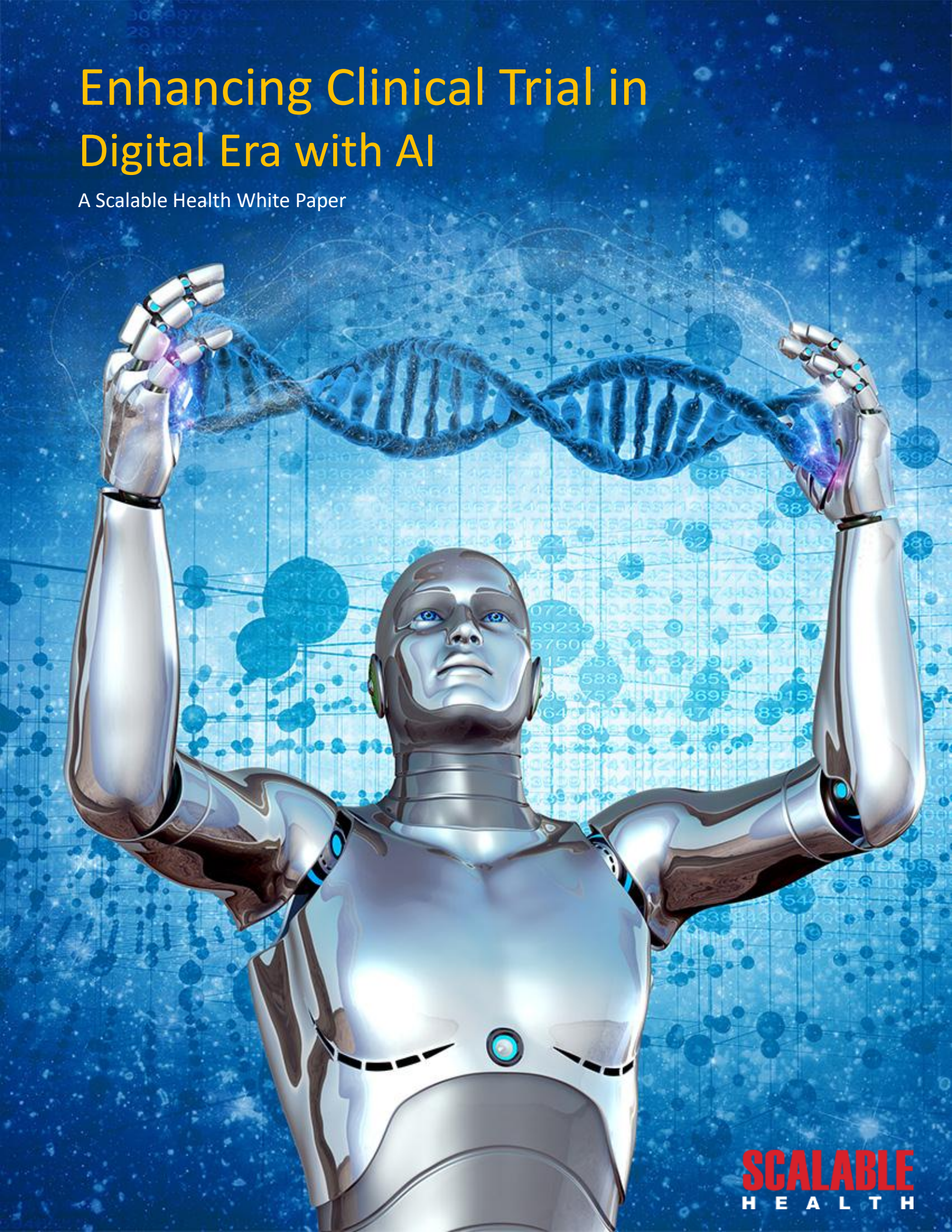
Enhancing Clinical Trial in Digital Era with AI

A Scalable Health White Paper



SCALABLE HEALTH

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EXECUTIVE SUMMARY

The healthcare industry is itself a universe. Few other industries are as diverse, expensive, and complex as medicine. Yet, it has been quite slow to embrace the power of data to increase outcomes and realize the potential of today's digital technologies.

