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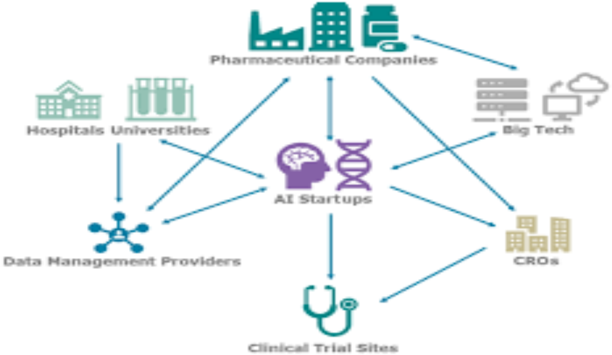
Single Day Event

Paranthaman M,
Premier Research

APPLICATIONS OF ARTIFICIAL INTELLIGENCE IN CLINICAL TRIAL

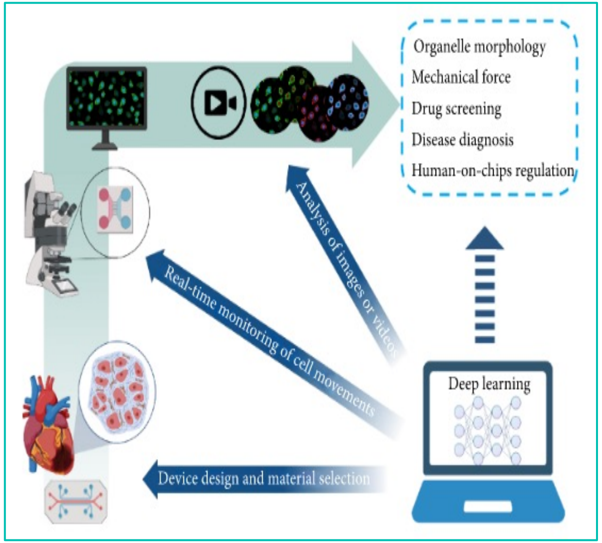


Objectives

Overview about the applications of Deep learning and its applications across various platforms in Clinical trial

Medical imaging on real time scenario & an idea about Synthetic data

Interesting Innovations/views/glimpses on Micro Physiological System or Organs on a chip.



Applications of AI enabled Tech in Clinical Trial

TRIAL DESIGN

- Assess feasibility of Protocol Design for Patient recruitment.
- Assess Site performance (e.g. .,Enrolment and dropout rates) with real time monitoring.
- Analyze and interpret - structured and Unstructured data from previous trials and scientific literature.

TRIAL START UP

- Mine EHRs and publicly available content including trial databases and social media ,to help match patients with trial by using NLP and ML.
- Expedite recruitment and create more representative study through cloud-based applications.
- Simplify and accelerate the inform consent process using e-consent.

TRIAL CONDUCT

- Assess site performance (e.g., enrollment and drop out rates) with real-time monitoring.
- Analyze digital biomarkers on disease progression and other quality-of-life indicators.
- Automate sharing of data across multiple data systems(databases)
- Enhance adherence through smartphone alerts and reminders.
- e-Tracking of medications using smart pillboxes and tools for visual confirmation of treatment compliance.

STUDY CLOSEOUT

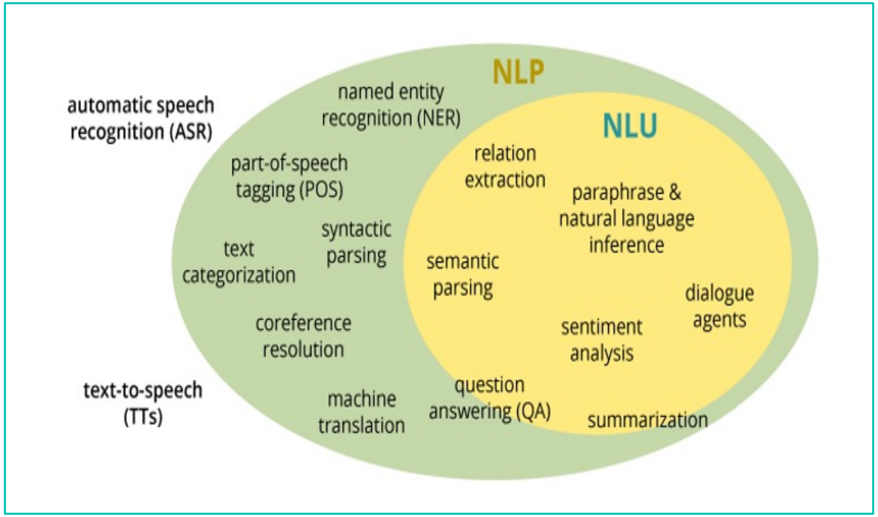
- Complete sections of the final clinical report for submission using NLP
- Data Cleaning by ML methods

