



# Artificial Intelligence in Clinical Trials

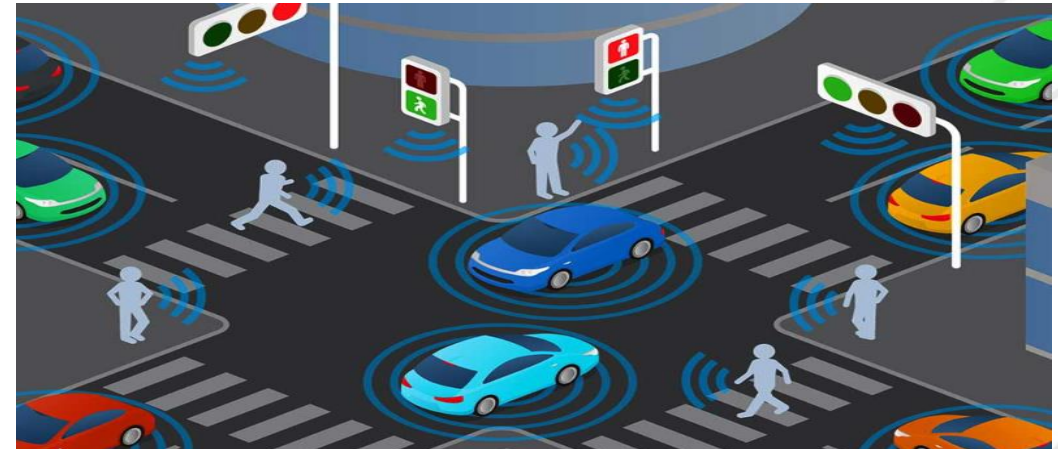
## MHRA StEM

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7 May 2019

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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

