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Health Sciences

Artificial Intelligence in Clinical Trials

MHRA StEM

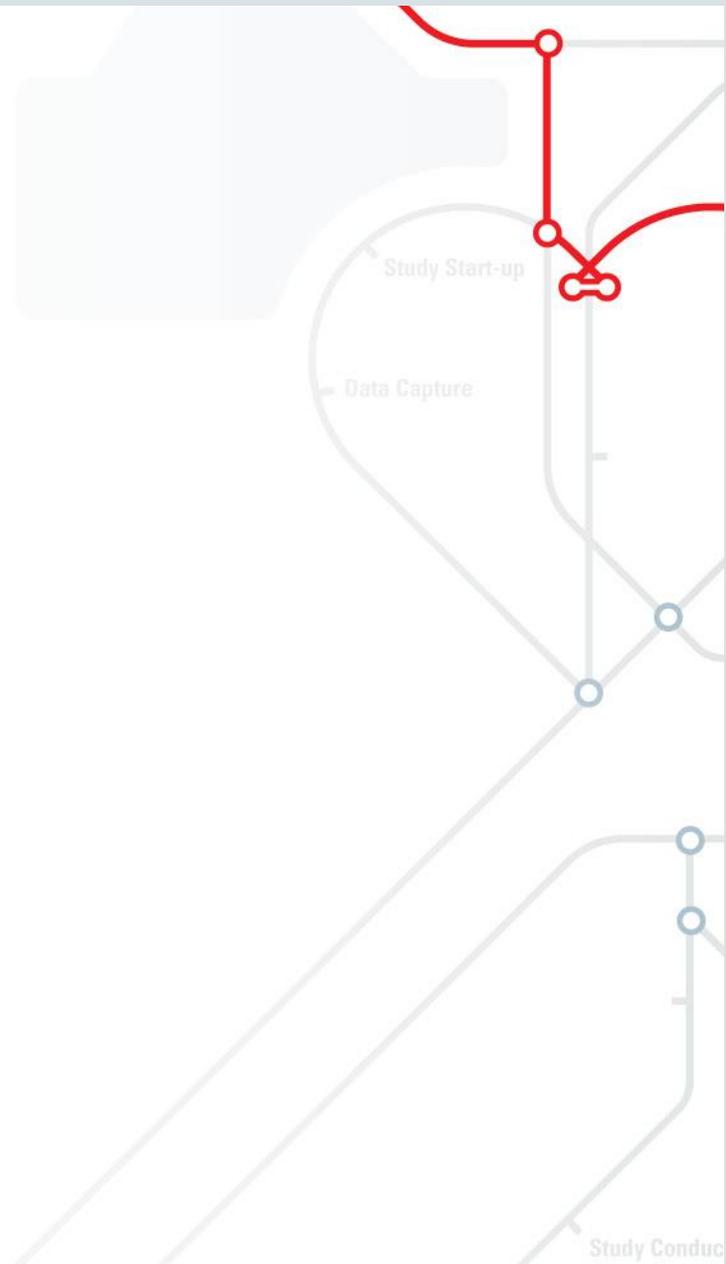
Jonathan Palmer
Senior Director, Product Strategy, Digital Trials
Oracle Health Sciences Global Business Unit
7 May 2019

