Trend 4: The increase in virtual trials tips the balance toward remote interactions, improves patient data, and lowers the cost of clinical trials

- Modern technologies including telemedicine, digital health tools, AI, and machine learning help researchers reach a wider clinical trial participant pool through cost-efficient virtual trials, gather data accurately, and generate richer insights.
- A hybrid approach that combines both virtual and in-person clinical trials can deliver significant benefits but creates its own challenges, including compliance and potential difficulty interacting with researchers to address problems.
- We expect that hybrid trials will bring beneficial medicines to patients more quickly and less expensively, through robust data governance, transparency, and participant connections that realize efficiency benefits while mitigating risks

Companies are increasingly exploring virtual trials as a path to reduce drug time to market, an even greater imperative as drug development costs have spiraled into billions of dollars. Virtual trials can reduce patient dropout rates, accelerate enrollment, and increase data collection. A variety of technologies enable this trend, including telemedicine, wearables, and biometric sensors. Virtual clinical trials also improve

health equity by increasing access to a broader and more diverse patient population and providing researchers with richer data.

However, the need for in-person clinical trials persists because technological inefficiencies and talent shortages impede the ability to scale virtual trials – and patients will also want to see the doctor in person. Many practitioners lack the technology proficiency to conduct virtual trials, and they do not trust these outcomes as much as in-person trials. Initial virtual trial setup is often more expensive than for traditional trials, though speed to market and other factors do offset these costs. Additionally, many trial designs do not translate well to virtual models, such as for patients with Alzheimer's disease.

Hybrid models combine virtual and in-person trials and can optimize outcomes and reduce costs. Technologies including AI improve hybrid trials by detecting, analyzing, and improving patient clinical trial experience. For example, AI tools can analyze not only patient voice content but also their expressions and tone of voice. This behavioral data, combined with other datasets on factors like social determinants of health, improves the richness of data and, potentially, health outcomes.

Enhanced patient experience

Elements of modern clinical trials have existed for centuries. However, the gold standard of randomized controlled trials only dates to the 1940s. After decades of fine-tuning these processes, researchers are again discovering new ways to advance medical knowledge, reduce suffering, and save lives.

Traditionally, clinical trials have been conducted at hospitals, laboratories, and other centralized locations — all under the watchful eyes of medical professionals. This approach has generally served researchers well. However, it is time-consuming, expensive, and limits the trials' potential population, a primary research challenge.

For the past decade or so, researchers have experimented with virtual trials that allow participants and physicians to engage in trials from any location, with data collected and collated digitally. Remote patient monitoring, wearable devices, artificial intelligence, and other virtualization tools allow life sciences companies to create remote clinical trials that can be as effective as, and in some cases more effective than, conventional trials.

Virtual clinical trials leverage digital technologies across the clinical trial process, from design to patient recruitment to analysis and sponsor reporting. Some technologies enable continuous monitoring using wearables, sensors, health monitors, and even ingestible devices that provide practitioners near real-time visibility.

Unlike traditional trials conducted at bricks-and-mortar research facilities, virtual trials allow remote participation in studies using telemedicine and digital health tools. "Virtual trials aim to make clinical research more patient-centric and inclusive," says Ian Storr, associate partner, healthcare and life sciences R&D lead, EMEA, Infosys Consulting. (See Figure 1 for a summary of critical differences between traditional and virtual clinical trials.)

Figure 1. Differences between traditional and virtual clinical trials

Feature	Traditional clinical trials	Virtual clinical trials
Location	Conducted at fixed physical sites	Site-less: Participants engage remotely from any location
Participant access	Geographically limited	Geographically open
Data collection	Periodically, through in-person visits to trial sites	Continuous and real-time
Patient engagement	In person	Remote and digital
Cost	Higher operational costs	Lower operational costs
Regulatory acceptance	Established	Evolving