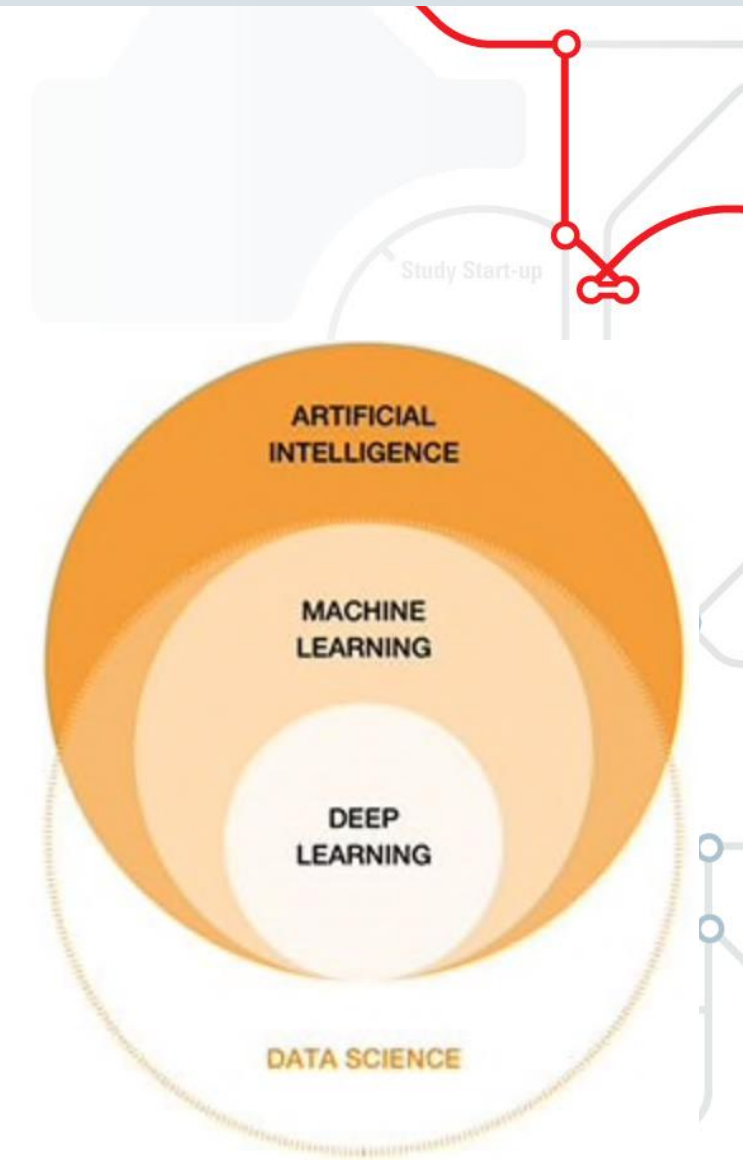
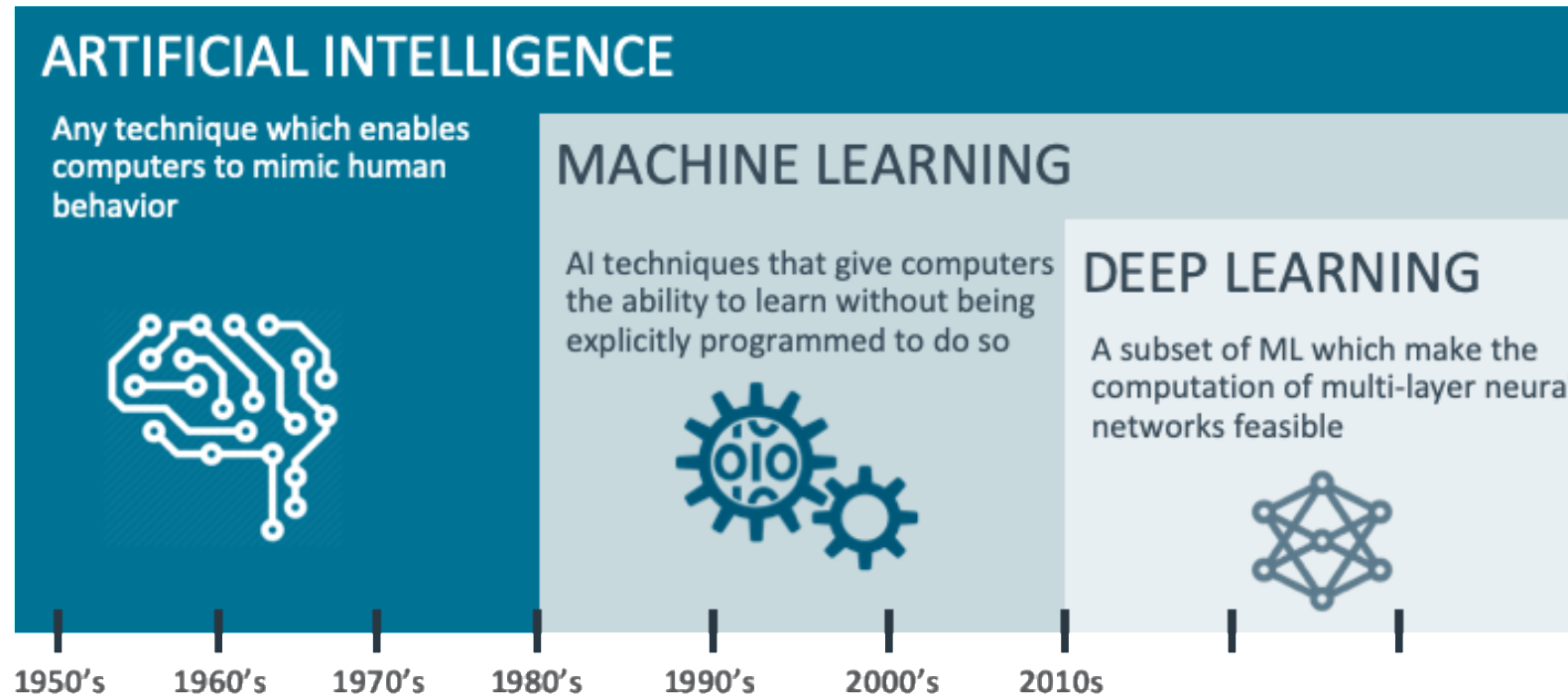
1990's

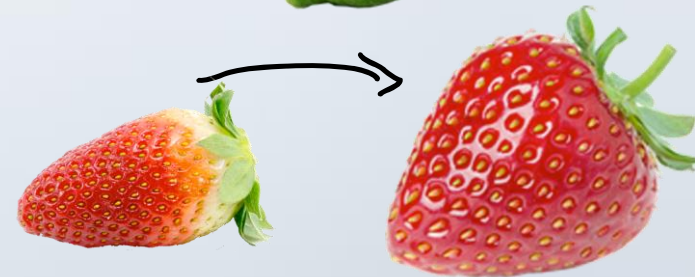
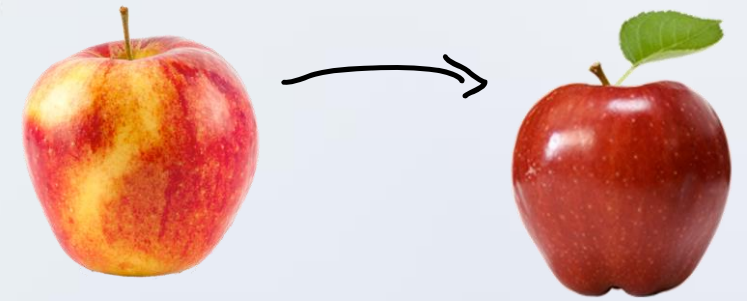
2000's

