

# AI IN PHARMA – MYTH OR REALITY!

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# SOME TERMS IN AI

**Artificial Intelligence (AI)**, sometimes called **machine intelligence**, is intelligence demonstrated by machines, in contrast to the **natural intelligence** displayed by humans and other animals

**Natural language processing(NLP)**, a branch of artificial intelligence concerned with automated interpretation and generation of human language.

**Machine learning (ML)** is the subset of AI which deals with algorithms and statistical models that computer systems use to effectively perform a task without using explicit instructions.

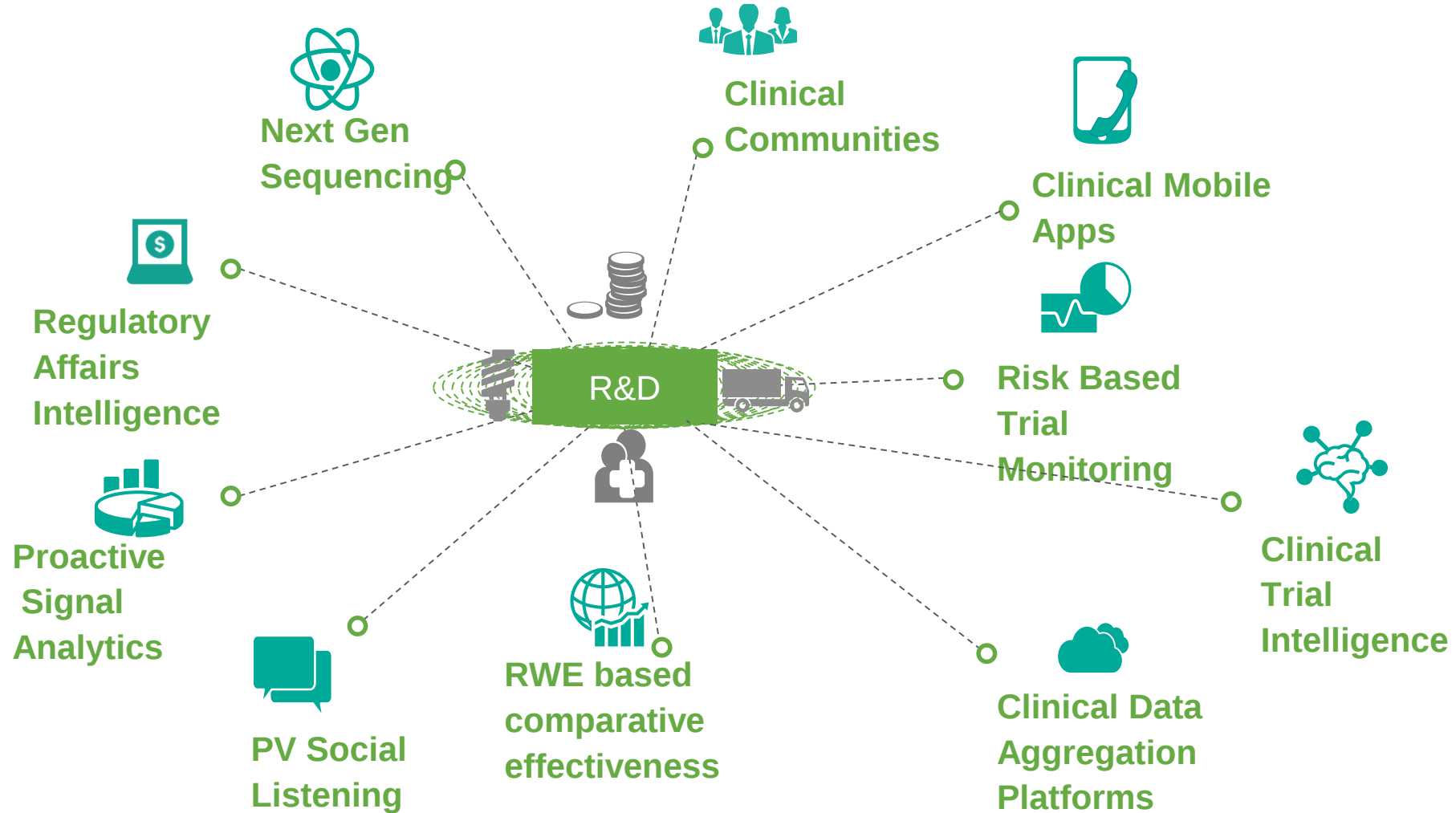
**Deep learning** is part of family of machine learning methods inspired by human nervous systems

**Robotic process automation (RPA)** refers to software that can be easily programmed to do basic tasks across applications like human workers. It is designed to reduce the burden of repetitive, simple tasks on employees.

# INTELLIGENT AUTOMATION SPECTRUM



# POTENTIAL USE CASES – R&D



# REAL LIFE EXAMPLES

## **FDA upgrades approach to certifying new AI products**

The new Digital Health Innovation Action Plan is part of the agency's broader effort to improve oversight of technologies.

FDA's Pre-Cert Pilot Program to review products, including AI, is another step in a series of steps FDA plans to take to "reimagine" its oversight of digital health tools.

FDA's goal in piloting the Pre-Cert program has been to support new tech, as well as learn from new developers about their products.

The FDA's De Novo pathway is well-suited to meet the goals of the Pre-Cert program. It's a pathway for low- to moderate-risk devices to obtain marketing authorization. The FDA's Excellence Appraisal could streamline a De Novo submission.

