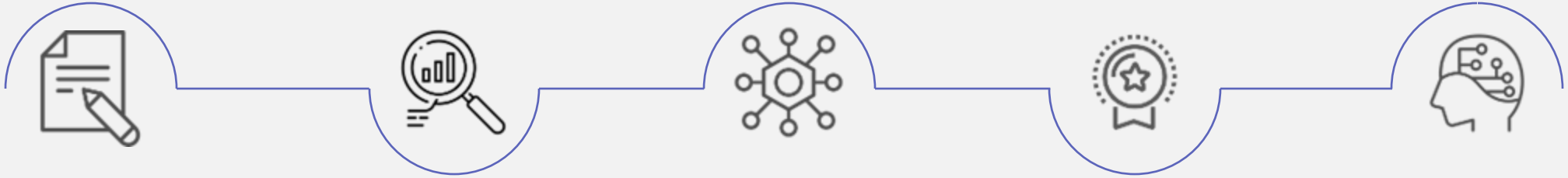
About the HDI Council

The HDI council was established in 2022 as **think tank** of multidisciplinary and international healthcare actors aiming at advancing recommendations on regulatory frameworks and promoting opportunities for using **AI and data in the healthcare sector**.

Find out more at
https://healthdatainnovation.eu

#DATASAVESLIVES

The **objectives** of the HDI Council are focused on demystifying current and upcoming regulations on AI and data in the industry while promoting opportunities for research and deployment of new technologies.



Promote and share **best practices** on data usage for healthcare evolution

Facilitate **data-driven approaches** in HC systems

Unleash new initiatives on **secondary use of data**

Accelerate harmonization and **data-sharing standards**

Improve the usage of **AI and advanced analytics**

Our **members** are multidisciplinary and international experts representing the main segments of the healthcare industry.

20 experts in **2022**
24 experts in **2023**

Participation in the HDI Council is on a **voluntary** basis.

Experts represent the perspective of their industry sector but are not engaged in an official capacity.

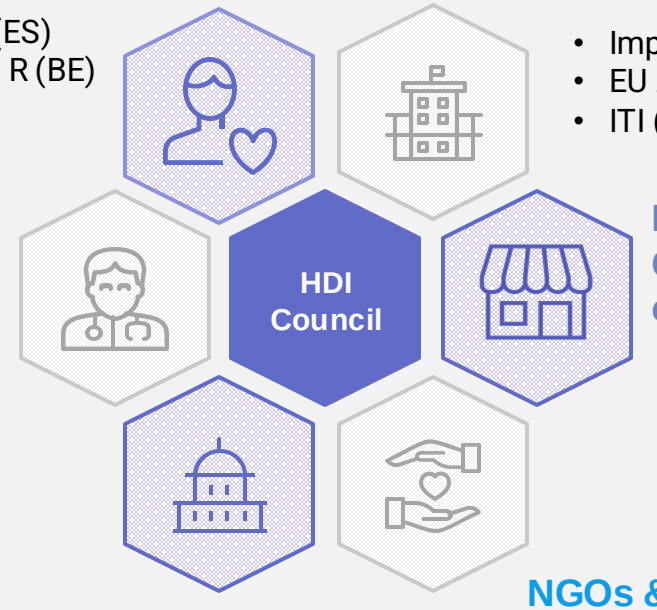
Overview of represented organisations:

Patients

- Foundation 29 (ES)
- Patient Support R (BE)

Research Institutions

- Imperial College London (UK)
- EU *H.Pylori* Registry (ES)
- ITI (ES)



Physicians & Health Workers

- INCLIVA (ES)
- Karolinska University Hospital (SE)
- Udine University (IT)
- IPO Porto (PT)
- CHU-Brugmann (BE)
- University of Latvia (LV)

Life Sciences & Healthcare Organizations (commercial org.)

- Takeda (CH)
- Microsoft (BE)
- Decentriq (CH)
- SLP Lawyers (IT)
- Stratejai (BE)

Payers & Regulators / Government

Advisors for governmental or international policies and regulations

NGOs & IGOs

- Novartis Foundation (CH)

Each edition has a specific flavour and **narrative** to comprehensively address challenges of healthcare systems.

2022

Personalised medicine through a data-driven healthcare

- Information management regulations (Data Act, GDPR, HIPAA, Schrems)
- Impact of MedTech technologies (wearables, VOCs, emerging biomarkers, virtual reality)

2023

AI in healthcare

- Applications of AI in healthcare with examples from clinical practice and international research projects
- Data regulations – preliminary analysis of EHDS and its impact on European healthcare systems

2024

Generative AI and data

- The rise of generative AI in healthcare
- AI regulations (AI Act)
- Data regulations (EHDS, European Data Act, Data Governance Act)

Successful outcomes from previous editions

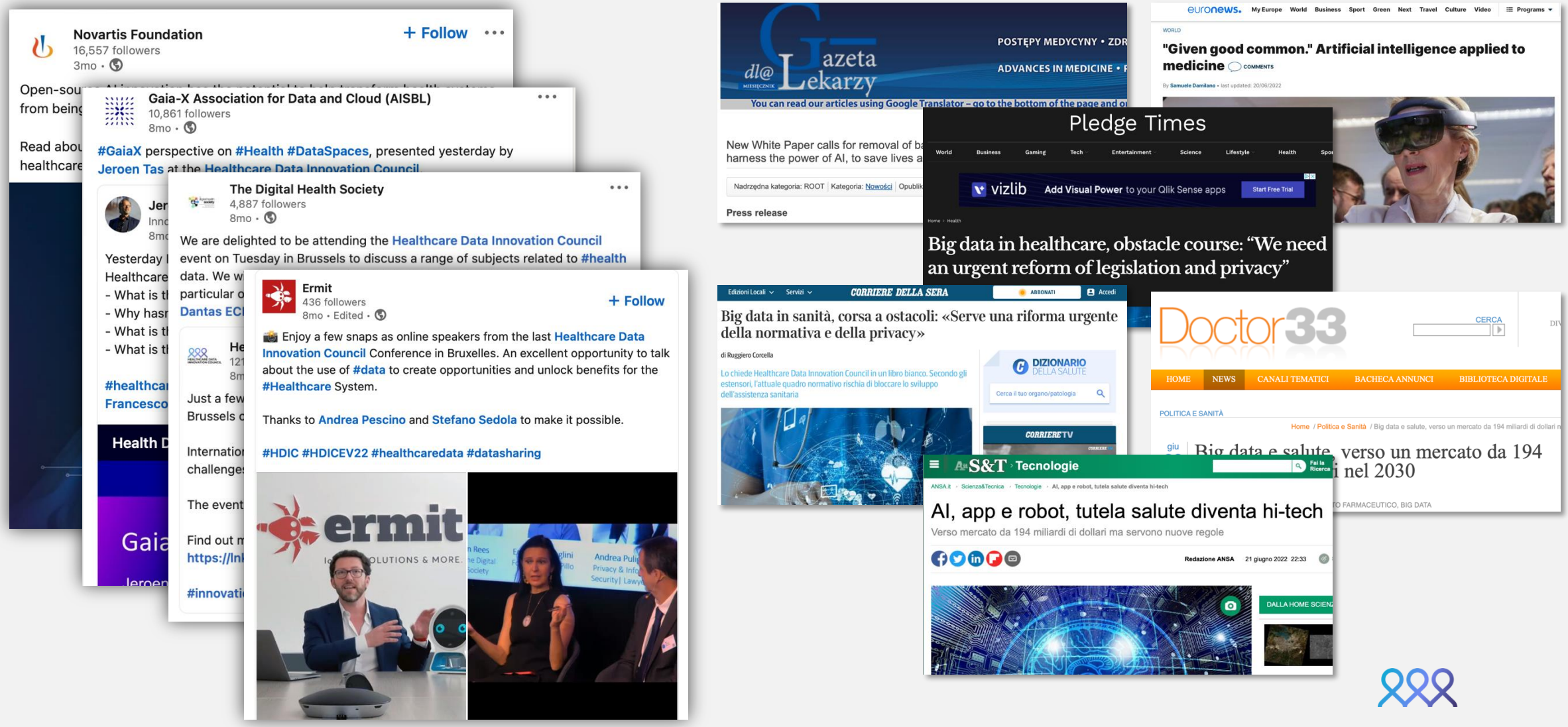
2022

- Established a **network of experts**
- Interviewed **key industry players**
- Promoted the culture "**Data saves lives**"
- Strong synergies were established with **Gaia-X team**
- Published a **White Paper** with recommendations and calls to action
- Built an online **stories** repository
- International **visibility** on various media

2023

- **Consolidated and expanded** the network
- **International events** to promote the work of the Council (in Milan, Brussels and Zurich)
- Spurred **collaboration initiatives** in research projects
- Drafted an **annex with takeaways and recommendations**
- Shared some **use cases and stories**

The Council successfully connected with other EU initiatives and gained international visibility



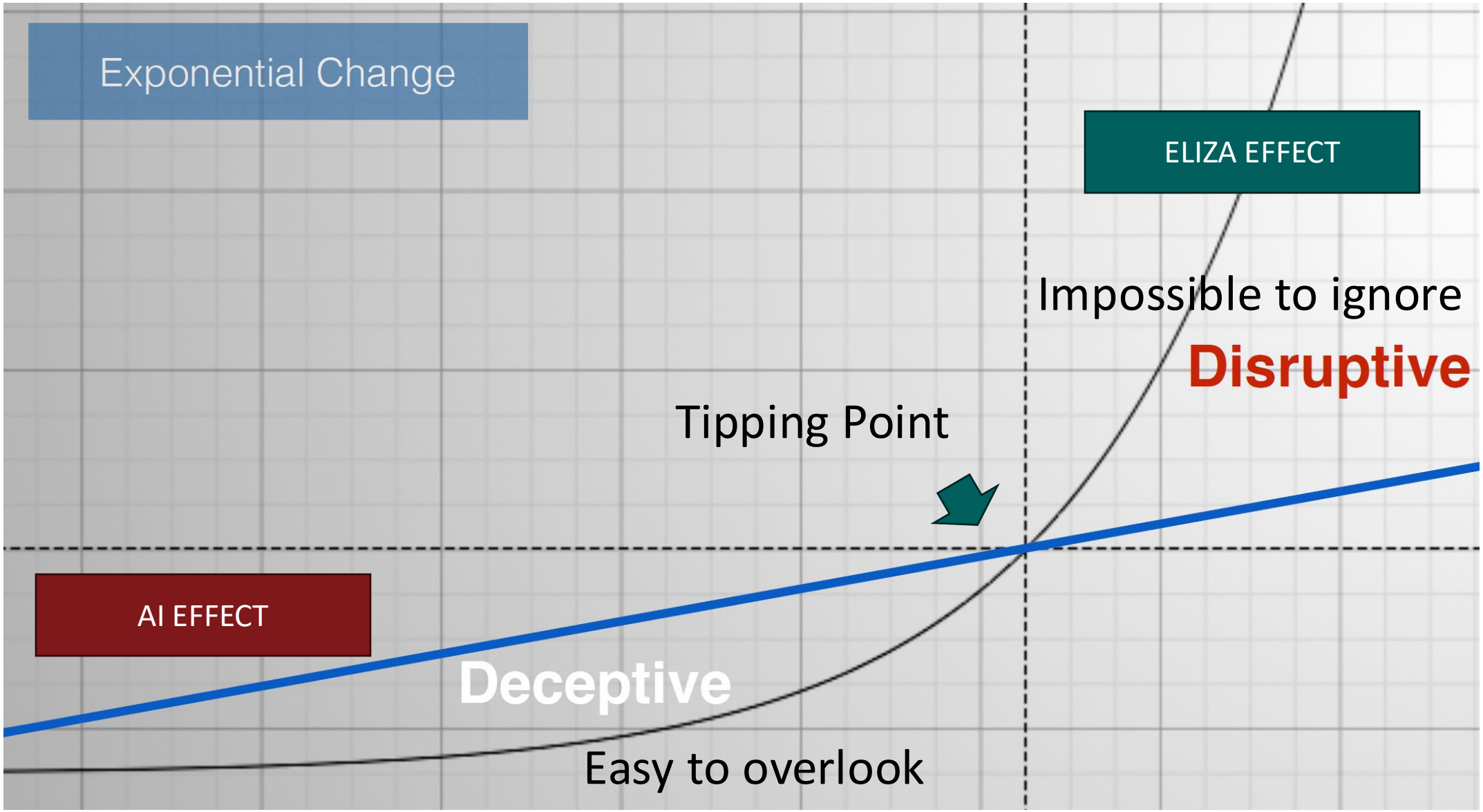
Innovative AI technologies transforming care and medical research

