

Digital Reimagination™ of Clinical Trials

Abstract

Digital technologies can help reimagine clinical trials, to overcome the common challenges of on-time patient recruitment, retention, adherence, and stringent clinical trial execution timelines faced by life sciences companies. The Digital Five Forces—mobility and pervasive computing, cloud, Big Data, Artificial Intelligence and robotics, and social media—offer opportunities to reimagine clinical trial processes.

Instilling Change with 'Digital' in Clinical Trials

Pharmaceutical organizations are constantly striving to optimally design and execute clinical trials in patients. These activities often consume a significant portion of the research and development (R&D) budget, and failing fast in trials is often considered as good as getting success. A report from the Tufts Center for the Study of Drug Development (CSDD) deduces that the cost of developing a prescription drug that gains market approval is US \$2.6 billion.¹ Companies are increasingly integrating R&D information for quicker and improved decision-making and leveraging computational methods and predictive analytics techniques to improve clinical trial productivity and success rates. As the healthcare ecosystem matures, there are tremendous opportunities to examine and fine-tune emerging patient-centric strategies in trials. Digital technologies offer new possibilities to reimagine clinical trials, and also bring about a paradigm shift in the way trials are designed, executed, and analyzed.

Changing Context and New Opportunities

The primary purpose of a clinical trial is to identify drug efficacy and safety parameters in humans. The timely completion of a trial depends on numerous factors, including site performance, timely recruitment of patients, dropout rate, patient adherence and compliance to the treatment, and the ability to take related decisions faster. As patient-specific factors can lead to delays during trials, a strong digital connect presents an opportunity to build trust with patients. Moreover, with the advent of technology, there are newer avenues to analyze trial information differently and generate more evidence.

Digital Clinical Trials

Pharmaceutical organizations are constantly striving to optimally design and execute clinical trials in patients.

A framework for the adoption of digital technologies comprises three levels:

1. Digital Enablement: Digitization initiatives for improving processes and systems
2. Digital Transformation: Digital initiatives to transform business processes and systems

3. Digital Reimagination™: Creating something fundamentally new, leveraging the Digital Five Forces

This framework can be followed to develop the concept of Digital Clinical Trials, encompassing transformation of the various clinical trial processes. A Digital Clinical Trial can be defined as one that:

- Brings a paradigm shift in the way a site plays a role during clinical trials
- Leverages the true potential of the Digital Five Forces for Digital Reimagination™ of clinical trials
- Takes full advantage of the evolving digital landscape in the healthcare ecosystem
- Reaps benefits from the evolving digital consumer economy and establishes trust with digital patients
- Uses innovative solutions to improve R&D productivity

The key drivers for Digital Clinical Trials are innovative patient-centric trial designs, improvements in productivity, and an increase in success rates.

Eli Lilly Unveils Innovative Digital Study Design Platform

At eyeforpharma's 2014 Patient Centered Clinical Trials, Thomas Krohn, Director of Clinical Open Innovation at Eli Lilly, showcased a breakthrough digital study design platform and process that study teams are currently utilizing. The system and process is not only improving the quality and efficiency of study design, but also enabling Lilly to execute patient-centric protocols.

Reimagining Clinical Trial Processes of the Future

From a futuristic perspective, digital clinical trial processes can eliminate the current risks and challenges by leveraging the capabilities of digital tools and techniques. This entails:

- **Overhauling Study Design:** Digital clinical trials deploy model-based study design where advanced analytics techniques are used to develop study models and optimize study parameters. These are based on real-world longitudinal patient data, historical trial data, and past trial² study experiences.
- **Digitizing Site Selection and Setup:** Digital clinical trials leverage advanced analytics-based selection of sites, relying on key factors such as past performance of sites, suitability for the trial, and risk prediction. Sites across the world can be ranked based on the historical site performance and external sources.³ This method incorporates digital site engagement, which includes a virtual tour of facilities, ranking and quality measurement, digital information exchange with sites, and digital training and engagement of site personnel.

Pfizer's social media clinical trial recruitment pilot

In an industry first, Pfizer used social media to recruit patients, and mobile phone and web-based technology to collect study data for a virtual clinical trial. The US Research on Electronic Monitoring of OAB Treatment Experience (REMOTE) study had FDA backing and aimed to increase patient compliance, lower withdrawal rates, and gather real-time data.

Boehringer Ingelheim Study Rewrites Clinical Equation, Removes Sites Entirely

Boehringer Ingelheim, United Biosource Corp., Healthrageous (a digital health management provider) and other partners are evaluating a behavioral modification program designed around an online digital health coaching tool, a home test kit, and a wireless glucose meter that transmits data directly to clinical monitors. The program is entirely patient-centric—no site visits, no travel, no time off work or weekends, and no hassle or inconvenience for the participant.