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



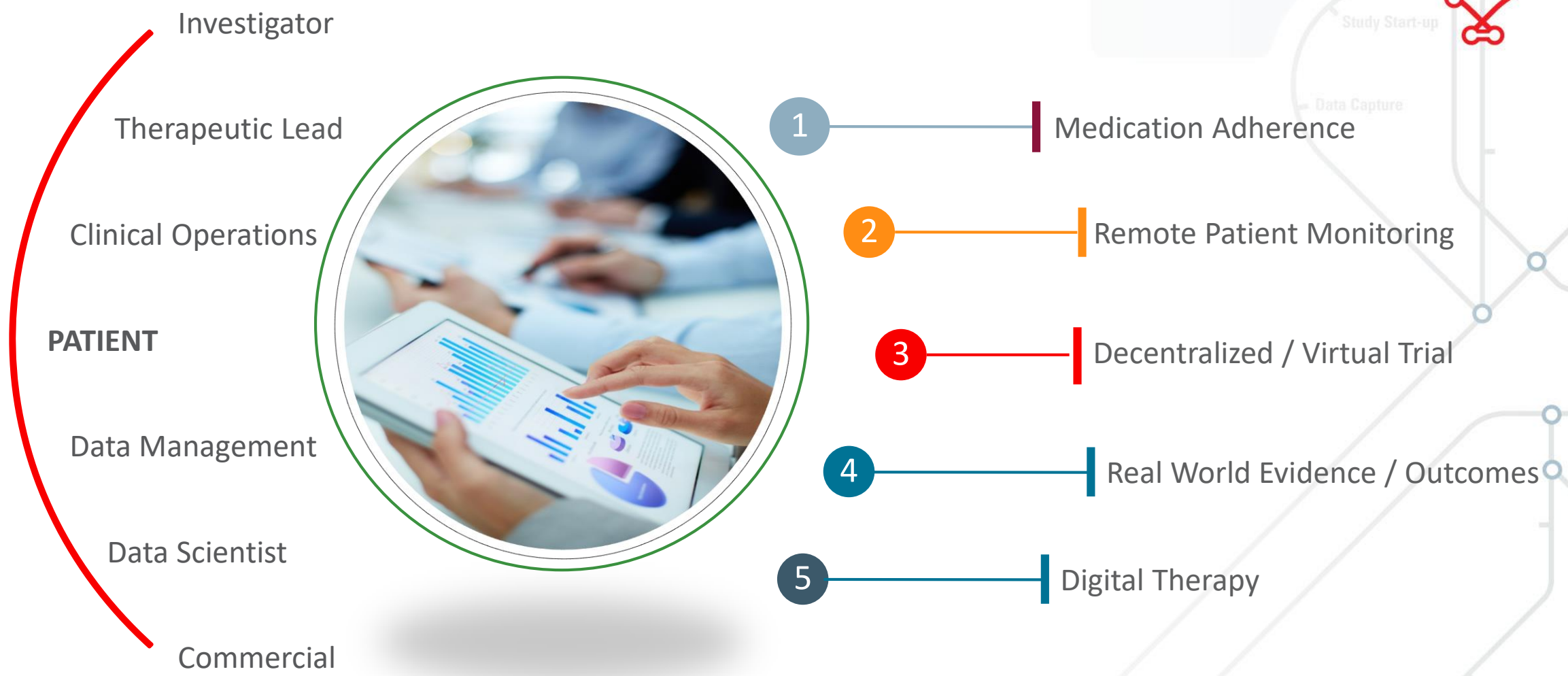
OMRON®

## Cuffless, Continuous



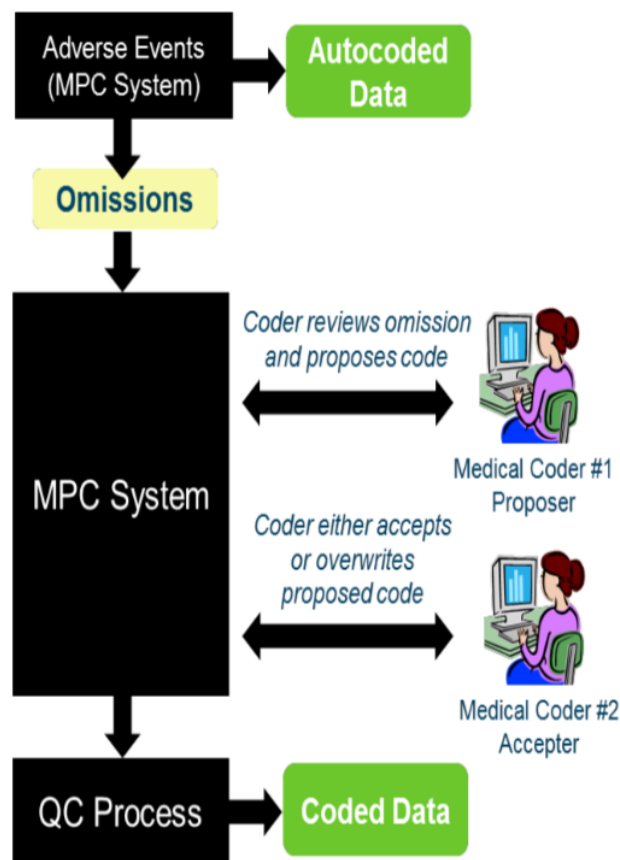
# Digital Clinical Trials

Disruptive Change is Happening Now

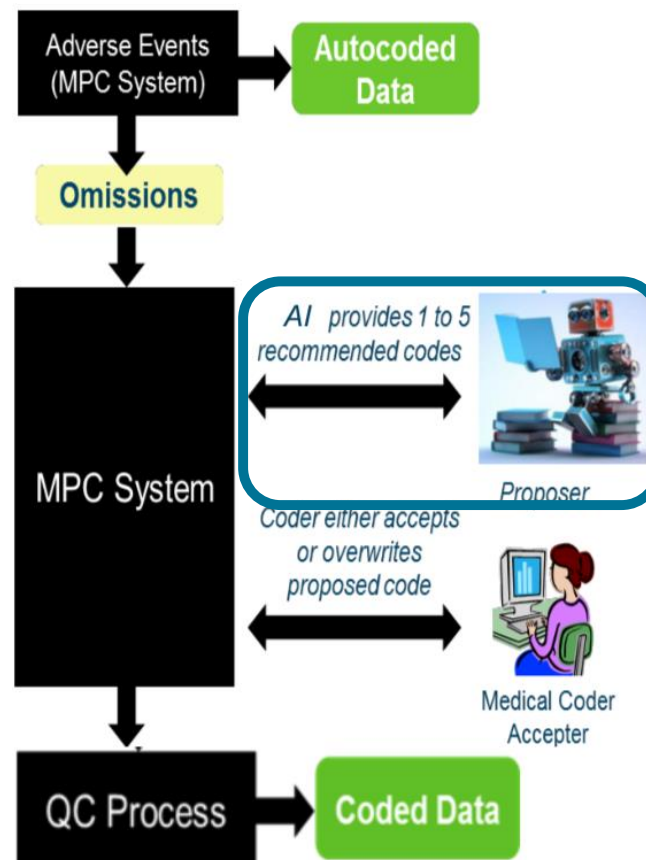