Andrea Pescino
Co-founder and partner, Stratejai

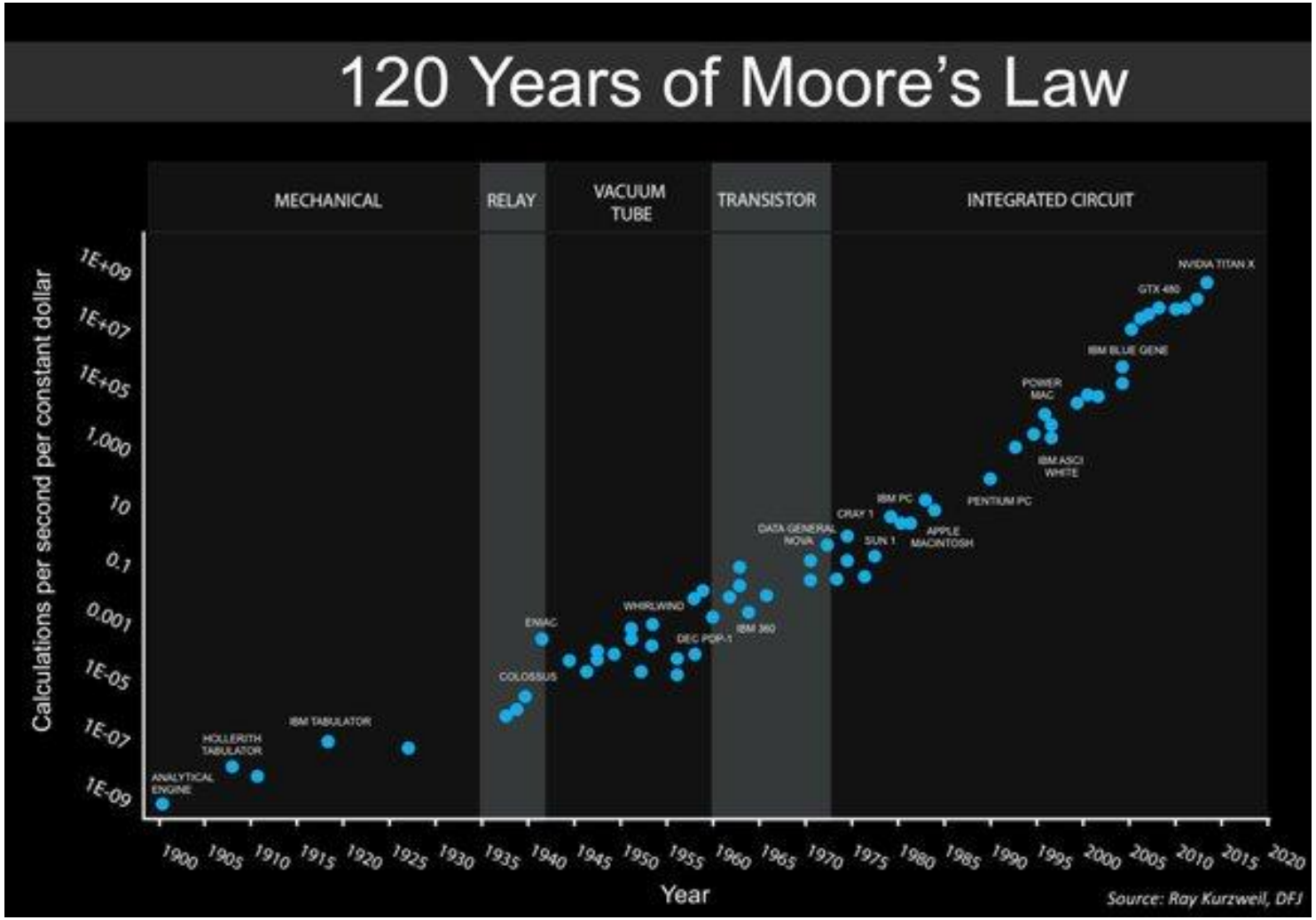
Innovative AI technologies transforming healthcare

Andrea Pescino
a.pescino@stratejai.com

STRATEJAI


Exponential Change
ELIZA EFFECT
Impossible to ignore
Disruptive
Tipping Point
AI EFFECT
Deceptive
Easy to overlook

Computing capacity at fixed dollar



Artificial Intelligence and Foundation models

STRATEJAI

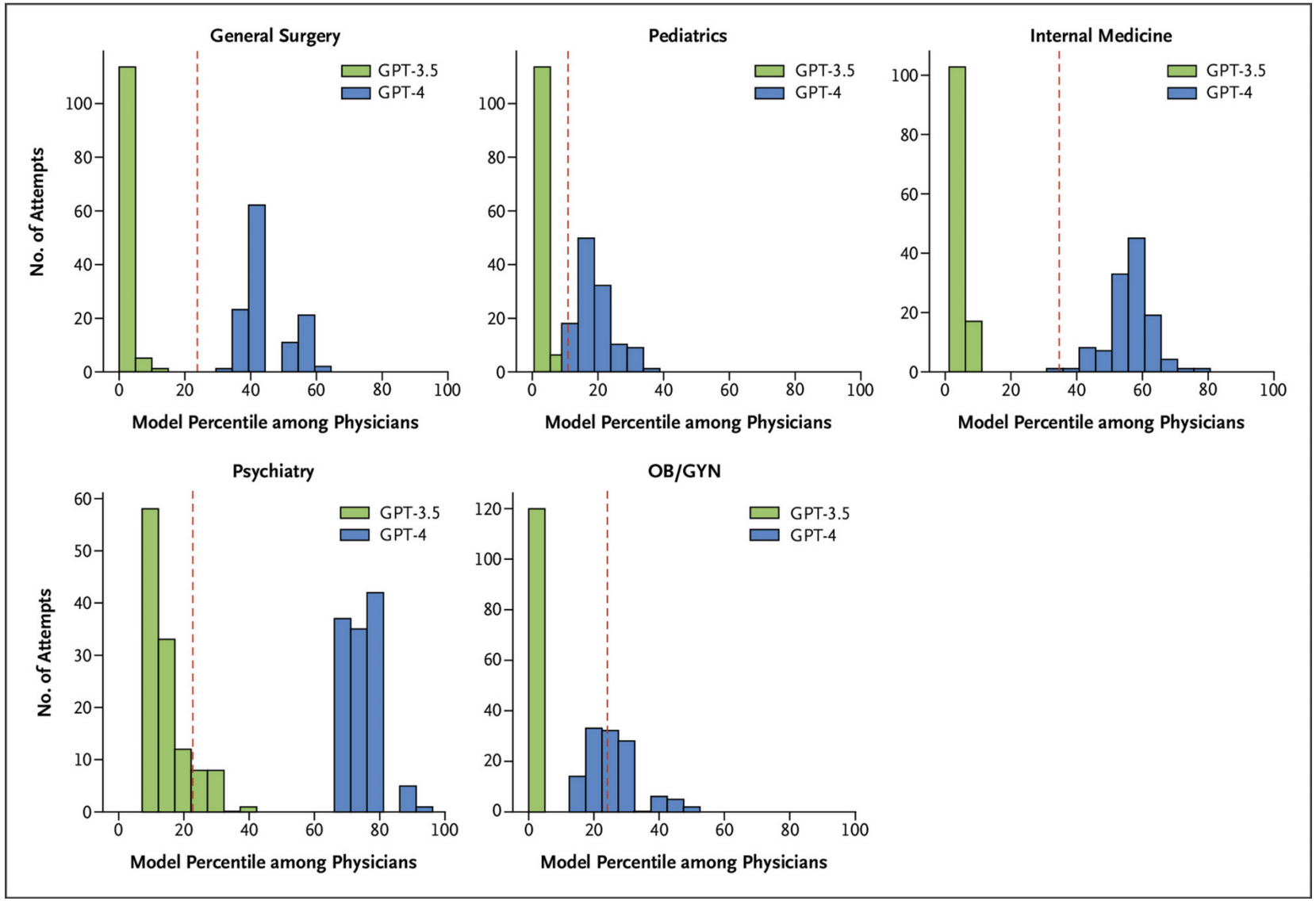
GPT versus Resident Physicians — A Benchmark Based on Official Board Scores – Katz et al.

12 April 2024 – Tel Aviv University

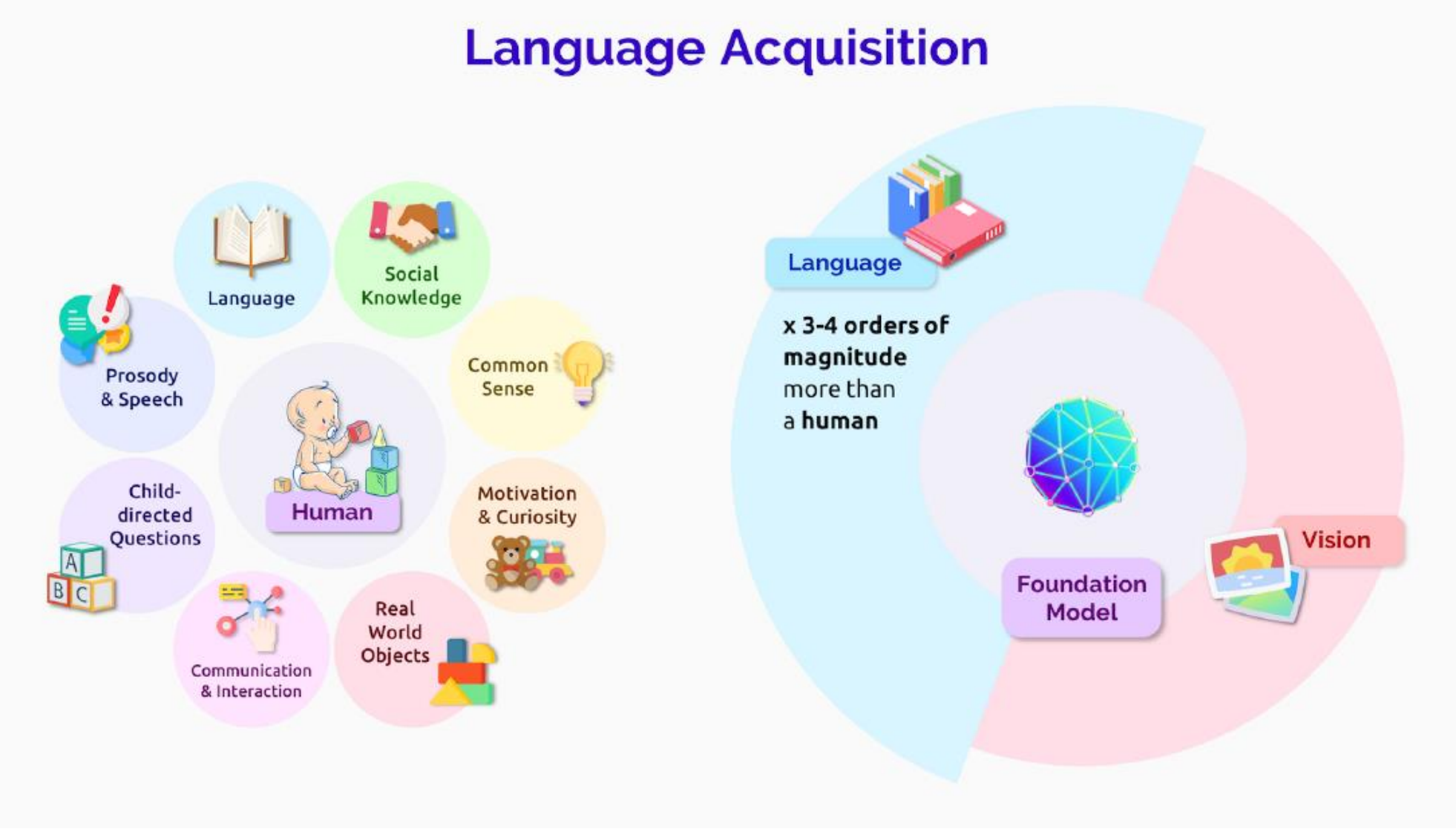
- Comparing GPT-3.5 (Free at the time), GPT-4 and a large cohort of physicians (849)
- All residents who took an medical specialist license examination in Israel in 2022
- Across the core medical disciplines: Internal Medicine, General Surgery, pediatrics, psychiatry and obstetrics and gynecology (OB/GYN).
- To account for model stochasticity, each model for each examination was tested 120 times.

- The strong power of benchmarks

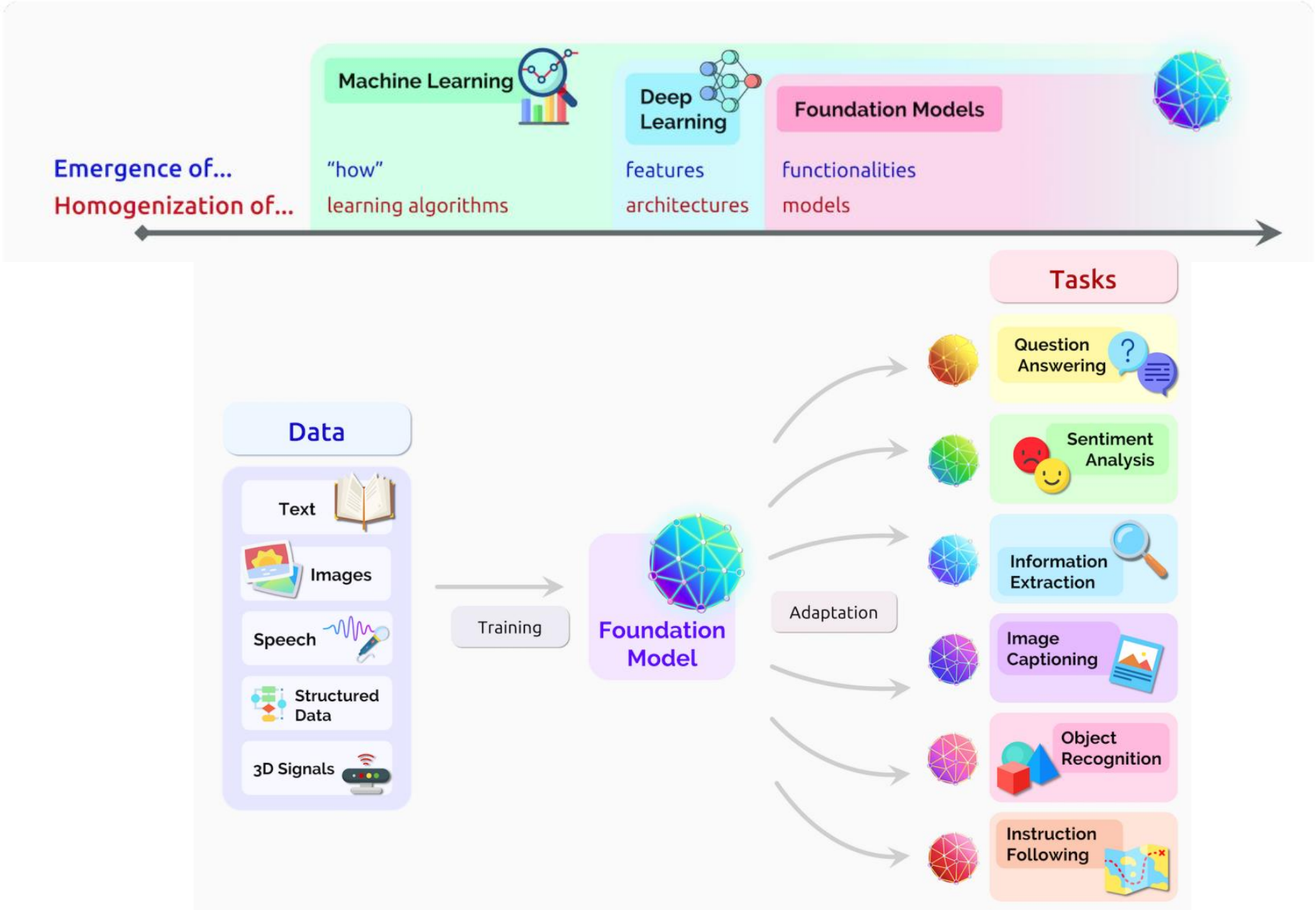
GPT versus Resident Physicians — A Benchmark Based on Official Board Scores – Katz et al.