Natural Language Processing

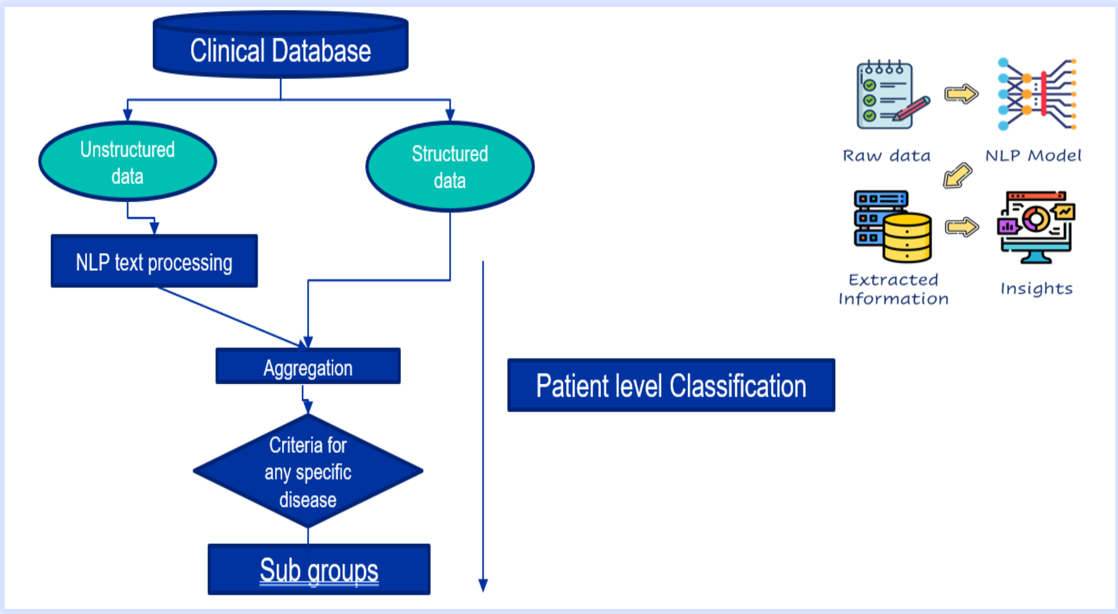
1.What is NLP ?

2.Why NLP for text mining ?

3.How it is being used in Clinical Trail?



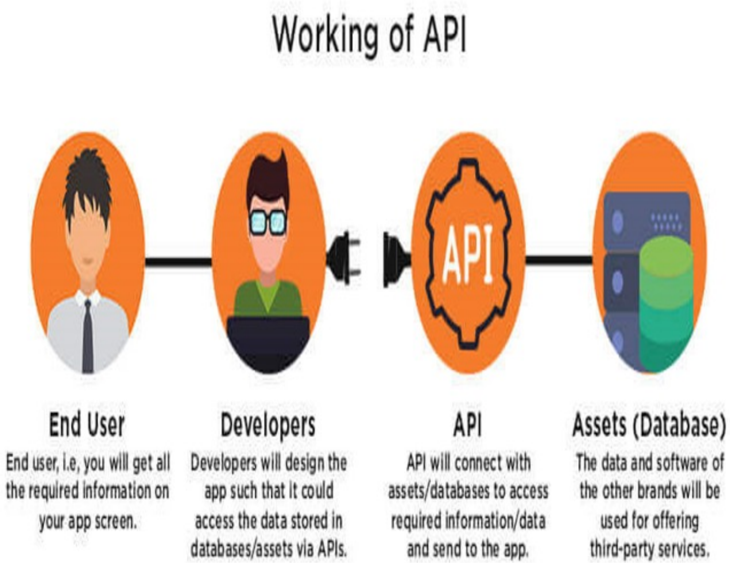
For an instance, Patient level classification using NLP



Application Programming Interface(API)

