U.S. FOOD & DRUG ADMINISTRATION

Artificial Intelligence

Anticipating the Opportunities and the Challenges for Therapeutic Development

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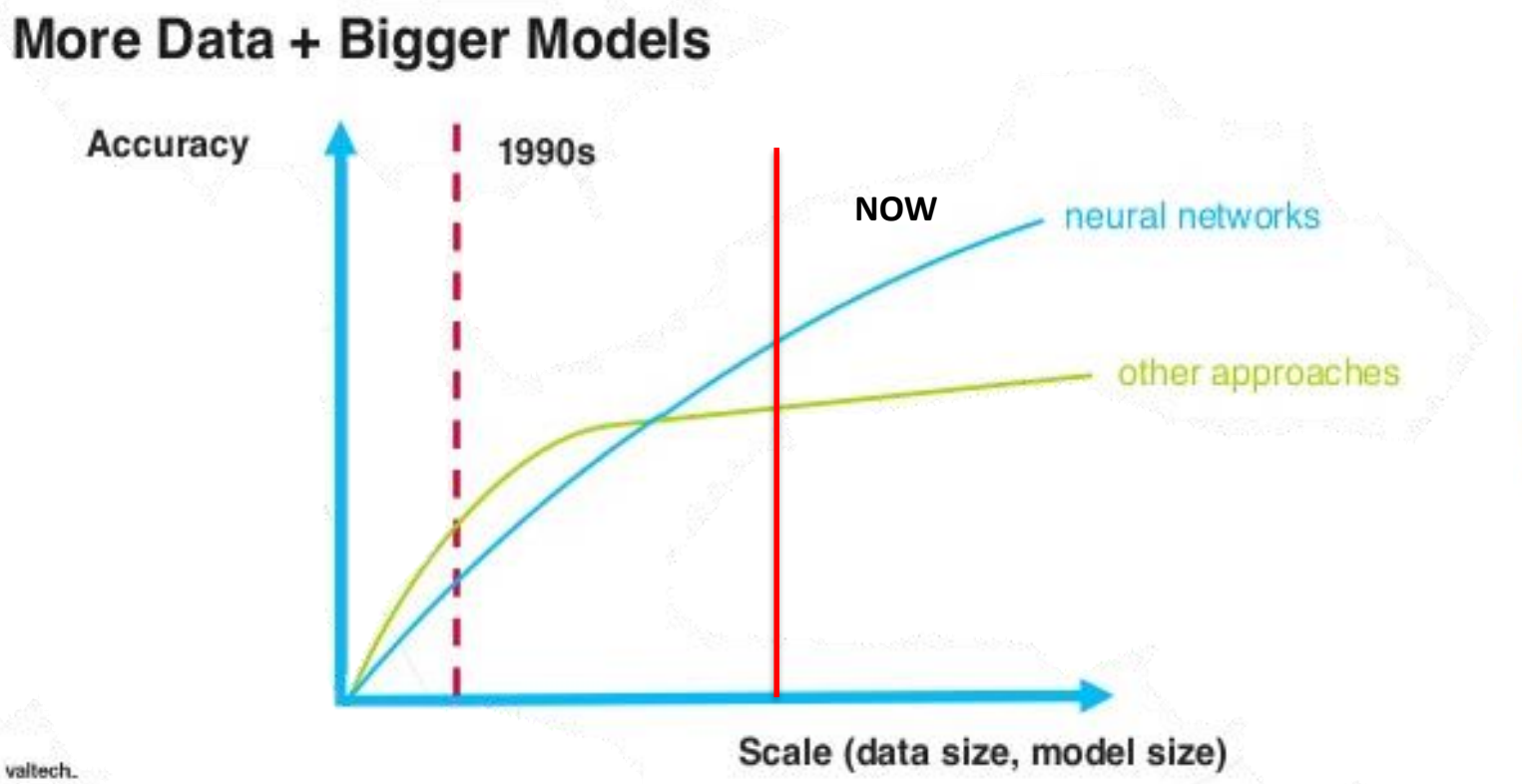
The views in this presentation do not necessarily represent the policies of FDA