# Medical Coding

## 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

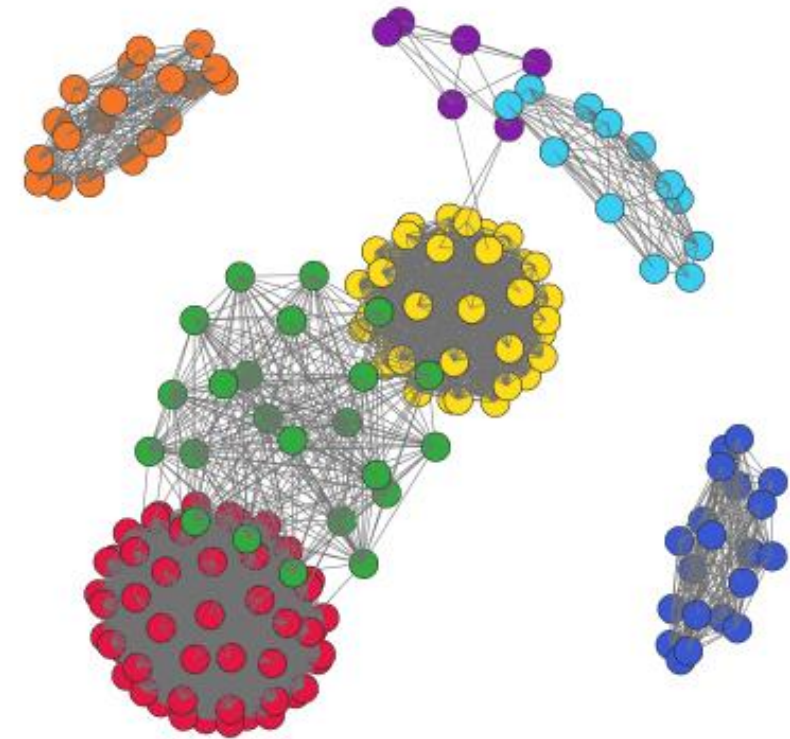


- The Problem
  - Large country, widely distributed population
  - Severe lack of pathologists/medical staff per region
  - Ultimate diagnosis too late in disease progression
- AI Solution