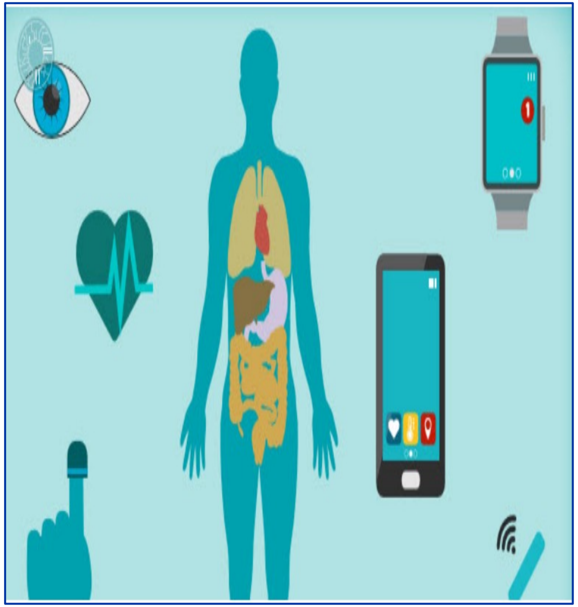
Application Programming Interface(API) which is a software intermediary that **allows two applications to talk to each other**.

The ClinicalTrials.gov application programming interface (API) provides a toolbox for programmers and other technical users to use to access all posted information on ClinicalTrials.gov study records data.



Wearables device in Clinical Trials

- New real-world data and potential endpoints ,objectively collected.
- Lowering costs, improving effectiveness.
- Less clinical site time.
- Earlier decision-making through access to near real-time data.
- More insightful patient phenotyping -improve inclusion and exclusion criteria to demonstrate the safety and efficacy more efficiently.
- From the numbers pulled from clincaltrials.gov, we can see just how many studies are currently being conducted using wearable devices. From a high level, there have been about **1,400 trials** conducted,
- with about **540** of those that have been completed. The remaining trials (**around 880**) are still active is some form.



AI - Chart of Successful areas and required data characteristics in drug discovery

Successful applications of drug discovery

Target identification and Validation

- Target identification and prioritization based on gene-disease associations
- Target drug ability predictions.
- Identifications of alternative targets.

Compound screening and lead discovery

- Compound design with desirables properties
- Compound synthesis reactions plans

Preclinical development

- Tissue specific biomarker identification
- Classification of drug response signatures

Clinical development

- Determinations of drug response by cellular phenotyping in oncology
- Precise measurements of the tumor microenvironment in immuno-oncology

Required improvements

Target identification and Validation

- Current data are highly heterogeneous ;need standardized datasets
- Comprehensive data from disease and normal states
- Metadata from both successful and failed clinical trials

Compound screening and lead discovery

- Large amount of training data needed for modelling
- Numerous protein structures

Preclinical development

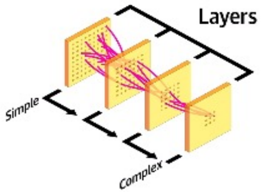
- Biomarkers: Reproducibility of models based on gene expression data
- Dimension reduction of single-cell data for cell type and biomarker identification.

Clinical development

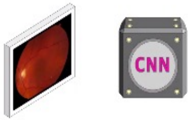
- Pathology : Well-curated annotations for broad-use cases.
- Gold standard datasets to improve interpretable about the models

Medical Imaging based on CNN – Convolution Neural Network

The convolutional Neural Network CNN works by getting an image, designating it some weightage based on the different objects of the image, and then distinguishing them from each other.



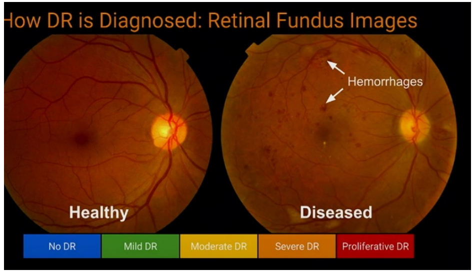
On pathological slides, It is correctly identifying the spatial orientation of chest radiographs and will automatically grading retinal images for diabetic retinopathy

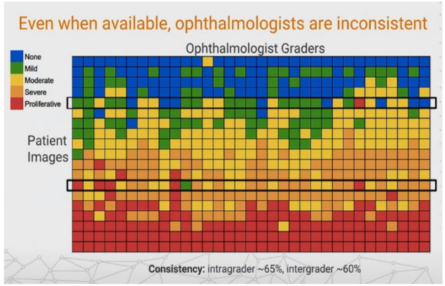


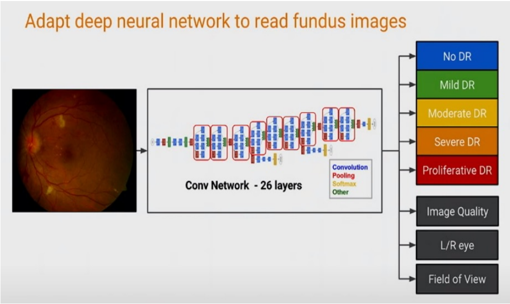
CNN helps to identify diabetic retinopathy for many patients as Patients with diabetic are not getting screened frequently enough owing to lack of expertise not available in the site sometimes.

