ARTIFICIAL INTELLIGENCE

In Clinical Research

Workshop
Modernizing Clinical Trials

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Artificial intelligence (AI), sometimes called machine intelligence, is intelligence demonstrated by machines, in contrast to the natural intelligence displayed by humans and other animals. In computer science AI research is defined as the study of "intelligent agents": any device that perceives its environment and takes actions that maximize its chance of successfully achieving its goals. Colloquially, the term "artificial intelligence" is applied when a machine mimics "cognitive" functions that humans associate with other human minds, such as "learning" and "problem solving".

https://en.wikipedia.org/wiki/Artificial_intelligence
Growth opportunities in healthcare are hard to come by without significant investment, but artificial intelligence (AI) is a self-running engine for growth in healthcare. According to Accenture analysis, when combined, key clinical health AI applications can potentially create $150 billion in annual savings for the US healthcare economy by 2026.

Opportunity?

As AI continues to become more prevalent and adoption flourishes, healthcare organizations must enhance their underlying structure to be positioned to take full advantage of new AI capabilities.

WORKFORCE. The nature of work and employment is rapidly changing and will continue to evolve to make the best use of both humans and AI talent. For example, AI offers a way to fill in gaps amid the rising labor shortage in healthcare. According to Accenture analysis, the physician shortage alone is expected to double in the next nine years. AI has the power to alleviate burden on clinicians and give workers tools to do their jobs better. For instance, AI voice-enabled symptom checkers triage patients to lower-cost retail or urgent care settings and direct patients to the emergency department only when emergency care is necessary. AI can address an estimated 20 percent of unmet clinical demand (see Figure).
AI to develop Therapeutics against Alzheimer's and Parkinson's disease

BenevolentAI has already made progress, in accelerating drug development.

Atomwise pioneered the use of deep neural Networks for structure-based drug design.

Insilico Medicine lead optimization and pre-clinical validation of drug-candidates.

Verge Genomics AI to develop Therapeutics against Alzheimer's and Parkinson's disease.

What AI can do for us now

**TECHNOLOGY**
- Could reproduce limited cognitive pattern
- Growing the computing power of devices
- Growing the Robotic technologies
- Growing the storage capacity
- Growing battery technology

**ENVIRONMENT**
- Everyone will be introduced in a new connected world
- Presence of Big Data
- Everyone has a PDA (i.e. smartphone)

**VALUE CREATION FOR STAKEHOLDER**

**BIG PHARMA/BIOMEDICAL COMPANIES**
- May increase their own market value with AI;
- More efficacy and efficiency on research and improvement on their products

**PATIENTS**
- May have access to personalized therapy
- May save time and have a better qol
- May have warning and research improvement

**PHYSICIANS/RESEARCHER**
- May Improve the research program
- May analyze big data in no time
- May support diagnosis
Modernizing CT

Data is value (STRENGTH)
Everything is based on data evidence. We must preserve it, and be compliant with regulatory requirements (i.e. Privacy)

Bureaucracy (THREAT)
Especially in Italy, bureaucracy stops investment and generate inefficency

Patient is the king (WEAKNESS/OPPORTUNITY)
Patient must be at the center of the trials...

Integration with new technologies (OPPORTUNITY)
E-pro, AI, wearables could improve the clinical research.
Modernizing CT

- Italy was 3° largest pharmaceutical market (2015)
- Only 9 in the number of registered clinical trials
- The big problem is the slow approval process
- If we centralized trial authorization we could have a 1.1 bilion Euros of incremental trial investments over 3 years
Number of CT in Italy
Why does CT Fails?

Well, failures in clinical research usually occur in two dimensions:

1. Project failure, e.g. the budget has been overspent, project targets haven't been achieved and deadlines haven't been met.
2. Research failure, e.g. not being able to reach statistical significance in a research area and so failed to prove the efficacy of a drug or obtain controversial results.

Obviously both dimensions cover two very large areas of clinical research. For sake of ease, let's assume that we have met the following research conditions:

1. The candidate drug is safe and efficacious;
2. The study design is adequate;
3. The study is conducted according to Good Clinical Practice;

Interestingly enough, when we focus on the project management side of clinical studies, we found that the surveyed experts identify the project manager's skill set as the most common source of issues.

50% of unsuccess rate derive by uncorrect Project management

Source: https://cyntegrity.com/7-reasons-clinical-trials-fail/
What AI can do for us applied on a CT

01 Reduce Costs of a CT
Less time means less money. We could use AI such as a really quick tool to analyze large amount of data and simulate trials.

02 Improve the research process with more efficiency and efficacy
Using AI we could save time and be more efficacy/efficiency. Creating a new machine learning models to anticipate issues and enhance research programs.