Now is the time to bring changes into the healthcare industry. The good news? Well, we are not talking about the EHRs (Electronic Health Records). Rather, it is a powerful catalyst for changes in healthcare system- intelligent health- is a reality now!

Smart healthcare service implies making machines central to our healthcare condition by systematizing routine procedures and methods so clinicians can use deep learning to recognize critically sick patients and give actionable insights for care. Thus, clinicians will be able to more productively and viably analyze and treat patients. Smart healthcare service also implies computerizing billing, documentation, and administrative procedures so that clinicians can concentrate on addressing each patient's needs.

Parallel to these developments is the digital revolution, which is rapidly changing what is conceivable in health services. Technologies create profoundly unique ways to deal with care and open healthcare to new and non-customary players. Lower costs, intelligent devices, and higher usage of new technologies have all redefined how patients manage their health and interact with care systems.

Innovative solutions and digital systems can essentially change how we manage ill health and sickness; how we manage and share health information; and, how we handle the main drivers of persistent issues in healthcare to enhance outcomes and value.

Finally, digital health implies caring for one patient while also caring for millions of patients. It implies moving from sick care to wellbeing protection and from individual health to population health. Digital health supports success in medicinal services' main objectives: improved patient experience, enhanced population health, and low expenses.

Medical artificial intelligence (AI) is predicted to increase in predominance in clinical trials this year due to the capacity of computers and machines to perform tasks generally requiring human thought. This new capacity should eventually enhance the quality, security, and time-to-market of rising treatments.

This white paper reviews the future of digital health. It discusses the development of and obstacles to new digital technologies and presents requirements for embracing the use of information, machines, and analytics to deliver higher quality and more productive care. It likewise incorporates genuine cases that exhibit the clinical and financial advantages of integrating digital tools into workflow and patient care.

CLINICAL TRIAL CHALLENGES

While we can anticipate the advantages of AI in enhancing healthcare, the adoption of these innovations is not without considerable potential perils. Clinical settings, healthcare provision, and patient information require the highest level of precision, quality, security, and privacy. For all its promise, the world of healthcare faces innumerable challenges.

Consistent accuracy: Having great accuracy in the process of a clinical trial is a must, but AI is still in its infancy. Although AI systems consist of integrated datasets, in a clinical setting AI might face data and scenarios that have not been integrated properly, thus reducing accuracy and reliability. This puts patients at a higher risk of hospitalization.

Security: The medical data collected by devices is sensitive; it should be protected with the highest security measures. There is a great difference between non-clinical and clinical use of data. Data from non-clinical smart wearables can be put into clinical AI systems, and would be essential to classify clinical level accuracy and reliability within the system.

Innovation is defied by digitization and risk-aversion: All the applications of AI in healthcare are structured by a fundamental philosophy: do no harm. This attitude is literally harming people. The ultra-traditionalism of the healthcare system safeguards patients, but also damages them by limiting innovation.

Lack of organized data sets: Due to the absence of organized data sets, researchers in clinical trials face many issues, such as identification concerns, privacy concerns, etc. Advanced analytics requires collecting huge amounts of data from numerous sources. Given the regulatory, practical, privacy, legal, and cultural complexities, convincing traditionally siloed systems to share data from unorganized data sets represents a major hurdle.

Integrating and implementing technology: The integration of new technologies has been a burden for many practitioners and clinicians. There is a misconception that the implementation of AI requires a huge amount of data, but that is not the actual issue in healthcare. The actual issue is understanding the situations that call for bringing these technologies together .

Participation of Volunteers: A clinical trial relies heavily on volunteers willing to participate in studies. Therefore, the participation of volunteers is highly important in carrying out trials safely.

Selection process: The selection process makes it difficult for practitioners to analyze large amounts of medical data quickly. This leads to higher chances of missing eligible patients for a clinical trial.

Precision: Each examination process is tough and requires many individuals. Besides, each patient is different. Every trial must be completed with the utmost precision and transparent.