- **Improving Patient Connect:** Digital clinical trials offer complete digital connect with patients selected through screening of health records.⁴ They are informed and recruited in the trial digitally instead of at trial sites. According to a recent Tufts CSDD report, social media is being used to recruit patients in nearly 11% of all trials.⁵ During the trials, patients are engaged with various tools of telemedicine, eHealth, and mHealth, including adherence tools, compliance tools, visit reminders, patient query resolution workflows, and patient and family education.
- **Enhancing Trial Monitoring:** Digital clinical trials use advanced analytics and visualization for risk-based supervision of trials. This would include risk-based monitoring, remote site monitoring, and automated verification of information exchanged with sites. Innovative concepts include recording patient videos pre- or post-site visits, and noting their feedback and experiences using ePRO and eCOA tools as monitoring agents.

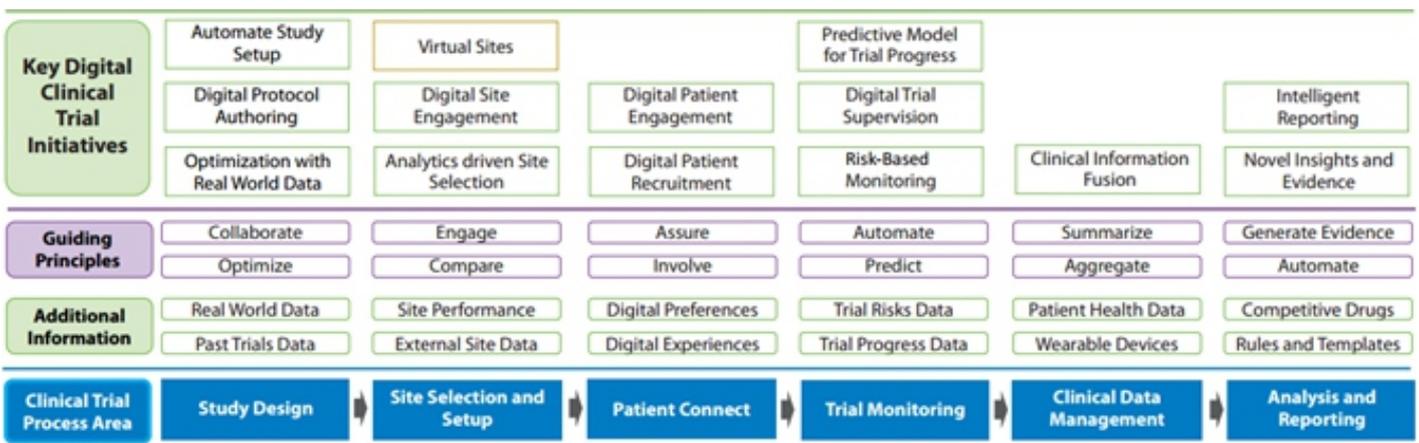
GSK experiments with digital biomarkers to optimize clinical trials

GlaxoSmithKline (GSK) is experimenting with wearable mobile health devices linked to cloud services in clinical trials as part of a bid to better engage with patients, speed up the process, and capture data more effectively. GSK is working with Medidata, Vital Connect, and ActiGraph to test six healthy human subjects and see how the wearable sensors perform. The joint initiative assessed the capabilities of mobile health sensors tools and evaluated how they could be used to enable a new model for clinical trial conduct that aligns site and patient needs with faster study execution and reduced costs.

- Improving Clinical Data Management:** Digital clinical trials perform clinical information infusion where cloud platforms collect and integrate patients' clinical data from various sources, such as from trials using Electronic Data Capture (EDC) systems, wearable devices, telemedicine support, and electronic medical and health records. This information is linked and stored in semantic repositories for auto aggregation and summarization for analysis.
- Refining Trial Analysis and Reporting:** Digital clinical trials leverage advanced and predictive analytics to generate novel insights and evidence on benefit risk assessment of drugs, patient subgroup performance, and the genetic basis of outcomes.⁶ It also integrates with real-world data for evidence on how the drug performs and its cost effectiveness in a clinical setting. Analysis output is fed into intelligent reporting systems where report sections are automatically generated and assembled.

Pfizer's Precision Medicine Analytics Ecosystem delivers better treatments

Precision Medicine Analytics Ecosystem is a program that connects the dots among genomic, clinical trial, and electronic medical record data to spot opportunities to quickly deliver new drugs for specific patient populations. The idea is to combine genomic data sets from internal and external sources using the platform's data standards and processing capabilities.



The digital clinical trial landscape, summarizing key initiatives, additional information that can be leveraged, and the main guiding principles across each process area of the clinical trial

Conclusion

Pharmaceutical organizations need to evaluate their preferences and priorities to finalize the roadmap to adopt digital clinical trials. Certain initiatives can be adopted horizontally across different therapeutic areas while others may be specific to a particular area.

The need of the hour is to envisage the future, with aspirational yet realistic targets, and step into the era of digital clinical trials. Prompt action by drug development companies has the potential to bring competitive differentiation in the way drugs are developed through clinical trials.

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