For an instance from real time scenario,

- Diabetic retinopathy is the fastest growing cause of blindness .
- **There are only an estimated 15,000 ophthalmologists in India and only 45,000 optometrists against a required 125,000**. With a population of more than 1.32 billion people, this means, a serious shortage of medical professionals leading to severe handicap in both screening and treatment of eye ailments in the country.


How DR is Diagnosed: Retinal Fundus Images
Hemorrhages
Healthy
Diseased
No DR
Mild DR
Moderate DR
Severe DR
Proliferative DR


Even when available, ophthalmologists are inconsistent
Ophthalmologist Graders
None
Mild
Moderate
Severe
Proliferative
Patient Images
Consistency: intragrader ~65%, intergrader ~60%


Adapt deep neural network to read fundus images
Conv Network - 26 layers
Convolution
Pooling
Softmax
Other
No DR
Mild DR
Moderate DR
Severe DR
Proliferative DR
Image Quality
L/R eye
Field of View

Synthetic data

- **What is Synthetic data , is it sounds curious?**
- **How it helps in Clinical trial?**
- **Why isn't being used it by everybody?**

Overview of Micro physiological systems (MPS) or Organs-on-Chips based on “Deep Learning”

Microfluidic-based organs-on-chips (OoCs) are rapidly developing technology in biomedical and chemical research and have emerged as one of the most advanced and promising *in vitro* models.

The miniaturization, stimulated tissue mechanical forces, and microenvironment of OoCs offer unique properties for biomedical applications.

Microfluidic-based OoC technology is proposed to fill the gap between traditional two-dimensional (2D) cell culture and animal models and to gradually replace animal studies

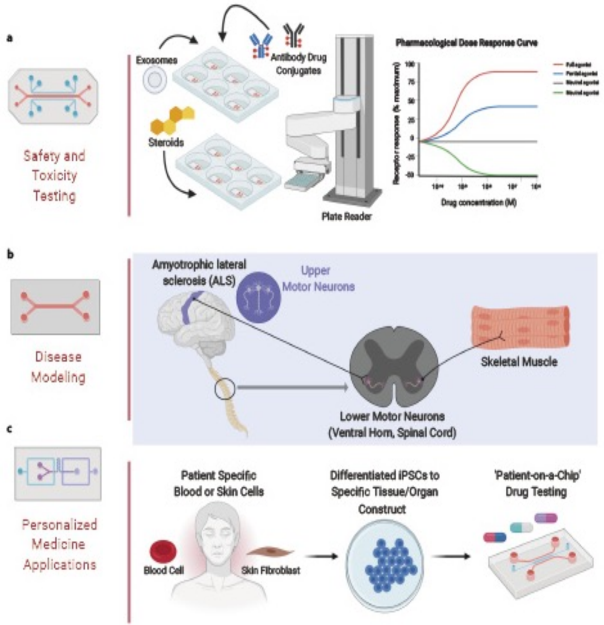
Why MPS is being recommended?