Source: Infosys Knowledge Institute and Infosys Consulting

Virtual trials have several advantages over traditional trials. First, they are less invasive. Use of sensors in these remote trials can collect minute details such as patterns of patient movements, gait, pace, chest expansion while breathing, steadiness, and so on – all without the patient having to manually record and share that data. A patient just needs to be within a reasonable range of the device that's in their house, according to David Champeaux, lead partner, health and life sciences, EMEA, Infosys Consulting

The sensors that virtual trials use provide more and better data that is less prone to bias. This creates an environment conducive to better insights, thanks to continuous monitoring that extends into real-world settings. Data collected in this manner is more accurate and comprehensive. This is data that would not be otherwise captured, and is continuous, rather than only capturing a single reading at a point in time. Finally, virtual trials increase diversity and inclusion – in the sociodemographic sense, but also in that they can include geographically diverse participants, such as those with rare diseases.

"Neither patients nor investigators of rare diseases are concentrated geographically. A hybrid clinical trial design requires the patient to visit the investigator site only periodically, greatly reducing the time and travel burden," observes George Hunnewell, senior vice president and general manager, US, BASE life science.

Researchers have long struggled to create trials that balanced people of various ethnicities, ages, genders, and income levels. The US Food and Drug Administration's 2015-2019 Drug Trials Snapshot found that only 7% of trial participants were Black, slightly more than half their percentage in the overall population. Hispanic residents in the US were also underrepresented, while white and Asian residents were overrepresented.

Champeaux notes the importance of identifying and enrolling a diverse group of patients into trials and to connect additional datasets during clinical trial research. Beyond information from electronic health records, these datasets will help researchers understand social determinants of health, broader social context, and life experiences.

Start-up costs are a hurdle

For many the entry point to these virtual trials has been driven by cost. In the US, clinical trials account for about 40% of research and development costs. Researchers found that because of recruitment challenges, more than one fifth of some medical trial categories end early or are closed. Approximately 80% of trials are delayed, at significant cost against expected regulatory filing commitment. The cost of these challenges adds up quickly for life sciences companies. In the US, organizations spend about $6,500 to recruit each patient for a study, and dropout rates often top 30%. When researchers must replace a person for noncompliance, the cost to recruit a new patient averages $19,533.

Cost–benefit analysis shifts

Despite the steep initial cost, the life sciences sector is investing heavily in virtual trials, establishing a clear trajectory toward adoption, powered by manufacturers and capital markets. The market was estimated at $8.6 billion in 2023, with an anticipated compound annual growth rate of 7.1% from 2024 to 2032.

Although virtual trials are expensive to start, one of their key advantages is that they reduce the length of clinical trials – reducing the cost of trials. According to one study, the virtual clinical trial can bring down the median duration of the trial from 16 months to four months. Experts estimate that virtual trials reduce study costs by 25%.

With advancements in AI and generative AI, especially its ability to handle data, the cost-benefit analysis of implementing virtual trials will shift. This will lower the cost of clinical trials for companies. Life sciences companies are likely to further increase their investment in virtual clinical trials in the next five to seven

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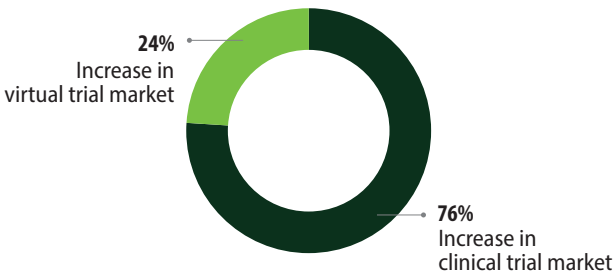
years, with the goal to reduce clinical trial cost from the current 40% to 50% of the overall R&D investment. In our estimate, the increase is expected to contribute approximately 24% to the overall projected growth in the expenditure of clinical trials market over the next two years (Figure 2).

Our research backs this up as well. Analyzing our survey data and data from other proprietary and public sources found that companies are currently increasing spending in virtual clinical trials. Our conservative estimate anticipates the virtual clinical trials to increase by nearly $1.5 billion in the next two years, with average increase of $750 million each year (Figure 3). This huge investment will most likely come from the largest revenue companies (greater than $10 billion).

