Reimagining clinical trials in the age of the digital patient

Deloitte
Biopharma R&D has helped change the face of disease management over the years. Yet many in the field admit that clinical development has fallen behind in adopting digital technologies, which have the potential to change how research organizations can engage with patients, innovate in patient care, and execute processes to drive efficiencies. To access other Deloitte content on this topic, please visit [www.deloitte.com/us/life-sciences-randd](http://www.deloitte.com/us/life-sciences-randd)
Introduction

In 1943, the first modern clinical trial for treatment of the common cold was conducted in Great Britain. Over 1,000 patients from across the nation participated in the double-blinded trial. Each patient traveled an average of two to three hours by train or car to reach a single, centralized trial location. All observations by clinical investigators were written by hand, and it took 18 months to synthesize the results and generate a report.

When looking back on this trial from a 21st-century perspective it appears archaic: Patients had to go to great lengths (and distances) to participate; had little visibility into the trial results; and received minimal amounts of their own clinical trial data. Clinical investigators, meanwhile, had to perform their jobs using a limited set of diagnostic tools and paper-based recording devices.

What may be surprising is that the 1943 common cold trial and modern clinical trials have significant similarities:

• Trials are still largely conducted at physical sites, requiring the average patient to travel over an hour to participate.
• Paper is still used to document certain trial processes (such as medical products’ chain of custody).
• Trial operators still take months, or longer, to complete their analyses.
• Trials still require substantial financial investments.
• Patients still have limited visibility into their clinical trial data and are not able to seamlessly share that data among their medical providers.

Although yesterday’s and today’s trials share a number of traits, significant progress has been made in digitizing clinical trial processes and health data. Clinical data is now largely collected through electronic data capture (EDC) systems; patient medical records are digitized in electronic health records (EHRs); and patients can give electronic consent for research organizations to leverage their information. These advancements, and others, have given rise to the over 30,000 trials now conducted annually.

Still, despite investments in digitization and the rise in the number of trials and subsequent medical breakthroughs, a puzzling situation is emerging: Patient engagement is decreasing. Two-thirds of trials today do not have enough patients enrolled, and 30 percent are cancelled after they start due to insufficient participation.

This lack of patient participation may be partially explained by a disconnect between patients’ clinical trial expectations and experiences. Patients’ lives today are increasingly digital and they have been conditioned to expect technology to deliver significant conveniences. While clinical trial operators have digitized certain processes, they are not yet able to deliver the seamless experience that patients have come to expect from non-health care industries.

The content of this paper:

• Outlines the key digitalization trends that are affecting patients and how these patients expect clinical trials to meet them on their terms
• Summarizes trends that have potential to further transform and disrupt patient health care experiences
• Defines how clinical trials can be reimagined across pre-trial, mid-trial, and post-trial activities
• Describes the key processes, industry ecosystem partnerships, and technologies that are needed to bring this reimagination to life.
• Builds upon research Deloitte published previously on how digital technologies can transform clinical development.
Rise of the digital patient

Our growing reliance on digital devices and communications—the Internet and its instantaneous access to information, social media, online shopping and banking, smartphones, the list goes on—has turned us into digital consumers who expect every product or service interaction to be a seamless, omnichannel experience (figure 1). And if an industry or company can’t meet our expectations, chances are they will be disrupted by someone who can.

Take, for example, the taxi industry. Consumers historically accepted the inconvenience associated with hailing a cab—until the combination of industry inaction, smartphone proliferation, and global positioning system (GPS) advances enabled Uber and Lyft to rapidly penetrate the market and disrupt the taxi business. The result can be seen in 65,000+ Uber vehicles operating in New York City versus 14,000 yellow taxis.4

Consumers’ expectations for a seamless digital experience in health care tend to be lower than for other industries. This is attributed to, in part, the perception that health care is significantly more complex than other types of services; also, patients ascribe much of the quality of their health care experience to the medical providers with whom they directly interact. Patients may be frustrated by having to fill out paper medical history forms, but they overlook this inconvenience if their nurse/doctor is capable, friendly, and engaging.