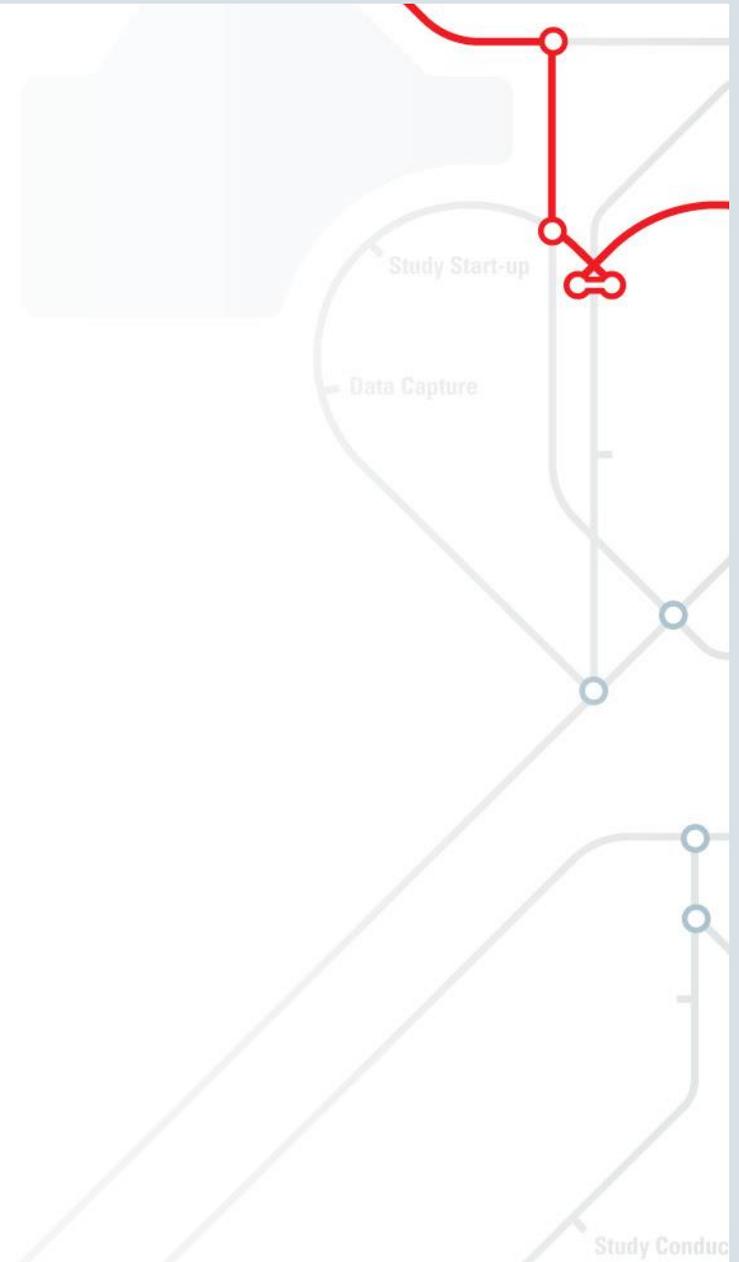
jonathan.palmer@oracle.com

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Artificial Intelligence – Embedded in our lives



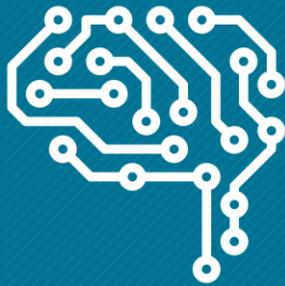




Artificial Intelligence & Machine Learning

ARTIFICIAL INTELLIGENCE

Any technique which enables computers to mimic human behavior



MACHINE LEARNING

AI techniques that give computers the ability to learn without being explicitly programmed to do so



DEEP LEARNING

A subset of ML which make the computation of multi-layer neural networks feasible



1950's

1960's

1970's

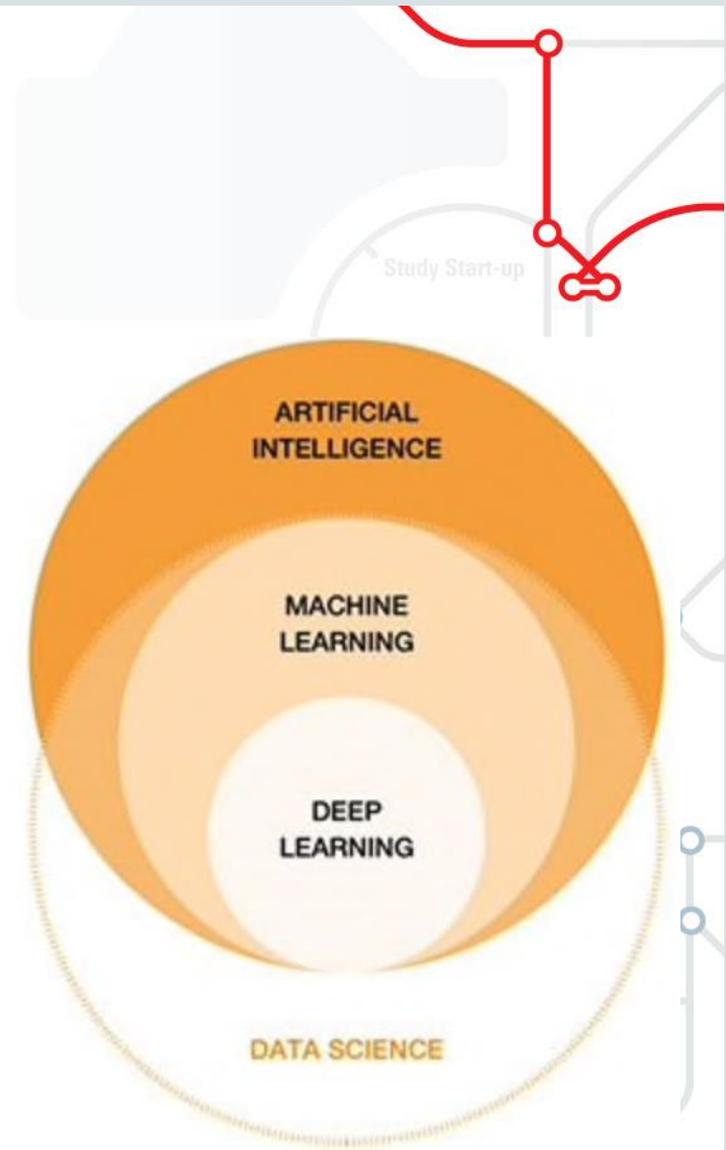
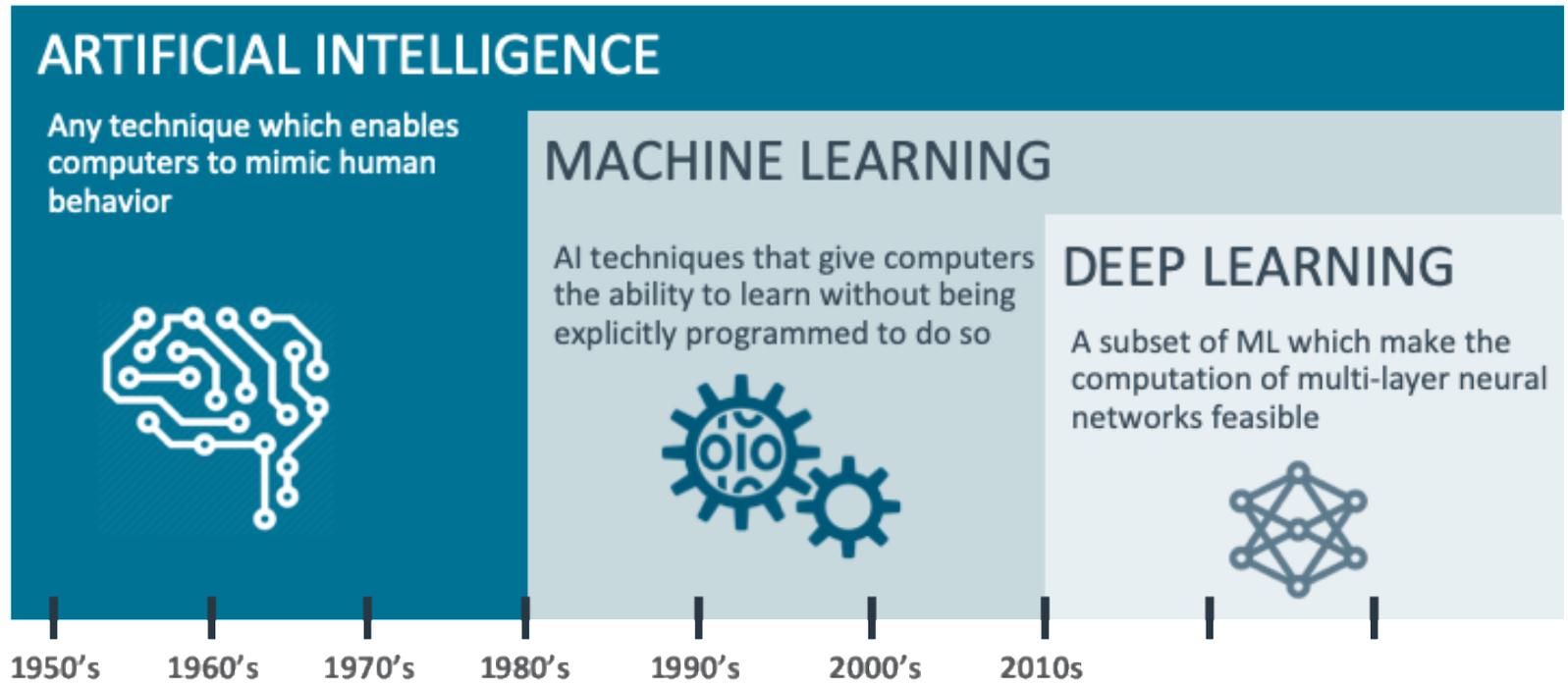
1980's