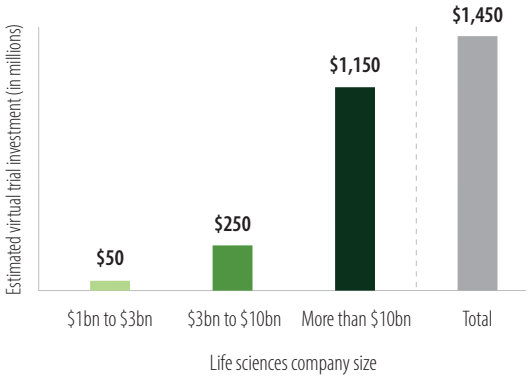
We also surveyed several subtrends supporting hybrid trials (Figure 4). Of the investment options covered, the highest priorities were decentralization and data-driven patient centricity. However, the distribution for the top four priorities was

Figure 2. Virtual clinical trials market expected to increase over the next two years



Source: Infosys Knowledge Institute

Figure 3. Virtual trials to increase by nearly $1.5 billion in the next two years



Source: Infosys Knowledge Institute

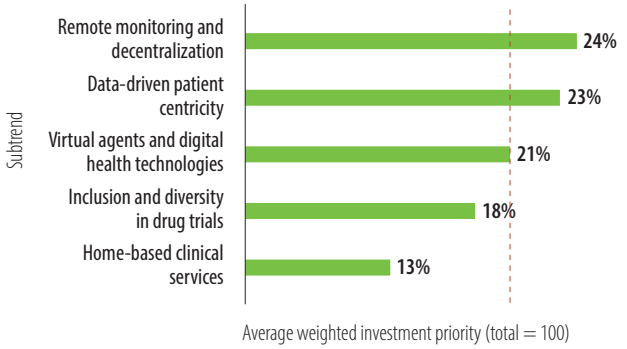
tight, with virtual agents and diversity in trials following with slightly lower priority. Homebased clinical services stood out as the lowest investment priority investment area.

Our further research indicates that the pharmaceutical industry is committed to increasing diversity and inclusion in clinical trials. In 2022, a multi-institutional study of 32,000 people in the US who participated in new drug trials in 2020, only 25% were Black (8%), Asian (6%), or Hispanic (11%) — compared with the 40% these ethnic minority groups comprise in the US population. This disparity is relevant because social determinants of health — everything from age to ethnicity to geography to environmental conditions — affect the way people experience a disease.

Looking ahead: AI innovations

Technologies are evolving to support this changing field, providing the life sciences industry with innovations designed to simplify, enhance, and even transform

Figure 4. Life sciences firms prioritize decentralized trials and data-driven patient-centricity



Note. Percentages do not total to 100 due to rounding.

Source: Infosys Knowledge Institute

clinical trials. In the next phase of virtual trial development, AI is expected to shape how medications and treatments are created, tested, and approved. Generative AI will enable companies to better understand the patient experience — a perennial challenge in clinical trials.

Anne Bichteler of Infosys Consulting describes a virtual trial scenario where AI-enabled voice companions accompany patients throughout their day, asking them how they are feeling and reminding them to perform critical steps to adhere to trial protocol. Then this data and face-reading technology detect and analyze sentiment, providing insights into how people physically experience a clinical trial.

When practitioners have access to these nonverbal messages, they can pinpoint early signs that a patient is considering dropping out and suggest solutions.

In addition, Bichteler says that natural language processing and sentiment analysis can predict patient adherence to protocols, dropout, and later behaviors.

Combined with behavioral science expertise, researchers can adapt trial elements to provide a frictionless patient experience. Technology can also reinforce positive behaviors and improve patient experience, engagement, and attrition.

Life sciences companies are also tapping into the strengths of machine learning to find patients for clinical trials. Amgen, Bayer, and Novartis are training AI to scan health records, prescription data, and insurance claims to locate patients quickly and accurately. Virtualization dramatically increases the patient population, so AI is a natural fit to digest this volume of data. If algorithms are designed well, this approach also decreases the risk of physician or researcher bias.