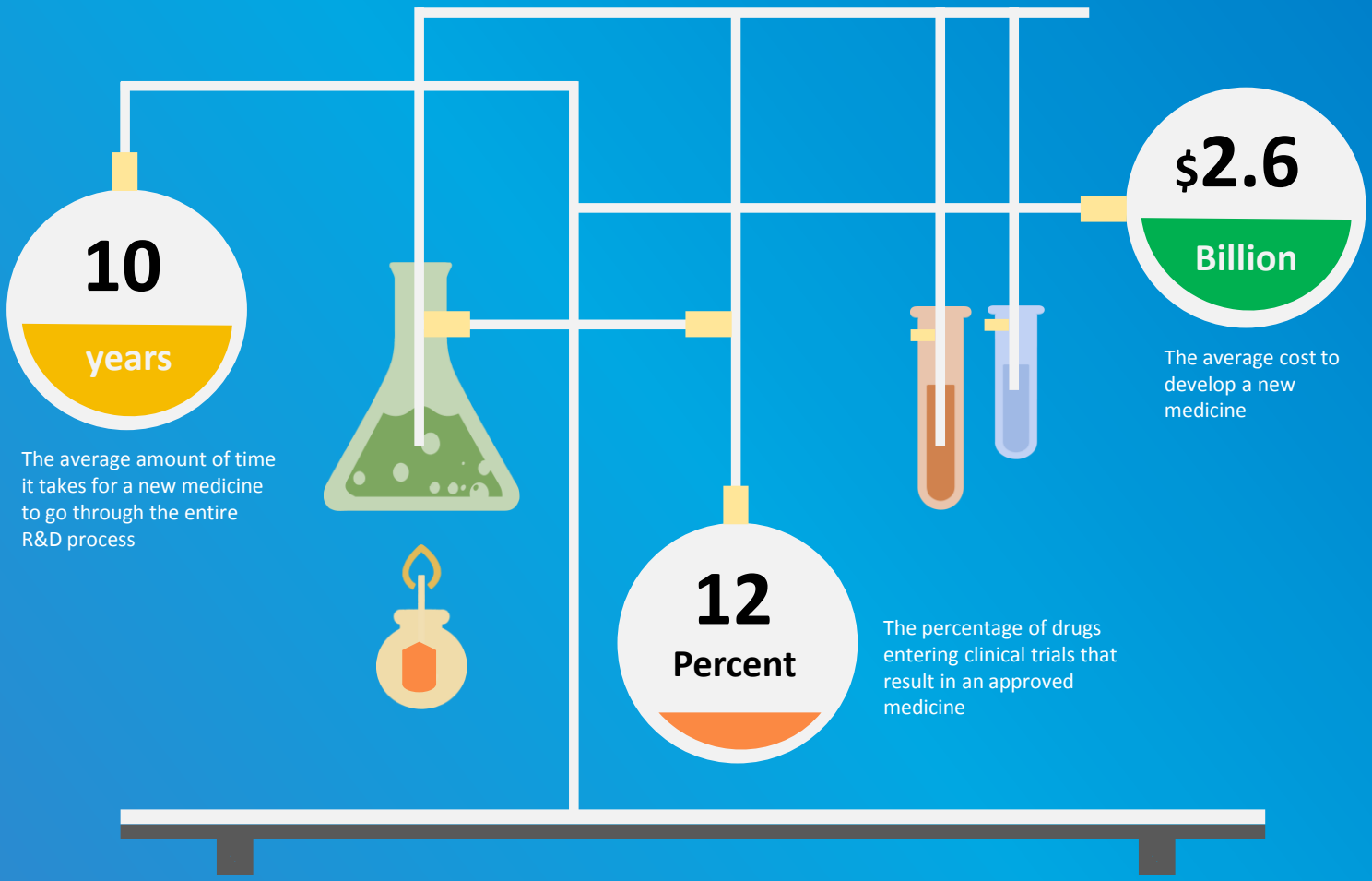
Cost: The entire clinical trial process takes a huge amount of money, from finding suitable patients to completing new drug manufacturing and recruiting a clinical investigator. The cost to even begin a trial is gigantic.

Subject Compliance: Compliance with untried product usage in a clinical trial is vital to identifying the true efficacy and safety of a product. Classic means of compliance have been pill counting and self-reporting. However, both these means have been repeatedly demonstrated to be unpredictable, regularly miscalculating the degree of compliance.