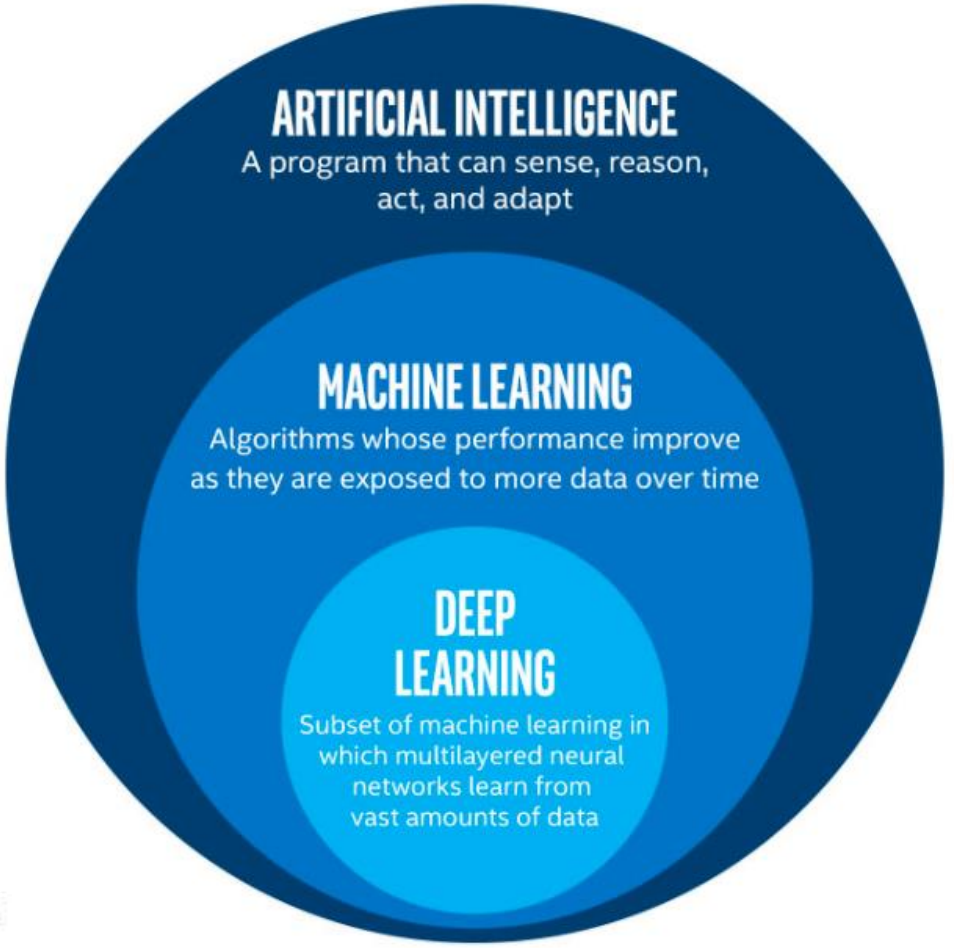
Disclosures: None

Convergence of Large Data Sources and Powerful Computing Capabilities



Cited in - https://towardsdatascience.com/deep-learning-performance-cheat-sheet-21374b9c4f45