Vitro Models

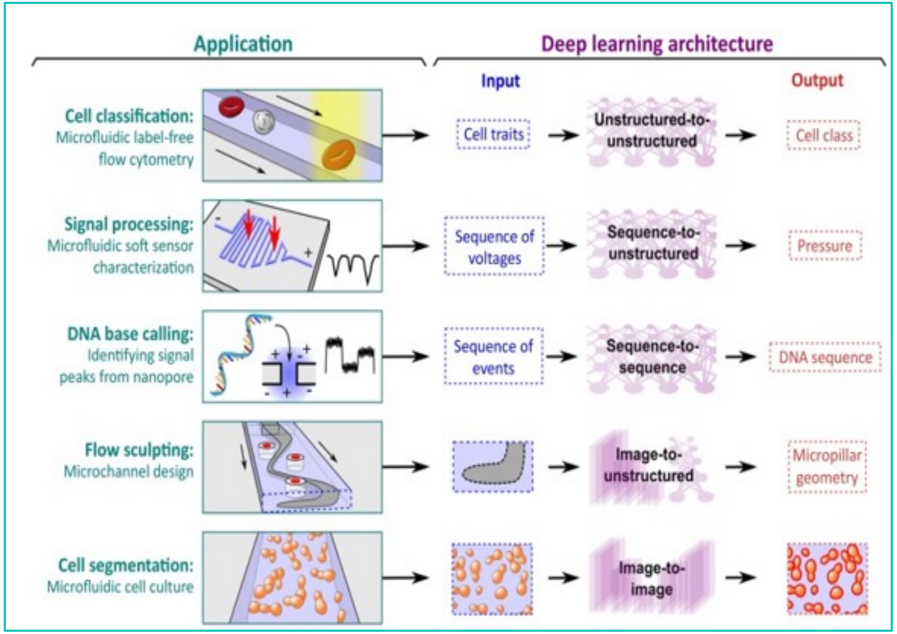
Vivo Models

Use cases

- Clinical questions & Clinical End points.
- FDA starts seeing tissue-chips in the regulatory decision-making process as well



Here's a simple image how Microfluidics works with Deep Learning

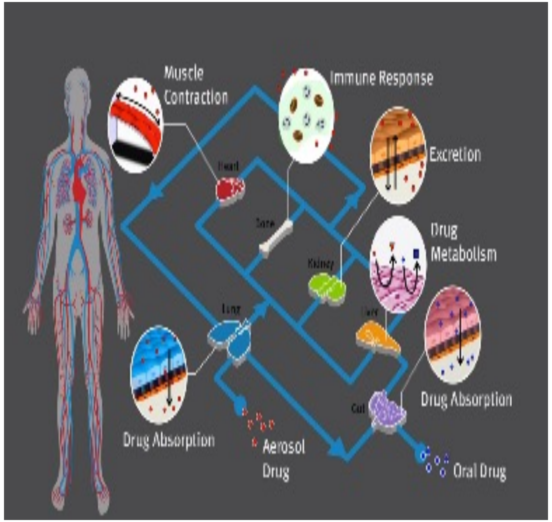


OoCs have clear potential in improving the drug development process, particularly within preclinical safety assessment and ADME applications.

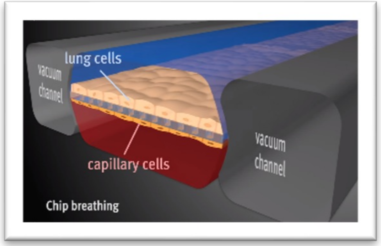
An organ-on-a-chip is a micro-scale system used for mimicking the human body environment.

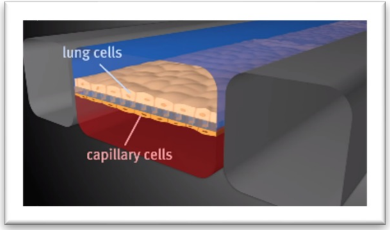
The goal for organ-on-a-chip is to develop human tissue models for disease modeling and drug testing.

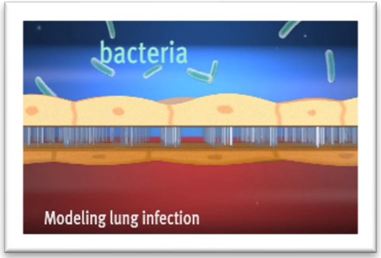
They use microfluidics, along with cells, to imitate the physiological and mechanical conditions experienced in the body.

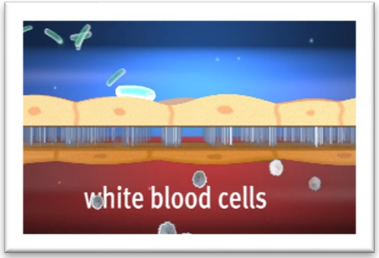


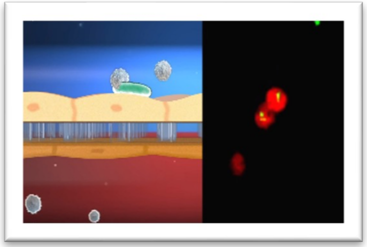
Here're the images for your view

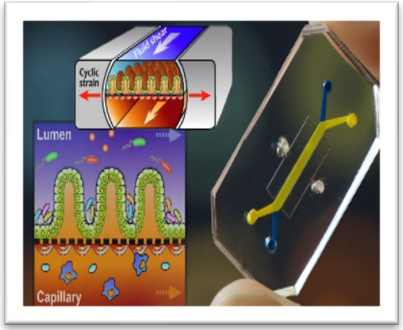












Q&A Discussions about AI in Clinical trial

Thanks for your patience!!

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