Artificial Intelligence in Clinical Trials
MHRA StEM

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Artificial Intelligence – Embedded in our lives
Any technique which enables computers to mimic human behavior

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

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DEEP LEARNING
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## Mapping to Machine Learning Terms

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

1 in 3 American Adults have High Blood Pressure

Cuffed

Cuffless, Continuous

OMRON®
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

Investigator
Therapeutic Lead
Clinical Operations
PATIENT
Data Management
Data Scientist
Commercial

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Medical Coding

- 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

Smart Pill – Otsuka Abilify

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

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

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

Montalban et al. ECTRIMS 2018
### 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

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<table>
<thead>
<tr>
<th>Technology (Digital Medicine, Genomics, AI &amp; Robotics)</th>
<th>Proportion of workforce affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Telemedicine</td>
<td></td>
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<tr>
<td>2. Smartphone apps</td>
<td></td>
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<tr>
<td>3. Sensors and wearables for diagnostics and remote monitoring</td>
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<tr>
<td>4. Reading the genome</td>
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<tr>
<td>5. Speech recognition and natural language processing (NLP)</td>
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<tr>
<td>6. Virtual and augmented reality</td>
<td></td>
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<tr>
<td>7. Automated image interpretation using AI</td>
<td></td>
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<tr>
<td>8. Interventional and rehabilitative robotics</td>
<td></td>
</tr>
<tr>
<td>9. Predictive analytics using AI</td>
<td></td>
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<tr>
<td>10. Writing the genome</td>
<td></td>
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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%
Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making

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)

- Medical Records
- Documents
- Narratives
- Medical Records
- Medical images

Discrete Numeric Data
- Structured

Machine generated, Forms
- Semi-structured

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