  - Mobile clinics perform photocervicography
  - Magnified real time image stored in database
  - AI helps triage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

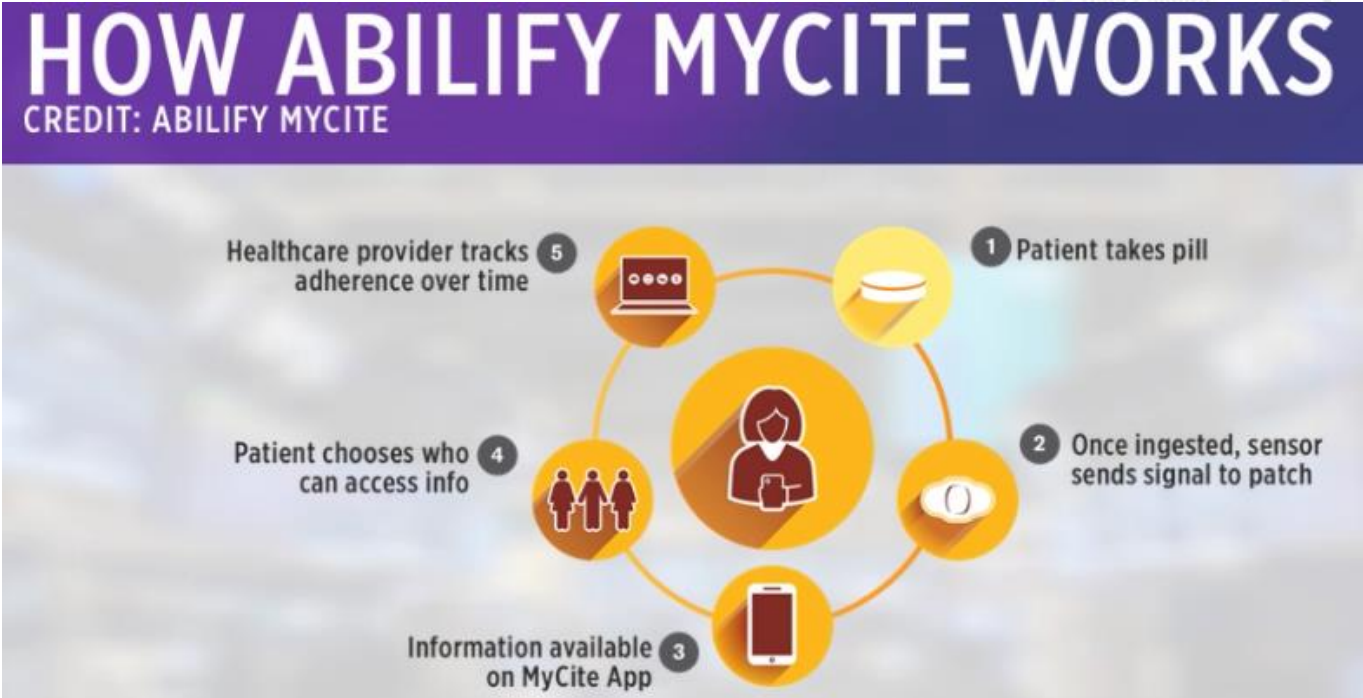
## Medical Ingestion Recognition – AI Cure



AI Cure Medical Ingestion Recognition features include:

- 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

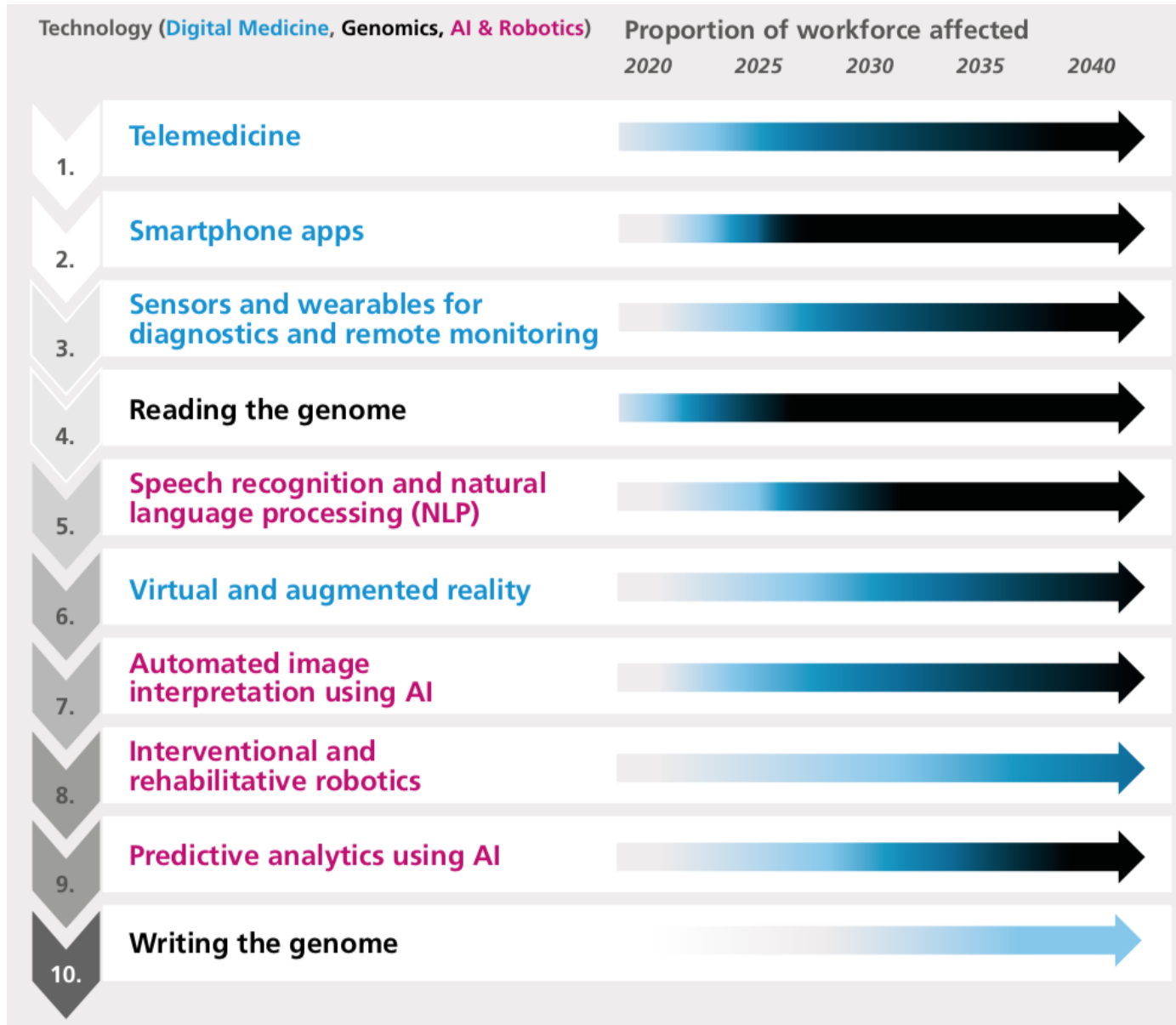
## Floodlight correlates with clinic and patient assessments

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





# UK National Health Service Digital Strategy



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

Arrow heat map represents the perceived magnitude of impact on current models of care and, by inference, on the proportion of workforce affected

<20%	20%	50%	>=80%
[Light blue square]	[Medium blue square]	[Dark blue square]	[Black square]