THE CHALLENGE OF

DEVELOPING NEW TREATMENTS AND CURES

Innovative medicines offer great hope to patients and the healthcare systems, but developing these new treatments and cures is a complex and risky undertaking.



10 years — The average amount of time it takes for a new medicine to go through the entire R&D process

$2.6 Billion — The average cost to develop a new medicine

12 Percent — The percentage of drugs entering clinical trials that result in an approved medicine

BETWEEN 1998 AND 2014:

The number of unsuccessful vs successful attempts to develop medicines to treat certain diseases

	Unsuccessful attempts	Approved medicines
ALZHEIMER'S DISEASE	123	4
MELANOMA	96	7
LUNG CANCER	167	10

MORE THAN 7,000 — The number of medicines currently in development around the world

70 PERCENT — The Percentage of new medicines in development that are potential first-in-class therapies, meaning they use a completely new approach to fighting a disease

42 PERCENT — The percentage of new medicines in the pipeline that have the potential to be personalized medicines

REIMAGINING CLINICAL TRIAL PRACTICES OF THE FUTURE

Today, an ideal storm of demographic, financial, technological, and ecological components has created an advanced revolution in healthcare industry. These incorporate the unmaintainable cost of care; a move to value-based repayment, in which results and effectiveness drive remuneration; the desperate requirement for enhanced access to care; and the development of precision medication.

From a cutting-edge point of view, digital clinical trial procedures can wipe out present dangers and difficulties by utilizing the abilities of digital tools and methods. This involves:

- **Renovating Study Design:** Digital clinical trials use a model-based study outline where best-in-class analytics strategies are utilized to create study models and enhance analytics parameters. These depend on real longitudinal patient information, chronicled trial information, and past trial study encounters.
- **Digitizing Site Selection and Setup:** Digital clinical trials use a progressed analytics-based determination of sites that depends on key factors, including past performance of sites, appropriateness for the trial, and hazard forecast. Locales over the world can be positioned in view of recorded site performance and other sources. This strategy consolidates digital site engagement, which incorporates a virtual tour through offices, positioning and quality estimation, digital data exchange with sites, and digital training and engagement of a site's work force.
- **Enhancing Patient Connection:** Digital clinical trials offer comprehensive digital connection with patients chosen through the screening of medical records. Patients are educated and enlisted in the trial carefully rather than at trial sites.
- **Improving Trial Monitoring:** Digital clinical trials use advanced analytics and visualization for hazard-based supervision of trials. This incorporates hazard-based monitoring, remote site observing, and mechanized confirmation of data exchanged with sites. Creative ideas include recording patient videos before or after site visits and noting their criticisms and encounters using ePRO and eCOA instruments as monitoring specialists.
- **Improving Clinical Data Management:** Digital clinical trials perform clinical data infusion and incorporate patients' clinical information from different sources: for example, trials utilizing Electronic Data Capture (EDC) frameworks, wearable gadgets, telemedicine support, and electronic therapeutic and wellbeing records. This data is connected and put away in semantic storehouses for auto-aggregation and summarizing.
- **Filtering Trial Analysis and Reporting:** Digital clinical trials use predictive and advanced analytics to produce great insights and evidence on the hazard evaluation of medications, patient subgroup performance, and the hereditary basis of results. It likewise coordinates with genuine information to provide evidence on drug performance and cost adequacy in clinical settings. Analysis yields are put into smart reporting frameworks where report segments are naturally produced and amassed.

CLINICAL TRIAL PROCESS

Phase	Length	Number of People*	Purpose		
Phase 1	1 month	10-20	Is it safe !	How does the body process it	What are the side effect
Phase 2	3-12 months	50-75	Is it safe !	How well is it working	How much should be taken
Phase 3	6-12 months	100-300	Is it safe !	How well is it working	Does the benefit outweigh the risk

If successful

FDA Approval

Application submitted → Application reviewed → (6-12 months) → Application approved → Available to public

Phase	Length	Number of People*	Purpose		
Phase 4	3-12 months	100-300	Is it safe !	Are there more side effects	Cost effectiveness & composition to other similar drugs

*15 healthy participants

*15 healthy participants with CF

*Number of months of participants involvement

*number of participants varies based on body characteristics

CLINICAL TRIALS DRIVEN BY ARTIFICIAL INTELLIGENCE

The increasing expense of clinical trials and the difficulties associated with procuring, examining, and separating information from medicinal big data makes the development of medical artificial intelligence (MAI) necessary.

