

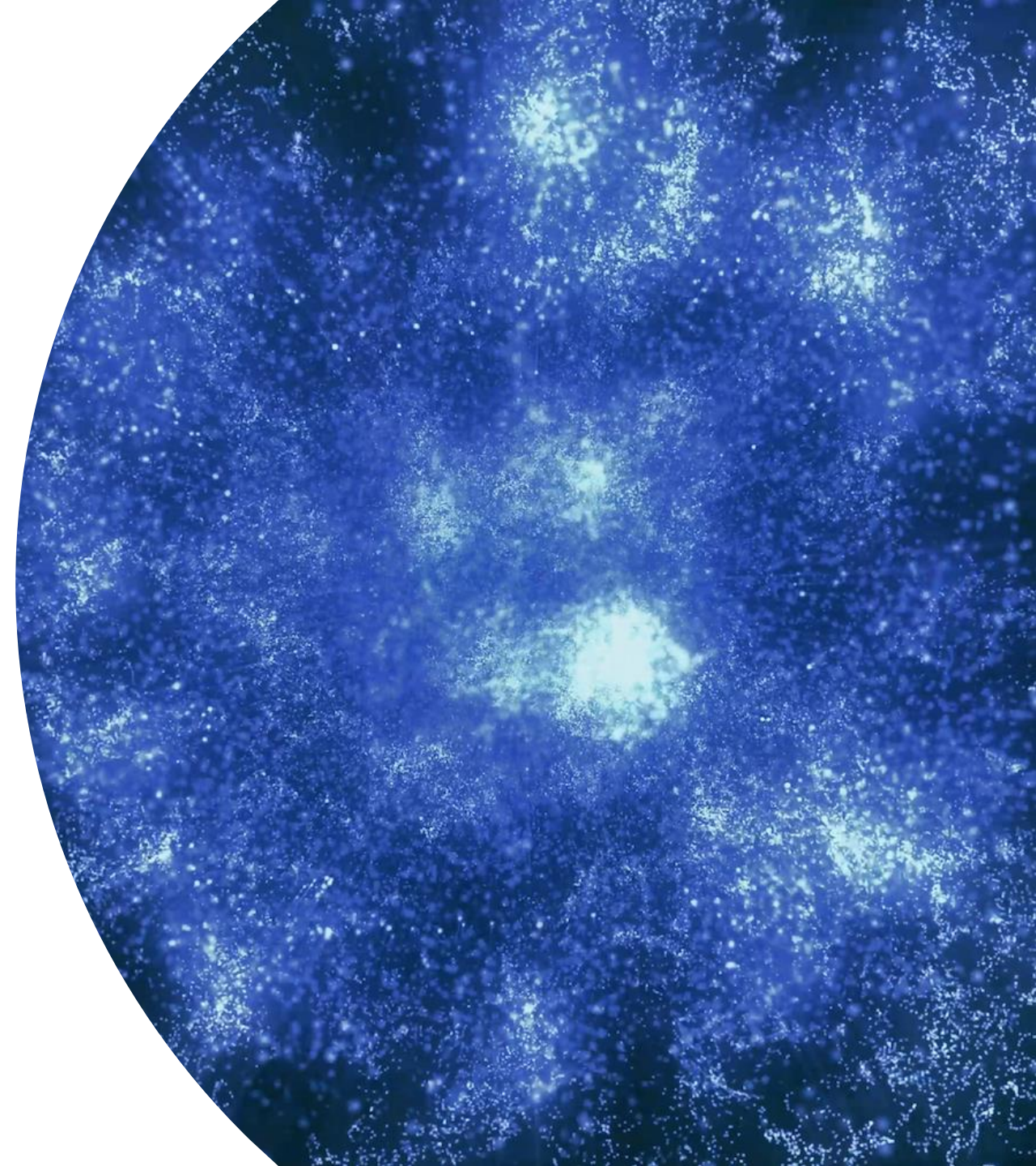


# Harnessing AI to Expedite R&D

Sridevi Nagarajan, Ph.D

Head, Digital Regulatory Strategy