Yet, this situation is changing. New digital health products and services that originated in the consumer market, such as wearables, smartphone apps, and social media-based disease support groups, have started to alter what patients expect from the health care industry.5 In fact, a 2018 survey of 650 patients revealed that 92 percent believe that improving experiences (such as through innovative technologies) should be a top priority for the health care industry, up from 71 percent in 2017.6 A trend toward digital health is also evident in the startup market: $8.1 billion in capital was funneled into new technology-based health care organizations in 2018. This represents a 42 percent year-over-year increase.7

Figure 1. The digital consumer

Streaming entertainment  Social media  Smartphone apps  Wearables  Online banking  Digital news  Instantaneous information
We are witnessing the rise of the digital patient, in which expectations from consumer-oriented product and service experiences are crossing over into the health care industry. However, much work still needs to be done to move health care onto a more equal, digital footing with other industries. The disparity is acutely evident in clinical trials, where there are significant digital gaps in the way processes are performed (e.g., finding a trial) versus how similar consumer services are provided. Figure 2 provides examples of these discrepancies.

## Figure 2. Clinical trials vs. consumer services

<table>
<thead>
<tr>
<th>Clinical trial process area</th>
<th>Similar digital consumer service</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Finding a clinical trial</strong></td>
<td><strong>Finding a hotel online</strong></td>
</tr>
</tbody>
</table>
| On average, finding a clinical trial is a manual and cumbersome process that takes 4+ weeks, as patients commonly need to search through a centralized government website (NIH.gov) and read extensive information before identifying a suitable clinical trial.


<table>
<thead>
<tr>
<th><strong>Matching with a trial</strong></th>
<th><strong>Matching with a date via an app</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>To match with a trial, patients need to submit extensive medical documentation and other information to the trial organizers, and then wait an extended period of time to hear whether or not they are a match. Trial-matching services are emerging but remain limited in scale.</td>
<td>Matching with a date through an app is as seamless as reviewing a person’s biography and signaling if you like them by simply swiping on a mobile screen. If the other party feels the same, then both are notified immediately that a match has occurred.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Participating at a trial site</strong></th>
<th><strong>Banking virtually</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials are primarily held at a physical location—such as a hospital—that requires patients to constantly travel to the site to receive their medication and/or be monitored. The use of virtual or remote trials is growing but is not commonplace.</td>
<td>The highly regulated financial industry has made it possible for consumers to easily conduct traditionally in-person transactions (e.g., depositing a check, obtaining a loan) virtually using a mobile app. People can plug into the global financial system almost anywhere via their smartphones.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sharing medical information</strong></th>
<th><strong>Sharing information across platforms</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>During and after a clinical trial, the ability to share medical information with a patient may be confined to a limited set of data (e.g., lab results) and is usually shared through a point-to-point solution—such as an electronic medical record (EMR)—that may lack interoperability with a patient’s other health devices (e.g., smartphone app) or with their other providers’ systems.</td>
<td>Consumers typically find that they can share virtually any type of information (messages, photos, documents) across multiple information-sharing platforms. It doesn’t matter if someone is using an Android or Apple phone; they can still communicate with one another without issue.</td>
</tr>
</tbody>
</table>
In addition to current trends giving rise to the digital patient, two others are emerging that may further alter patient expectations for the health care industry and, potentially, disrupt established players. These include development of an electronic life record and monetization of patient medical data.

The electronic life record

Traditional electronic health records (EHR) track a patient’s medical history, notes from their doctors, lab results, prescriptions, and similar data. However, a recent study from a leading health plan determined that the information captured in an EHR represents just 40 percent of the factors that impact a patient’s health. The other 60 percent, including lifestyle and behavioral factors, are tracked and stored elsewhere—often, completely outside of health care. This gap represents a lost opportunity to conduct data analyses that could be used to more accurately predict a patient’s health.

Among pertinent lifestyle and behavioral factors are:

- **Socioeconomic data**: Income/occupation, education, household composition, zip code
- **Behavioral data**: Exercise regimen, diet, grocery purchase patterns, medication adherence, stress monitoring
- **Financial data**: Household income, spending categorization, financial stressors

When a consumer goes to the grocery store, for example, each scan of a product barcode builds a repository of their purchasing history that the store can use to push discounts or special offers to the consumer. Feeding this information into the consumer’s EHR could allow medical providers and clinical researchers to determine if a patient’s diet was affecting their health or causing adverse reactions to their medication.