# REAL LIFE EXAMPLES

## **FDA Launches App to Support Clinical Trials, Real-World Evidence Collection**

**The MyStudies app will facilitate the collection of real-world evidence through mobile devices and expand the diversity of information for clinical trials.**

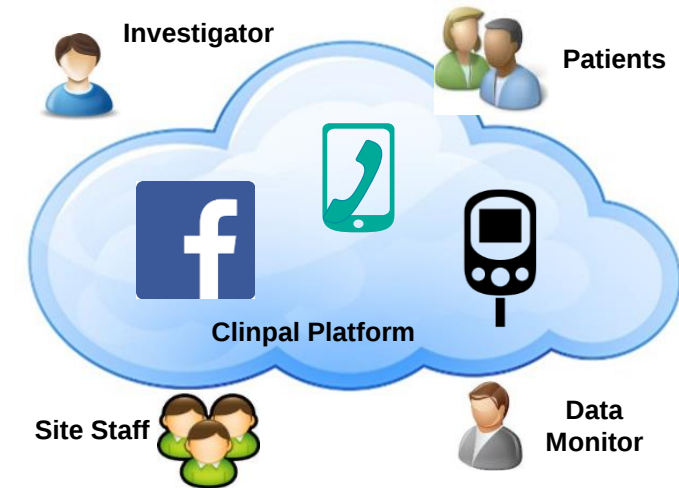
The FDA has introduced the new MyStudies app, which will collect real-world evidence through mobile devices and increase the diversity of information available for clinical trials and other healthcare research.

After conducting a successful pilot study with Kaiser Permanente, the FDA has decided to release the open source code and technical documents that will allow researchers and developers to customize the MyStudies app.

Stakeholders can adapt the tool to fit their clinical trial and real-world evidence needs, while also **complying with the FDA's regulations for data authenticity, integrity, and confidentiality**

# REAL LIFE EXAMPLE – REMOTE CLINICAL TRIALS

- Digital technologies employed for VERKKO remote online phase IV clinical trial for diabetes.
- Developed in collaboration with **Sanofi, Languard** and **Mendor** to study the use of an online clinical trial platform integrated with **Mendor's 3G-enabled wireless blood glucose meter** in a completely remote setting.
- 60 patients recruited through **Facebook**
- **No site visits**
- Patients self-registered in **Clinpal cloud platform**
  - Signed informed consent electronically
- Patients connected the smart, wireless glucose meter with their personal Clinpal account



**66%**

Improvement in  
trial efficiency

**4.6/5**

Satisfaction by  
trial participants

# REAL LIFE EXAMPLES

## Healthcare algorithms cleared by the FDA

**Viz.ai**'s Contact is a clinical decision support (CDS) tool that analyzes CT results and highlights cases that may have experienced a stroke

**IDx**'s IDx-DR is an AI software system for the autonomous detection of diabetic retinopathy in adults who have diabetes.

**MaxQ AI**'s Accipio Ix is an AI workflow tool designed to help clinicians prioritize adults patients likely presenting with acute intracranial hemorrhage.

**Imagen**'s OsteoDetect uses an AI algorithm to scan X-ray images for a common type of wrist bone fracture, known as distal radius fracture.

The cloud-based **DreaMed** Advisor Pro is a diabetes treatment decision support product that analyzes data from continuous glucose monitors, insulin pumps and self-monitoring to determine an insulin delivery recommendation.

**AliveCor** received 510(k) clearance back in 2014 for **the AF algorithm**, an app-based algorithm that works with the company's smartphone ECG device to detect atrial fibrillation.

# REAL LIFE EXAMPLES

## Healthcare algorithms cleared by the FDA (cont'd)

AliveCor also received **clearance for two more related algorithms**: the Normal Detector, which assures patients that their personal ECG is free of abnormalities; and the Interference Detector, a tool that automatically detects whether interference could be compromising their ECG test.

**Apple's** latest ECG-equipped smartwatch comes with **an algorithm to detect irregular heart rates**.

**Bay Labs' EchoMD AutoEF software** assists cardiologists by using an algorithm to automatically review relevant digital video clips collected from an echocardiography study, rates their quality and then selects the best to calculate ejection fraction, a key measure of cardiac function.

The Coronary Calcium Scoring algorithm from **Zebra Medical Vision** offers a coronary artery calcification score from a patient's ECG-gated CT scan.

**Arterys Inc. received 510(k) clearance** for its Arterys Oncology AI suite, a web-based platform that helps clinicians analyze ARIs and CT scans for signs of potential liver and lung cancer.

# REAL LIFE EXAMPLES

## FDA permits marketing of clinical decision support software for alerting providers of a potential stroke in patients

The Viz.AI Contact application is a computer-aided triage software that uses an artificial intelligence algorithm to analyze images for indicators associated with a stroke. Artificial intelligence algorithms are a type of clinical decision support software that can assist providers in identifying the most appropriate treatment plan for a patient's disease or condition.

The Viz.AI Contact application is designed to analyze CT images of the brain and send a text notification to a neurovascular specialist if a suspected large vessel blockage has been identified. The algorithm will automatically notify the specialist during the same time the first-line provider is conducting a standard review of the images, potentially involving the specialist sooner than the usual standard of care in which patients wait for a radiologist to review CT images and notify a neurovascular specialist. The notification can be sent to a mobile device, such as a smart phone or tablet, but the specialist still needs to review the images on a clinical workstation.

The company submitted a **retrospective study of 300 CT images** that assessed the independent performance of the image analysis algorithm and notification functionality of the Viz.AI Contact application against the performance of two **trained neuro-radiologists for the detection of large vessel blockages in the brain.**