A DIGITAL REDESIGN FOR CLINICAL TRIALS

By Nate Beyor, Karalee Close, Nayel Hakim, Martin Shapiro, Michael S. Ringel, and Brendan Smith

Digital technologies continue to disrupt nearly every industry, including health care. Pharmaceutical companies are ideally positioned to benefit from today's innovative technologies, given the industry's massive data sets and difficult development cycles, but pharma R&D has thus far been slow to adapt.

With the explosion of electronic health records (EHRs) and the extraordinary penetration of both mobile technology and the Internet of Things, the right conditions are in place for digital innovation in clinical trials. To date, however, efforts have largely focused on digital replacement of existing standards—screens in place of paper—even though the more critical need is for a digital redesign of processes and workflows to take advantage of this fundamentally different medium.

A robust ecosystem of specialized startups is emerging, offering solutions to various challenges along the end-to-end R&D value chain, from study design and trial operations to data management and report writing. Companies that have adopted these digital tools are seeing impressive results: lower costs, improved outcomes, enhanced data quality and operational efficiencies, and shorter time to market for new products.

Barriers To Integrating Digital In Pharma R&D

The pace of digital adoption lags in health care, even as digital technology transforms many other industries.

Two key factors may make pharma companies reluctant to innovate: regulatory concerns and data privacy concerns. These issues are legitimate and should be faced head on. Regulators are increasingly open to the use of digital tools that promote appropriate use of medicine. In 2017, for example, the FDA initiated its Digital Health Innovation Action Plan, which provided guidance on digital health products and piloted a precertification program for software-based medical devices. And although updated guidelines on information

privacy—such as the EU's General Data Protection Regulation—do require new approaches to patient data management, pharma companies can, for the most part, ensure data privacy while still innovating by adopting offerings that already exist in the digital marketplace.

Leading companies aren't letting any such barriers stand in the way of innovation. In our work with pharma clients, we have seen digital technologies accelerate clinical trials, improve data sets, and lower costs. The key is to understand how to invest resources in a way that enhances pharma R&D today and establishes a strong foundation for the future.

What's Happening Now In Digital Clinical Trials—And What's Next

Owing to the complexity of clinical trials, there is no one-size-fits-all solution to the challenge of digitization. And given that pharma companies spend more than $50 billion annually in clinical development, it is no wonder that the opportunities for digital are so varied. Nevertheless, many specialized startups have started to gain real traction.

For the sake of simplicity, we can divide the clinical trial process into six stages: study design and protocol development; site selection and initiation; patient recruitment and enrollment; trial monitoring; clinical data management; and statistical analysis and report writing. (See the exhibit.)

In the subsections that follow, we outline how digital innovation is occurring across these stages and offer a preview of further advances that are right around the corner.

Study Design and Protocol Development

Startups are developing new, patient-centric offerings to enhance study design. Companies are pioneering siteless virtual trials that allow subjects to interact with investigators through video communication. With all-digital interfaces and minimal brick-and-mortar site requirements, companies can execute trials more efficiently and consolidate data more easily, accelerating the process at every step.

We expect to see this capability improve further in the future, as new engagement platforms emerge and offer innovative ways to capture data, monitor patients, and deliver care. Although the benefits of these standalone interventions in terms of clinical outcomes have yet to be established, the technologies' cumulative effects on patient engagement and on the timeliness of interventions will undoubtedly be positive.

Site Selection and Initiation

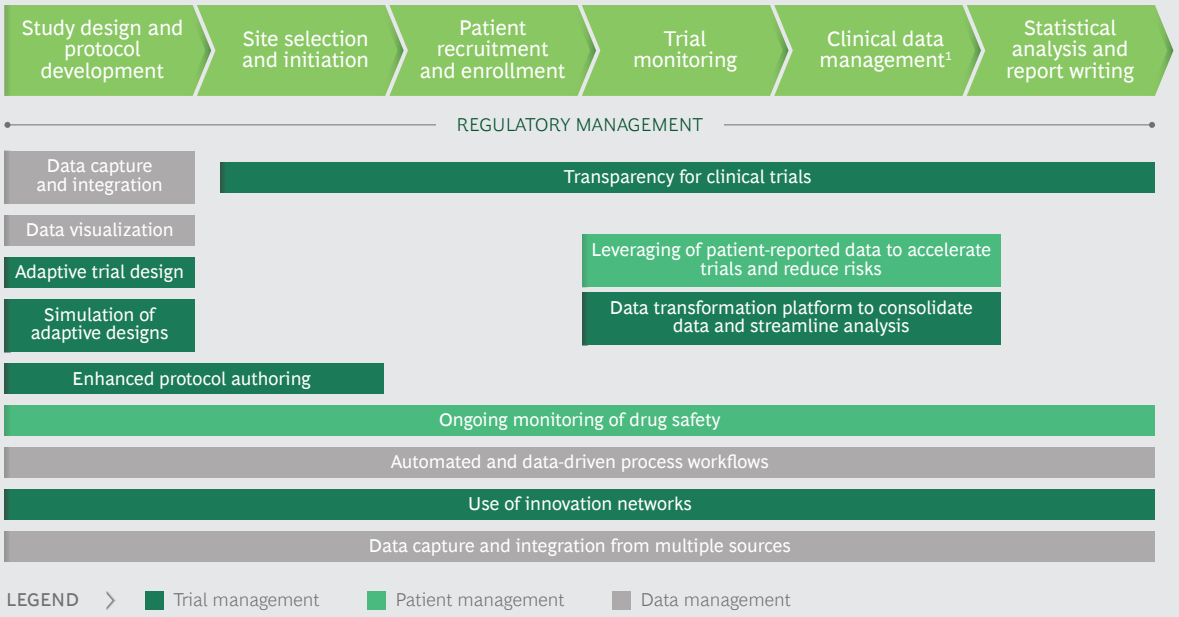
Several companies are reimagining the site selection and initiation process. By using cutting-edge analytics to stitch together multiple data sets, startups can enable evidence-driven site selection. They can also analyze data—from EHRs, claims and billing records, disease registries, home health-care records, and mobile devices—to identify new and previously inaccessible patient pools. And they can use artificial intelligence to analyze unstructured clinical data, including doctors' notes, pathology reports, and operating notes, to find patients that best match clinical trial criteria.