https://www.scribd.com/document/355752799/Jeff-Dean-s-Lecture-for-YC-AI



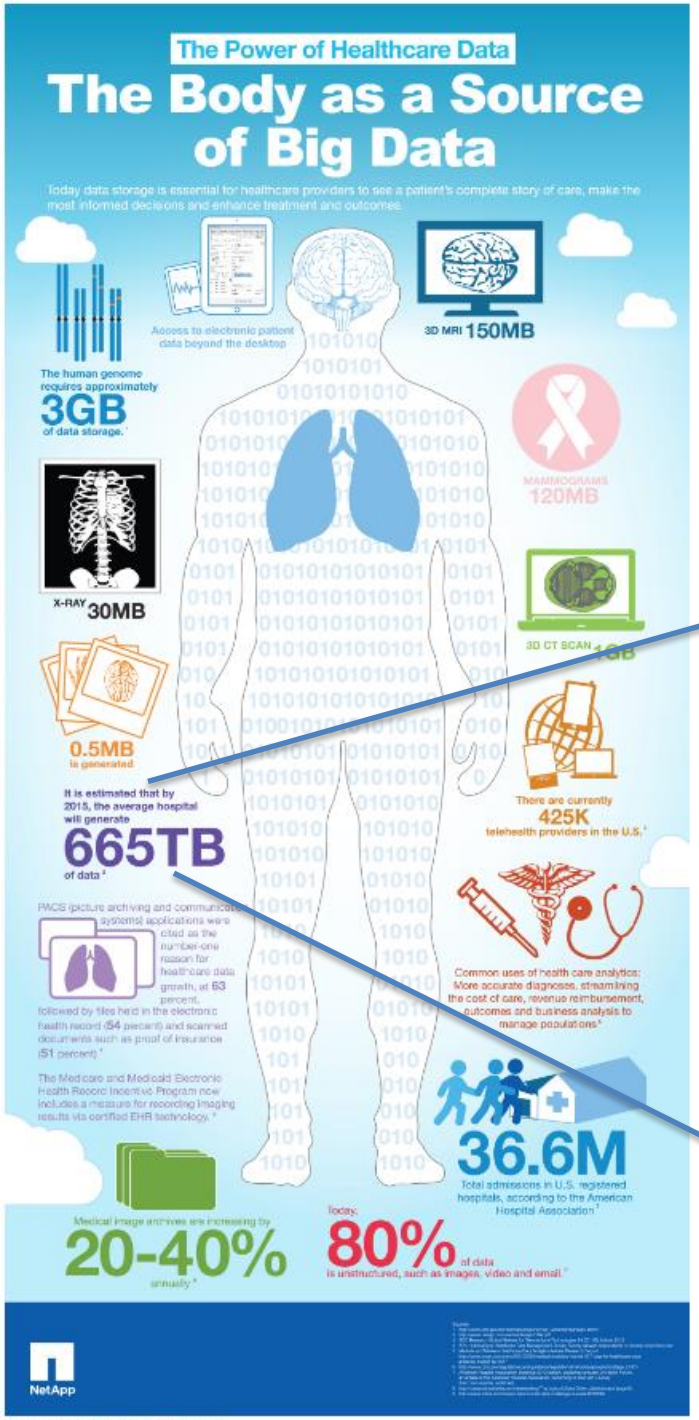
How AI, machine learning and deep learning fit together (Source: Prowess)