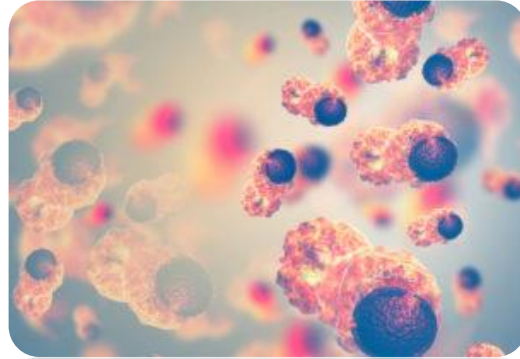
23 April 2024



# Technologies that will change Healthcare by 2030



**AI & Generative AI**



**Personalized medicines**



**Digital Twins**



**Quantum Computing**



**Process automation 2.0 (RPA)**



**Cybersecurity**



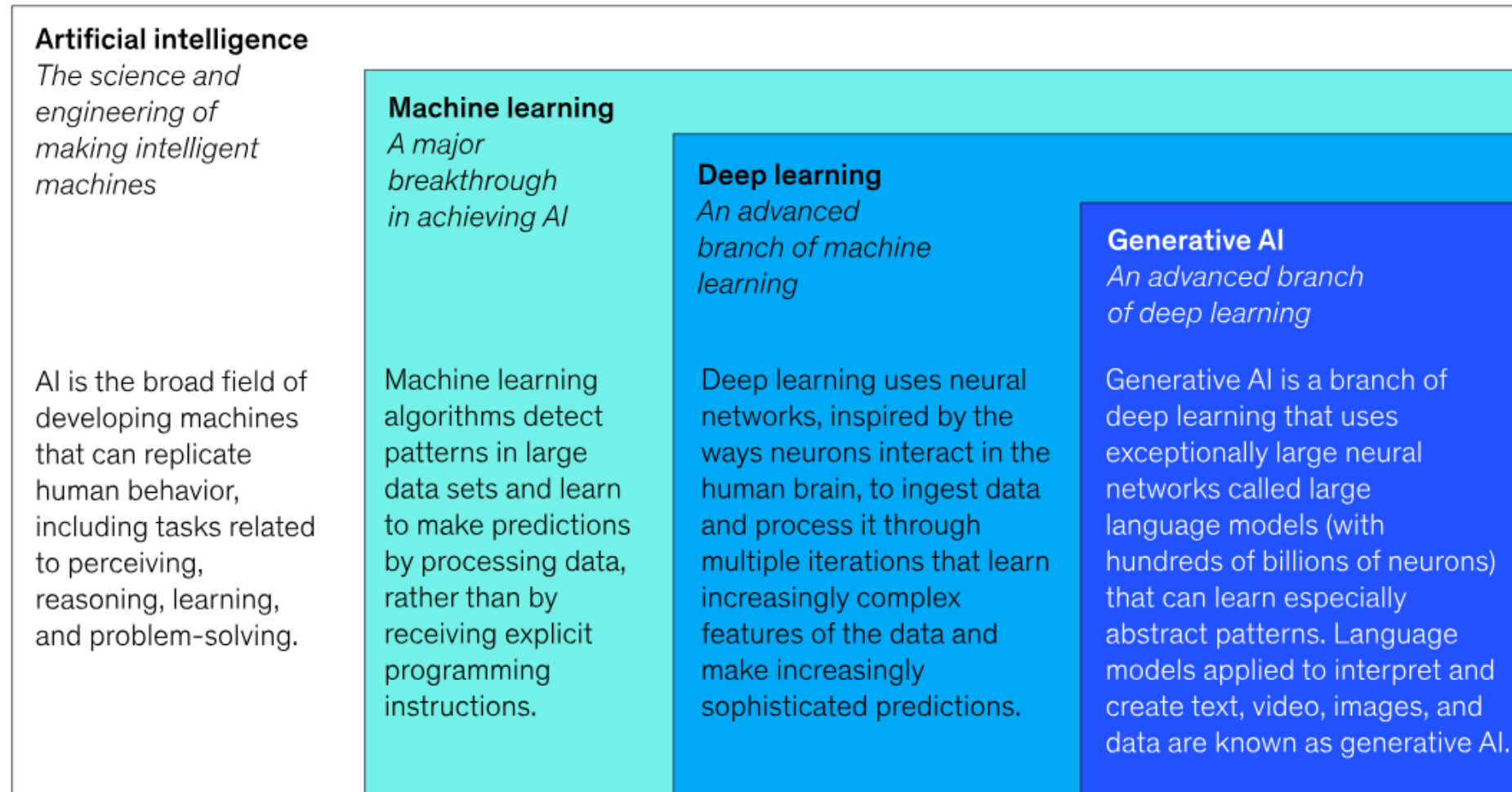
