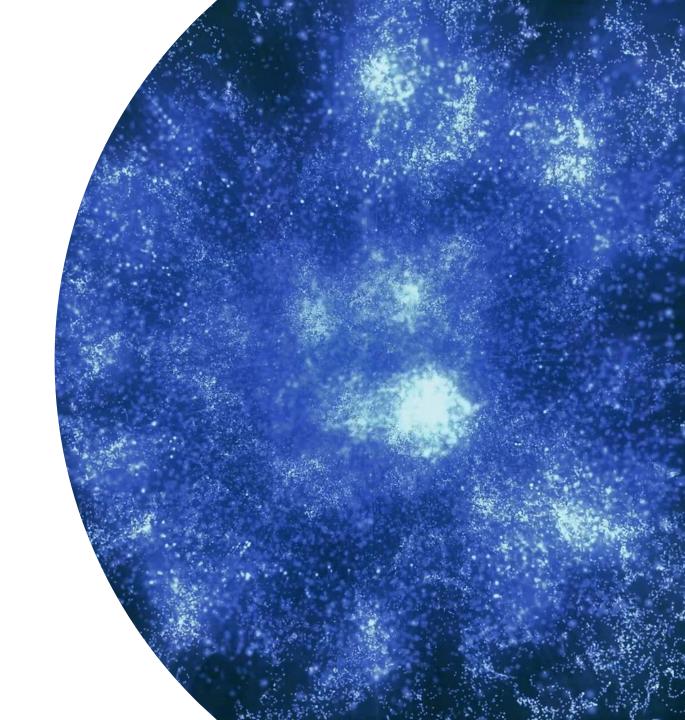


Harnessing AI to Expedite R&D

Sridevi Nagarajan, Ph.D

Head, Digital Regulatory Strategy



Technologies that will change Healthcare by 2030









Quantum Computing



Process automation 2.0 (RPA)



Cybersecurity



Cloud computing



Understanding AI

The evolution of artificial intelligence

Artificial intelligence

The science and engineering of making intelligent machines

Al is the broad field of developing machines that can replicate human behavior, including tasks related to perceiving, reasoning, learning, and problem-solving.

Machine learning

A major breakthrough in achieving Al

Machine learning algorithms detect patterns in large data sets and learn to make predictions by processing data, rather than by receiving explicit programming instructions.

Deep learning

An advanced branch of machine learning

Deep learning uses neural networks, inspired by the ways neurons interact in the human brain, to ingest data and process it through multiple iterations that learn increasingly complex features of the data and make increasingly sophisticated predictions.

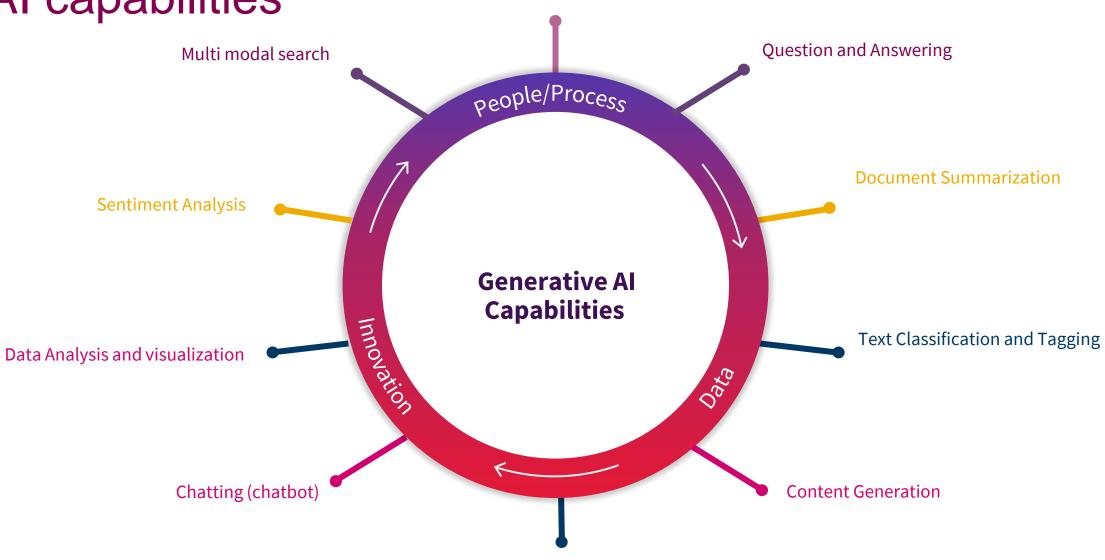
Generative AI

An advanced branch of deep learning

Generative AI is a branch of deep learning that uses exceptionally large neural networks called large language models (with hundreds of billions of neurons) that can learn especially abstract patterns. Language models applied to interpret and create text, video, images, and data are known as generative AI.



