Intelligent Automation for Clinical Trials

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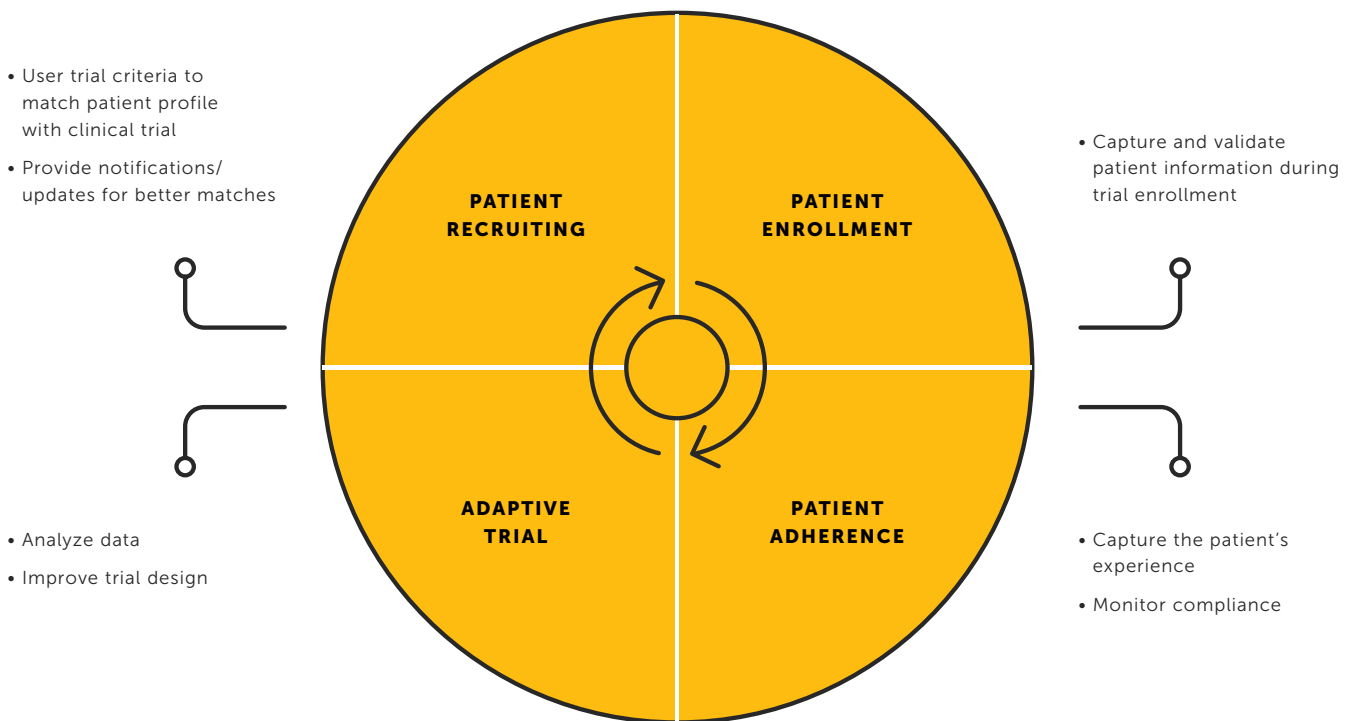
INTRODUCTION

With rising healthcare costs, increased pressure to adhere to drug development regulations and the need to process data in an unbiased, reproducible and rapid way, the pharmaceutical industry is turning to technological solutions to save money and streamline the clinical trial process. From the start of drug discovery through FDA approval, only one in 10 drugs that enter clinical trials makes it to market. Although there is no benchmark for drug-related expenditures, the process for clinical trials takes an average 7.5 years and costs between $161M –$2B per drug.[1]

Clinical trials fail for a variety of reasons, including the inability to recruit enough participants, mid-trial patient dropout, severe patient side effects and poor data collection methods resulting in missing established endpoints. These challenges offer an opportunity ripe for Intelligent Automation (IA) to provide practical solutions to address the clinical trial process.

