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Impacts of Artificial Intelligence on the Development of Medical Products

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What is Artificial Intelligence?

Human Intelligence or behaviors demonstrated by machines

- pattern recognition
- image recognition
- voice recognition
- understanding of natural language

Reasons for Rapid Rise in Adaptation

Faster Computing

Better access to historical data

New Algorithms

Innovative Potential

The Possibilities are Endless!

Google's CEO Sundar Pichai and numerous other technology experts have called AI "as profound as electricity".*

Google Home/Alexa

Movie, Music, Shopping Genre Preferences

In Vitro Diagnostics

Radiological Medical Devices

Delivery Drones

Military Weapons

Early Disease Detection

Robots and Robotic Devices

*As reported by the UN Office of Communications and Technology

Why is this Impactful?

Current global landscape in health and social care

- Highly challenging environment, demanding innovative approaches
- Unprecedented global transmission of new diseases and emerging health issues
- By 2050 the world's population over the age of 60 years will be about two billion
- Shortages of healthcare professionals continues to grow
- Older adults are living longer with chronic problems and disabilities

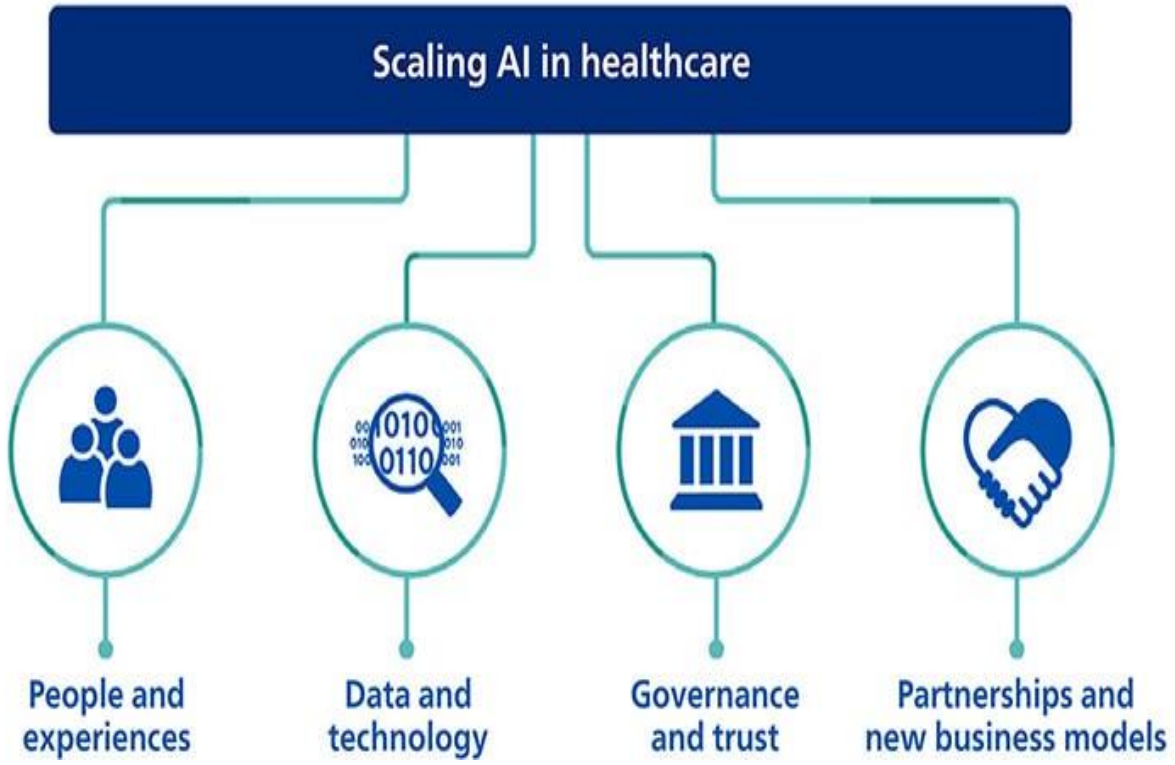
Enablers and Barriers to Healthcare Market Adaptation

Key Barriers

- Missing and Disparate Data
- Complexity Challenges
- Computer Hardware Design Limitations
- Lack of Talent/Expertise

Key Enablers

- New Talent
- Evidence Based Results
- Entrepreneurial Spirits
- Regulations

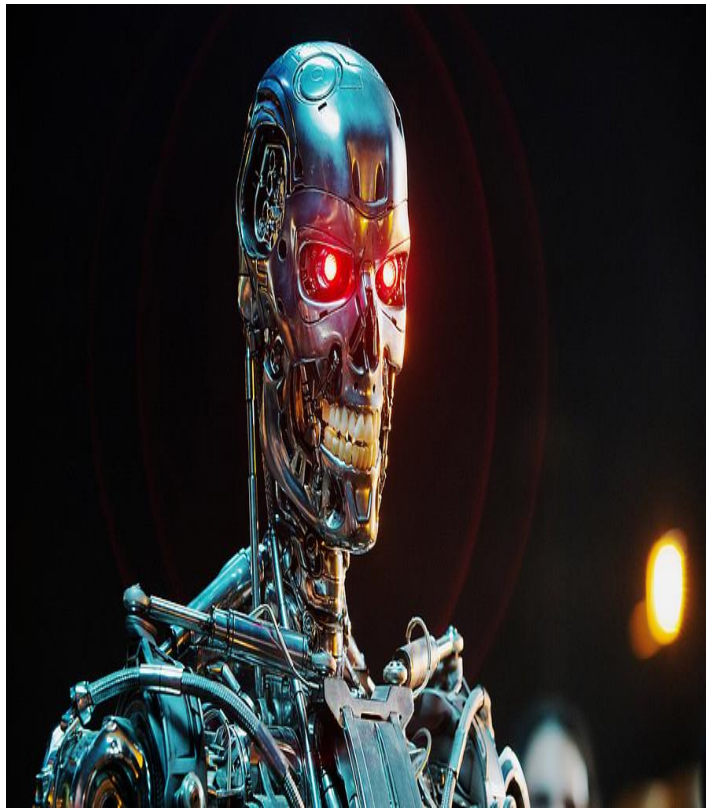


Current Landscape
Sources of Funding

Already recognized the use of artificial intelligence (AI) and robotics provides a major opportunity towards meeting these challenges