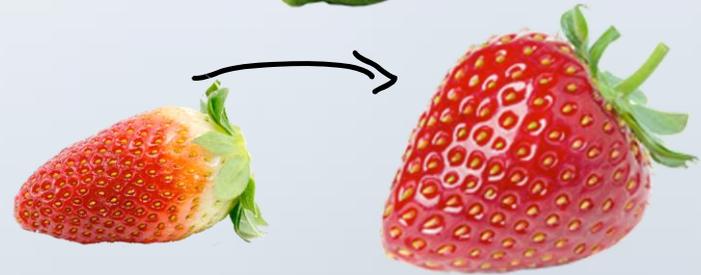
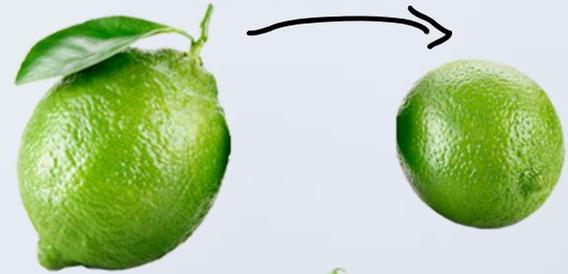
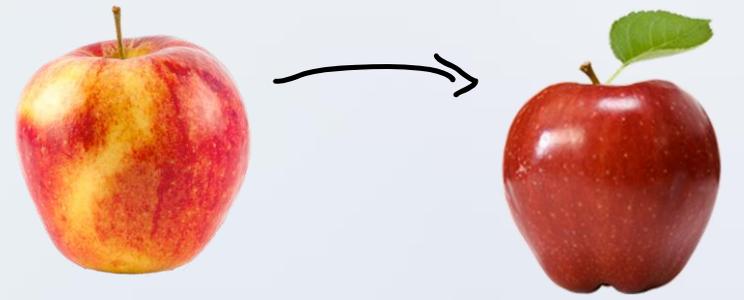
1990's

2000's

2010s

Artificial Intelligence & Machine Learning

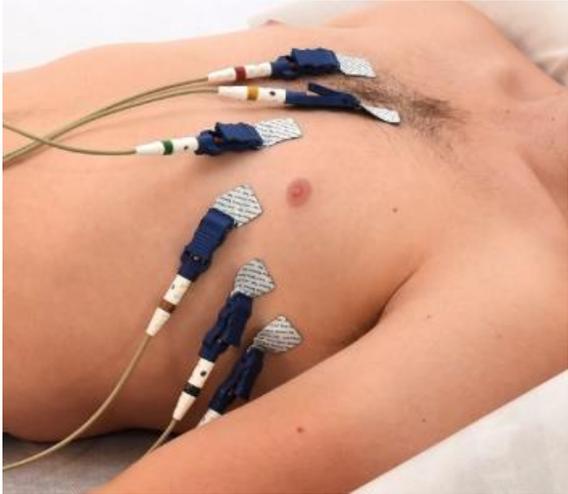




Mapping to Machine Learning Terms

Term	We used	Data scientist might use
Technique	Classify (fruit)	Classification, clustering, time series. etc.
Algorithm	“Deep learning neural network” in your brains	Neural network, decision tree, k-means clustering, etc.
Training Data	The initial basket of fruit	Data set supplied by IT, often setup and cleaned up by data scientist
Model	This is what identified the fruit	Look at the data and score, classify, etc.
Training the model	You figured it out	Adjust different parameters in response to the data to make it more accurate
Testing the model	The left over fruit	Always reserve some data that the model hasn't seen to test.
Model deployment	Sent you to fruit packing line	Make model available to app developers, execs, analytics tools etc.
Model update	Brought you back for more training	Build a new model or re-train the old on additional data. Must re-deploy

