Tech
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DIGITAL ENABLEMENT
IN CLINICAL TRIALS

Whitepaper

INTRODUCTION

Clinical Trials are pivotal for the approval of new drugs. The Pharmaceutical organizations are constantly striving to optimally design and execute clinical trials. To develop a drug and bring it to the market today, it costs an average of $2.6 bn, and only one in ten drugs in development are approved. According to a recent report by ZS associates[1] half of this cost is due to prolonged timelines for drug development, which are dominated by inefficiencies in clinical trial design and implementation. Key challenges which result in the delay of clinical trials are:

1. Patient recruitment and retention: As per a recent study by ZS associates, approximately 80% of clinical trials fail to meet enrolment deadlines, and 30% of Phase III studies last longer than expected due to challenges in patient recruitment. 30 % is the average patient dropout rate across all the clinical trials. Poor patient retention often results in unusable data and high investment losses. The main reasons for dropping out are inconvenient schedule or location, the intensity of the process, and misunderstanding of the expectations and adverse effects.

2. Complex regulations and inefficiencies in clinical data management: Complex regulations coupled with an increased variety of data and data sources in a clinical trial makes data management a cumbersome task. A recent study by Oracle Health Sciences and Pharma Intelligence, that surveyed over 155 biopharma companies on the clinical data management concerns and challenges indicate that building and managing clinical study databases is a herculean task because of manual processes, lack of real-time access to clinical trial data, and data governance issues.

Pharmaceutical Companies are increasingly looking at innovative ways to enhance clinical trial productivity and improve success rates where digital technologies are offering new possibilities to bring about a paradigm shift in the way trials are designed, executed, and analyzed.

DIGITAL ENABLEMENT

Clinical trial design, set up, execution, and closeout involves a series of coordinated activities with multiple stakeholders. As it involves many manual processes, oversight becomes difficult. With the help of technology, existing business processes can be automated and simplified to make knowledge-based decisions so that most processes can be scheduled and routed automatically.
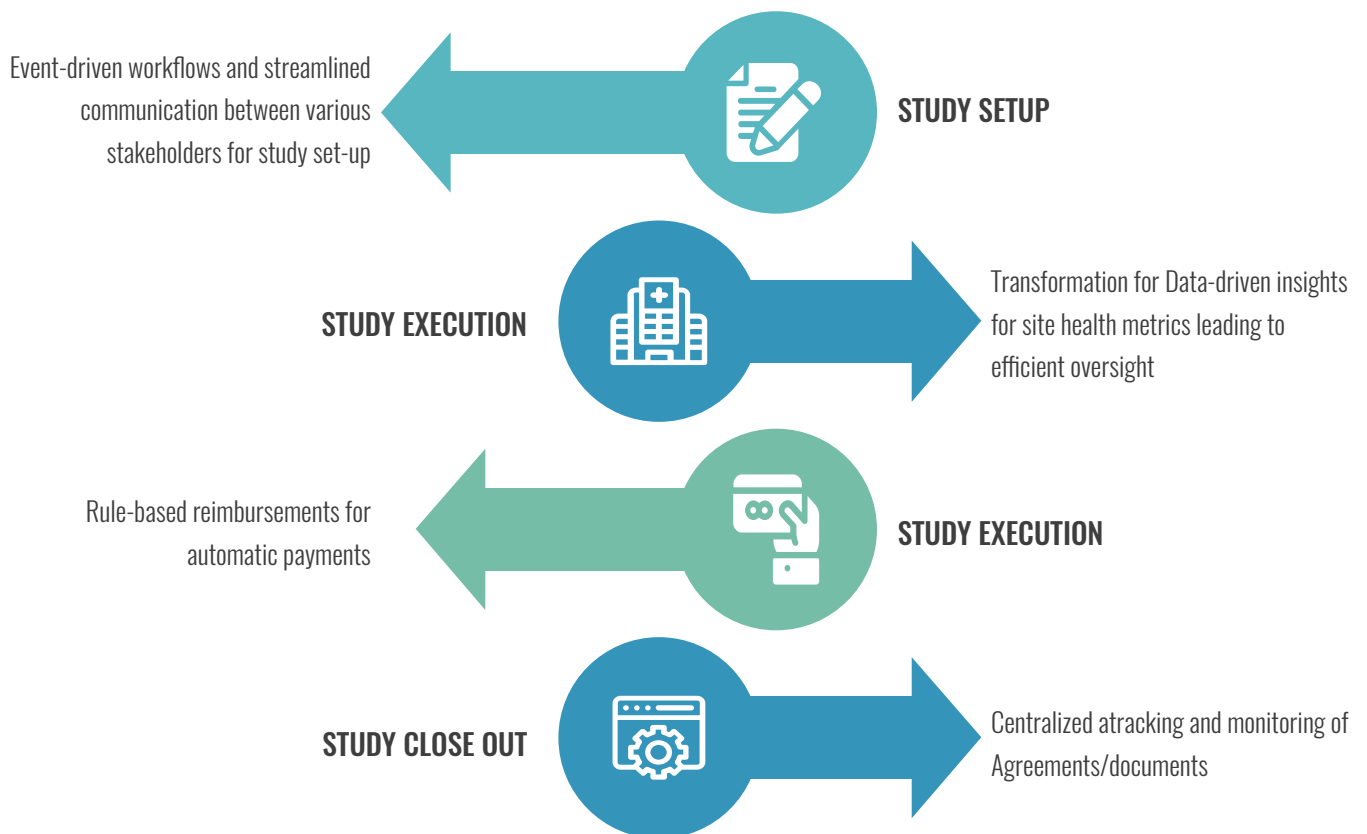
BUSINESS PROCESS AUTOMATION