Gen AI capabilities

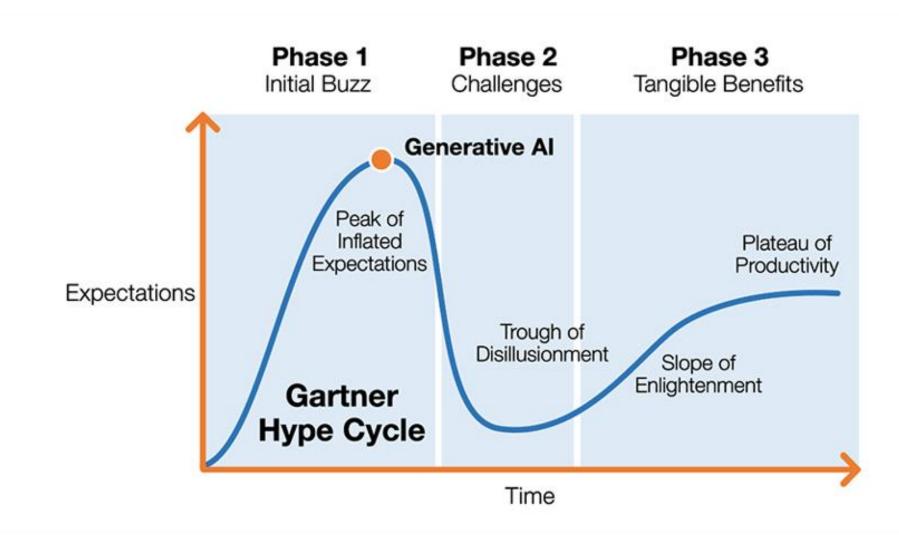


Entity extraction

Semantic Search



Where are we today?



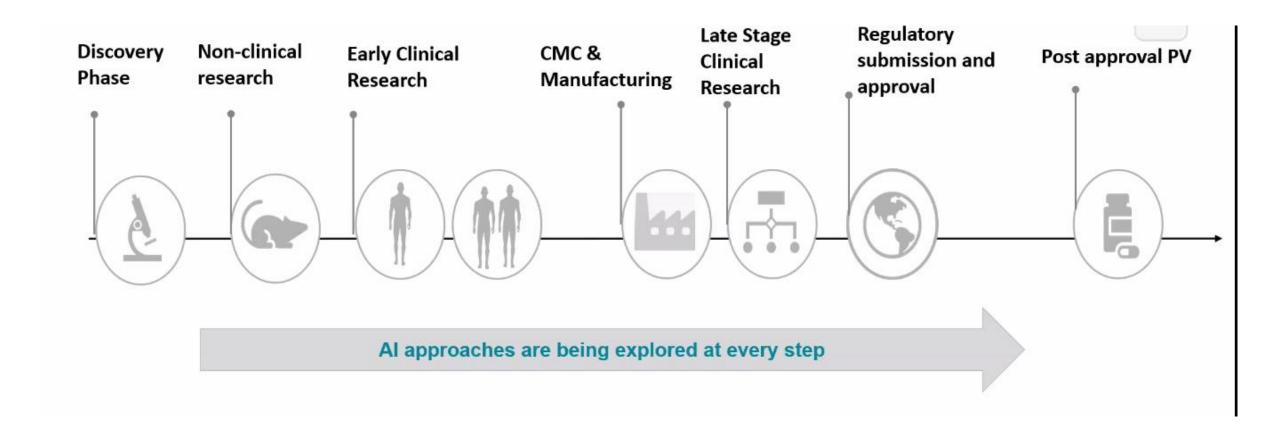


EU AI Act 2023

- **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





Al in Clinical Operations



Protocol Co-Authoring





CRF design from Protocol



Design Optimizer



Regulatory Intelligence/HAQ



Study Setup



Post-Surveillance/ PV intelligence



Patient facing AI chatbots



Portfolio/Asset Management



Al can have an impact to support Clinical Trials & Patients



Translating Medical terminologies to simple language



Decentralized Clinical Trials

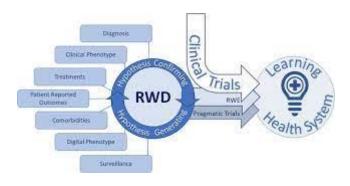


Connecting Patients to Clinical trials





Patient facing AI chatbots for understanding disease or drug information



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



Confidentiality Notice

This file is private and may contain confidential and proprietary information. If you have received this file in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorized use or disclosure of the contents of this file is not permitted and may be unlawful. AstraZeneca PLC, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, UK, T: +44(0)203 749 5000, www.astrazeneca.com