EKG/ECG – From Bed to Pocket



Blood Pressure Monitoring – Evolution to Disruption

1 in 3 American Adults have High Blood Pressure

Cuffed



Cuffless, Continuous



Digital Clinical Trials

Disruptive Change is Happening Now

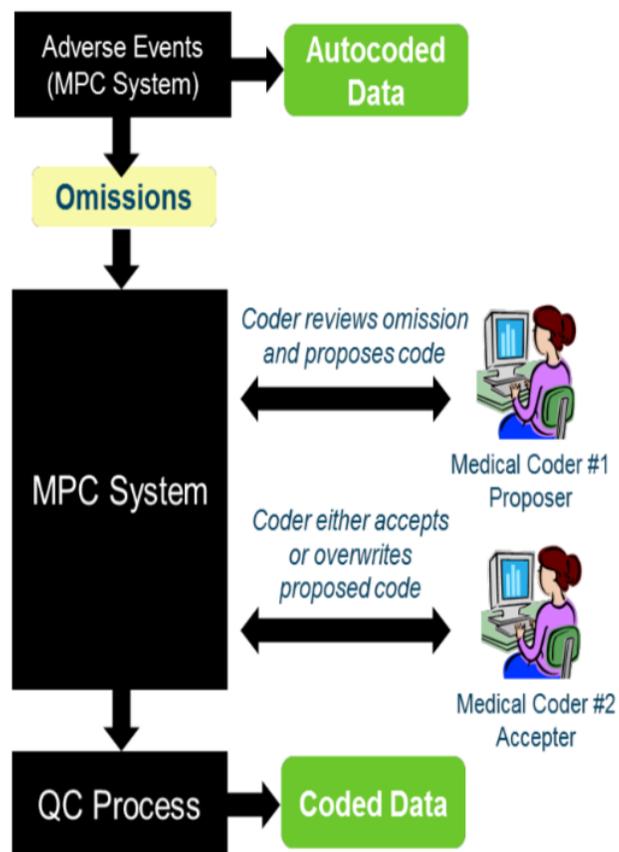


- 1 Medication Adherence
- 2 Remote Patient Monitoring
- 3 Decentralized / Virtual Trial
- 4 Real World Evidence / Outcomes
- 5 Digital Therapy

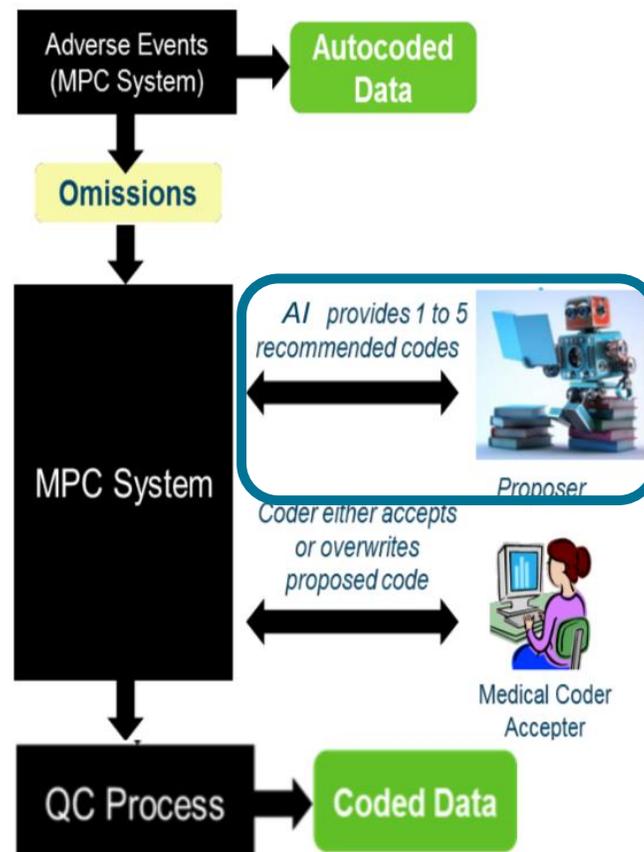


Medical Coding

Without AI



With AI



- Central medical coding team
 - Clinical trial data and PV cases
 - Increased workload
 - Skilled resources hard to find/train
- AI Solution
 - Trained with Bayer data
 - Substitutes the Proposer role
 - MPC (Bayer core coding platform) sends omission to be coded
 - AI returns suggestion
 - Coder accepts or overwrites