Practical Uses of IA Solutions

- User trial criteria to match patient profile with clinical trial
- Provide notifications/ updates for better matches

- Capture and validate patient information during trial enrollment

PATIENT RECRUITING

PATIENT ENROLLMENT

ADAPTIVE TRIAL

PATIENT ADHERENCE

- Analyze data
- Improve trial design

- Capture the patient's experience
- Monitor compliance

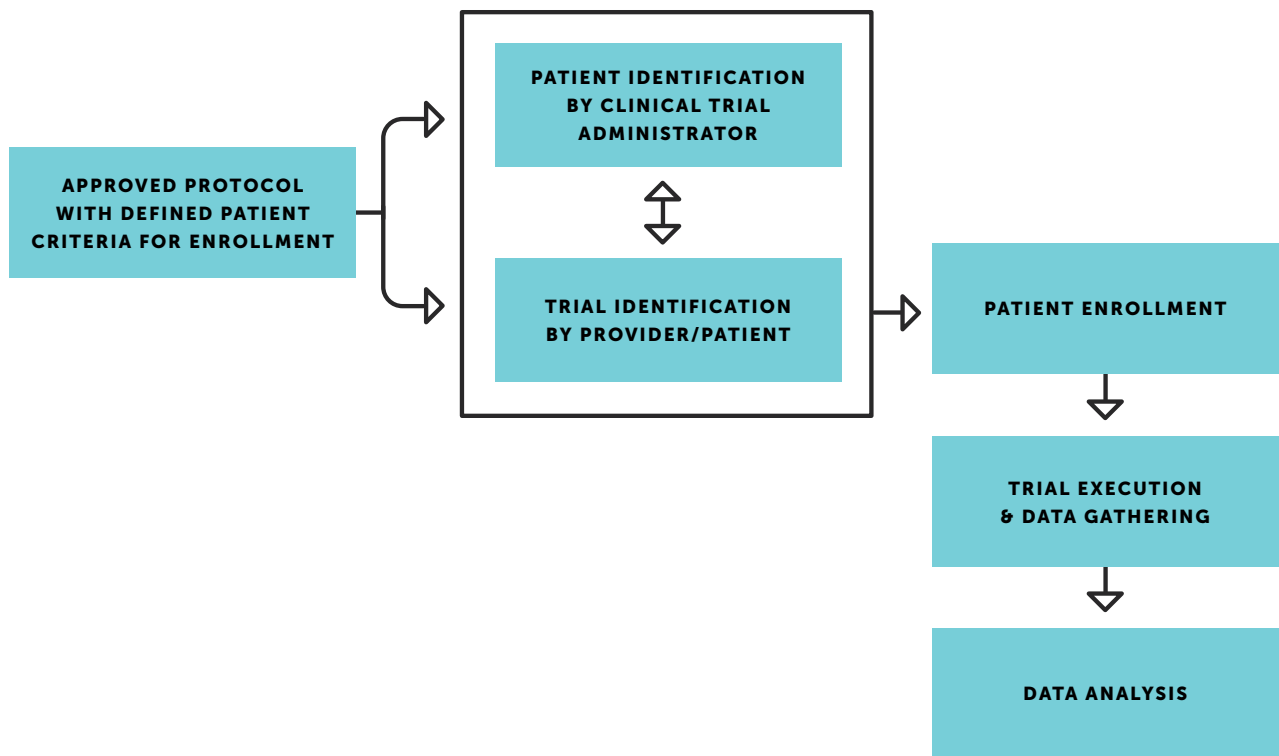[1] https://emanatelifesciences.com/2019/09/13/can-ai-speed-clinical-trials/

FINDING THE MOST EFFECTIVE CLINICAL TRIAL FOR PATIENTS

Patient identification and recruitment can be a slow, inefficient and often manual process. As many as 86% of clinical trials do not reach recruitment targets within their specified time periods.[2] This is caused by various issues — the target patient population and provider being unaware of a possible match to trial; a patient profile not fitting the trial requirements; the patient mismatch not being identified in a timely manner; or the trail administrators not being able to identify possible candidates. IA is a viable solution to help address enrollment timeline challenges by helping providers identify the best trials while simultaneously assisting administrators in identifying patients.