Supplementing individuals' insights with machine intelligence creates an exponential effect. Machine learning can help clinicians in their ordinary clinical assignments, such as data control and information extraction, diagnosis devising, deciding remedial decisions to anticipate clinical results, and enhancing the quality and lowering the cost of clinical trials for better patient care.

- **Patient Recruiting and Data Gathering**

Most clinical trials today are driven without coordinating data from patients. Third-party providers in the midst of patient visits gather the most data. With the creation of portables, the Internet of Things (IoT), and especially wearables, billions of people are now easily providing critical data. This offers a chance to catch significant data from patients in a consistent and advantageous way. With the touch of a button, patients can decide to specifically share their data for clinical trials over their cell phones . Moreover, this data is significantly more logical, exact, and top notch: something we couldn't envision with manual clinical trials.

- **Constant Improvement**

Clinical trial processing frameworks are gradually moving to the cloud, with versatile information for transmitting data and custom structures for breaking down that information. This allows for an approach to running persistent and self-learning trials with prominent accuracy.

- **Mutual Resource Pool with Crowd Sourcing**

Patient data can now be shared among different facilities through a cloud framework, making it even more alluring for patients to take an interest in trials around the world.

- **Guarantee Adherence**

Given that native recordings made over cell phones are ceaselessly transmitted to the cloud, it is currently feasible for clinics to learn about irregularities in patients’ drug intakes in real-time and to remind patients if they neglect to take their medicines.

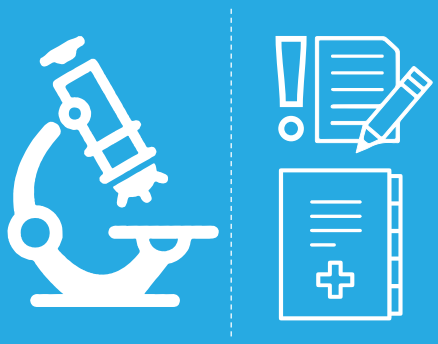
- **Calculate Drug Effectiveness**

Few people have identical body types; thus, different individuals can respond uniquely to similar pharmaceuticals. Modernized reasoning is a compelling technique for envisioning drug outcomes, since it addresses human variation and other collaborating qualities. With AI, it is possible to predict which patients with specific infections would profit the most with a drug.

Structures and efficacy of existing small molecules

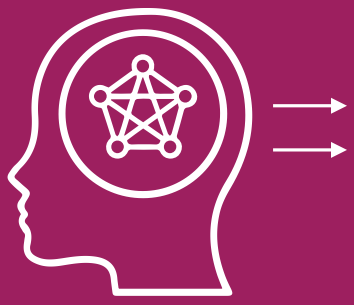
Patient DNA, RNA, protein and metabolite profiles

Clinical trial efficacy and adverse events information

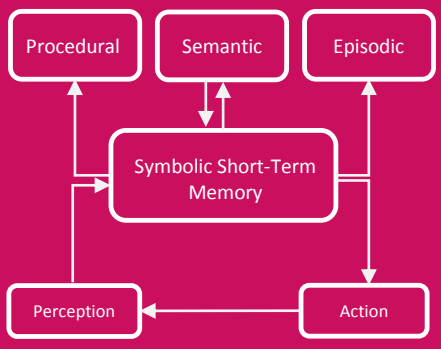


Human Like Intelligence

CLINICAL TRIAL COGNITIVE ARCHITECTURES

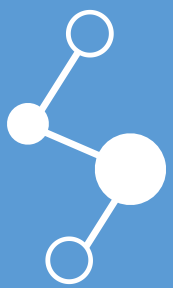


Neural Networks



Symbolic Short Term Memories

Next-generation of antibiotics and cancer therapies



Health predictions & Personalized and precision medicine

Faster & safer clinical trials for cancer and biologics

HOW ARTIFICIAL INTELLIGENCE MET DRUG DEVELOPMENT: USE CASES

Pharmaceutical organizations have the chance to gain from Artificial Intelligence (AI). Drug organizations consistently examine huge amounts of data looking for possible therapeutic value. This procedure can be tedious and expensive: 1-6 years for preclinical improvement, costing about $1 billion; and 6-12 years for clinical advancement before FDA endorsement, costing about $1.4 billion; with an aggregate likelihood of around 8 percent of getting an improvement. With an end goal of accelerating this procedure, enhancing proficiency, and diminishing medicinal services costs, some pharmaceutical organizations have executed frameworks uniting science, computational modelling, and AI, though with mixed results.