Remote Cervical Cancer Screening in Cameroon

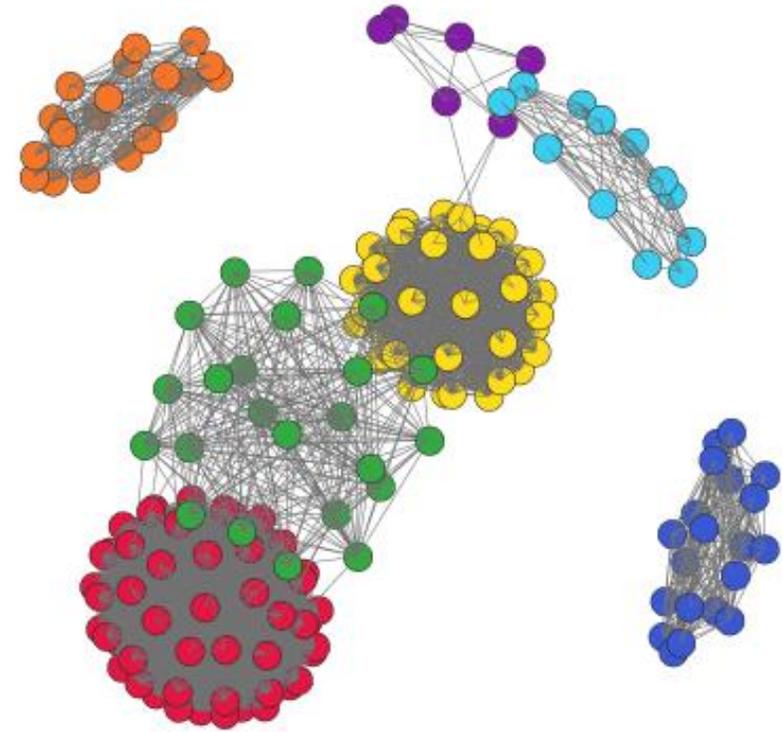


- The Problem
 - Large country, widely distributed population
 - Severe lack of pathologists/medical staff per region
 - Ultimate diagnosis too late in disease progression
- AI Solution
 - Mobile clinics perform photocervicography
 - Magnified real time image stored in database
 - AI helps triage images for early detection

University of Alabama Medical Center & Cameroon Women's Health Program

Safety Case Management

- Automated Document Classification
- MedWatch, Literature, VAERS, social media, AE forms, etc
- Classify and Categorize data to identify relationships and signals
- Uses Machine Learning, NLP, Clustering



Each dot represents a document

Medication Adherence

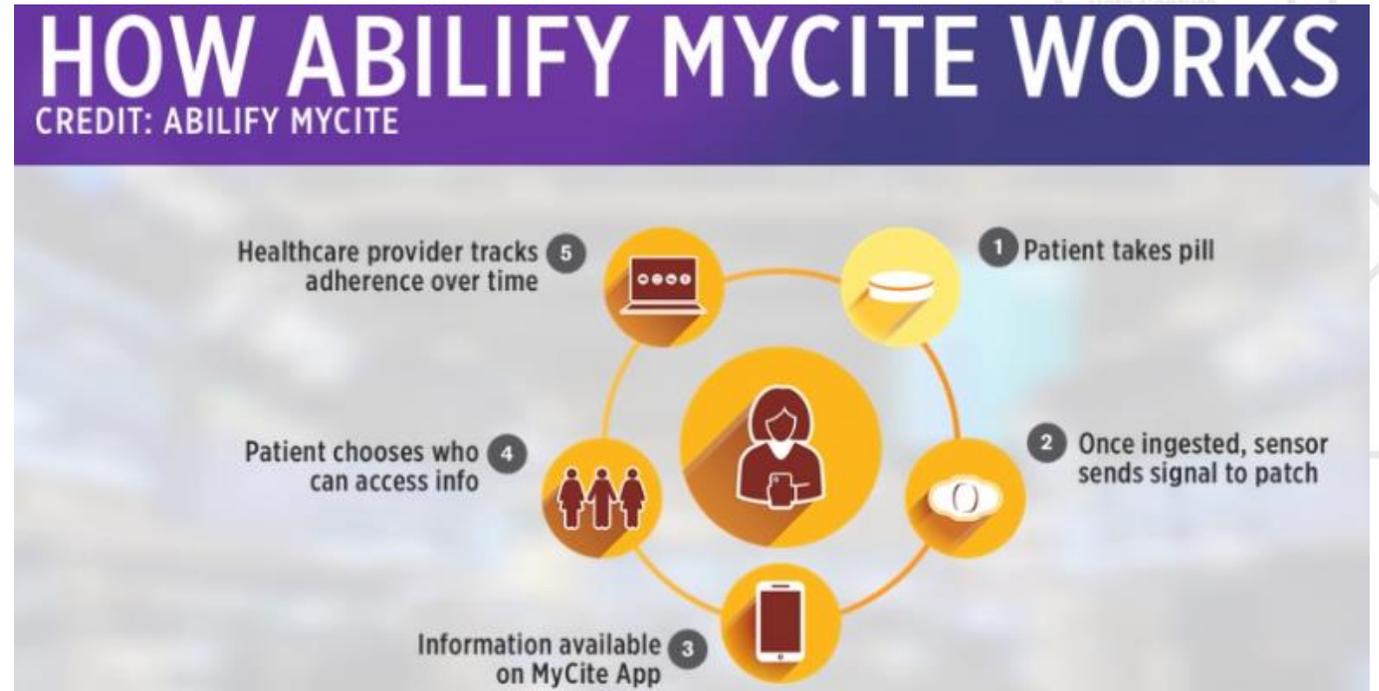
Increased Adherence / Increased Retention / Reduced Fraud

Medical Ingestion Recognition – AI Cure



- HIPAA-compliant facial recognition
- Automatic medication identification
- Real-time ingestion confirmation
- Fraud and duplicate enrollment detection
- No video review is needed
- Download application onto any smartphone
- Analytics allow for pre-emptive intervention
- Assistive technology for greater patient engagement

Smart Pill – Otsuka Abilify



The Washington Post

This \$1,650 pill will tell your doctors whether you've taken it. Is it the future of medicine?