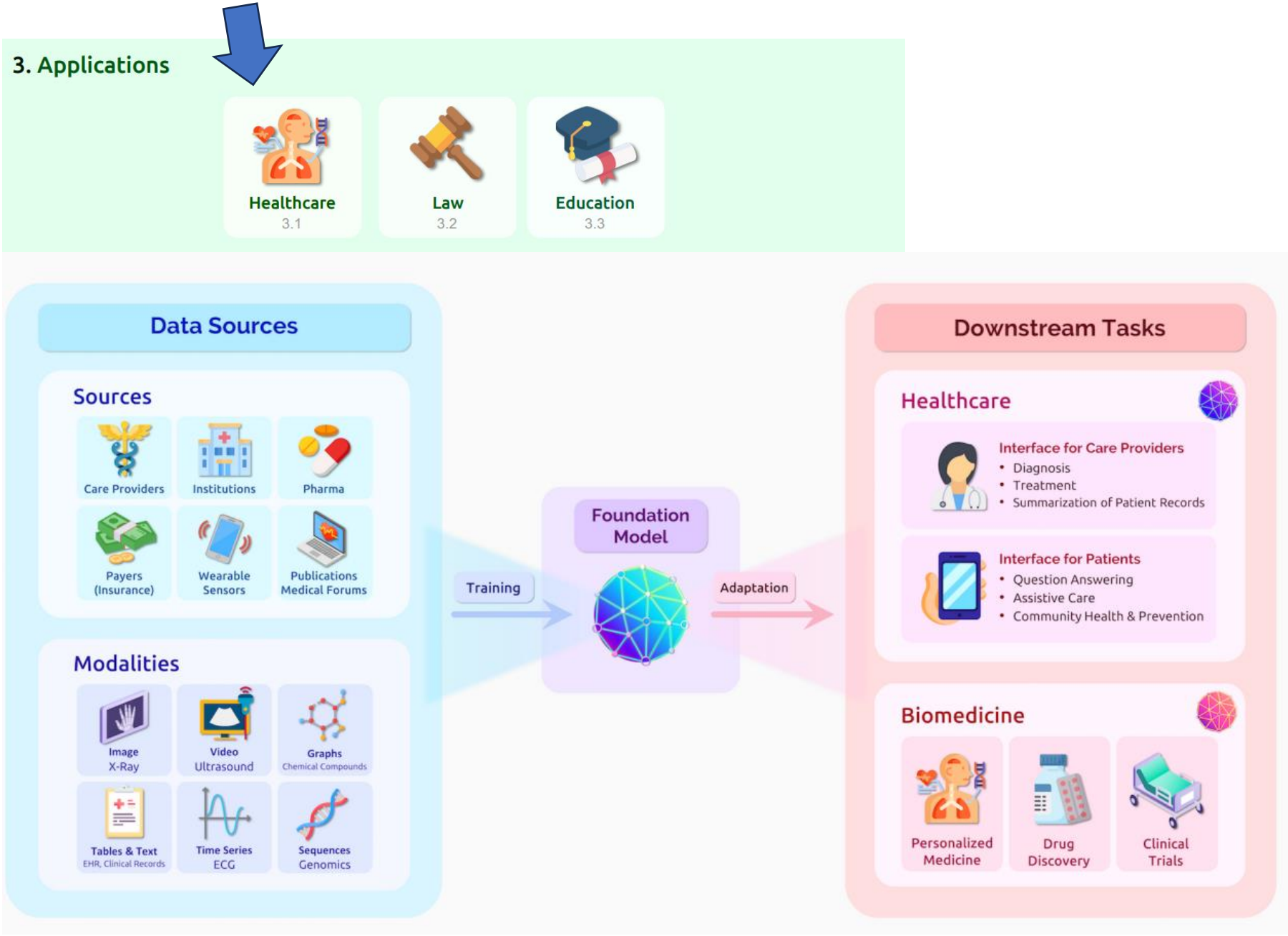
AI Foundation Models



On the Opportunities and Risks of Foundation Models - Center for Research on Foundation Models (CRFM) - Bommasani et. al

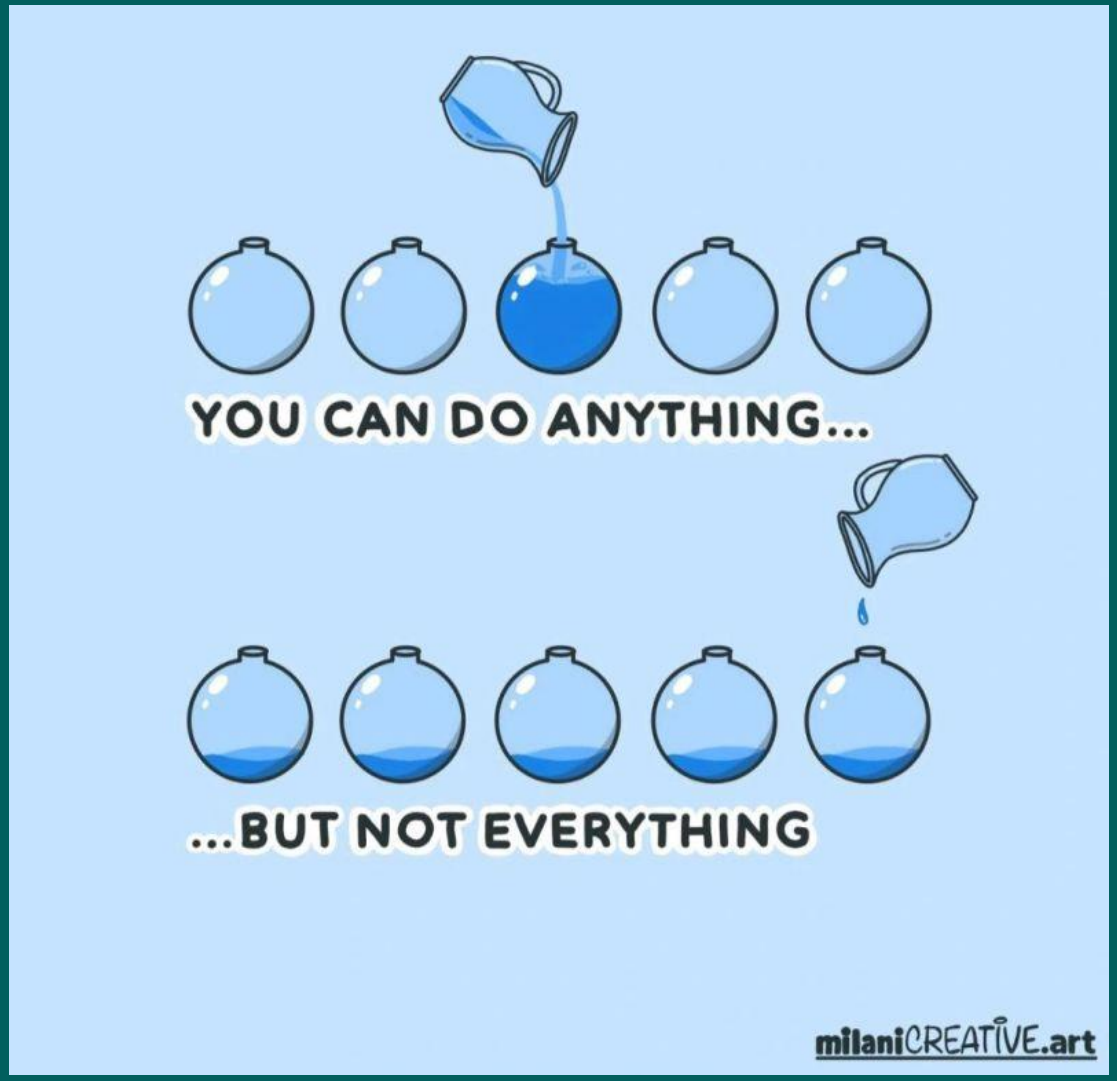


On the Opportunities and Risks of Foundation Models - Center for Research on Foundation Models (CRFM) - Bommasani et. al

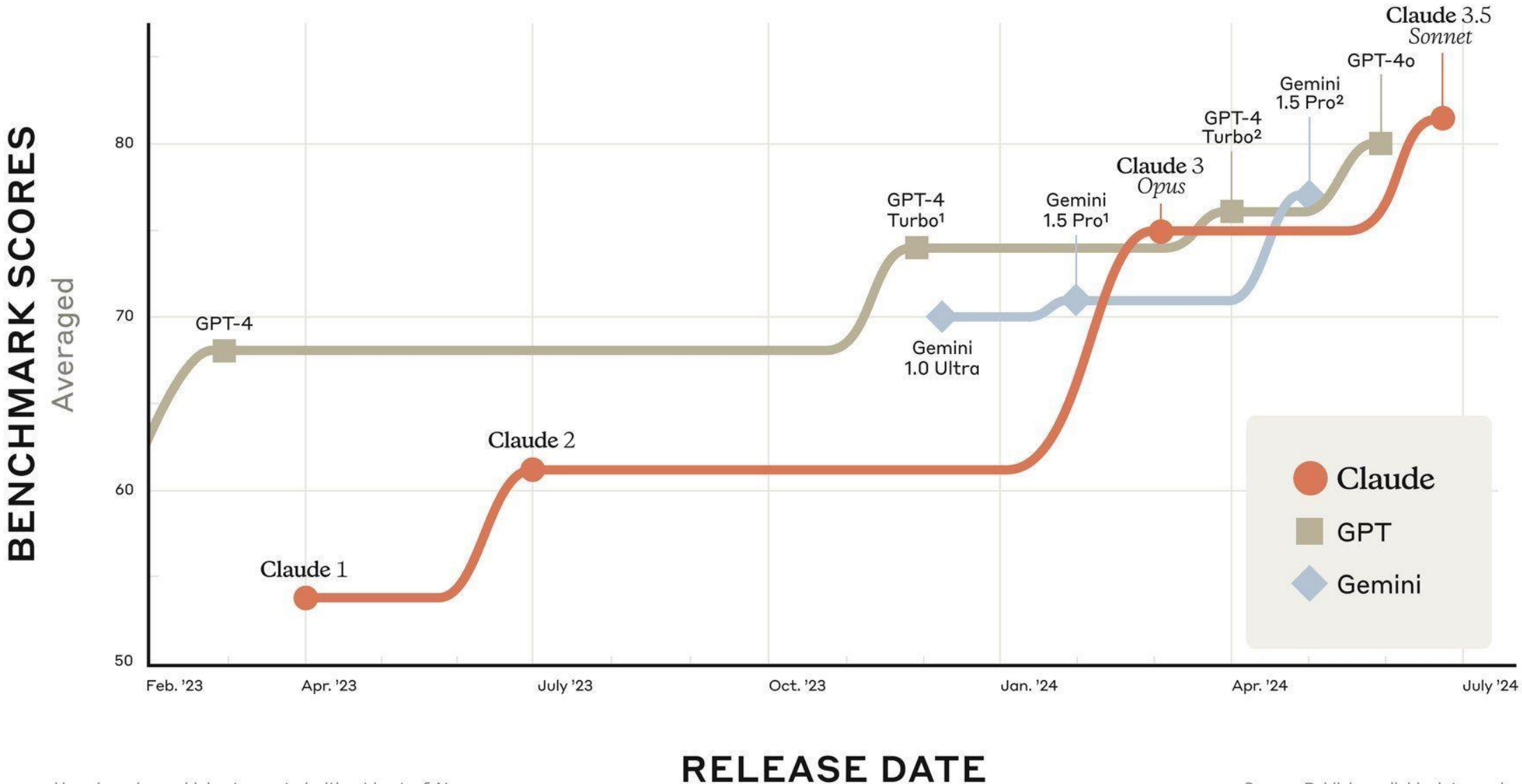


On the Opportunities and Risks of Foundation Models - Center for Research on Foundation Models (CRFM) - Bommasani et. al