This convergence of different types of data (health, socioeconomic, behavioral, and financial) is already starting to take shape. New health and wellness mobile applications allow consumers to input personal information (nutrition, exercise, financial) to create a more holistic profile of their life.

This trend, albeit still in its infancy, could give rise to an **electronic life record (ELR)** that expands the boundaries of a traditional EHR. If ELRs come to fruition, patients may require that clinical trials accept their version of the ELR as both the repository of their life history and the de facto platform that will track their medical activity during and after a trial.

Monetizing patient data

Over the last decade many companies have become successful not by creating new, innovative products or services but by figuring out how to leverage and monetize consumer data. Facebook, for example, has grown into one of the world’s largest companies by capturing user data and developing targeted advertisements. Similarly, Google tracks users’ GPS movements and mobile app use; this allows the company to optimize its search algorithms and enable brands to target consumers with advertisements at opportune moments. These examples illustrate how consumer data has become an extremely valuable asset—one that is likely to continue growing in value as more data is captured across digital devices and platforms.
Moreover, regulators and consumers also recognize how valuable data is and are starting to push back against technology companies. New regulations are beginning to emerge that place greater privacy restrictions and transparency obligations on how companies can use a person’s data. The governor of California recently proposed that citizens be paid a “data dividend” for the value that technology companies derive from their data. At the federal level, the bipartisan DASHBOARD Act has been proposed in the Senate; it requires technology companies to disclose the financial value of a user’s personal data.

In the health care industry, the value of patient data has always been well understood. Pharmaceutical organizations, for example, have proved willing to pay for access to rich data sets. Roche recently paid over $1.9 billion for Flatiron Health, a health IT company that applies big data approaches to medicine, including clinical trials.

There has long been an ecosystem of companies aggregating and processing personal health data for the purpose of monetizing it. As interoperability progresses and consumer control advances, the value added by data aggregators is likely to lessen and monetization opportunities shift to the consumer.

The rise of connected health devices is generating increasing amounts of relevant health data that provides patients with new opportunities to take a leading role in consolidating their data and, ultimately, being compensated for its use. The rise of the ELR may further empower patients with richer and more diverse data sets that they can donate or sell to clinical research organizations. Moreover, recognition of data’s value may result in patients demanding that they receive access, ownership, and control over their clinical trial data.

“The rise of the ELR may further empower patients with richer and more diverse data sets that they can donate or sell to clinical research organizations.”
The rise of the digital patient, heightened expectations for a more seamless and digital health care experience, and potential challenges arising from ELR and patient data ownership issues, place the future of clinical trials at a critical juncture. Trial sponsors and operators should consider responding by:

1. Reimagining how digital technologies can improve the patient experience in a clinical trial
2. Identifying the processes, ecosystem partnerships, and technologies that will be needed to create these new patient experiences

Reimagining the patient experience

Pharmaceutical sponsors, clinical sites, and investigators can apply learnings from consumer-oriented industries to pre-trial, mid-trial, and post-trial processes to reimagine the patient experience across the end-to-end clinical trial journey.

In general, the patient experience should be consistent across the trial continuum (pre-trial, mid-trial, post-trial), and trial sponsors and operators should identify ways to make trials more patient-friendly. Figure 3 on the following page identifies key patient journey points that may benefit from being reimagined.
Reimagining clinical trials in the age of the digital patient

Figure 3. Clinical trial reimagination opportunities

Pre-trial

**Simple trial searching**
Similar to an online travel service that provides hotel recommendations based on user preferences, patients interested in participating in a clinical trial should be able to effortlessly search for available trials online with the assistance of digital advisers who provide guidance and aid in the decision-making process.

**Automated trial matching**
Similar to online dating, once a patient identifies a trial they want to participate in, they should be able to submit their digitized medical history (through their EHR or personal tracking apps) and receive a fast response indicating either that they have been matched or explaining why they were not selected; the latter should include a recommendation for a different trial.

**Full trial e-consent**
Similar to the step-by-step guidance digital tax services provide, once a patient is selected for a trial they should be guided through steps that: 1) clearly describe what they will experience and what data will be sourced from them; and 2) request their electronic consent, which will span the course of the trial.