Increase in device data and self assessments

Floodlight correlates with clinic and patient assessments

Functional domain	Floodlight test	In-clinic outcome	Patient self-assessment
Mobility/ambulation	 5 U-Turn Test	 Timed 25-Foot Walk 	 MSIS-29* 
Cognition	 Digital SDMT	 Oral SDMT 	 MSIS-29* 
Hand motor function	 Pinching Test	 9-Hole Peg Test	 MSIS-29* 

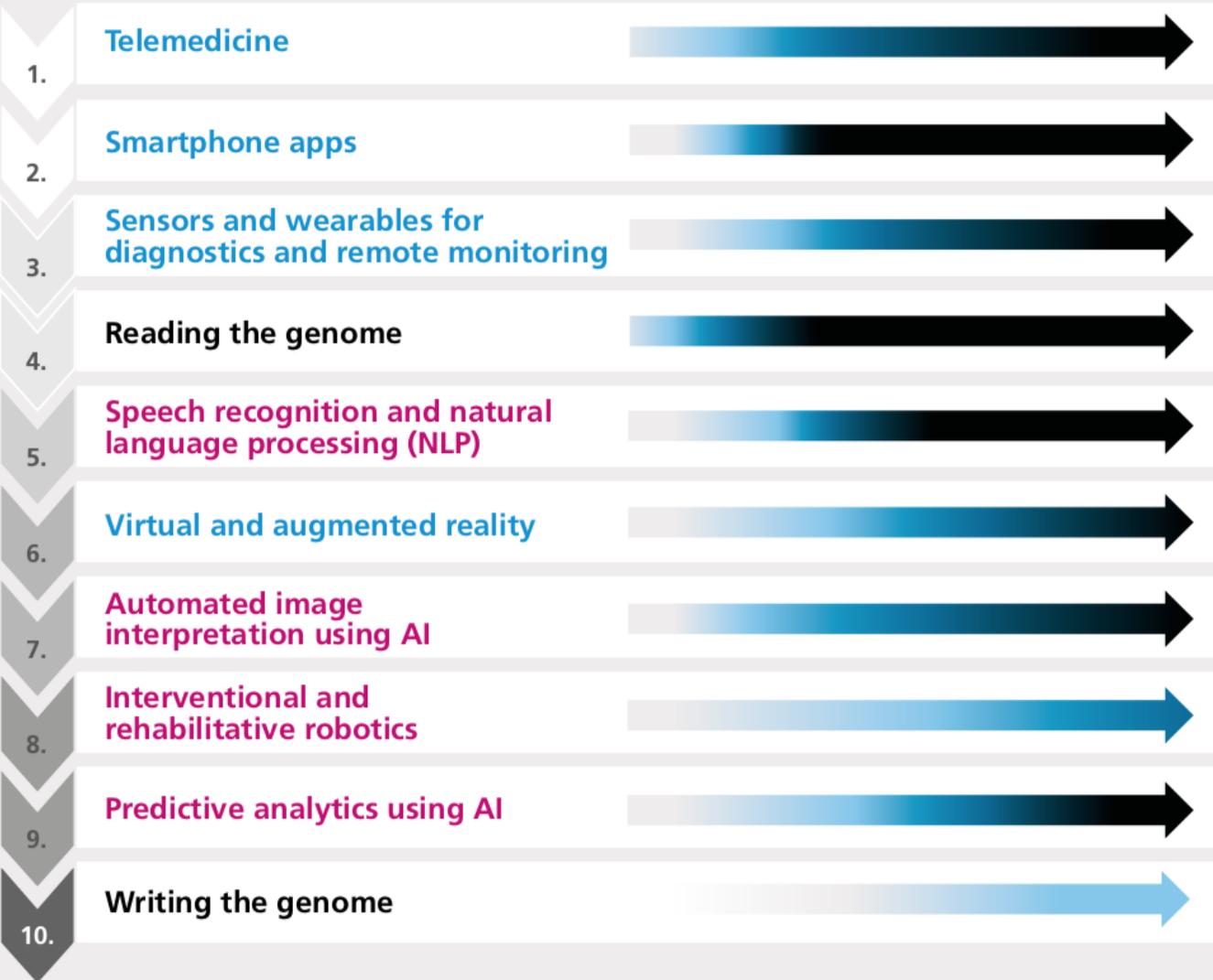
*Functionally relevant items only
MSIS, MS Impact Scale; SDMT, Symbol Digit Modalities Test

Montalban et al. ECTRIMS 2018



Technology (Digital Medicine, Genomics, AI & Robotics) Proportion of workforce affected