Health Data are Available

BUT Needs

Structure, Organization, Verification, Cleaning

AI CAN HELP



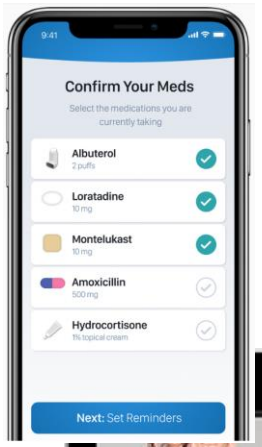
Infographic courtesy of NetApp

It is estimated that by 2015, the average hospital will generate

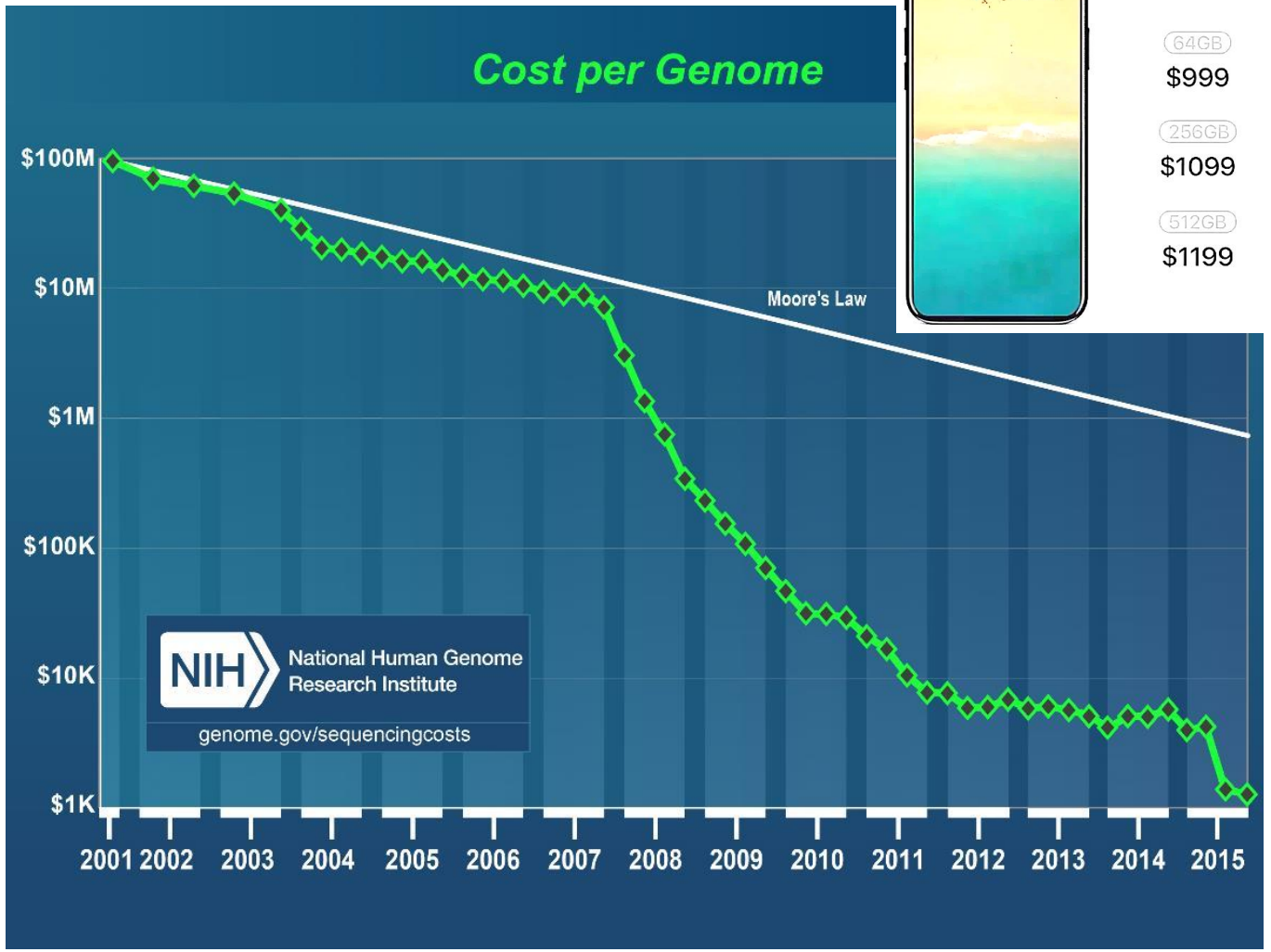
665TB

of data [1]

Digital Health Explosion + Genomic Data are Increasingly Available



Cost of Genomic Data comparable to iPhone X



64GB
$999
256GB
$1099
512GB
$1199

Why does the FDA cares?

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1. **Potential to help advance every phase of drug development**
   - Discovery and target identification
   - Preclinical
   - Clinical
   - Post-market
2. **Key to FDA's efforts on multiple fronts (Real-world evidence, mHealth, etc.)**
3. **Capabilities for facilitating and refining clinical trials**