**Cloud computing**



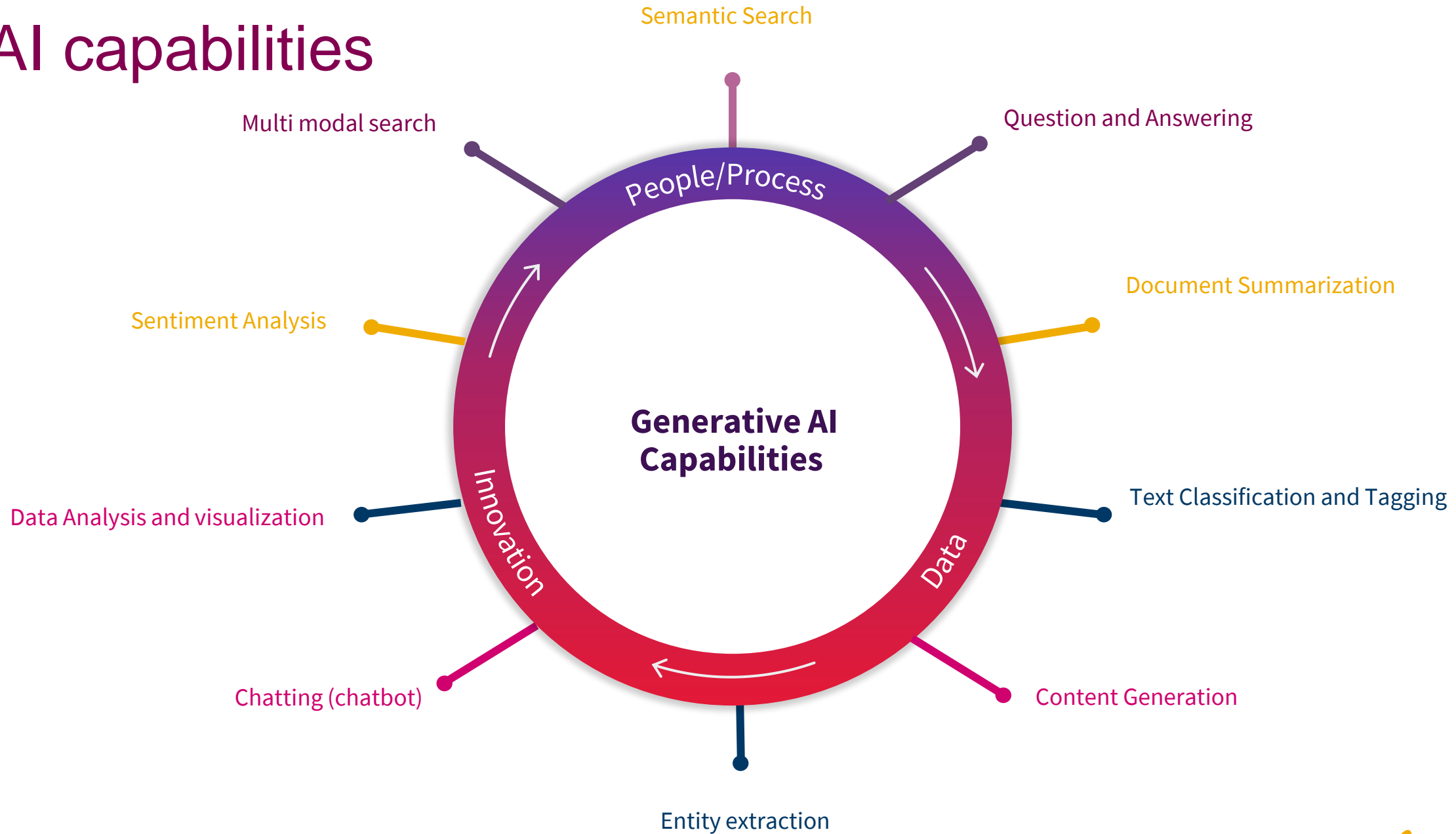


# Understanding AI

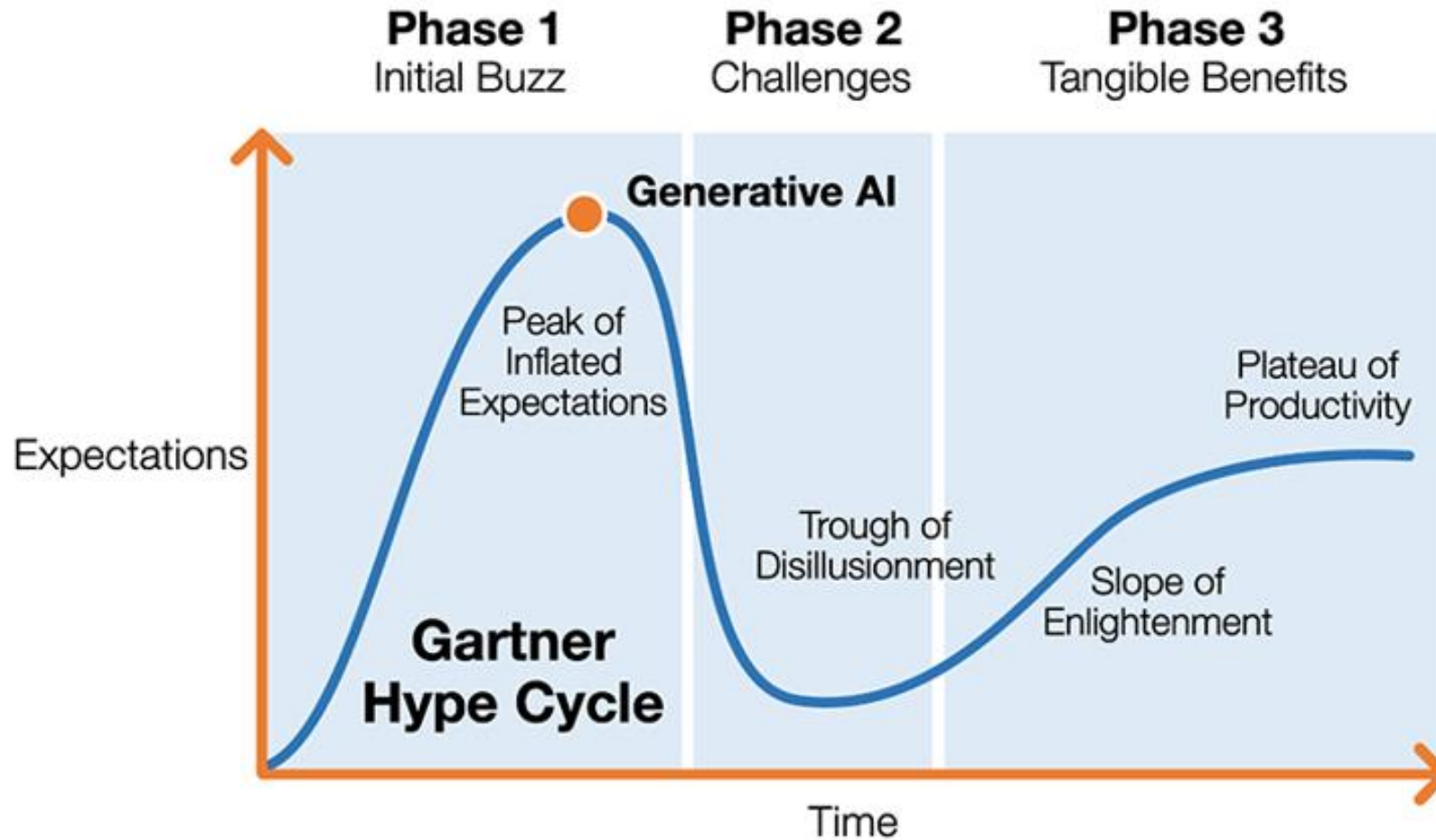
## The evolution of artificial intelligence