Study set up is often considered as the slowest phase as a series of activities like site selection, regulatory document submission, subject enrollment, and budget allocation needs to be taken care of. Reliance on legacy systems further delays the process. With business process automation, automated workflows can be created that direct team members through the various regulatory and organizational SOP requirements specific to countries and sites.

Ensuring appropriate oversight of all clinical trials sites is a critical component in clinical trial **study execution**. High manual processes and the lack of a centralized site health monitoring platform makes oversight cumbersome. Automation of the business processes involved in site health monitoring results in improved data quality through faster issue identification, and proactive management of site issues without additional resources.

During **the study closeout phase,** pharmacovigilance data must be shared with multiple partner organizations which is currently a laborious process. Using role-based process management it is possible to capture responsibilities of each partner for various activities and periodically monitor these responsibilities.

Process automation can also be used for streamlining reimbursement related activities. Nearly 80 % of clinical trial payments are processed using a combination of manual, excel based processes, and single disparate systems. Because of this, payments are often delayed are inaccurate. With rule-based business process automation, payments can be tracked efficiently.

Event-driven workflows and streamlined communication between various stakeholders for study set-up

STUDY SETUP

STUDY EXECUTION

Transformation for Data-driven insights for site health metrics leading to efficient oversight

Rule-based reimbursements for automatic payments

STUDY EXECUTION

STUDY CLOSE OUT

Centralized atracking and monitoring of Agreements/documents

Business process transformation across different stages in clinical trial

Apart from business process automation, various other new-age technologies are creating an impact in clinical trial management.

Social media and online platforms aid in patient recruitment and retention by collaborating with them and reducing the burden of trial participation. Science 37, a clinical research company leveraged a telemedicine platform to conduct a virtual phase 2 trial. It screened more than 8000 individuals and enrolled 372 participants within seven months, thereby reducing projected enrollment time by approximately 30-50 %. With the help of **smartphones and connected devices,** it is possible to remotely monitor patients. A leading biopharma company used an application connected to smartphone sensors (accelerometer, gyroscope) to monitor patients in a multiple sclerosis study. Analysis found that results from remote patient monitoring were comparable to in clinic assessments. It is possible to mine huge amounts of data and derive insights smartly using **cognitive technologies like AI/ML.** Antidote, through its platform Antidote match mines data from clinicaltrials.gov and uses machine learning to create eligibility criteria for multiple studies. The Platform automatically generates a questionnaire by translating complex medical terms to easy to understand language for patients.

Blockchain technology helps to secure communication between stakeholders and bring in accountability and transparency into the reporting process of clinical trial, thereby providing secure and synchronized data submission. The technology helps in creating an inconvertible digital ledger to document, the single point of origin of a compound or a substance and the various compositional changes it undergoes through the various testing and approvals. Also, study protocols can be kept under cover until the study has been completed. Later the protocol can be verified without any concern about the study protocol being tampered.

Clinical trials generate a vast amount of data, sorting and management of this data is of critical importance. Sponsors of clinical trials rely on clinical data **visualization and analytics** to manage studies and make better "go/no-go" decisions based on real-time clinical trial metrics. Data visualization and business intelligence tools enhance risk-based monitoring by highlighting non-performing sites and triggering a monitoring visit, thereby reducing a monitoring cost.

A scalable and flexible platform capable of leveraging the new age technologies and overarching the existing applications in the clinical trial landscape and seamlessly integrating with them to act as a centralized point of access for information for all the stakeholders is imperative. It would offer a lot of benefits like:

- Better decision making in study management and portfolio optimization through increased availability of more accurate and measurable data

- Enhanced efficiency and effectiveness of clinical operations workflows through Business process automation, advanced analytics, and reduced complexity of the system landscape

- Higher patient compliance due to direct patient and caregiver engagement through the integrated digital platform

- Harmonized data formats leading to superior data quality

- Huge cost savings by enhanced productivity and efficiency

CONCLUSION

Increased clinical trial costs, coupled with a higher percentage of trial failures and an increase in patient-centric trials, have caused a surge in demand for technology adoption in clinical trials. The need of the hour is to envisage the future and step into the era of digital clinical trials.

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