Value of adaptation – Foundation models



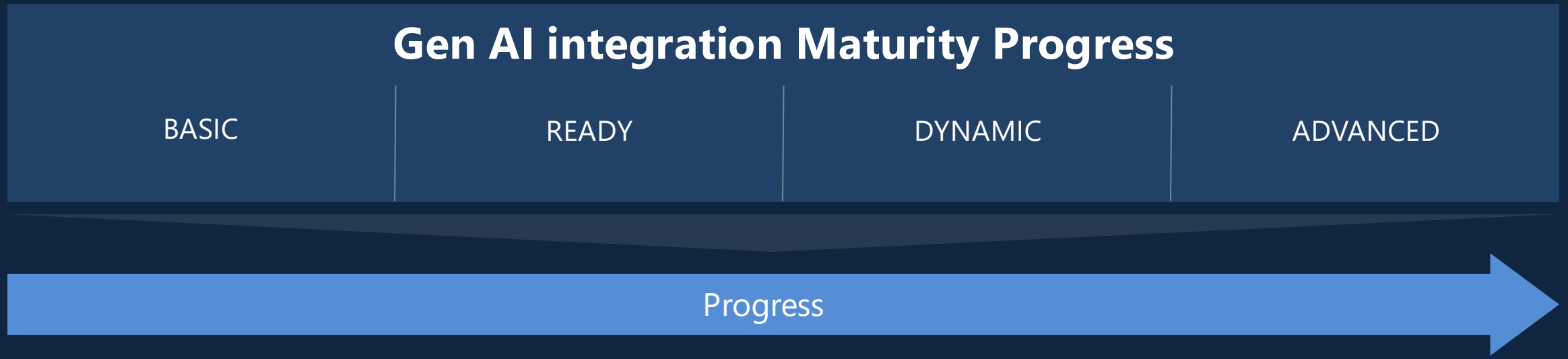
AI model release and capabilities timeline



Averaged benchmarks are highest reported without best-of-N: MMLU, GPQA, MATH, MGSM, DROP F1, HumanEval pass@1, MMMU, AI2D, ChartQA, DocQA, Mathvista

Source: Publicly available data; evaluation scores are the average of representative scores found online.
1 = Initial release; 2 = Second release

Integration Maturity Scenario



Phase 1 – Vast Majority

Awareness

- Discovery of the Technology
- Spotted usage by bottom-up adoption

Adoption

- Understanding the value of the tools
- Distribution of specific tools to users
- Basic training

Evolution

- First integration with docs and data (RAG)
- Dedicated teams to test basic solutions
- First basic applications (API)

Adaptation

- Foundation Model Approach
- Fine-tuning on internal, curated data
- Dedicated structured training journeys

Optimization

- Multiple Model Picking based on requirements
- Optimization strategies and ops
- Dedicated R&D

Architectural Impact

- Multi-Agent applications
- Embodiment and infusion on products and core applications

AI Agents

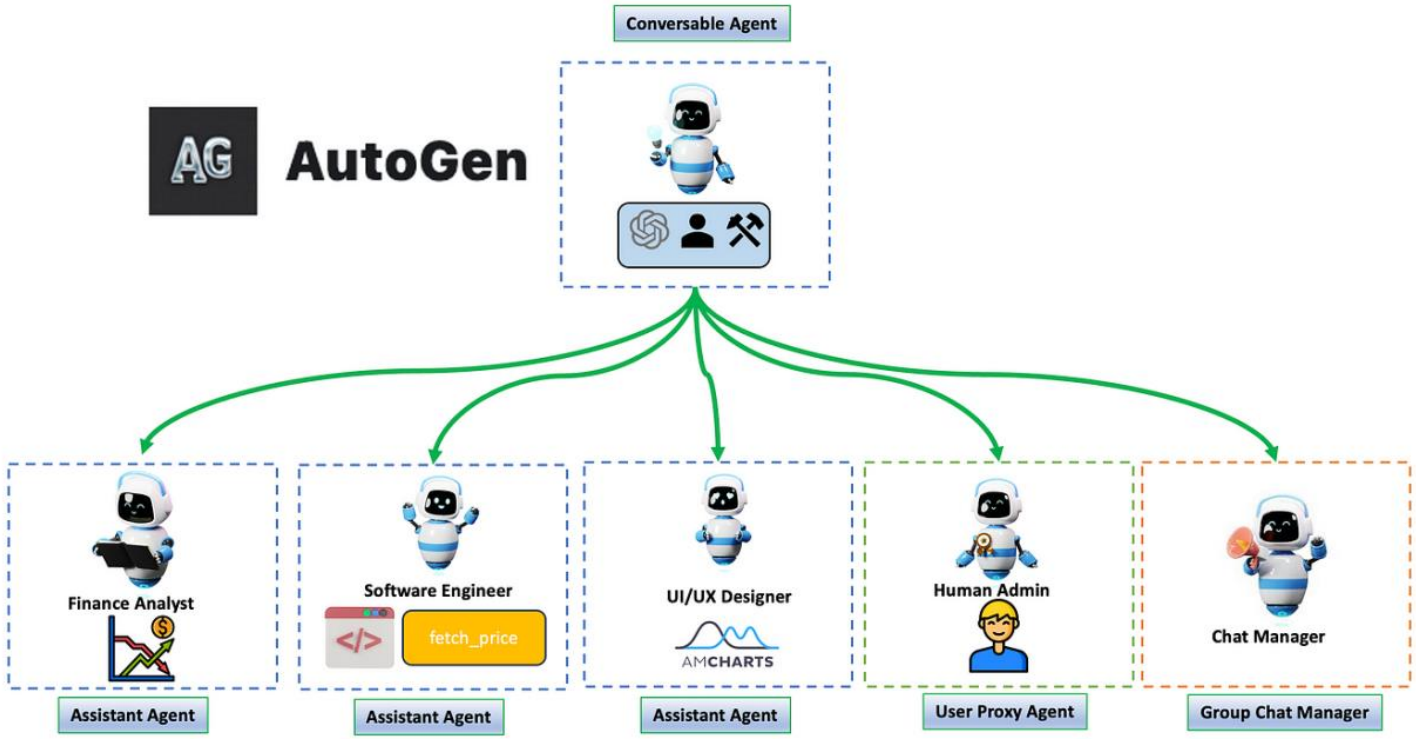
Multi-agent applications are set to redefine software solutions.

Agents will employ interchangeable models as their core engines

Agents will be built on various AI techniques, both numerical and semantic

Continual adaptation and optimization of agents will be crucial

Agents don’t need to be conversational! (They need it for interacting with humans)