Clinical trial sites are using these tools to differentiate themselves from the competition and to partner more effectively with pharma companies throughout the site selection process. As these technologies scale and as algorithms for mining EHRs continue to improve, site selection will become an increasingly automated and data-driven process.

Patient Recruitment and Enrollment

While proper site selection is important, pharma companies must supplement it with a robust digital patient recruitment strategy. Clinical development teams typically advertise through traditional channels such as TV, radio, and print. But digital technology provides access to new hyper-targeted marketing approaches, and savvy digital marketers have rebranded themselves to enhance their competitiveness in this space.

Digital Innovation Can Enhance Every Stage of Clinical Trials



Source: BCG analysis.
[1] Includes data aggregation and cleanup.

Digital recruiting is already taking off, but many companies still haven't adopted digital consent forms. Innovative consent processes, such as those being deployed by Emilie Scientific, may enable companies in the clinical development arena to use technological advances to speed clinical trial recruitment and consent. We anticipate rapid development and significant impact in the development of digital consent.

Trial Monitoring

Digital innovation in trial monitoring has gained momentum as startups have begun using their existing platforms to support the clinical trial journey. As companies invest more in real-world evidence, patient-reported outcomes (PROs) will find their way more frequently into trials. For example, the Clinical Trials Transformation Initiative is a public-private partnership that publishes endpoint recommendations in order to facilitate the uptake of digital technology in clinical trials.

Thanks to remote hardware and electronic PROs, clinical development teams now have powerful tools for assessing, tracking, and intervening at levels that were not possible with traditional methods. In addition, because they can now remotely capture abundant data, companies can begin to unlock entirely new data sets, develop new statistical models, and identify more valuable endpoints to accelerate and increase the precision of trials.

Clinical Data Management

The official start of a trial marks the beginning of a rich data-generation phase that offers multiple opportunities to aggregate, analyze, clean, and visualize data sets. Specialized companies are gaining healthy momentum from their offerings in clinical data management, electronic data capture, and the burgeoning field of electronic clinical outcome assessments.

Statistical Analysis and Report Writing

Mapping electronic data capture to a study data tabulation model (SDTM) is a challenging process that traditionally consumes large amounts of time and resources. Organizations follow many different processes in creating SDTM domains. Not only is the ability to store, extract, and reuse metadata critical with regard to the trial in question,

but also it can accelerate future studies. Effective use of technologies such as machine learning can help standardize data sets, integrate legacy data, and improve data analysis and visualization. There is still plenty of room for growth in this area, particularly as neurolinguistic programming and machine learning technologies mature in the coming years.

A New Approach To Digitization

Often, companies undertake digitization with a focus on straightforward digital replacement—that is, by digitizing tasks previously done with pen and paper. But it is not enough to take a long, paper-based survey and translate it into a digital document. Instead, companies need to change their approach fundamentally. Digitization offers an opportunity to create a more clinically valuable tool, such as a short, daily, electronic symptom tracker.

Digitization typically progresses through three stages:

- Examination of existing data sets to obtain a baseline for current operations
- Exploration of ways to access new data, such as by using patient health records and digital engagement metrics, to support more-nuanced decision making
- Analysis of data patterns and introduction of new processes to drive continuous improvement

Given the complexities of clinical trials and the intricacies involved in each step of the process, pharma companies cannot use digital technology as a hammer. Instead, they must experiment case by case to determine the use cases that deliver maximum value. New platform technologies designed to collect data and optimize through multichannel experimentation are becoming more sophisticated all the time, and companies that identify the right opportunities can dramatically accelerate the pace and success of their clinical trials.

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