- UK: AI and Health & Care Awards
  - a program of the NHS AI Lab set up to accelerate the safe, ethical and effective adoption of AI in healthcare backed by a record level of funding up to £14.1 billion from 2023 to 2025
- US: New ARPA-H Institute
  - $2.5 billion for new within NIH with initiation in FY24
- Health care AI startups
  - experienced record private investor funding in the third quarter of 2020, with 122 deals adding up to more than $2 billion with continued growth expected

Challenges



- How do we address Intellectual Property Rights?
- Regulations control access to personal information/health information but AI gathers everything in its path.
- Constantly changing set of parameters to be tested and validated.
- Garbage in/Garbage out.
- War Stories already out there.

Food and Drug Administration Perspective

- **AI solutions have the potential to improve**
  - Automation and learning of medical devices
  - Efficiency of diagnostic/therapeutic development and commercial manufacturing
  - Regulatory assessment
  - Post market surveillance
- **Resulting in**
  - increase in accuracy of predictive modeling,
  - Enabling efficient automation of medical devices and manufacturing processes,
  - leveraging knowledge management resources to improve regulatory review, and
  - focus and improvement to post market surveillance.

US Regulatory Landscape
(689 Entries in FDA webpage search for AI)

4/2018: Marketing Authorization of artificial intelligence-based device to detect certain diabetes-related eye problems

4/2019: Statement from FDA Commissioner Scott Gottlieb, M.D. on steps toward a new, tailored review framework for artificial intelligence-based medical devices

2/2020: Marketing Authorization of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

1/2021: FDA Releases Artificial Intelligence/Machine Learning Action Plan

4/2021: Marketing Authorization of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer

4/2023: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions Draft Guidance Document to Industry and FDA Staff

Popular Areas of Research Interest at FDA

AI/ML-based medical devices:

- Data augmentation, transferring learning, and other novel approaches to enhance AI/ML training/testing for small clinical datasets.
- Study design and analysis methods for AI/ML-based computer-aided triage (CADt).
- Non-clinical phantoms and test methods for assessing specific imaging performance claims for DL-based denoising and image reconstruction algorithms.
- Imaging phantoms and computational models to support QI and radiomics assessment.
- Assessment techniques for evaluating the reliability of adaptive AI/ML algorithms to support non-clinical test method development.
- Assessment approaches to estimate and report the robustness of AI/ML to variation in data acquisition factors.
- Technical factors influencing AI reproducibility for digital pathology applications.
- Methods for assessing the generalizability of AI performance in digital pathology applications.

Popular Areas of Research Interest at FDA (continued)

- Improving efficiency of reviewing regulatory submissions.
  - Studying how AI can combine diverse data so clinical trial results can be analyzed in a more comprehensive and expeditious way.
  - Processing and evaluation of individual case safety reports
  - Pharmacometrics, the science that quantifies drug, disease, and trial information, to aid efficient drug development, and/or regulatory decisions.
  - Advance precision medicine, by predicting patient responses based on baseline patient characteristics.
  - Computer models that use genomic data to predict the mean inhibitory concentration (MIC) for pathogens and antimicrobials surveyed for the National Antimicrobial Resistance Monitoring System (NARMS).
  - Researching image blending to expedite development and performance assessment of mammographic computer-aided diagnostic (CAD) devices.
  - Developing a framework with a CERSI partner for measuring robustness of ML models to contextual changes in the real-world data and inform regulatory decision-making by categorizing which contextual factors matter for a particular intended use and how to better define the context of appropriate use.
  - Commercial drug manufacturing to improve quality decision making.

Breaking News!!!

- 5.10.23: FDA releases discussion paper and request for Feedback.
  - *Using Artificial Intelligence and Machine Learning in the Development of Drugs & Biologic Products.*
    - *Current and Potential use*
      - *Drug Discovery*
      - *Nonclinical Research*
      - *Clinical Research*
      - *Post Marketing Surveillance*
      - *Advanced Pharmaceutical Manufacturing*
    - *Considerations*
      - *Overarching Standards & Practices and discussion of FDA perspectives*
    - *Next steps and Collaboration*
      - feedback and future discussions with stakeholders can help inform future regulatory activities. FDA's
      - CDER, CBER, CDRH, including DHCoE, aim to initiate a discussion with stakeholders and solicit feedback on three key areas in the context of AI/ML in drug development:
    - NOT FDA guidance or policy
    - FDA does not endorse any specific approaches for the use of AI/ML in drug development

Things to Consider

- Artificial Intelligence creates challenges much like the introduction of the internet decades ago.
- AI/ML may alter regulatory approval pathway to De Novo from traditional paths at least until new product codes are identified.
- Evolving environment that requires due diligence to stay abreast of events.
- Be careful what you ask for….

https://www.youtube.com/shorts/-Wr6v-QnRCQ

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Q&A

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