The drug discovery and improvement process has been long, moderate, and costly. AI is a promising innovation that could be connected to many stages of drug discovery and advancement, including target identification, lead streamlining, drug repurposing, patient identification proof, etc. AI can more productively recognize better targets by rapidly seeking a great many references over various sources. Treatment of perpetual and deadly diseases, like Alzheimer's Disease, could benefit from such new advancements.

AI Saves Almost Half the Money and Time for Drug Discovery:

BERG Health, a 6-year-old startup incorporated by Carl Berg in Silicon Valley in February 2017, stood out as truly newsworthy when they declared that their AI had chosen a drug candidate for rare cerebrum diseases; that drug has now entered clinical trials as a monotherapy. The AI-based BERG Interrogative Biology Platform guided the drug candidate, named BPM 31510-IV, through early advancement. By examining patient information from a large number of cancer patients, the AI assembled a siloed disease model and recommended conceivable drug treatments.

Legitimately required administrative testing requires that all drug candidates finish through animal tests; this prerequisite is not likely to change soon. Yet, the possibility to choose a drug candidate from human information may speed up the drug advancement process and lessen the attrition rate of drug applicants, thus reducing overall costs. BERG's President and Co-Founder, Niven Narain, claims that his AI took a fraction of the time and less money compared to conventional techniques.

Drug Target Identification and Toxicity Forecast:

Notwithstanding the overwhelming drug improvement process, FDA-endorsed drugs are often pulled back from markets. This is principally because of symptoms or toxicities, which is an aftermath of the polypharmacology of medications. Polypharmacology is the use of multiple drugs, which can have side effects besides the planned restorative impacts. Cyclica Inc., a Canadian startup company, and One Three Biotech, a spin-off of Weill Cornell Medical College in New York, are two organizations now using AI and Big Data with the end goal of drug target identification and side-effect forecasting.

Cyclica Inc., established in 2010, uses a suite of computational calculations. Their predictive analytics platform, Ligand Express™, is used and approved through third-party associations, enabling customers to foresee a drug candidate's reactions before clinical trials; this empowers more educated R&D choices. Working in the same field as Cyclica is One Three Biotech. This organization's AI, BANDIT, helped Oncoceutics Inc. foresee the objectives of ONC201, a first-in-class particle that is being assessed in 5 clinical trials. Their outcomes were later affirmed through in-vitro examinations, and the physiological pertinence of the anticipated cooperation was developed by dissecting clinical specimens.

Low-priced Drug Development, Low-priced Healthcare:

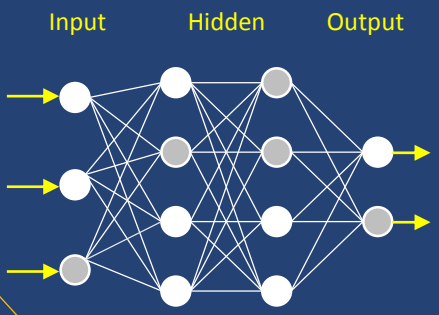
Throughout the last five years, AI has made progress in different parts of drug improvement and is being used by new biotech companies and average-sized medication disclosure organizations. However, AI is yet to be incorporated by Big Pharma enterprises. AI has changed different sectors and can possibly do the same in the pharmaceutical business by expanding drug improvement proficiency and lowering drug attrition levels, thus diminishing drug advancement costs and guaranteeing less expensive healthcare services.