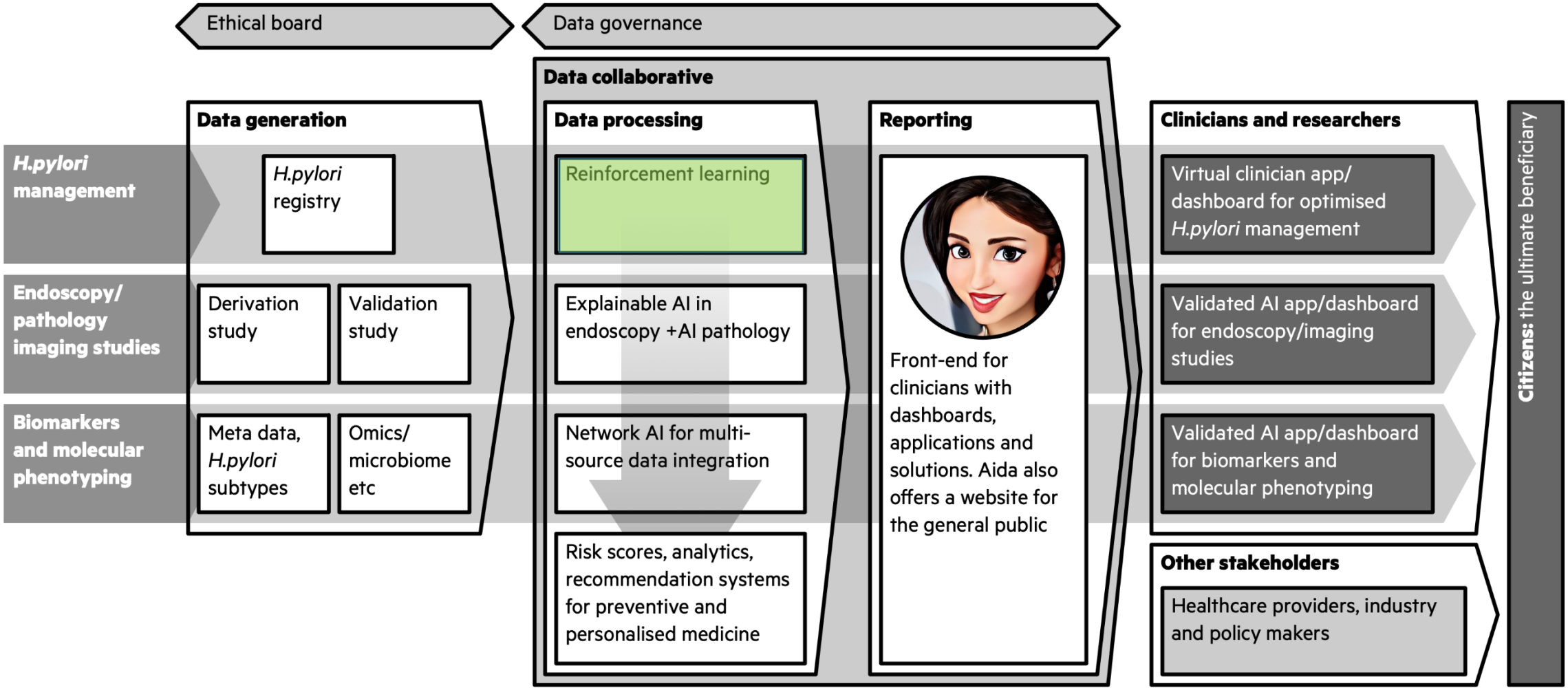
AutoGen as an example

Applied experiences

STRATEJAI

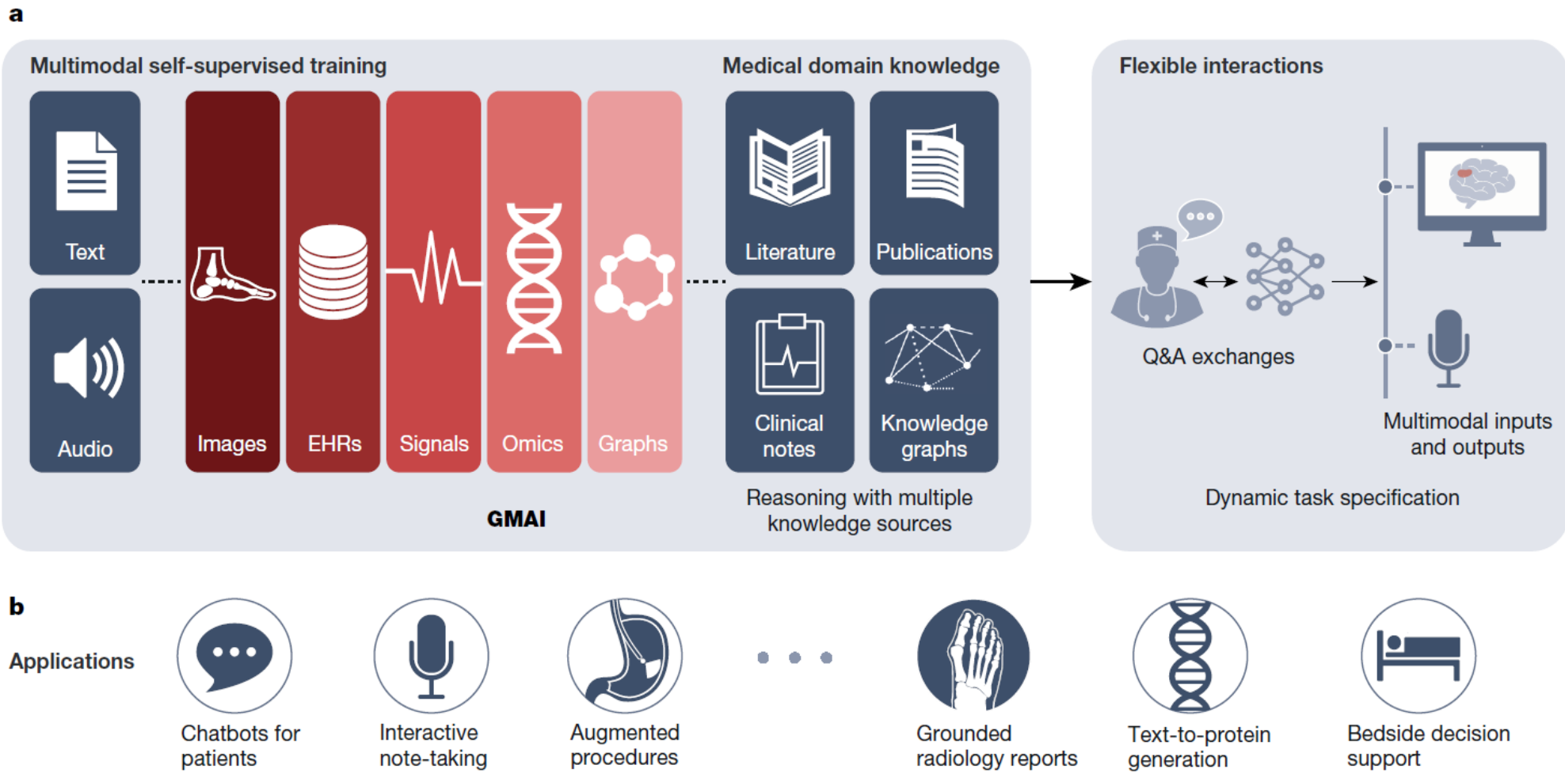
AIDA

An Artificially Intelligent
Diagnostic Assistant
for gastric inflammation



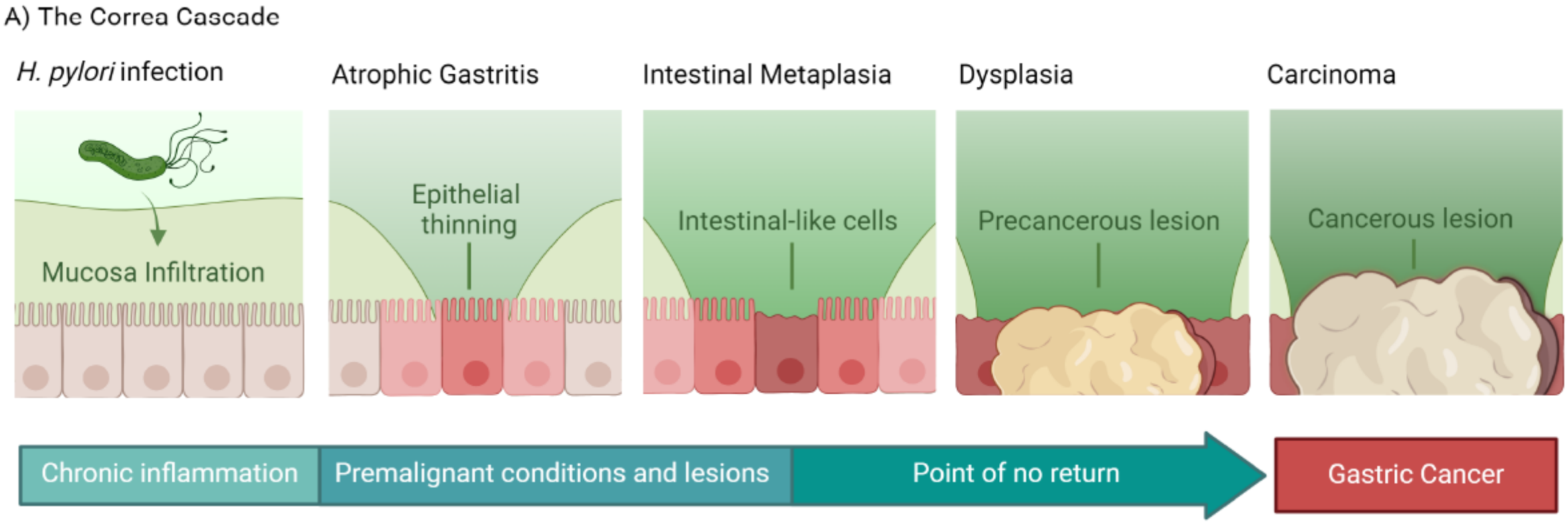
Co-funded by the European Union
UK Research and Innovation

Foundation Models



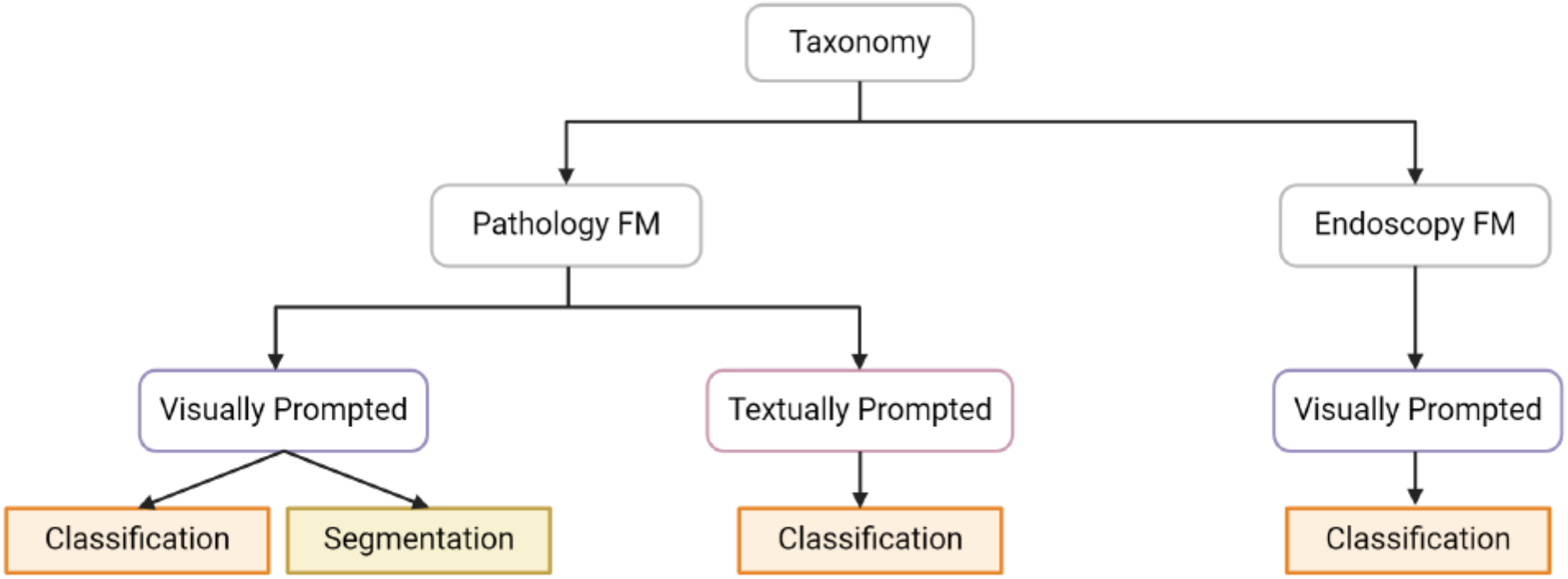
Ref: *Foundation models for generalist medical artificial intelligence, Moor, Banerjee et. Al.*

Foundational Models for Pathology and Endoscopy Images: Application for Gastric Inflammation – AIDA consortium



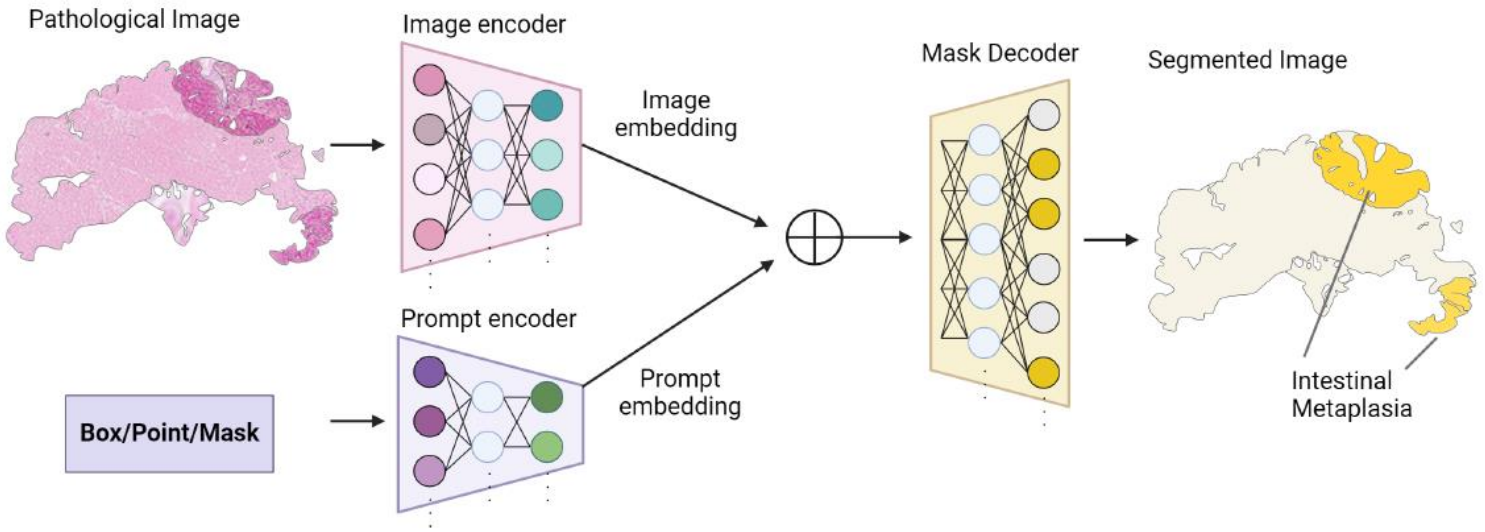
Foundational Models for Pathology and Endoscopy Images: Application for Gastric Inflammation – AIDA consortium

A)

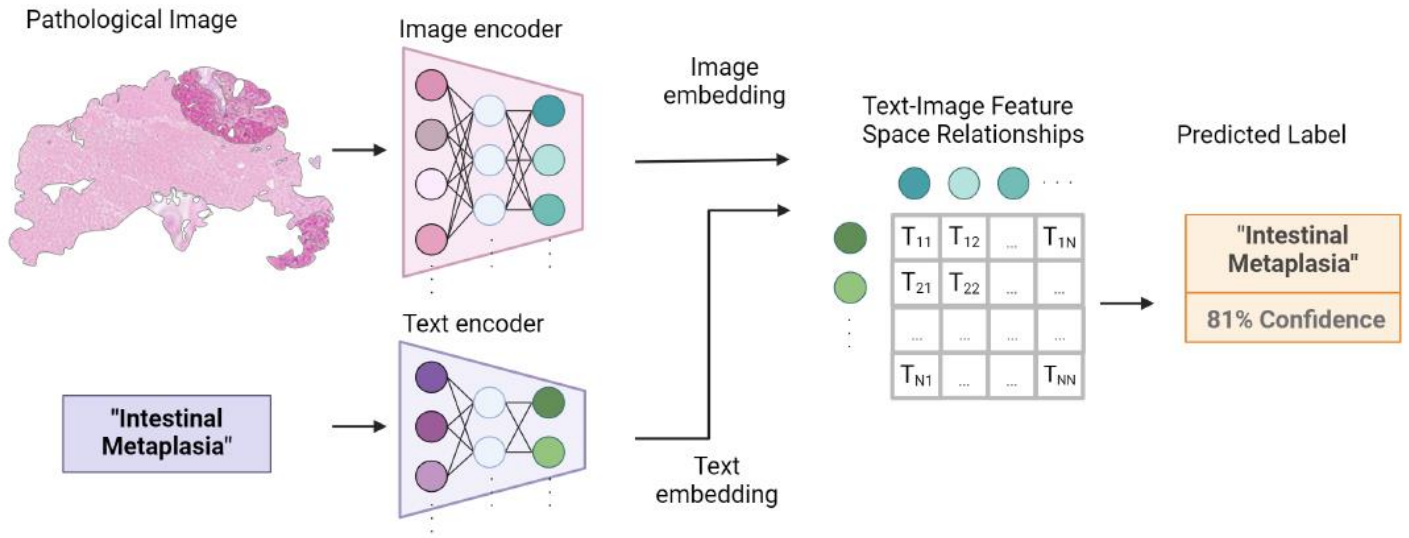


Foundational Models for Pathology and Endoscopy Images: Application for Gastric Inflammation – AIDA consortium

C)



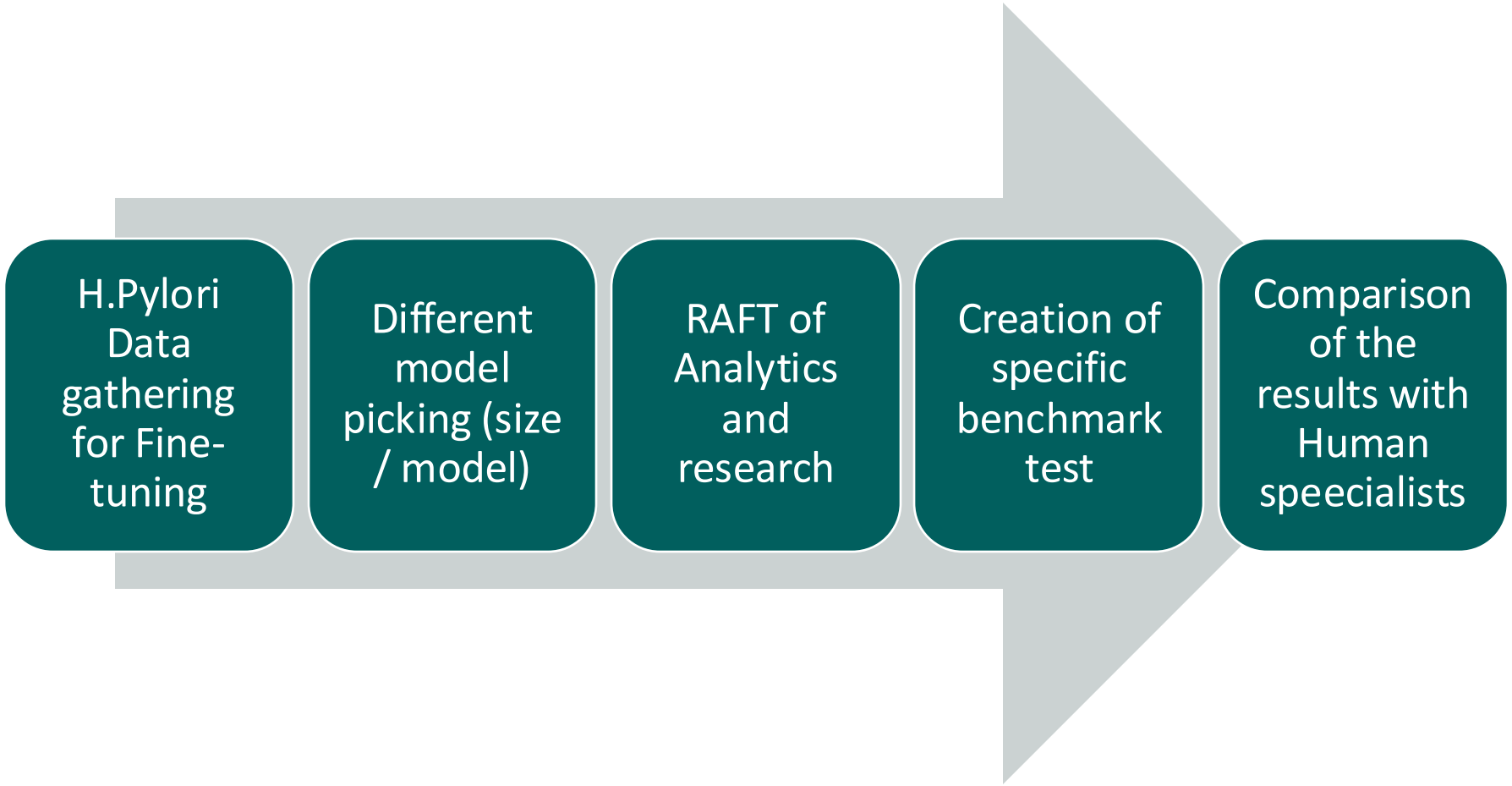
D)