Why does the FDA cares? *(cont.)*

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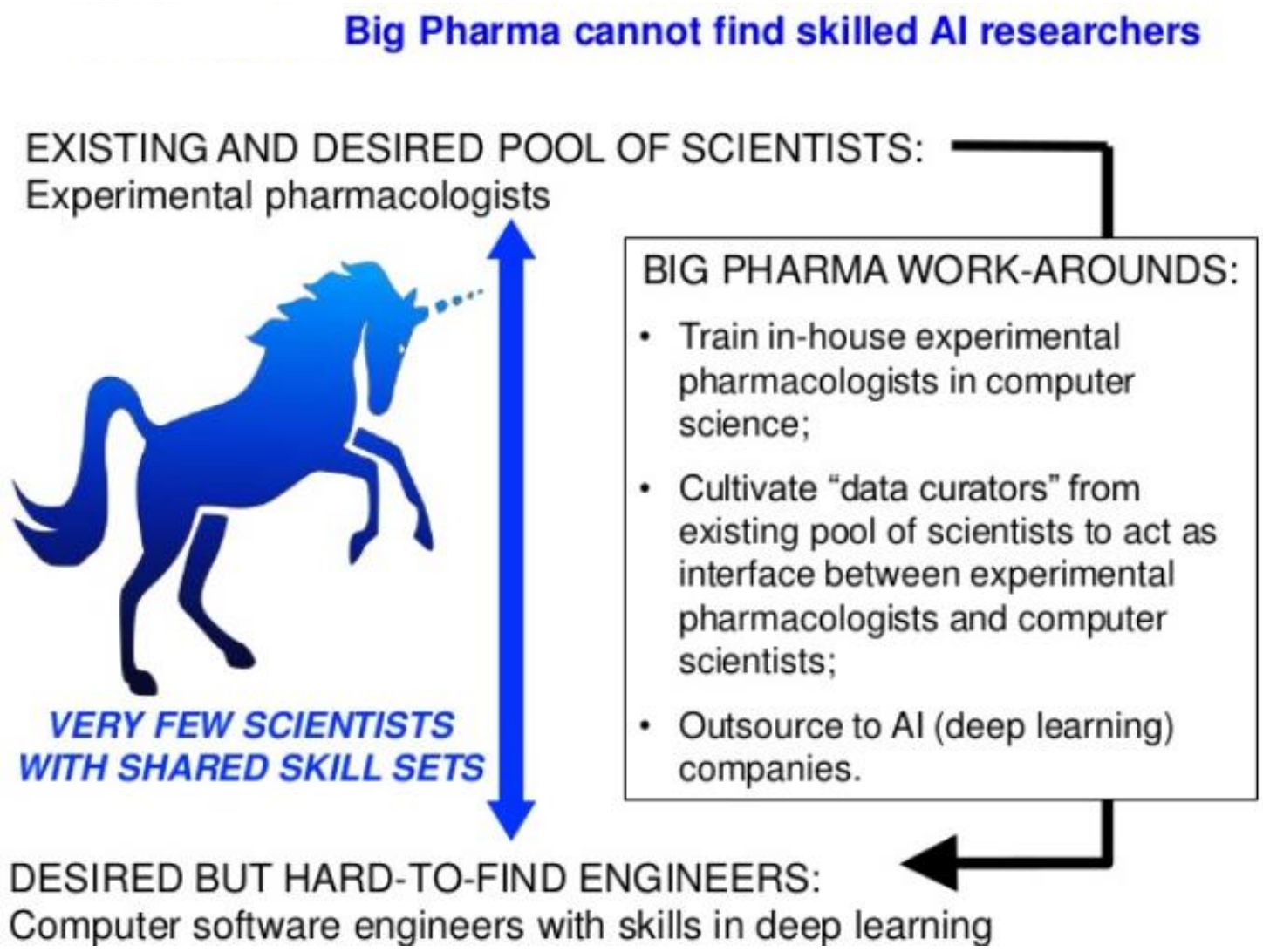
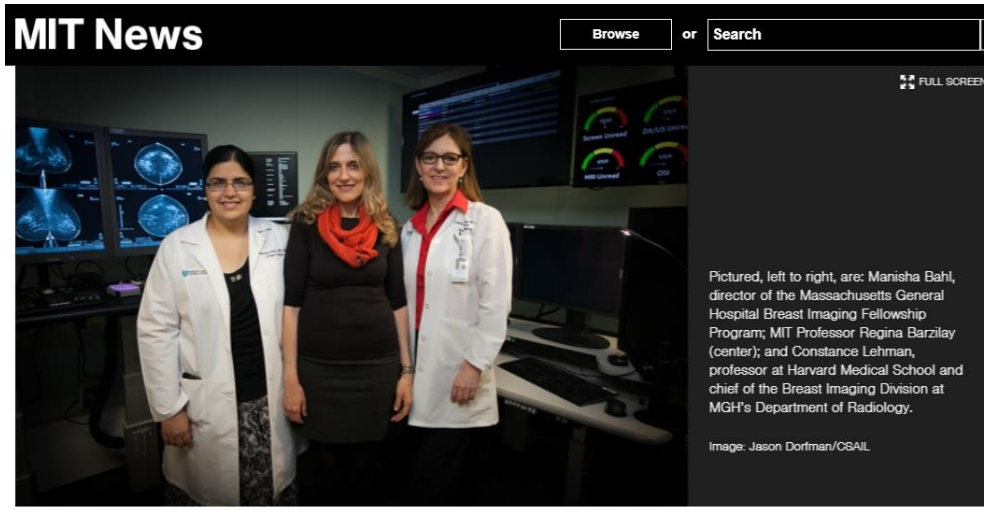
1. Increasing need for relevant expertise
2. Understanding the hype vs. reality in necessary
3. Importance of establishing standards and shared understanding among stakeholders



Slide by Gerry Higgins, M.D., Ph.D. University of Michigan.

The Great Potential for AI In Therapeutic Development



Using artificial intelligence to improve early breast cancer detection

Model develop

January 17, 2018

Artificial Intelligence in Manufacturing, Pharma, and Financial Services

Executive leaders need to examine practical use cases to put AI to work in their enterpris
by their industry.