Some additional use cases that have advantages and are appropriate for AI application are:

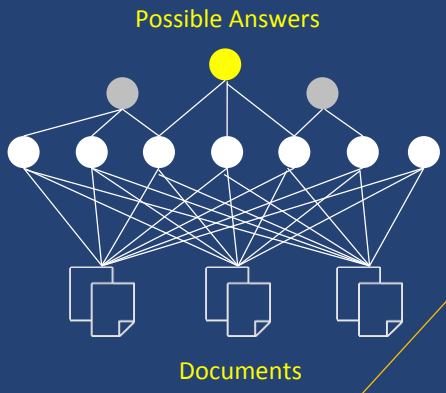
- UPMC cooperated with IBM's Watson to enhance inventory network performance in its healthcare system. UPMC is one of the country's largest incorporated healthcare delivery services and funds frameworks with more than $12 billion in income. Watson's restorative procurement ability and UPMC's domain mastery, along with an independent organization called Pensiamo, have the mission of enhancing supply-chain performance in healthcare systems.
- AI has also made progress in the capacity to mine data held inside therapeutic records. Google DeepMind, for instance, is working with Moorfields Eye Hospital in east London and the UK's National Health Service (NHS) by mining medical records to create better and faster health services.

ARTIFICIAL INTELLIGENCE ECOSYSTEM

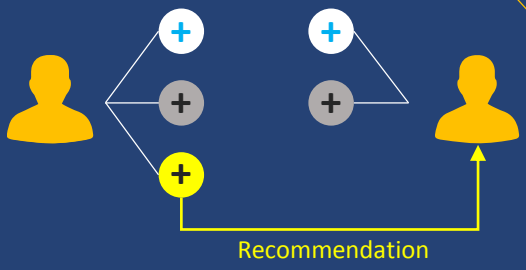
DEEP LEARNING



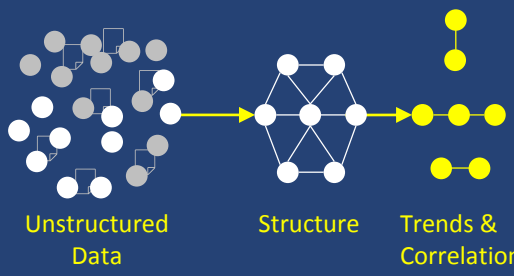
EVIDENCE BASED

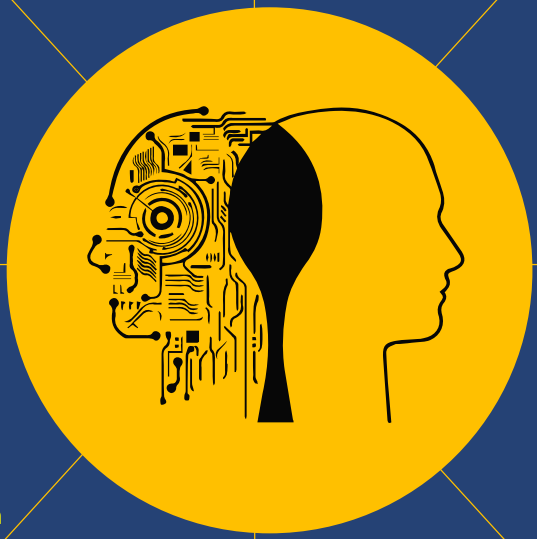


RECOMMENDATION ENGINES

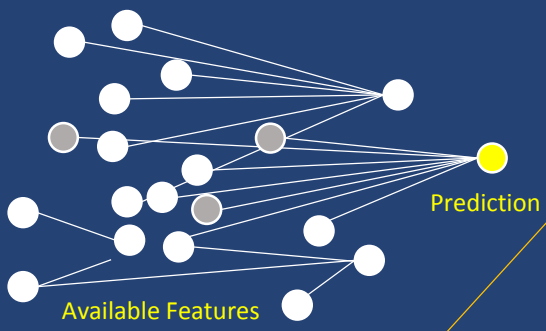


MACHINE LEARNING

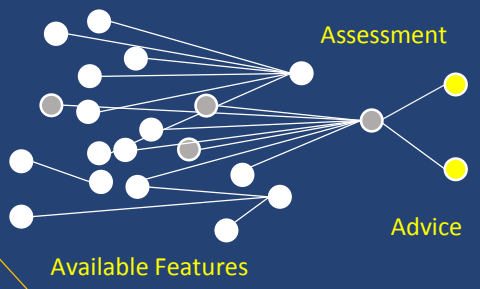




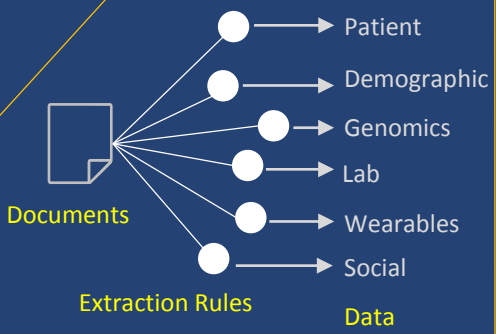
PREDICTIVE ANALYTICS



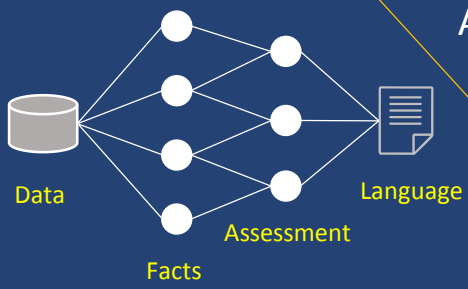
PRESCRIPTIVE ANALYTICS



NATURAL LANGUAGE PROCESSING



NATURAL LANGUAGE GENERATION



RETHINKING A STRATEGY FOR AI

Changing populations require new models for understanding patient-driven care. Tuning in to patients' genuine requirements can lead to the creation of new value-added services using technology. Access to digital technologies empowers medical service experts in all sectors. Overall, a more extensive healthcare eco-system emerges in which everyone cooperatively develops. Advancing medical services into the future begins with rethinking.

Rethink Business Models

Presently proactive and adaptable, healthcare business models can react quickly to changing patient needs or statistic shifts. Digitized plans of action can:

- Integrate: Merge wellbeing, anticipation, observing, etc. for patient-centered health services beyond intense care
- Study: Measure an organization's qualities while eliminating activities with less value
- Contribute: Share clinical research for greater insights to offer customized treatments
- Build: React to rising sectors like corporate wellbeing and therapeutic tourism
- Broker: Balance supply and demand and coordinate and accommodate patients' requirements for services

Rethink Business Processes

Straight and one-dimensional medical processes can extend care under new models, bringing patients and experts closer together. Present-day procedures can:

- Optimize counteractive action systems, engaging healthcare consumers
- Develop clinical decisions and diagnostics with access to keen information
- Boost observation and response with digital and intelligent advances, encouraging early discovery and expectation
- Engage patients and cultivate joint efforts between all caregivers for all-inclusive care
- Provide real-time care and correspondence to dispense with transmission blunders, create constant transparency, and enhance value-added care
- Restructure resource planning to improve productivity inside and across organizations

Rethink Work

New models and procedures can develop a community where all benefit, changing the way experts work and develop. For instance:

- Physicians can now organize more educated and empowered patients, surpassing the conventional hierarchy and "spot counseling" state of mind
- Nurses, as personal care givers, accept more obligations for greater effect in care procedures
- Clinical choices are less demanding with better access to data at any place and any time
- A new setting for clinical specialists empowers translational research and encourages creativity

CONCLUSION

The collective disruption from AI and IoT will reshape our lives in a sensational way unimagined by most healthcare organizations today. However, AI is still in its infancy and doesn't yet have the capacity to supplant a doctor.

AI has the capacity to comprehend natural language and clinical notes alongside structured information like numbers and dates. It also has the capacity to build theories in view of evidence. Due to these abilities, AI is being considered for AI-Powered Clinical Trials, of which the healthcare and pharmaceutical industries would be the greatest beneficiaries.

Artificial intelligence holds prominent potential to change clinical research and lower costs related to disease management, successful ageing, and the discovery and improvement of new medicines. AI has a promising future. Pharmaceutical companies need to assess their needs to create a pathway to adopting advanced clinical trials. Certain activities can be embraced horizontally over various medical areas, while others might be particular to specific areas.

It is necessary and important to conceive of the future with optimistic yet practical targets and venture into digital clinical trials. Prompt action by drug development organizations can result in competitive differentiation in creation of drugs through clinical trials.

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