# Gen AI capabilities



# Where are we today ?

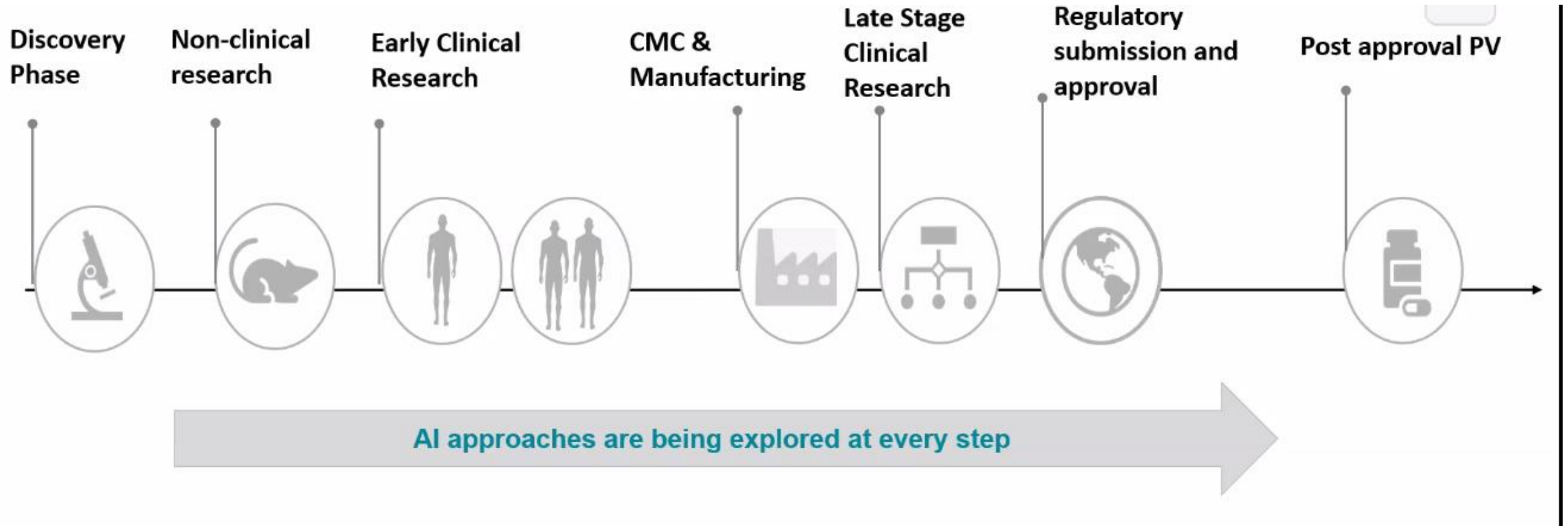


# EU AI Act 2023

- **EU AI Act:** First regulation on artificial intelligence
- It establishes guidelines for large, powerful AI models, aiming to prevent them from posing systemic threats to the Union. The act also provides robust protection for citizens and safeguards vulnerable sectors of the economy against potential technological abuses.
- Members of the European Parliament (MEPs) emphasized the importance of enabling SMEs, to create AI solutions without facing undue pressure from industry. To facilitate this, the agreement encourages the implementation of regulatory sandboxes and real-world testing. These initiatives, overseen by national authorities, allow for the development and training of innovative AI technologies before their introduction to the market.
- The AI Act adopts a risk-based approach, categorizing AI applications into different risk levels, including unacceptable risk, high risk, limited risk, and minimal/low risk.



# AI has the potential to touch early step in drug development



# AI in Clinical Operations



**Protocol Co-Authoring**



**Design Optimizer**



**Study Setup**



**Patient facing AI chatbots**



**CRF design from Protocol**



**Regulatory Intelligence/HAQ**



**Post-Surveillance/  
PV intelligence**



**Portfolio/Asset Management**

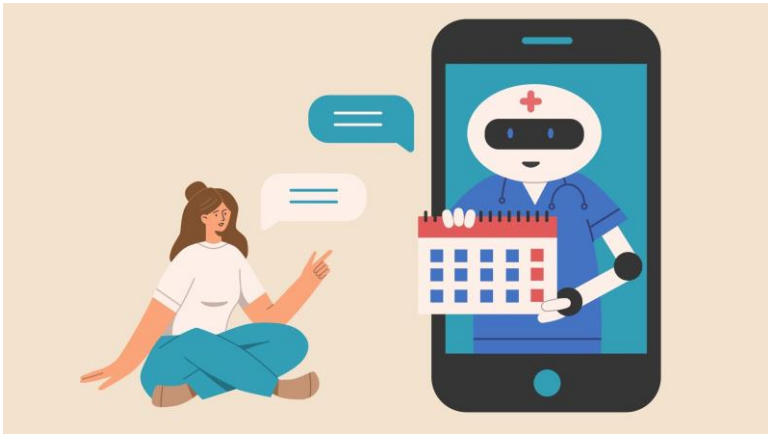




# AI can have an impact to support Clinical Trials & Patients



**Translating Medical terminologies to simple language**



**Connecting Patients to Clinical trials**



**Patient facing AI chatbots for understanding disease or drug information**



**Decentralized Clinical Trials**



**Audio/Video digital communications**



**RWD/E and Outcomes**



# All opportunities come with a set of Challenges

- Akin to any influential technology, a host of challenges have emerged, encompassing matters of
- **REGULATION, VALIDATION, TRANSPARENCY, TRUST, ETHICS, AND BIAS.**
- How does it work?
- How do we accurately analyze its performance?
- How is the data safeguarded
- Model validation
- Perception of Bias
- Patient data rights, privacy and communications



# Call for Collaboration

- As Generative AI continues to accelerate in power and complexity, human decision-making and strategic approaches must adapt and evolve to keep pace with its rapid progress and consequent challenges.
- Crafting meaningful and measurable action plans in response to these challenges requires tailored partnerships that mirror the specific context of the challenge being addressed.
- In the endeavor to positively steer the integration of Generative AI into benefitting patients through transparent decision-making, a broad array of essential collaborators warrant consideration:
  - Patients and caregivers
  - Regulators
  - Digital and Innovation leads
  - Data Scientists
  - Information Technology sector
  - Pharmaceutical, device, and diagnostic industries
  - Payers
  - Healthcare providers
  - Academia and researchers



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