AI and LLM agents to improve *H.Pylori* treatments and awareness

STRATEJAI

The research



Takeaways

AI is growing steadily and will become a key enabler of Healthcare

ChatGPT catalyzed a pivotal shift, reshaping perceptions of AI's potential

Data Will remains a critical asset for every organization, both at a clinical and research level

Foundation models needs a maturity journey to be adapted and optimized

The future of applications and solutions lies in leveraging diverse intelligent agents and technologies and it will be strongly impactful

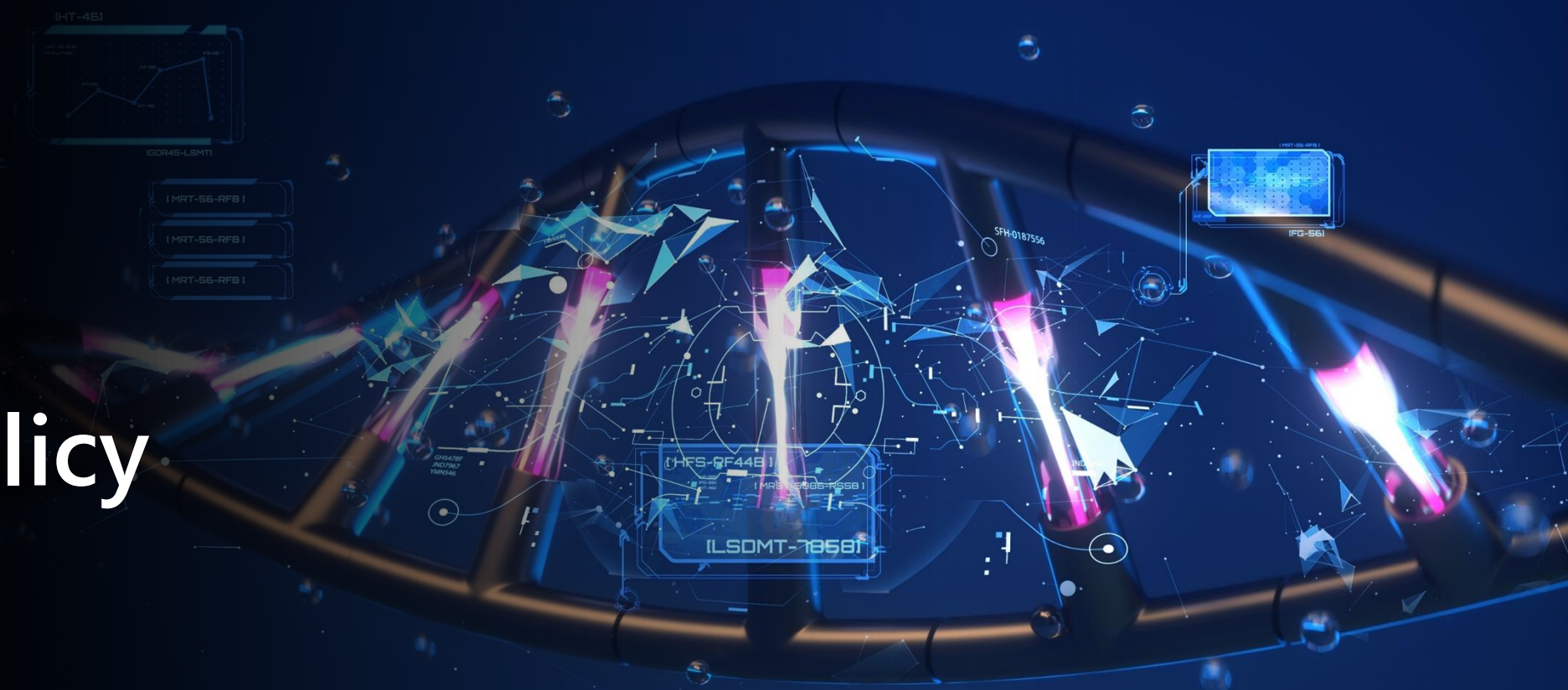
STRATEJAI

AI and healthcare policy in Europe

Tjade Stroband
Director European Government Affairs, Microsoft

Microsoft

EU health and AI policy

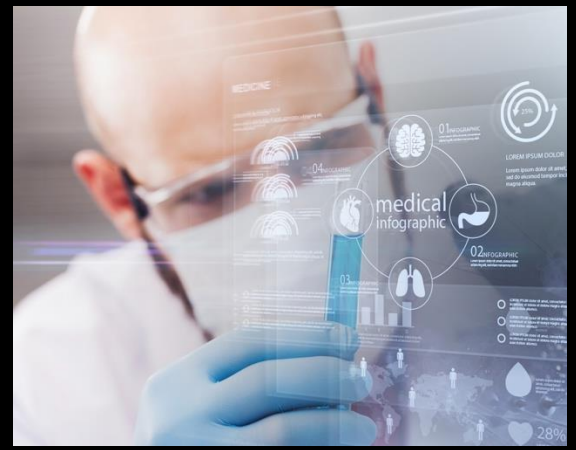


How AI transforms healthcare

Enhance patient engagement

Improve clinical and operational outcomes

Accelerate scientific innovation



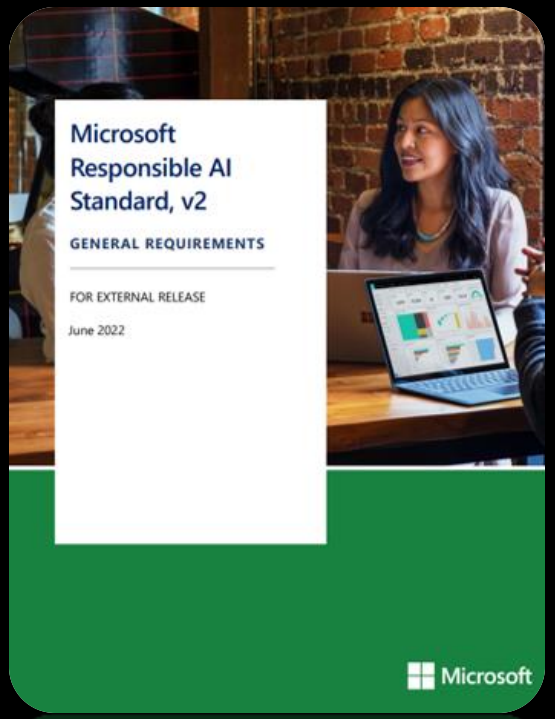
The Draghi Report

*“ Access to **health data** is one of the preconditions for the development of AI in the pharma industry but is **constrained** by fragmentation.*

*In particular, although GDPR contains options to use patient data for health research, **take up has been uneven** across Member States, **preventing** the industry from tapping into a wealth of available electronic data. ”*

The Tech Stack for AI

Microsoft's approach to Responsible AI



Principles

Fairness

Privacy & security

Transparency

Reliability & safety

Inclusiveness

Accountability

Corporate Standard

Goals
Requirements
Practices

Implementation

Training
Tools
Testing

Oversight

Monitoring
Reporting
Auditing
Compliance

Key Priorities for the Evolving AI Policy Landscape

Risk-based approach

Governance frameworks that differentiate between **high- and low-risk scenarios** to support innovation and provide protection where it is needed most

Regulatory architecture that matches the technology architecture

Laws that **reflect the relevant layers** of the AI technology stack and **distribute responsibility** across the AI value chain appropriately

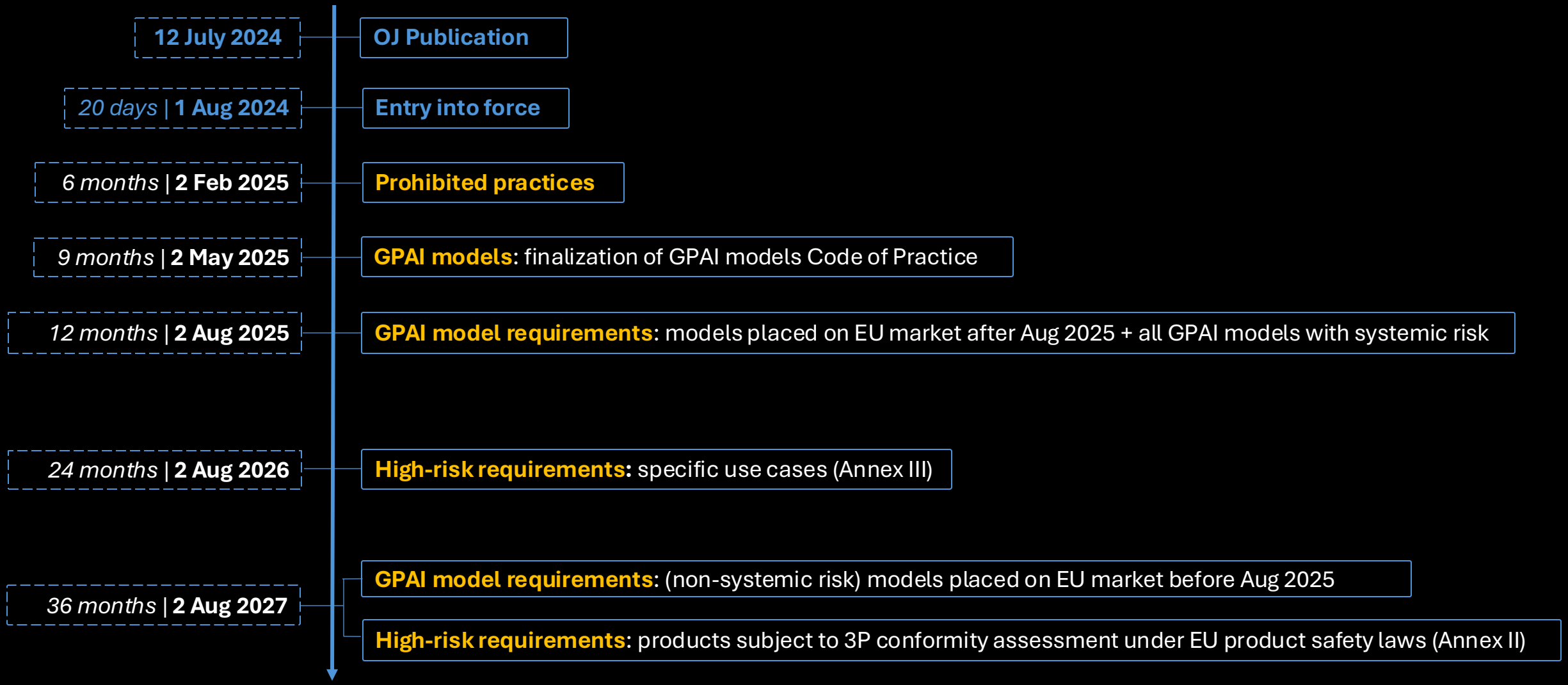
Advancing AI measurement and science

Create definitions, processes, and risk-based **international standards for AI systems** that can inform regulatory and legislative frameworks

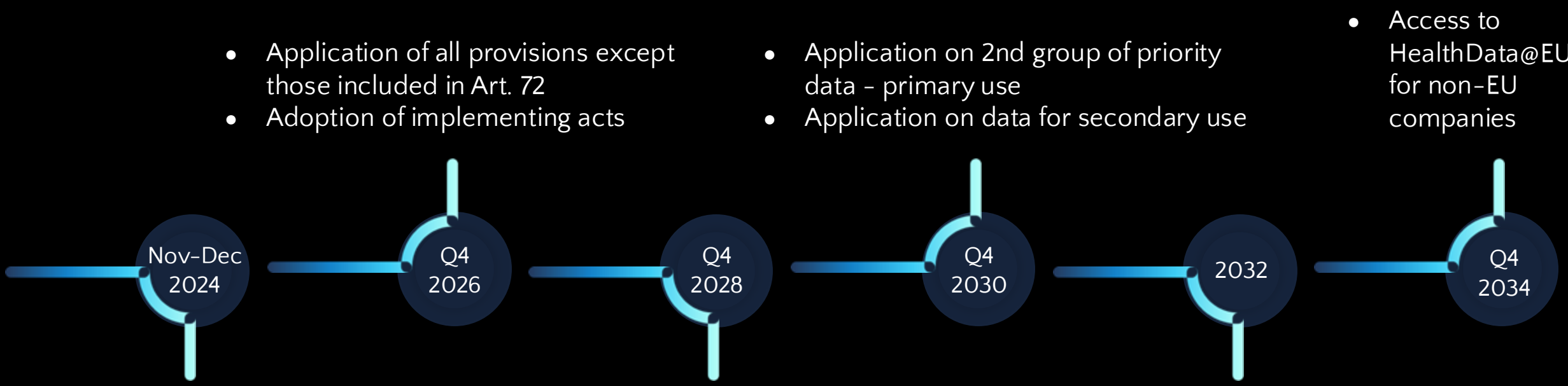
Ensuring centralised, streamlined enforcement

Streamline roles & responsibilities of enforcement bodies; avoid double regulation; rely on **existing laws** where possible; ensure **clear lines** between regulators and safety institutes

EU AI Act: staggered application



EHDS: from entry into force to review



VDL II Commission 2024-2029: Health Priorities

Olivér Várhelyi (HU)

Commissioner designate for Health and Animal Welfare
DG SANTE / HERA

*" Completing the **European Health Union**, by further diversifying supply chains, **improving access to the most advanced treatments**, boosting the **competitiveness**, **resilience and security of health systems** and working on strategic inventories "*

Medicines
- propose a Critical Medicines Act
- conclude work on the pharmaceuticals reform
- lead on European Biotech Act

Medical devices
- stepping up [MDR] implementation
- evaluating need for potential legislative change

Cybersecurity
- prepare European action plan on cybersecurity of hospitals and healthcare providers

Health data and AI
- complete the European Health Data Space
- promote the uptake of artificial intelligence, notably through clear and timely guidance on its use in the lifecycle of medicines
- make proposals to scale up genome sequencing capacities

Microsoft

[HT-46]
[GOR45-LSMT]
[MRT-S6-RFB]
[MRT-S6-RFB]
[MRT-S6-RFB]
SFH-0187556
[FG-S6]
[LSDMT-7858]

Fireside chat: how regulations are affecting development of AI tools that can be transported into practice. A focus on EHDS and EUCAIM

Stefano Sedola
Co-founder and partner, Stratejai

Ricard Martinez
Director of the Chair for Privacy and Digital Transformation Microsoft, UV

Leonor Cerdá Alberich
Biomedical engineer IIS La Fe and EUCAIM

TRAIN: how Europe is paving the way for trustworthy AI tools for healthcare

Elena Bonfiglioli
GM Global Health Pharma and Life Sciences, Microsoft

Microsoft

Harnessing AI for a healthier tomorrow.

