CLINICAL TRIALS MADE SMARTER, FASTER

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A PROBLEM WORTH SOLVING

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Drug development is a highly complex and arduous task. Bringing a drug to market takes anything between 10 and 15 years and costs about US$400 million to a couple of billion US dollars. Once a drug is invented, it is patent protected against imitations for 20 years. Unfortunately, often eight years or more of those 20 are lost in obtaining FDA approval. Once the drug finally hits the shelves, it enjoys a run of a few short years before the generics attack.

Hence pharmaceuticals and life sciences companies are under severe pressure to shorten drug development costs and timelines. To do that, they need to attack multiple problem areas across the development lifecycle.

- During discovery, scientists have to zero in on a few compounds among thousands of possibilities, for further development. Thousands of experiments are done to understand how these compounds would behave inside the body, and their interactions with other molecules, effectiveness versus similar drugs, and more. Currently, for the most part, scientists use instinct honed through experience, trial and error, and a process of elimination to complete this analysis.

- Preclinical research checks the toxicity of the compounds with thousands of laboratory tests conducted inside test tubes and living organisms both. The overall preclinical phase – discovery, development and research – takes three to four years.

- Drugs that pass the preclinical tests are sent for clinical trials on humans. Clinical trials go through four phases to test safety, dosage, efficacy, side effects and adverse reactions. Starting with 20 to 100 people in phase 1, the trial administers drugs that make it through each stage to a progressively increasing cohort of patients. This takes several years and millions of dollars, at the end of which barely 10 percent of the drugs that started out make it to the FDA review.
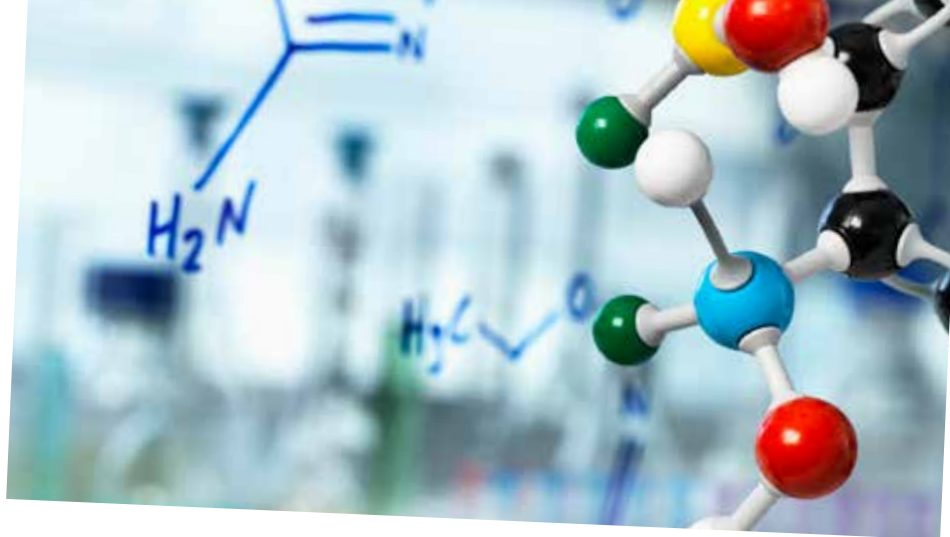
FINDING & FRAMING THE REAL PROBLEM

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Clearly, the process of drug development is a far cry from a regular product development lifecycle. There are intricacies and challenges at every stage, right from gathering, ingesting and analyzing enormous volumes of data to deciding which drugs to pursue, which to drop, and how many experiments to conduct. Therefore, bringing down the cost and time of drug development requires multi-pronged effort targeting not one bottleneck, but many.

SOLVING THE PROBLEM

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This is exactly what Artificial Intelligence (AI) and machine learning technologies promise to do. Based on the current state and evolution of AI, scientists believe it could significantly reduce the time and money pharmaceuticals and life sciences companies spend to bring a new product to market. For instance, it would be possible to streamline the early stages of drug discovery by using deep learning to predict the behavior of molecules and their likelihood of binding together. Or select the most important biological conditions to experiment upon with the help of machine learning algorithms instead of taking a hit and miss approach. Or even detect a drug's toxicity early, saving the fuss of a clinical trial, with the help of big data analytics. In fact, recent research suggests AI and automation could cut the cost of drug development by as much as 70 percent.

THE SOLUTION

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Implement a next-generation AI platform with strong data, knowledge and cognitive automation capabilities.

The data capabilities should ideally cover advanced analytics, machine learning, natural language processing (NLP), and optical character recognition. Using these, the platform ingests raw data from a broad set of external structured and unstructured sources and stores it in a "big data lake".

The platform's knowledge capabilities are derived from the ingested data. A combination of NLP and machine learning discovers relationships between various data elements to both enrich the data and provide context. A knowledge model is constructed with the data, its ontology and representations of process models, which can be used for further analysis and modification. Knowledge updates dynamically as new information is ingested.

Using cognitive automation, the platform creates insights from knowledge by conducting analysis, finding correlations, detecting anomalies and doing predictive modeling that could be used to form a prognosis. It also automates processes and tasks based on simple deterministic rules or more complex AI-based self-learning predictive automation, depending on the requirement. When used properly, both of these ensure that action taken is appropriate to the desired outcome.

Drug manufacturers can tap into these capabilities at different stages of the drug development lifecycle to reap enormous efficiencies and insights.

- Before commencing a clinical trial, use machine learning and predictive analytics to automate study design, simulate and identify optimum models and forecast the risks of each.

- Leverage process automation and text mining to create questionnaires based on defined templates, and predictive analytics to identify investigators closest to the protocol or study design. Use automation to review responses and match subjects to the sites that fit best.

- Apply predictive analytics and modeling techniques to assess and monitor risks and suggest mitigation measures.

- Get chatbots to engage with patients, urging them to take the medication and report feedback. Also use the bots to record changes in patient behavior.

- Automate data entry, review and analysis from start to finish.

THE OUTCOMES
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- Automate expensive clinical trial operations to save time and money, and improve accuracy.

- Minimize manual intervention to reduce manpower overheads.

- Easily extend automation to other processes during drug discovery and development, and preclinical research.

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