Mid-trial

**Real-time reviews**
Similar to rating a rideshare driver, patients should be able to give real-time feedback to the trial sponsor, clinical site, investigator/health care provider (HCP) with whom they interact so that their voice is heard. A positive rating also can be a competitive differentiator for sponsors.

**Data synchronization**
Similar to communicating across mobile platforms, data generated during a clinical trial (e.g., lab results, trial notifications) should be provided in an interoperable format that can work with a destination of their choosing, such as a health app on their phone or another provider’s health system.

**Remote participation**
Similar to a virtual learning course, patients participating in a clinical trial should be able to access their medication, track vitals, confirm adherence, share data, and interface with a doctor virtually from the comfort of their home.

Post-trial

**Data exchange**
After a trial has been completed, patients should receive access to all of their captured medical information and be given the option to “donate” this data to the sponsoring organization for clinical research or to other philanthropic causes.

**Data marketplace**
Patients should be given the opportunity to monetize their data by selling or leasing access to other research organizations or by combining it with their lifestyle information to substantiate their ELR.

**Support groups**
Similar to social media interest groups, patients should be able to connect with other participants post-trial (to ensure blindness issues do not arise) to discuss their experience and support each other.
If this future vision of the clinical trial patient journey can be realized, the patient’s perception of clinical trials—and, by extension, the clinical trial process in general—could improve significantly. This, in turn, could lead to increased enrollment rates, longer trial participation, and a strong patient commitment to the trial’s outcome.

**Enabling processes, ecosystems, and technologies**

Reimagining the patient journey requires reimagining clinical trial processes to support patient interactions; developing new ecosystems and partnerships to better collaborate; and employing innovative technologies to better share and analyze data (figure 4).

It is likely that a number of traditional trial processes will need to be altered and simplified to create more seamless patient experiences. Trial design, for example, should stipulate the procedures for sharing data with patients during and after a trial. Moreover, external processes that directly impact the patient also will need to be adjusted. For instance, the process for investigator/HCP interaction with patients through a virtual tool may require user training.

Process improvement and simplification should be coordinated across a trial sponsor’s ecosystem of partners to break down barriers and create smooth hand-offs so that the patient does not experience any disruption. Moreover, existing ecosystems may need to be expanded to include other technology companies and health startups so that a rich network of tools and services that assist patients (e.g., health improvement apps, social media groups) can be mobilized to augment patient support.

Additionally, as these reimagined processes and ecosystems naturally develop, there should be a concerted industry effort to adopt standards so that, regardless of the trial location or sponsor, a patient has a consistent experience.

**Figure 4. Patient journey—enabled by processes, ecosystems, and technology**

- **Processes**: Reimagining clinical trial processes to support patient interactions.
- **Ecosystems**: New ecosystems and partnerships to better collaborate.
- **Technology**: Employing innovative technologies to better share and analyze data.
Lastly, new forms of technology can be critical enablers to achieve simplified processes and better coordination among ecosystems. Specifically, the following technologies may play an outsized role in the reimagined clinical trial:

• **Blockchain**, the distributed ledger technology, will help create the “information backbone” through which information is shared throughout a clinical trial. Blockchain can enable information to be more easily shared across the boundaries of organizations participating in clinical trials and allow patients to establish their own digital identity on the network and use it as a platform to access data as well as provide consent.

• **Artificial Intelligence (AI)**, computer systems that can automatically perform tasks and compute complex calculations, will help streamline previously repetitive processes that caused friction for both patients and site staff. AI will also enable processing of large amounts of data to help uncover potential risks or issues during the trial, provide reminders or real-time assistance to patients, and support and augment investigators/HCPs by providing important information.

• **Mobile/connected devices**, smartphones and wearables that track and/or store patient-owned and -controlled information, will be key mechanisms to virtually and remotely track and solicit data from trial patients. These devices also may act as a platform where information and communication can be disseminated to patients throughout the trial.