Najaf Technical Institute, Al-Furat Al-Awsat Technical Univers

abcinj.ame7@atu.edu.iq

KEYWORDS: Rheumatoid Arthritis, Artificial Intelligence, Diseas

nature medicine

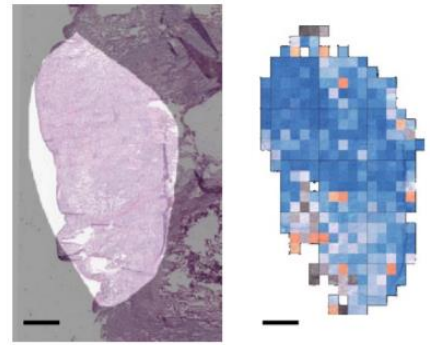
ARTICLES

https://doi.org/10.1038/s41591-018-0177-5

Classification and mutation prediction from non-small cell lung cancer histopathology

MEGAN MOLTENI SCIENCE 08.10.17 12:00 AM

WANT A DIAGNOSIS TOMORROW, NOT NEXT YEAR? TURN TO AI



ZDNet

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MUST READ: Apple iPhone XR: Three features I love, and one I hate

AI is going to transform the pharmaceutical industry. Here's how.

From lowering risk during drug trials to better study design and faster results, Big Data, the cloud, and AI are transforming how medicine gets made.

FDA is already seeing the use of AI

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FDA News Release

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

FDA approves AI-powered diagnostic that doesn't need a doctor's help

ASCRS AN ASCRS PUBLICATION
EyeWorld 20
Serving the Ophthalmic Community Since 1996
Celebrating 20 Years in Ophthalmology
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Ophthalmology news - NEWS & OPINION - First artificial intelligence system approved by the FDA to detect diabetic retinopathy

JUNE 2018

NEWS & OPINION

First artificial intelligence system approved by the FDA to detect diabetic retinopathy

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APR 12 | MORE ON QUALITY AND SAFETY

FDA approves first AI tool for detecting retinopathy, NIH shows machine learning success in imaging

New technologies bring the promise of earlier detection and automation, both with an eye on lowering costs.

AI can be Helpful in Exploring the Use of Real-World Data

Working Definitions

- **Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.**
- **Real-World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.**

RWE = RWD + Analytics

https://bmcmedicine.biomedcentral.com/track/pdf/10.1186/s12916-016-0627-1

Understanding the Complexities

Opinion | Ruth Bader Hat Guy? Let Our Algorithm Choose Your Hallo...

Machine learning has a spooky side. These algorithmically generated Halloween costumes show how artificial intelligence can reinforce human...

nytimes.com

Sometimes, the ways algorithms work can have unexpected and disastrous consequences. In 2013, M.I.T. researchers trained an algorithm that was supposed to figure out how to sort a list of numbers. The humans told the algorithm that the goal was to reduce sorting errors, so the program deleted the list entirely, leaving zero sorting errors. And in 1997, another algorithm was supposed to learn to land an airplane on an aircraft carrier as gently as possible. Instead, it discovered that in its simulation it could land the plane with such huge force that the simulation couldn't store the measurement, and would register zero force instead.

- AI prediction algorithms predict the most likely decision or answer that might be achieved using the input data (not necessarily the accurate answer).
- AI predictions and solutions could reflect flaws in algorithms and datasets and provide unpredictable "solutions".

https://www.nytimes.com/interactive/2018/10/26/opinion/halloween-spooky-costumes-machine-learning-generator.html

What is needed?

- **Understanding the functions and tasks that lend themselves to AI adoption and those that do not**

- **Shared understanding of principles and approaches that are essential in designing and adopting AI systems (beyond the hype)**
  - The need for a quality continuum in the design of AI systems (data and algorithms) to avoid "Garbage in, Garbage out."
  - The need to understand that AI is not necessarily the silver bullet for everything - those designing algorithms (and teaching) the machines can't comprehend or impute all of the essential variables.
  - AI systems can be limited by many factors
    - ❑ Learning data sets are imperfect
    - ❑ Algorithms have biases and assumptions impeded – can we control for that?, how?

What is needed? *(cont.)*

- **A convergence of multidisciplinary expertise to address the evolution of AI**
  - Computer science alone will not produce breakthrough AI systems for drug development
  - We need educational and training programs that connect essential disciplines and provide trainees with the needed skills

- **Pilots to explore the utility of AI systems - Evaluate successes and failures**
  - Failure here is not a standard concept – failure is an integral part of machine learning/training. Data from failures in a learning AI system = better AI system**.**
  - Transparency is key.

Food for thought

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- This is a rapidly evolving area – we must proactively engage as a community, anticipate innovations, and prepare to respond effectively.

- The FDA is eager to work with all stakeholders to facilitate innovations and shared understanding, and ultimately improve and protect public health

Rapid technological advances call for a proactive engagement by all stakeholders

Thank you!