## 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

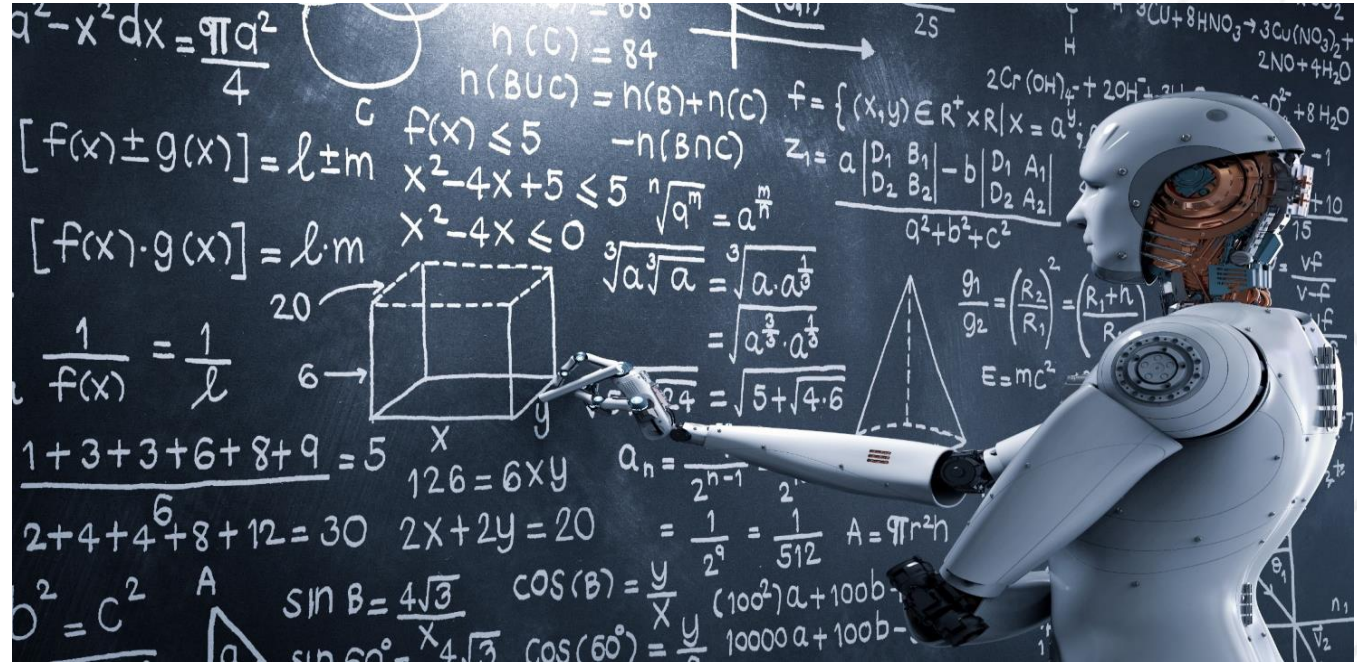
January 28, 2018

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

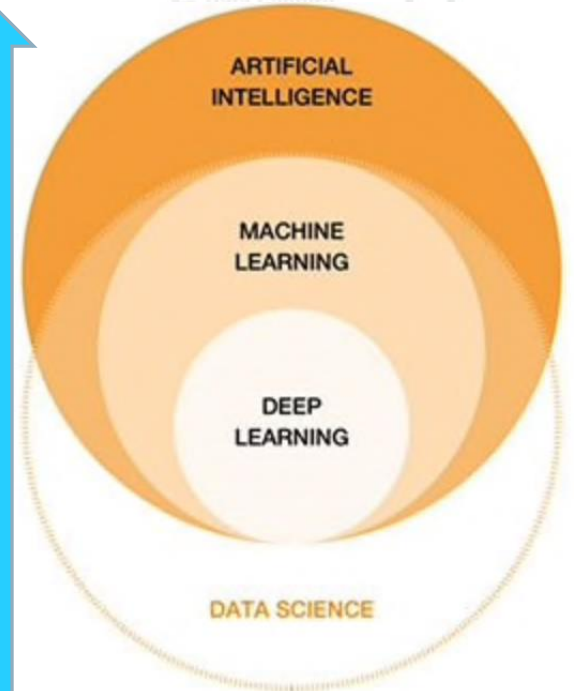
- Documents
- Narratives
- Medical Records
- Medical images

Human generated text, Images, Sound....