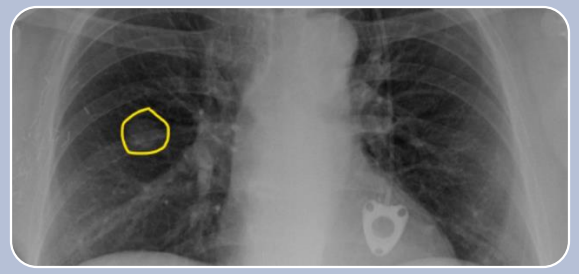
Trustworthy & Responsible AI Network (TRAIN)

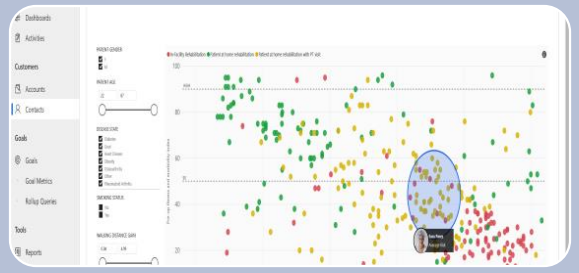
Elena Bonfiglioli
Global Business Leader Healthcare and Life Sciences
Microsoft

© Microsoft Corporation All rights reserved.

Harnessing AI for a Healthier Tomorrow

Providing trusted and integrated cloud capabilities to deliver better experiences, better insights, and better care





Increased Number of Eligible Patients

- EHR (Pangaea)
- Radiology (Nuance)
- Eye (Topcon)
- Voice (Canary Speech)

Better Patient Experiences

- Chatbot
- IVR
- Avatar

Better Outcomes

- RPM
- Digital Health (coaching) Programs
- Prediction AI
- Clinical Trials Matching

Responsible AI

- Registration (Transparency)
- Algorithmo-vigilance (Value assessment)
- Bias Assessment/Mitigation
- Scalable Governance (Accountability)

Built on a foundation of:

Nuance AI Solutions

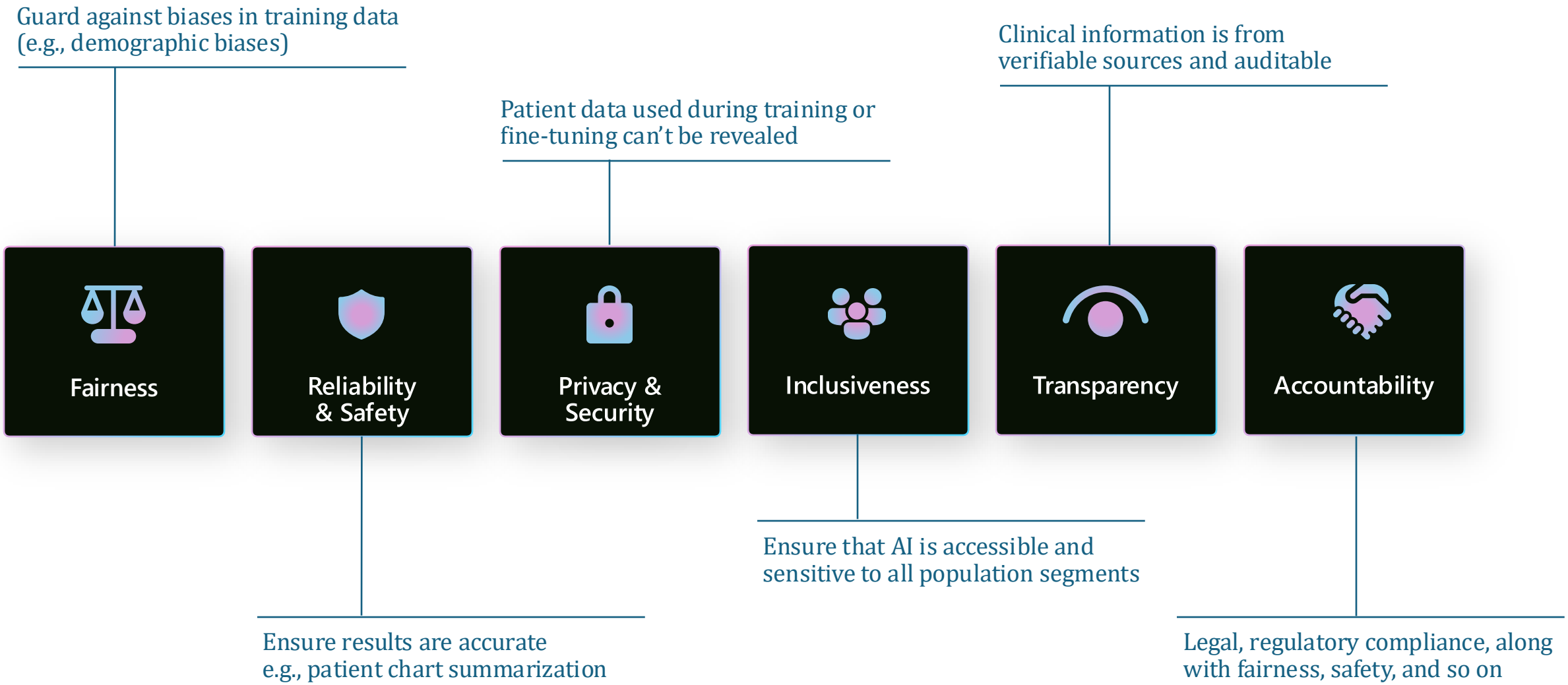
Proven AI solutions: 77% hospitals, 3X national average on quality benchmarks, 40% reduction in duplicate imaging

Microsoft Cloud for Healthcare

Make it faster and easier to provide more efficient care and help customers support their security, compliance, and interoperability of health data.

© Microsoft Corporation All rights reserved.

Responsible AI and Healthcare



TRAIN: Launched on March 11, 2024

New consortium of healthcare leaders announces formation of Trustworthy & Responsible AI Network (TRAIN), making safe and fair AI accessible to every healthcare organization

March 11, 2024 | Microsoft Source

ORLANDO, Fla. — March 11, 2024 — Monday, at the HIMSS 2024 Global Health Conference, a new consortium of healthcare leaders announced the creation of the Trustworthy & Responsible AI Network (TRAIN), which aims to operationalize responsible AI principles to improve the quality, safety and trustworthiness of AI in health. Members of the network include AdventHealth, Advocate Health, Boston Children's Hospital, Cleveland Clinic, Duke Health, Johns Hopkins Medicine, Mass General Brigham, MedStar Health, Mercy, Mount Sinai Health System, Northwestern Medicine, Providence, Sharp HealthCare, University of Texas Southwestern Medical Center, University of Wisconsin School of Medicine and Public Health, Vanderbilt University Medical Center, and Microsoft as the technology enabling partner. Additionally, the network is collaborating with OCHIN, which serves a national network of community health organizations with solutions, expertise, clinical insights and tailored technologies, and TruBridge, a partner and conduit to community healthcare, to help ensure that every organization, regardless of resources, has access to TRAIN's benefits.

Europe TRAIN was Launched at HLTH in Amsterdam on June 17th: Trustworthy and Responsible AI Network expands to help European healthcare organizations enhance the quality, safety and trustworthiness of AI in health - Stories (microsoft.com)

Founding Members in Europe

Erasmus MC (the Netherlands), HUS Helsinki University Hospital (Finland), Sahlgrenska University Hospital (Sweden), Skåne University Hospital (Sweden), Universita Vita-Salute San Raffaele (Italy), and University Medical Center Utrecht (the Netherlands), with Microsoft as the technology enabling partner, and Foundation 29, a nonprofit organization that aims to empower patients and transform healthcare through data-driven initiatives and innovative technologies.

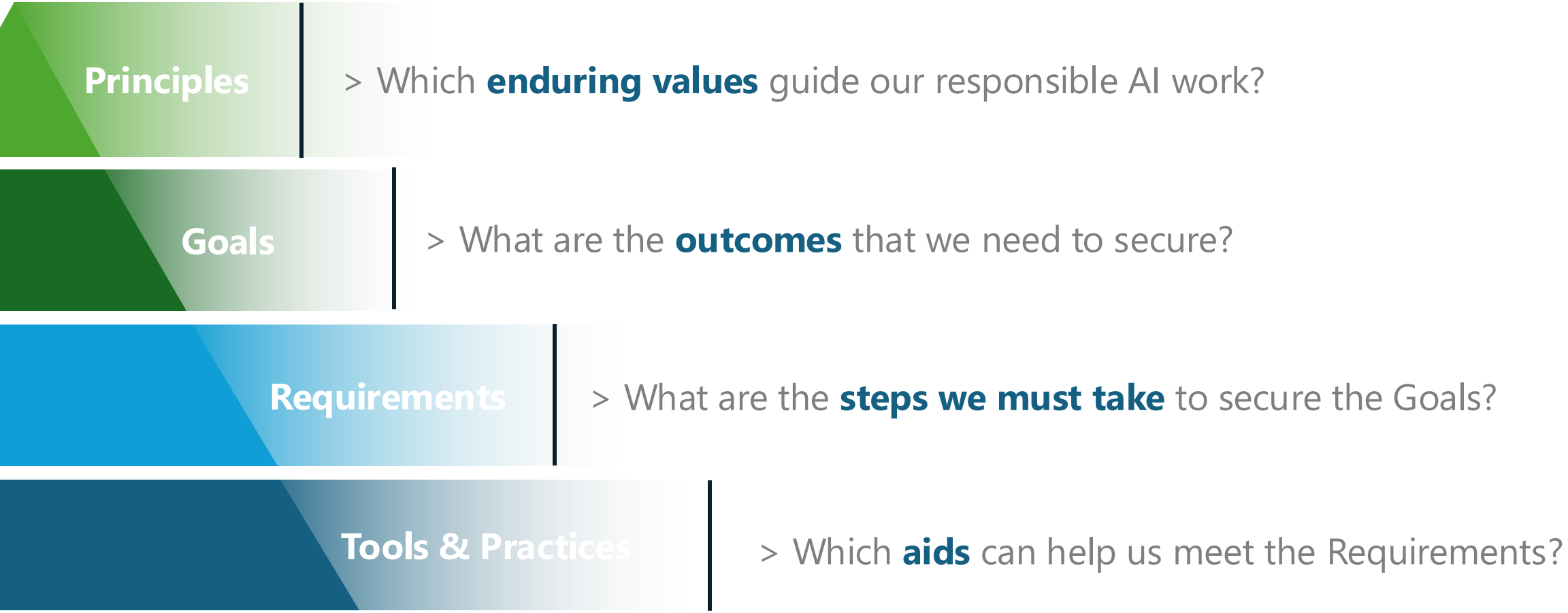
Responsible AI

HOW? TRAIN

1. Operationalizes RAI principles, leveraging **TECHNOLOGY**
2. Collaborates with
   - TRAIN members in standardized manner to populate **AI Outcomes Registry**
   - RAI Orgs (eg, CHAI, SAIIL, Valid AI, WHO)
3. Democratizes RAI for **low resource settings**

External website: **TRAIN – Trustworthy and Responsible AI Network (train4health.ai)**

The anatomy of the Responsible AI Standard



Four Key Questions to answer and adhere to

REGISTRATION

Can you identify all the AI you have running in your organization today?

LOCAL TESTING

Are you testing the AI on your local data sets, both pre- and post-deployment?

BIAS ASSESSMENT

Are you assessing for bias in the AI, and what measures are you applying to mitigate the bias?

GOVERNANCE

Do you have a scalable governance process in place?

Diving into RAI Safety Systems

Application

- Confidential Sharing
- Human in the loop
- Monitoring clinical workflows

AI

- Explainability, provenance
- Monitoring
- Feedback

Data

- Bias, stereotyping
- Outside of cohort training data
- Privacy
- Security

- Response Cues & Alerts
- Content Safety Rules
- Clinical Relevance assertion
- Self Verification
- Coding/Guideline following
- Specialized summarization
- Explainability/Provenance
- Real-Time monitoring

Microsoft

Health-Specialized Safeguards - Overview

TRAIN

Healthcare is a sensitive domain that has unique complexities and regulatory landscape.
Health-specialized safeguards are required to ensure quality and accuracy of Generative AI.