Figure 5 highlights examples of how the combination of processes, ecosystems, and technologies will symbiotically work in the “background” of the reimagined clinical trial to help enable the patient journey and improve the patient experience.
## Figure 5. Process, ecosystems, and technology examples

<table>
<thead>
<tr>
<th>Reimagination opportunity</th>
<th>Key process area</th>
<th>Required ecosystem</th>
<th>Enabling technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication delivery for remote trials</td>
<td>Clinical supply chain</td>
<td>Manufacturer, distributors, &amp; clinical sites</td>
<td>Blockchain</td>
</tr>
<tr>
<td></td>
<td>The process of ordering, tracking, and delivering medication can be enhanced to deliver medication to a patient during a remote/virtual trial.</td>
<td>Coordination across the entire supply chain ecosystem will be needed to ensure that the right medication reaches the right patient at the right time.</td>
<td>This technology can enable various supply chain entities to effectively share information through a distributed network to create end-to-end visibility that will reduce product waste and improve overall clinical trial efficiency.</td>
</tr>
<tr>
<td>Real-time reviews</td>
<td>Patient monitoring</td>
<td>Sponsor, clinical site, investigators, HCPs</td>
<td>Artificial intelligence</td>
</tr>
<tr>
<td></td>
<td>The process of surveying a patient’s sentiment and well-being can be altered to include real-time feedback throughout the clinical trial journey.</td>
<td>These stakeholders will need to outline the key milestones that will create patient feedback opportunities and ensure that action is taken to address criticisms.</td>
<td>AI-enabled assistance (e.g., Alexa or chatbots) could be leveraged to ask patients to rate their experiences and solicit specific information through a guided conversation.</td>
</tr>
<tr>
<td>Data synchronization</td>
<td>Study design</td>
<td>Sponsor, clinical site, investigators, HCPs</td>
<td>Mobile/connected devices</td>
</tr>
<tr>
<td></td>
<td>A new process can be added to the study design to account for the data types that will be shared during and after a trial. This includes identifying those data elements to which the patient must be blinded during the study and those which are unblinded.</td>
<td>These stakeholders will need to work together to coordinate tracking and analysis of patient data that ultimately will be shared.</td>
<td>Connected devices could serve as one of many potential endpoints where patient data could be stored.</td>
</tr>
<tr>
<td>Data marketplace</td>
<td>Post-trial data return</td>
<td>Multiple sponsors and other clinical research institutions</td>
<td>Blockchain, AI</td>
</tr>
<tr>
<td></td>
<td>A new process can be established to intake data from patients participating in a marketplace, be it through their donating data or companies purchasing data from them.</td>
<td>An industry-wide marketplace will need to be established where patients from different clinical trials can co-locate to make their data available.</td>
<td>Blockchain can be used to establish a decentralized marketplace network where no sponsor has an outsized role and where patient identities are shielded until a transaction agreement is completed. AI can be used to analyze data sets (non-patient identifiable) to determine which ones match a sponsor’s needs.</td>
</tr>
</tbody>
</table>
Moving forward

Thus far, the health care industry has incrementally moved toward realizing this paper’s vision of the digital clinical trial. If this future is fully realized, the reimagined clinical trial could significantly and positively impact both the health care industry and patients. Still, questions remain:

- Will digitization meaningfully increase patient participation in clinical trials? If so, will this lead to measurably faster drug development times and reduced costs?
- Will a patient’s digital expectations for other parts of the health care industry change based on their improved digital experiences in clinical trials?
- Will incumbent organizations’ business models become disrupted by startups that are able to provide new digital experiences? (See Deloitte’s publication on the future of health, which outlines potential business models in the year 2040.)
- With more access and ownership over their health information, will patients be more willing to share, lease, or sell it for clinical research? Or will privacy concerns lead to patients becoming more protective of their data?
- Will additional regulations be needed to monitor and protect patients as they gain greater access to and control of their health information?
- Will unintended consequences occur as a result of increased patient access to and ownership of their health data? As an example, could patient health data be traded like a “financial stock” in the future?

It is unclear at this point if any of the possibilities outlined in this paper will come to fruition. Yet, increased collaboration among commercial companies, government regulators, and patients may help to move forward the reimagined clinical trial in a positive way.
Reimagining clinical trials in the age of the digital patient

Authors

Deloitte

Aditya Kudumala
Principal
Deloitte Consulting LLP
akudumala@deloitte.com

Adam Israel
Manager
Deloitte Consulting LLP
adisrael@deloitte.com

Munther Baara
Clinical Innovation Expert
LinkedIn

Craig Lipset
Clinical Innovation Expert
LinkedIn
Endnotes