Even with advancements in technology, experts must often manually review patient charts to identify candidates for trials. For our example, information from the patient's EMR (e.g. patient history, vitals, lab results) can be effectively extracted through document processing and machine learning — technologies that are part of the overarching IA umbrella. With rule-based matching, the extracted information can be pinned against trial criteria to identify the best matches. The output is a report ranking the top clinical trial(s) for the patient to consider based on drug profile, location or duration of the trial. Leveraging robotic process automation (RPA)—another IA solution—a notification is sent through an EMR, the provider's communication portal or personal digital assistant to inform the provider of top clinical trial matches. This report can also be delivered to the patient through a patient portal associated with the health system. After discussing this information together, a provider can enroll the patient based on information that has been defined as the best trial option. This will result in fewer clinical trials failing due to patient enrollment.

APPROVED PROTOCOL WITH DEFINED PATIENT CRITERIA FOR ENROLLMENT

PATIENT IDENTIFICATION BY CLINICAL TRIAL ADMINISTRATOR

TRIAL IDENTIFICATION BY PROVIDER/PATIENT

PATIENT ENROLLMENT

TRIAL EXECUTION & DATA GATHERING

DATA ANALYSIS

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[2] https://www.contemporaryclinicaltrials.com/article/S1551-7144(17)30753-X/fulltext

ADDRESSING PATIENT ENROLLMENT & CLINICAL DOCUMENTATION CHALLENGES

Back in 2013, the biopharmaceutical industry sponsored 6,199 clinical trials in the U.S. with more than one million participants.3 Today, the number of clinical trials has almost doubled due to new, innovative, scientific approaches explored across a range of therapeutics.[4] Unfortunately, many researchers are still using paper-based forms to enroll, track and document essential data pertaining to clinical trials — an intensive, hands-on process that leads to avoidable human error. On average, 14 errors per 10,000 data fields[5] has resulted in $0.5MM[6] in data correction costs per clinical trial. Furthermore, using paper systems forces researchers, administrators and participants to input the data multiple times, making the data entry process much longer and less efficient while increasing the probability of transcription mistakes.

By using RPA or APIs, information can be captured from forms and other databases in a single system for proper patient data tracking. Once a patient decides to enroll in a clinical trial, an automated bot enters the patient's demographics and relevant health information into an external clinical trial database. When the data is registered, the patient is identified as an active trial participant and patient tracking is initiated. RPA is then applied to the patient's labs, vitals or other clinical trial documentation received from various sources during the remainder of the trial. The information from multiple external databases or printed forms will be directly extracted from the original documentation without human interaction. Through the integrated IA solution, the possibility of data entry error is minimized, allowing for more accurate clinical trial results, eliminating redundancies and streamlining the trial process.

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                   │    │    ADMINISTRATOR      │
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│ WITH DEFINED   │ │    ┌──────────────────────┐         │  └───────────────────────┘  │
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│ ENROLLMENT     │      └──────────────────────┘         │  │   TRIAL EXECUTION     │  │
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3 http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf
4 https://clinicaltrials.gov/ct2/results?cntry=US&recrs=b&recrs=a&recrs=f&recrs=d&age_v=&gndr=&type=&rslt=&fund=2&Search=Apply
5 https://www.researchgate.net/publication/23192704_Quantifying_Data_Quality_for_Clinical_Trials_Using_Electronic_Data_Capture
6 https://blog.longboat.com/data-collection-mistakes-a-cost-driver-for-poorly-performing-clinical-sites

USING PREDICTIVE ANALYTICS IN ADAPTIVE DESIGN FOR CLINICAL TRIALS

An adaptive clinical trial design is a flexible approach to modify the trial protocol based on observations or treatment responses of participants at specific intervals during the clinical trial.[7] While in the past this was not considered standard practice, adaptive design is now becoming widely accepted to make clinical trials more flexible, efficient and fast with improved outcomes in line with the study design. The process of modifying a clinical trial is expedited with the practical application of predictive analytics, which can be used to extract information from existing data sets to determine patterns and predict future outcomes or trends. When this IA technology is enabled correctly, it can further examine the validity and efficacy of a treatment regimen. As a patient's information is documented into the EMR or database (e.g. subject's diary, vitals, blood work and other patient information), a predictive analytics solution can integrate and analyze the data, resulting in forecast outcomes that guide changes to the trial design.