In addition, generative AI can be used to normalize electronic health records data that is unstructured and difficult to parse. The Truveta Language Model transforms electronic health records into clean, accurate data that researchers and physicians can use to improve patient care and trial outcomes.

Results are already promising. In our survey of life sciences leaders, 19% say that AI or generative AI is currently generating returns on their investment in the virtualization of clinical trials.

Another 40% say that it will achieve ROI within the next three years. And a large majority (80%) say the technology will or probably will achieve ROI in trial virtualization

in the next three years. These developments not only benefit companies but carry implications beyond virtual trials. Wearable or ingestible devices designed for remote patient monitoring can be adapted for use across digital therapeutics. (See Trend 2.)

Challenges for virtual trials

Although virtual trials offer significant benefits, they also demand more from patients in some ways and create new challenges while they attempt to solve existing ones.

In both in-person and virtual trials, researchers must train patients to meet trial expectations, such as dosing compliance and data collection, and minimize errors that result from unfamiliar devices or medication protocols. Patients need comprehensive training to ensure they clearly understand instructions and avoid actions that skew the results. Researchers must provide patients with regular reminders of study rules.

Virtual-only trials also risk creating new biases. Groups less comfortable with technology —older people and others that are less tech savvy — might not participate. To take part in a virtual trial, participants must learn and engage with the platform and perhaps new technology. They might have low confidence in the technology and not trust that their data is secure and private. In these cases, the tools empowering virtualization become a barrier to entry or increase the likelihood that patients will drop out.

The distancing effect of technology might cause patients to be more candid, while the lack of human interaction might make it easier for others to quit. One-on-one interaction gives physicians and researchers greater ability to answer questions and reassure patients about their concerns.

Life sciences companies also must contend with talent shortages and lack of training, making it more difficult to begin and scale virtual trials. As a result, companies could struggle to get launch trials, and outcomes could be questioned due to technical mistakes from researchers and patients.

To overcome these challenges, trials should prioritize training, increase transparency regarding biases and limitations, and build trust with participants. Virtual participant support networks are a mechanism to share information and experiences.

Communication between researchers and patients will mitigate attrition, and support network communications should occur at each stage of the research cycle. Fortunately, the virtualization model enhances ongoing communication.

An effective hybrid approach

Virtual and in-person trials each present complexities and challenges, yet they are an opportunity to create a more effective hybrid approach. Blending in-person engagement and digital interactions creates a trial environment that supports both patient and practitioner needs, while reducing the drawbacks of each. This hybrid approach is particularly valuable in high-risk trials, or

for complex procedures. A mixed model also helps reduce dropout. Combined with behavioral science, generative AI analytics, and access to broader datasets, life sciences companies can develop hyperpersonalized trial experiences.

As barriers to entry are removed, patients are more likely to engage with the trial and enabling technologies. Tools such as wearables and smart devices are unobtrusive and aid patients to stay on track. These tools minimize forgetfulness, improve adherence to trial expectations, and deliver monitoring data to physicians — removing much of the administrative burden on the participant.

Virtual clinical trial technologies help life sciences organizations improve trial patient identification and enrollment and create more diverse cohorts.

However, this requires connecting more datasets, developing insights from multiple sources, and moving beyond electronic health records. Data must include social determinants of health, gender, and broader social contexts.

This technology enhances data quality, access, and insights and supports removal of inherent biases. Generative AI-driven systems automate the patient identification process, which in turn reduces the burden on physicians and mitigates the risk of bias by selecting patients based on established criteria instead of preconceived ideas. As with other initiatives since the end of the pandemic, the initial rush to fully remote methods to conduct trials has since given way to a hybrid approach, which combines the benefits of in-person interaction with the scale and reach that technology can deliver.

However, hybrid and the rollout of technology brings its own issues. These include ensuring that data is used ethically and that robust governance is in place, and that care is taken to address issues of properly informed consent among patients who might be less familiar with the technologies being used by the trial organizers.

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