2020 2025 2030 2035 2040



UK National Health Service Digital Strategy

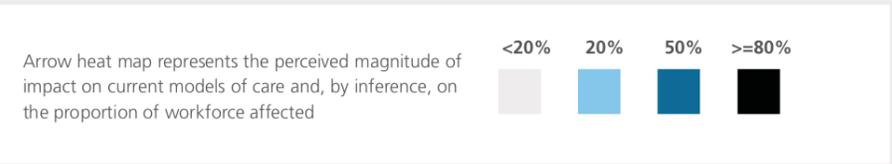


The Topol Review

Preparing the healthcare workforce to deliver the digital future

An independent report on behalf of the
Secretary of State for Health and Social Care
February 2019

Figure 1: Top 10 digital healthcare technologies and their projected impact on the NHS workforce from 2020 to 2040





News & Events

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Speeches by FDA Officials

Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making

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Remarks by Scott Gottlieb, M.D. as prepared for the Bipartisan Policy Center conference

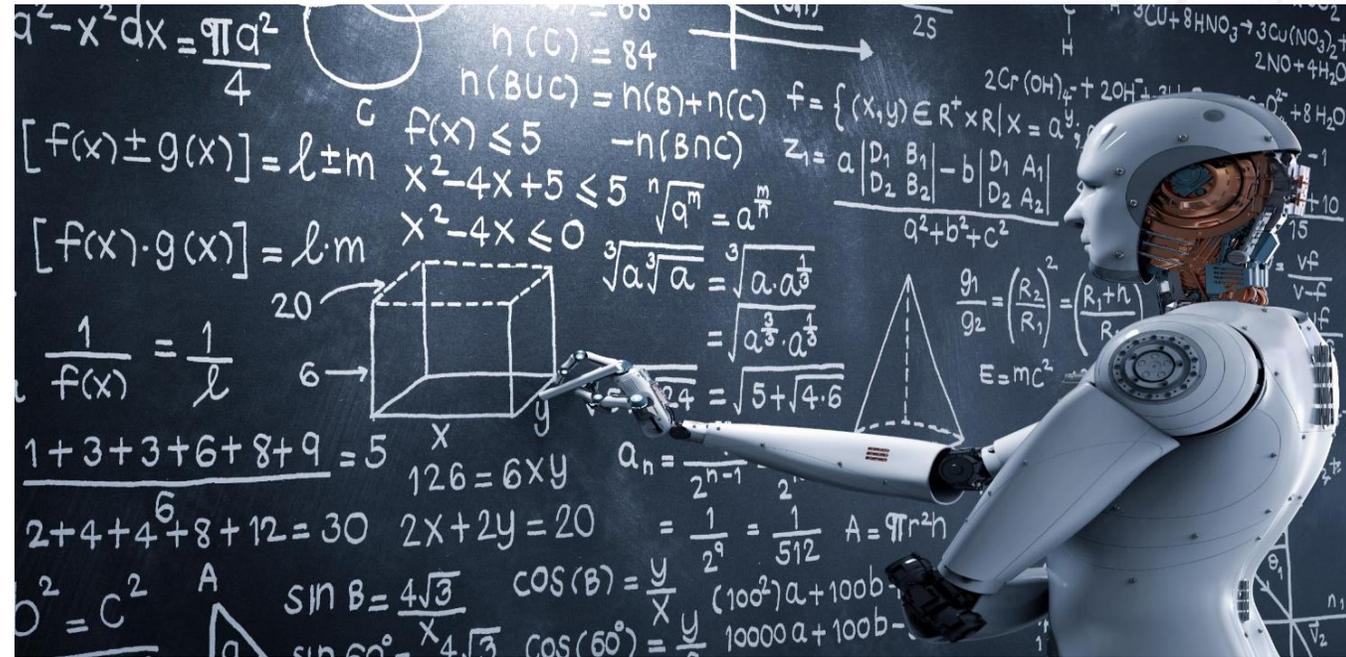
January 28, 2018

Good afternoon.

Digital technologies are one of the most promising tools we have for making health care more efficient and more patient-focused.

And more

- Trial Design
- Recruitment
- Behavioral Analysis
- Real World Evidence
- Medical Sensors
- Assisted Diagnostics



Data Complexity vs AI Complexity

- Blood Pressure
- Daily Step Count
- Pulse per second, 24x7 (86,400 data points per day)

Discrete Numeric Data



Structured

- Medical Records

Machine generated, Forms



Semi-structured

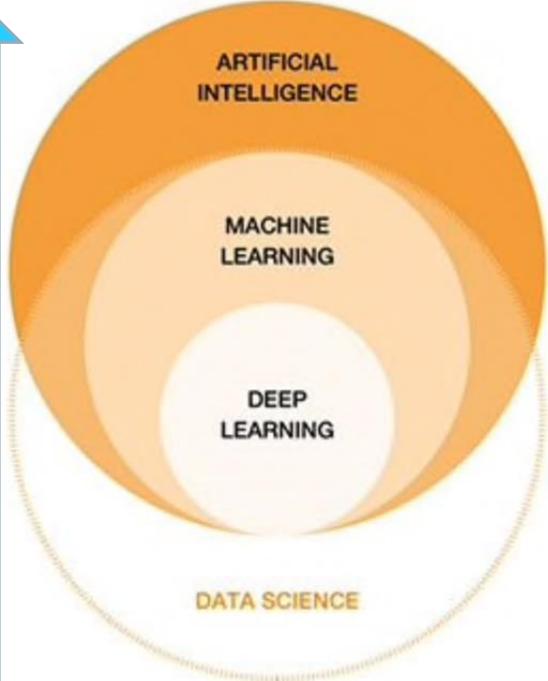
- Documents
- Narratives
- Medical Records
- Medical images

Human generated text, Images, Sound....