For example, imagine an adaptive trial for an innovative diabetic drug that controls a patient's A1C level and determines mortality rates as a secondary endpoint. Within the study, the predictive analytics tool identifies a set of characteristics from the patient's profile that tracks a normal A1C level. Based on the data set, patients who do not have those characteristics are identified with abnormal A1C levels or a negative result with the drug. If an outcome of the study is to show the diverging mortality rates of patients with controlled A1C levels, then the trial could be adapted to maximize the chances for a positive outcome by eliminating those patients with uncontrolled A1C levels and recruiting more patients with the appropriate profile. Although this is a simplified use case, more complex use cases have been identified for practical application to make better use of clinical resources such as time and cost.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5830330/
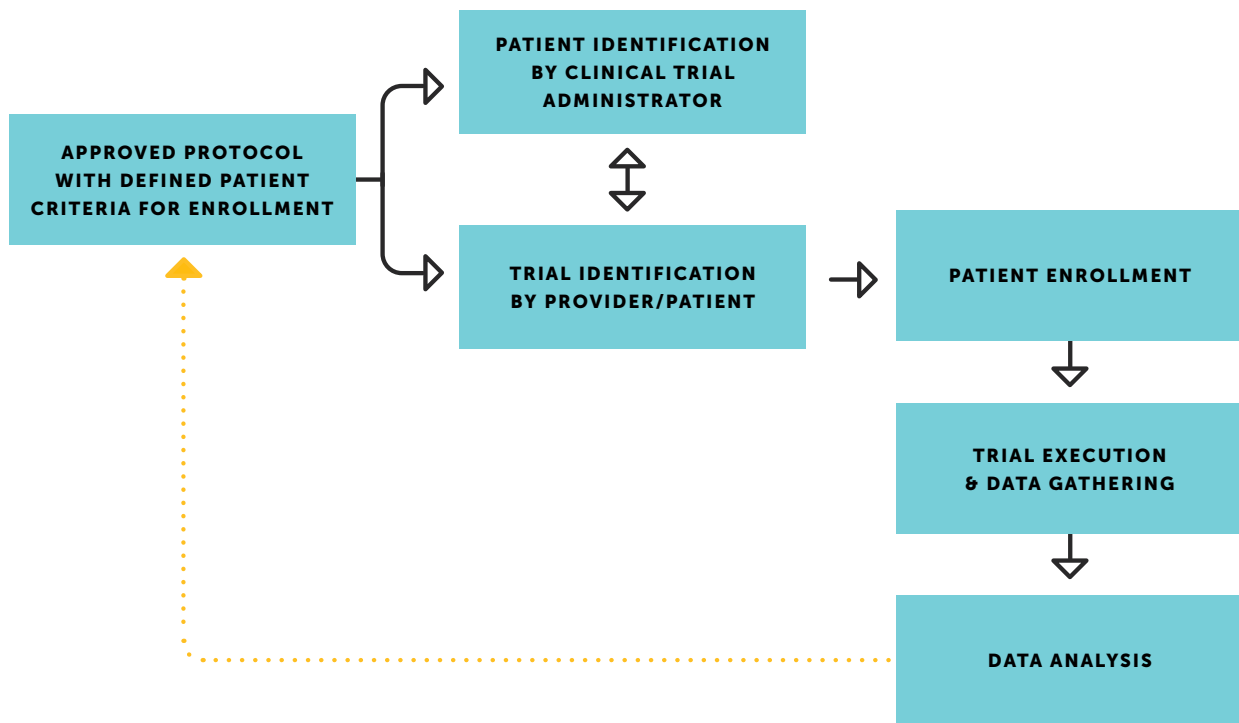
HELPING PATIENTS WITH MEDICATION ADHERENCE

The use cases discussed above demonstrate the advantages of IA within clinical trials from the perspective of the administrator or provider. Let's turn our focus back to the patient. A clinical trial helps determine whether drugs, therapies or vaccines that hold promise in the laboratory are safe and effective treatments for humans. When patients enroll in clinical trials, they agree to comply with the instructions from the clinical trial investigator, including biological testing, adherence to medication and subject diaries.

Clinical trial investigators have limited time with patients to make observations and assessments of how well a treatment is working. Capturing the patient's personal experience in a diary at a set time between office visits can unveil information about the safety and efficacy of treatment. The traditional approach for maintaining a diary is to use paper cards or booklets configured to help the patient follow directions from the clinical protocol. With the advancement of technology, digital apps and wearables that leverage the internet of things (IoT) and artificial intelligence (AI) can

provide an alternative to traditional methods. These technological advancements can address mandatory adherence while monitoring the patient experience.