Unstructured

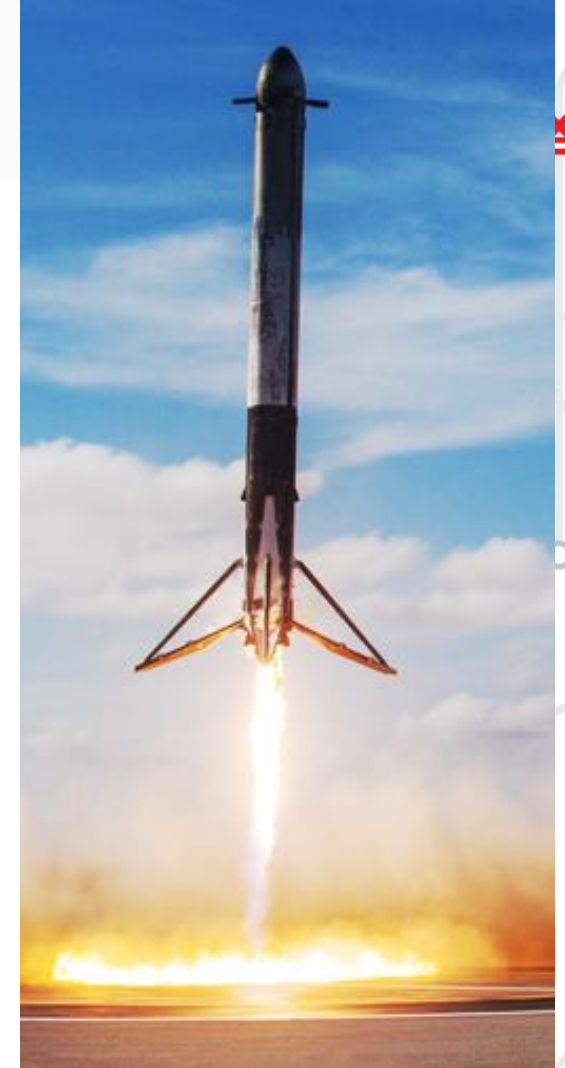
Data complexity





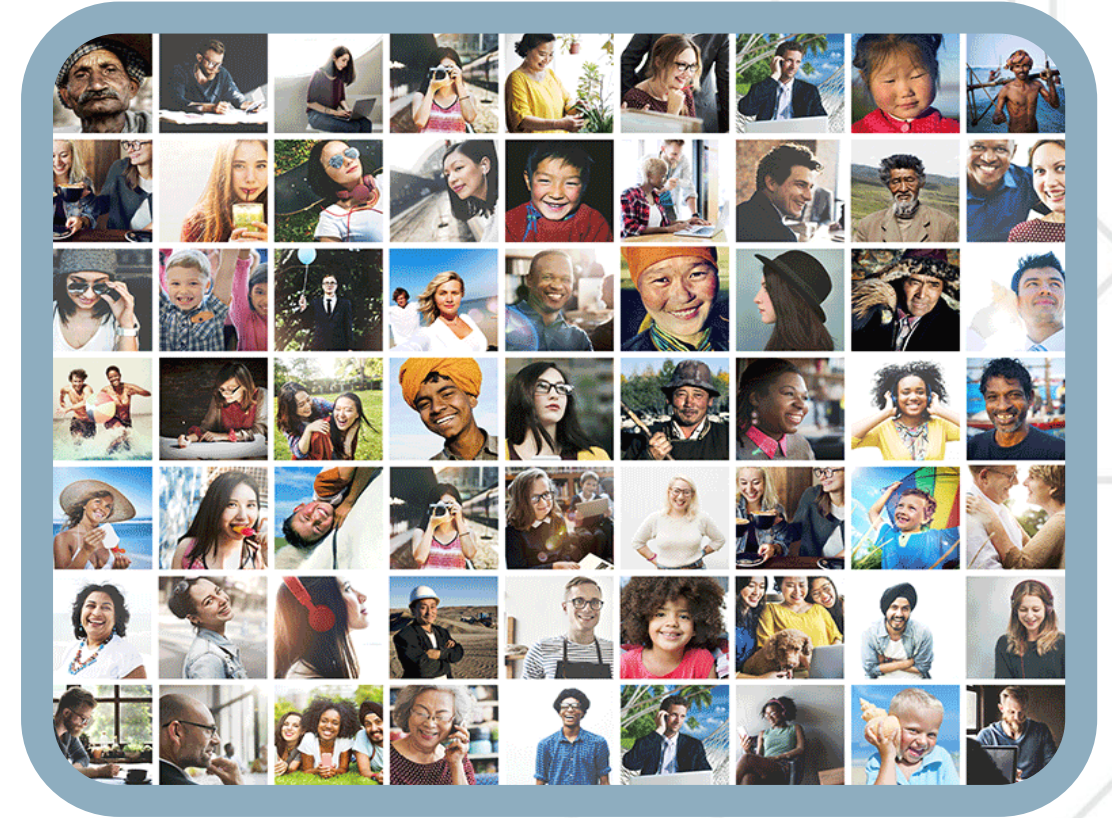
# Considerations

- 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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