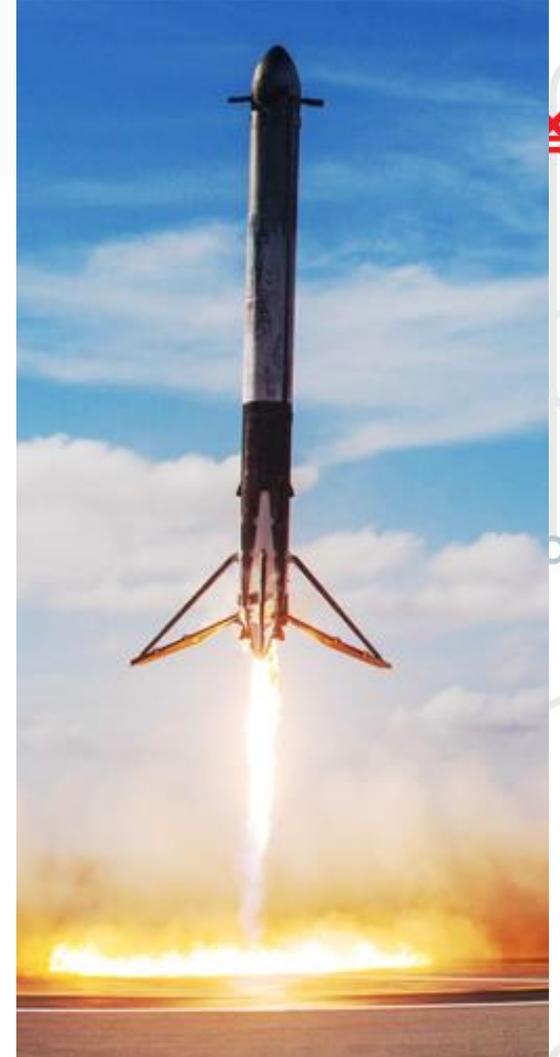
Unstructured

Data complexity



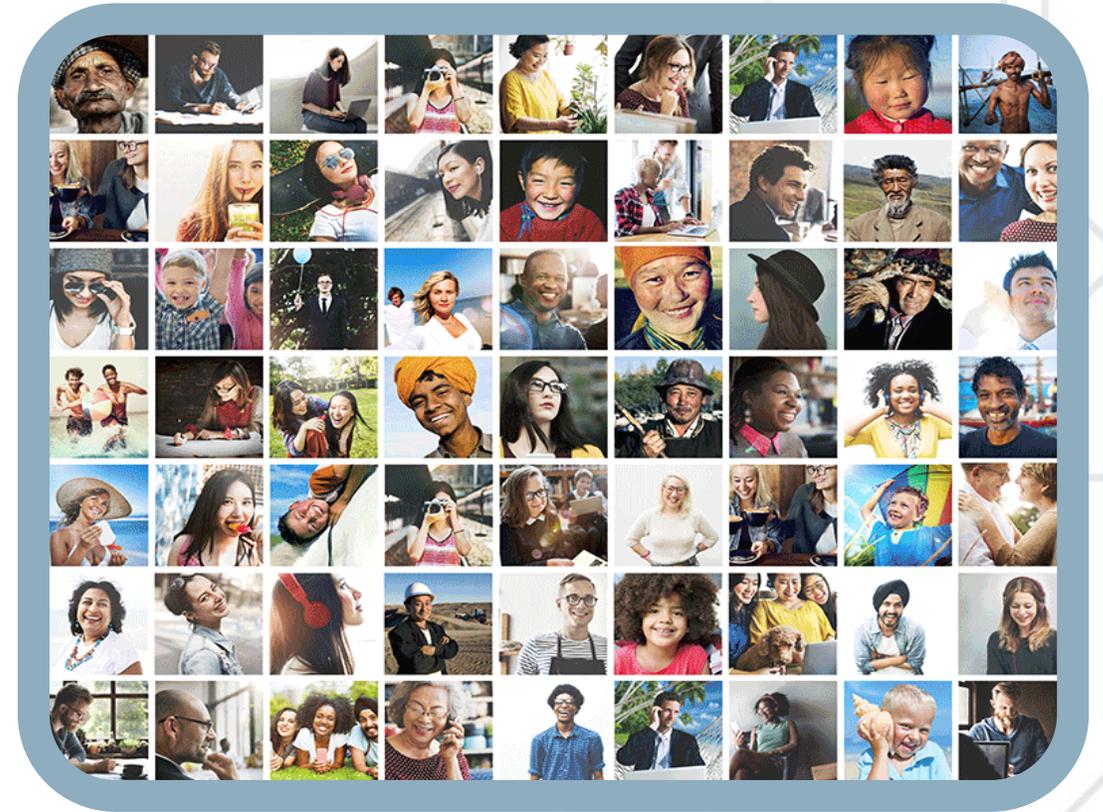
Considerations

- AI/Machine Learning requires training
 - Only as good as the training data
- Some use cases more suited than others
 - Discrete numeric data easier than unstructured text
- Validation
 - Methods widely used in other mission critical industries
 - Train with broad set of data
 - Test with unseen data



Data Driven Clinical Research needs Data Science

- Adoption of AI/ML/Data Science is critical
 - Biosensors
 - Medical Records
 - Images
 - Genomics
 -
- *Augmented* Intelligence
 - More meaningful way to consider AI
- Patients need better treatments
 - Better Science needs Data Science



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