03 Expand our knowledge
We can use AI to discover relationship and reproduce a cognitive process to evaluate new drugs or use old drugs to a new therapeautical indications.

04 Faster access to therapy for patients
Patience can enjoy new AI tools to be a part of the research program and be used in active way.
Value for Clinical Trials: data

What we don’t know

Exogenous data 60%

Factors that contribute to health outcomes, %

Social determinants of health ~40
Health behaviors ~20
Clinical care ~15
Nonmodifiable factors (e.g., genetics) ~25

Average amount of data generated over a person’s lifetime

1,100 terabytes (volume, variety, velocity, veracity)
0.4 terabytes (clinical data)
6 terabytes

What we could know

Genomics + Clinical Data

Source: Bureau of Labor Statistics; Robert Wood Johnson Foundation; IBM Watson (Latts L. The age of big data and the power of Watson. European Medicines Agency presentation. Updated April 1, 2017); McKinsey analysis
We could associate new features

We could create new services for the patient i.e. gaming and social link

Using new technologies we could have access to all data

We could define better protocols and understand the critical point

We could use new support tools based on Artificial Intelligence

We could identify and calculate the risks associated on a trials and preserve the data loss (i.e. RBM)

More efficancy and efficency

We use less resources to conduct a trials using automatized tools
Artificial Intelligence in Drug development process

1. Aggregate and Synthesize Information
2. Understand Mechanisms of Disease
3. Establish Biomarkers
4. Generate Data and Models
5. Repurpose Existing Drugs
6. Generate Novel Drug Candidates
7. Validate and Optimize Drug Candidates
8. Design Drugs
9. Design Preclinical Experiments
10. Run Preclinical Experiments
11. Design Clinical Trials
12. Recruit for Clinical Trials
13. Optimize Clinical Trials
14. Publish Data
15. Analyze Real World Evidence

WHERE A.I. is used in Drug Discovery

Optimizing CT with AI

**AiCure**
*Uses AI to:* Visually confirm medication ingestion via smartphone. **Allows researchers to:** Improve medication adherence in clinical trials.

**Imagia**
*Uses AI to:* Analyze radiological images to produce clinically actionable information. **Allows researchers to:** Predict a patient’s disease progression and treatment response, for clinical trial stratification and companion diagnostics.

**WinterLight Labs**
*Uses AI to:* Assess and monitor cognitive health by analyzing a short speech sample. **Allows researchers to:** Identify patients, screen patients, and evaluate response to therapy for clinical trials of mental health treatments.
Give the right instruments to the patient to be included in a trial optimizing the process.

Threats: European law of data managing.
Clinical Research

Find and create big data to analyze:
I.A. that harvest between several databases and aggregate data, Use Ai to extract structural biological knowledge to power drug discovery application

Cognitive approach to discover relationship
Uses AI to: Analyze genomic data related to cancer and other diseases, Find applications for existing approved drugs or clinically validated candidates.

Optimize the process:
Uses Ai to: create a Chat bot or machine learning system to prevent issue on clinical trials, Optimize oncology drug development with a biomarker monitoring platform and millions of patient datapoints

Match the right patients to the right cure
Uses AI to Enroll more patients in appropriate trials, or uses AI to Analyze medical records to find patients for clinical trials

Simulate clinical trials and silico
Uses AI to Run experiments in a central lab from anywhere in the world, or use ai to Optimize, reproduce, automate, and scale experiment workflows.

Publish data;
Uses AI to Write a draft scientific manuscript based on provided data.
Some projects that uses **AI**
In Bergamo Hospital

**Opportunity Project**
Optimization of treatment in patients hospitalized for acute heart failure and realization of a transitional care model based on risk stratification.

**App to decision support**
App created to give to the Physicians a second opinion

**Optimization of CT**
A Virtual avatar based on AI to optimize ongoing clinical trials

**ALFRED** (Automatic process pLanning support software For InteRnal Hospital and Ethic comitee Documental organization)

The project started with the aim of having a streamlined and automated flow of documents and information on clinical trials of Pope John XXIII Hospital and related centers.

We follow several project on rheumatology (image evidence) and hepatology

This project is based on wearables that could generate a significant data on a single patient and lead to a custom medicine process. All data will be analyzed using AI protocols.

Alfred is a first step in entering that health-managed and unmanaged healthcare, where scarce resources are valued to maximize the quality and supply of services provided to the citizen.

All projects are in place or in evaluation phase.
Artificial Intelligence in optimizing the CT conduction

Follow this link to see the video: https://cl.ly/sqj0
Looking for the future

Risk based analysis Approach, with main aim of anticipate issue
We must be aware about our limits and opportunities and be aware that Humans are always the key of success or unsuccess.
Thank You

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