By syncing wearable devices and/or digital apps with a patient's calendar, the patient can receive medication reminders, track basic vitals and be prompted to update his/her diary. With AI, the clinical protocol—including the time, location, vitals and any adverse events associated with the treatment—is documented. This will ensure real-time compliance rather than reliance on patient memory to administer or document the treatment regimen. Further, if a patient is required to videotape themselves taking the medication, AI can verify each video to ensure the patient has swallowed the medication and notify the EMR for compliance or non-compliance in place of a human administrator. Implementing this solution frees up administrators' time and allows them to focus on more value-add tasks, proper tracking and real-time results of the treatment regimen.
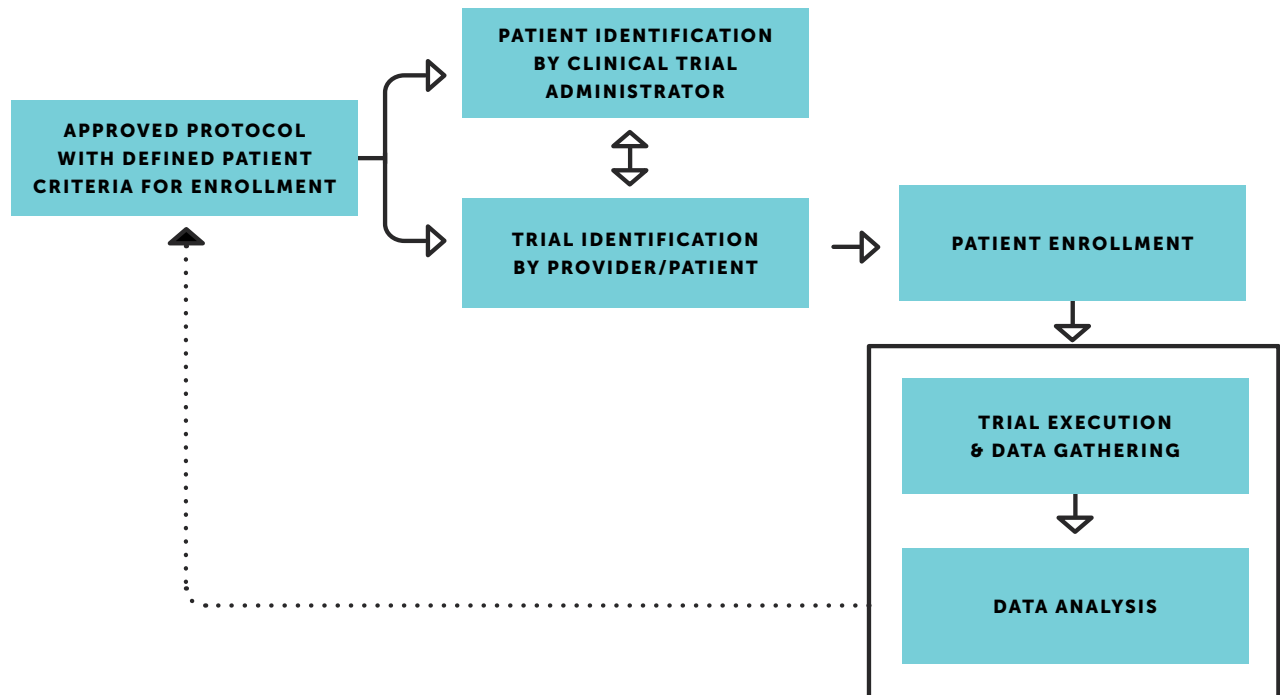
CONCLUSION

Every life-saving drug treatment starts with patients volunteering to participate in clinical trials. In addition to testing new drugs and devices, clinical trials provide a scientific basis for advising and advancing medicine. When researchers do not obtain the predicted outcomes, trial results can help point scientists in the right direction for future research. With the focus on reducing healthcare costs, providers are looking for ways to help match patients with the best available treatment options. By reducing data capture errors, clinical trial costs fronted by the sponsoring pharmaceutical companies can be addressed using IA.

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