- We created a suite of **healthcare-specific safeguards**, aiming to support 1P & 3P Copilots & Plug-ins
- Those Safeguards are **generalized** and served as an **API** by our service for healthcare copilots, supporting **configurable Safeguards**, being used by **multiple products and use cases**
- Serving as **building-blocks** for quality check, can be used as part of runtime flows, or for **evaluation**
- The Safeguards can be **chained** / **used together**, for optimization purposes
- The Safeguards leverage healthcare-specialized **smaller models**
- Safeguards have dependencies on one another

Categories of health-specific safeguards:

1. Clinical Safeguards
2. Healthcare Chat Safeguards
3. Healthcare Compliance Safeguards

Microsoft

Microsoft Confidential

Thank you

elenab@microsoft.com

The approach of regulatory sandbox – is an AI regulatory sandbox possible?

Martin Canter
AI & Data Expert, FARI Institute

FARI

AI FOR THE COMMON GOOD INSTITUTE BRUSSELS

FARI AI RESEARCH / INNOVATION HUB

FARI AI TEST / EXPERIENCE HUB

UNIVERSITÉ LIBRE DE BRUXELLES ULB VUB VRIJE UNIVERSITEIT BRUSSEL

Putting the technology promise at the service of society and its citizens.

FARI AI FOR THE COMMON GOOD INSTITUTE BRUSSELS

FARI is a non-profit university institute on AI, data and robotics focused on the Common Good. We are jointly initiated by two Brussels universities (VUB & ULB) - uniting the interdisciplinary expertise across 10 research groups on AI, data, robotics, social sciences, ethics, and law.

We do research and build bridges with public administrations, industry, and citizens, promoting ***sustainable AI, data & robotics with a focus on urban and public priority domains*** such as health, mobility, sustainable robotics, climate and energy, participatory and inclusive society.

Core activities

Research & Innovation

Education & Learning

Contributing to a Community of Practice

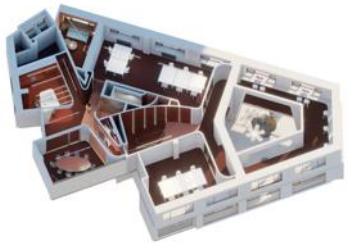
Mobility

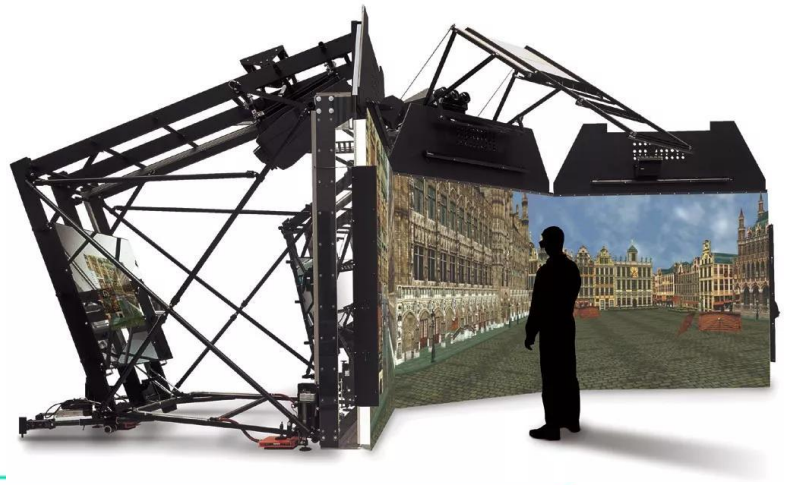
Climate & Energy

Health & Well-being

Resource Optimization

Participatory Society





FARI.BRUSSELS

The FARI Test and Experience Center (800m2)

Opened on March 23, 2023

A place where +15 demonstrations on AI, data, robotics and ethics will showcase these technologies and their potential impact.
In this space, events are organized to meet private, public, civic and scientific actors.

- 2024 => extension to 4th Floor
- Dedicated AI Academy Auditorium
- Research Offices

Test facilities (BARCO CAVE: 150m2 immersive room for Digital Twin visualisations)

FARI AI / DATA / ROBOTICS INSTITUTE BRUSSELS

AI Regulatory Sandboxing

Martin Canter

In the past:

Example:

- **Gen AI** used on politician's images to pass a message without their consent:
  - Belgium - deceased
  - Switzerland - opponent

Historically:

- Following **2008** economic crisis.
- UK initial idea and initiative with the UK Financial Conduct Authority (FCA)
- **FinTech sector** innovation needs to be balanced.
- Shared concept in multiple domains and forms.

The Basics

An "AI regulatory sandbox" means:

- A concrete and controlled **framework;**
- set up by a **competent authority;**
- which offers **providers** or prospective providers of **AI systems** the possibility to develop, train, validate and test, where appropriate in real world conditions;
- an **innovative AI** system,
- pursuant to a **sandbox plan** for a **limited time;**
- under **regulatory supervision**.

The Basics

Objectives: Article 53, 1.g:

- **Improve legal certainty** to achieve regulatory compliance with applicable regulations.
- Support the **sharing of best practices** through cooperation with the authorities.
- **Foster innovation** and competitiveness and facilitate the development of an AI ecosystem.
- Contribute to **evidence-based** regulatory learning**.**
- **Facilitate and** accelerate access to the Union market for AI systems, in particular when provided by small and medium-sized enterprises (SMEs), including start-ups.

In practice

A) “Basic service”:

- Risk assessment
- “Compliance coaching”
  - Hand books
  - Regulatory experts

B) “Extensive service”:

- + testing facilities (datasets, physical infrastructure)
- + *business advisory (development, funding)*
- Link to European Ecosystem: TEF, EDIH, data spaces, local testbeds and living labs, …

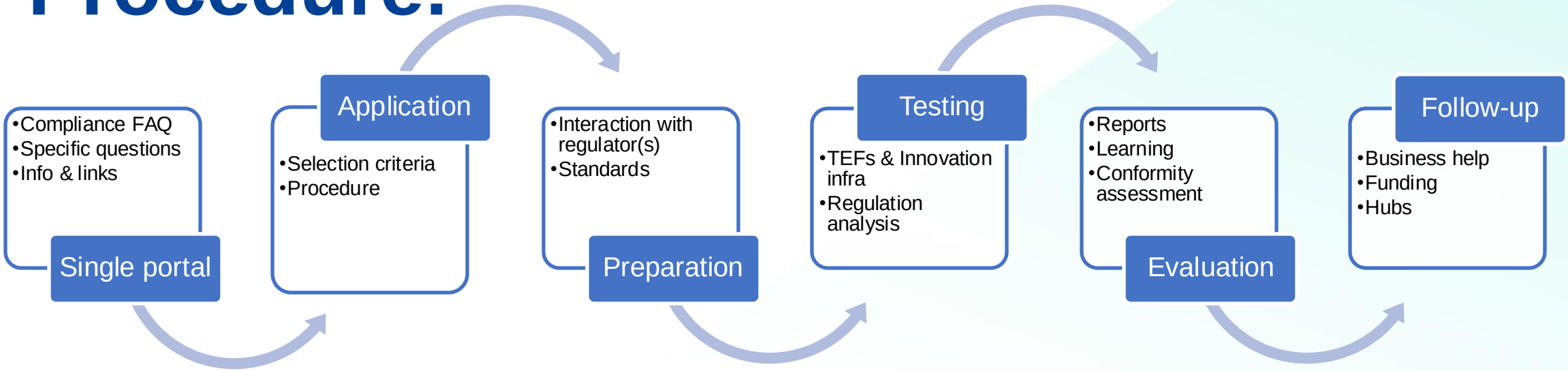
C) “Extensive service”:

- Liability limitation

<u>Stakeholders:</u>

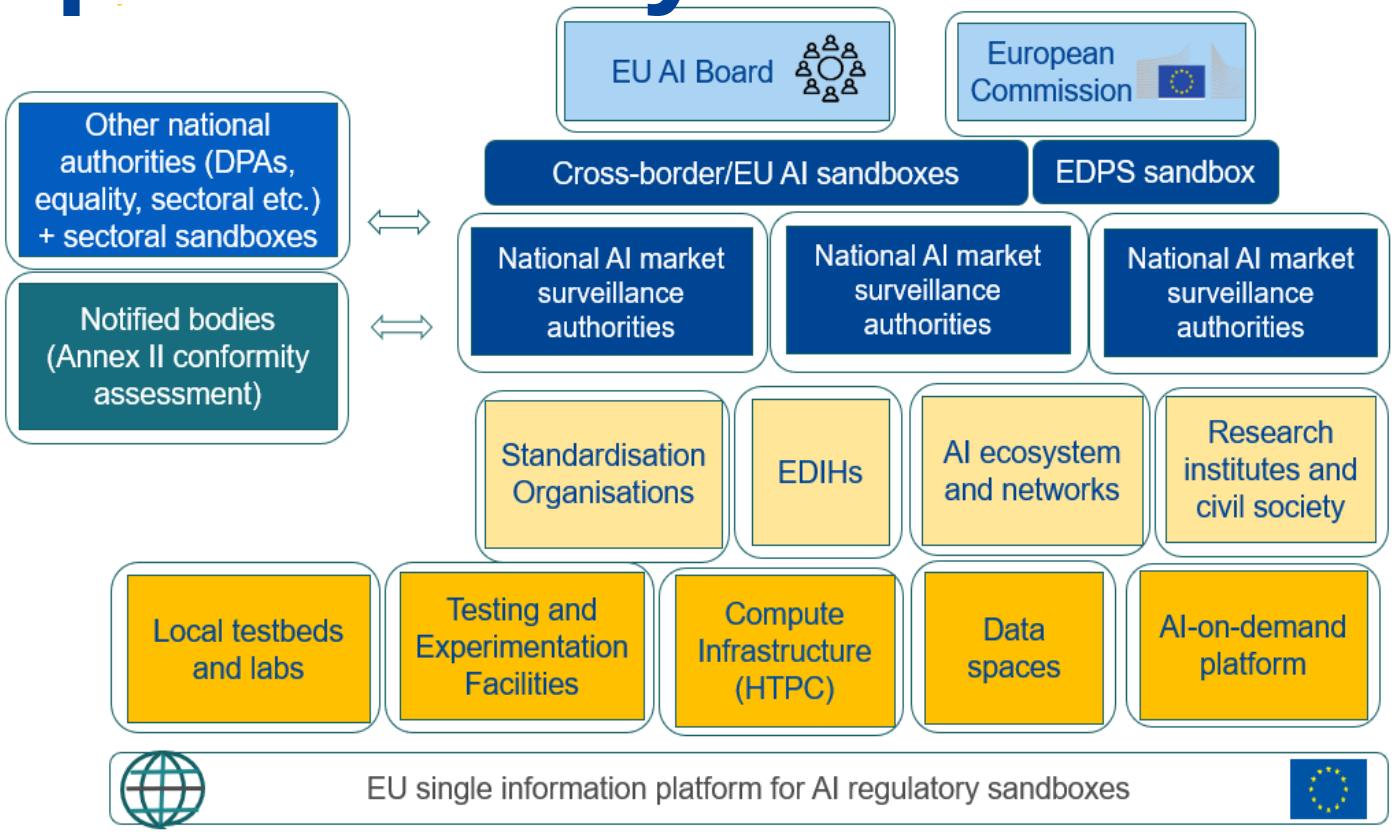
- Legal Experts
- Technical Experts
- Business Advisors
- Authorities and Regulators:
  - National Competent Authorities
  - Market Surveillance Authorities
- Innovators

Procedure:


•Compliance FAQ
•Specific questions
•Info & links
Single portal
Application
•Selection criteria
•Procedure
•Interaction with regulator(s)
•Standards
Preparation
Testing
•TEFs & Innovation infra
•Regulation analysis
•Reports
•Learning
•Conformity assessment
Evaluation
Follow-up
•Business help
•Funding
•Hubs

Innovators
AI Regulatory Sandbox
Regulators

European Ecosystem



In the European Union:

Advanced initiatives:

- **Netherlands:**
  - Pilot phase going on
- **Spain:**
  - Pilot project stopped
  - Local initiatives
- **Sweden:**
  - In development, TEF and RI.SE

Starting initiatives:

- **Belgium:**
  - Study started, no NCA yet

Next steps:

- **AI Act entry into force**
  - 24 months to comply: 08/2026
- **CSA Digital Europe :**
  - AI RS
  - Testing of AI
  - Coordination
- **Implementing Act:**

Use-cases

Example:

- **ANPR** cameras to detect mobile phone usage while driving.
- POC is developed and **works well**.
- In Belgium, **only the police** access ANPR cameras images.
- AI Reg SB: **Feedback** on inadequate **legislation** to be updated.

Example:

- Using **real population data** for socio-economic simulation does not respect **privacy**.
- **Advice** from the AI Reg SB towards the AI solution developer: Create **artificial dataset** that represents the same population distribution.
- This makes the use-case **compliant**, while keeping its potential for **usefulness**.
- AI Reg SB: **Sharing of best practices**, and foster innovation.

FARI AI / DATA / ROBOTICS INSTITUTE BRUSSELS

Contact:
martin.canter@fari.brussels

Roundtable: Perspectives on adoption of innovative AI technologies from industry, innovators, policy experts and research community

Stefano Sedola
Co-founder and partner, Stratejai

Gabriel Lopez
Government Affairs Director Microsoft

Sophie Tomlinson
Director of Partnerships and Communications, Datasphere Initiative

Tineke Van hooland
Deputy Secretary General, Bio.Be/Essenscia

Conclusions

Andrea Pescino
Co-founder and partner, Stratejai

Conclusions

01 Data are still a critical asset, and an opportunity for improving healthcare

02 Artificial Intelligence is coming rapidly and will have a huge impact on the sector

03 There are strong emerging initiatives to make AI more transparent, trustworthy and responsible, to help the adoption

04 The impact will be across the whole industry and on many processes

05 Europe has a huge opportunity to capitalize on innovation and research to make the whole healthcare sector sustainable and future-proof

Thanks to all

info@healthdatainnovation.eu

#DATASAVESLIVES