Integrating Technology, Science and Patient Insights to Reimagine Clinical Trials Virtually

Adoption of hybrid and virtual trials is increasing, resulting in the proliferation of technology solutions that enable trial virtualization. Technology is a key enabler of these trials, increasingly called decentralized clinical trials, however, successful implementation requires a seamless interplay of direct-to-patient services, new data management models, an optimized regulatory strategy and new processes that will ensure compliant delivery and enhanced patient experience.

Systematically linking these pieces of the puzzle together is vital for unlocking the benefits of decentralized clinical trials to increase patient access and retention by reducing patient burden, improving patient experience and increasing patient engagement. Collectively, these benefits may streamline study execution, accelerate study timelines and potentially reduce the cost of execution.

Reimagining the Clinical Trial Process with Patient Insights

Clinical trial technologies such as telehealth (telemedicine), eSource, electronic patient-reported outcome (ePRO), electronic Clinical Outcome Assessment (eCOA), electronic consent (eConsent), medication adherence tools and visit reminders are commonly deployed with the intent of reducing patient burden, increasing study compliance and patient retention and reducing the cost of delivery.

However, the benefits of these technologies can only be realized when the patient perspective is fully incorporated into protocol design. Comprehensive evaluation of technology applications must be considered a critical aspect of study design, in combination with other delivery elements. Sponsors must deploy platforms and devices that are easy and comfortable to use, as well as streamline data capture and lessen the burden of participation to prevent overwhelming the patient. Deploying too many devices and digital interfaces may be counterproductive by increasing the patient responsibility and inconvenience, which may negatively impact compliance and data quality.

Voice of the patient (VoP) surveys can provide critical insights on how to deploy patient-centric technology solutions that maximize trial outcomes. VoP also allows sponsors to understand how patients want to participate and become informed on what convenience means to the patients.

Platform Modularity, System and Data Interoperability for Enhanced Patient Experience

Hybrid and virtual trial technologies have the capacity to streamline data collection, reduce patient and site burden, improve data quality, reduce delivery cost and increase patient compliance and data transparency. Realizing these benefits in a decentralized clinical trial require a technology infrastructure that allows seamless cross-talk among trial micro-services and clinical delivery data platforms/domains.

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When possible, a single centralized platform that serves as a control tower is best. This approach allows all data to be centralized and patients or a study team to be notified of tasks or activities ensuring that all study activity accrues as expected.

With the proliferation of trial virtualization technologies in recent years, solutions such as ePRO, eCOA, telehealth, medication adherence, eConsent and many others, are routinely implemented on studies. These services are often provided by different technology vendors and require patients and sites to download multiple applications, interact with many interfaces and manage several devices or data portals leading to increased cost and delivery complexity.

The potential of these increased burdens highlights the importance of beginning with the patient perspective during study design. Patients can provide critical input on how many apps and devices they are willing to manage. Consider some of the best practices, such as:

- Using a single study app to enhance patient and site experience
- Connecting all other apps to the main study application
- Allowing patients and sites to engage with other study modules via single sign-on
- Consolidating connected devices (wearables and mobile phones/tablets) to reduce patient burden
- Deploying devices that can detect multiple signals (endpoints) to limit the number of devices and data portals managed by patients and sites

When disparate applications are deployed, it is critical to ensure that they are able to speak to each other via an application programming interface (API) that enables data transfer between the platforms. Allowing all technologies function as one is advisable. When technology is not deployed appropriately, it can lead to an increased burden on sites and patients and impact study compliance and data quality. Platform and system interoperability can help seamlessly integrate study stakeholders and enable large-scale process automation to streamline study delivery.

Transitioning from Site-Based to Virtual Delivery Blends Art and Science

Implementation of virtual trials requires selecting the optimal delivery approach. Sponsors must find the “sweet spot” to combine technology and services to enable decentralized clinical trials. Finding this balance requires a methodical decision-making process to understand an optimal delivery modality that can add value in today’s crowded landscape of trial virtualization solutions.

Selecting an optimal delivery strategy for decentralized clinical trials requires more than just new technology and incremental changes to protocols. The entire study design and execution process needs to be reimagined, from study goals and objectives to each patient touchpoint with technology and digital tools along with the study endpoints that will be collected and evaluated. The shift to a decentralized clinical trial also necessitates the proper integration of medical and scientific requirements, while maintaining strict regulatory compliance in all regions where the trial is to be performed.

It is necessary to conduct a comprehensive assessment of multiple factors including study objectives and phase, patient population, disease burden and patient acuity (the level of care that a patient needs), primary and secondary endpoints, safety profile of the drug and delivery geography, among many other considerations.

The outcome of this exercise helps determine the protocol suitability for decentralized setting, and an optimal technology and strategy for execution. It also enables proactive identification of operational risks and an assessment of the appropriate degree of virtualization to reduce patient burden, accelerate enrollment and increase retention.

No single application exists that can guide the design and development of an optimal decentralized clinical trial – or convert a traditional trial design to a decentralized one. Therefore, the science of evaluating all study components to identify the best delivery approach should be iterative and data driven. A few examples of considerations are provided below.

Study Design

- Phase and study objectives
- Study complexity
- Schedule of assessments (PK, MRI, etc.) and assessments that can be conducted remotely
- Centralized team to support patients and principal investigators (PIs)

Patient Population

- Difficult-to-recruit patient population or rare disease patients
- Patients with high disease burden and limited mobility can benefit from reduced site visits
- Distance to trial sites and the existing patient support ecosystem [patient services centers (PSCs), pharmacies, etc.]

Regulatory

- Countries with high receptivity to decentralized clinical trials
- Designing an ideal mixed-delivery modality that will guarantee study acceptance
- Engaging early and share protocols to get input

Technology

- Easy-to-use technology designed for everyone, including non-technology-savvy patient segments
- Technology Patient Advisory council to provide insights on technology design
- Centralized and integrated technology platforms for enhanced site and patient experience
- Consolidated devices (phones, tablets, connected devices/wearables)
- Scalable workflows that enable automation, alerts and reminders
- Interoperability with legacy delivery systems and platforms for ease of data sharing
- Patient privacy and data security to ensure regulatory compliance by country/region

Endpoint Measurements

- Validated instruments for collecting endpoints
- Demonstrate consistency between in-person vs. remote endpoint collection a potential validation strategy
- Optimal mix of onsite and remote endpoint measurement
- Data fraud and patient authentication
- Use of connected devices and wearables for passive data collection
- Use of central raters or central data collection to reduce variability and touchpoints
  For example, if collecting data remotely, the endpoints must be justified with a plan in place for obtaining accurate, reproducible results that can be validated as part of a globally combinable dataset

Compound Safety

- Drugs previously tested in patients
  Suitability of virtual elements, for example, first-in-human studies are not ideal; side effects that may require patient surveillance may not be suitable, e.g., suicidal ideation

Investigational Medicinal Product (IMP)

- Route of administration
- Cold chain vs. ambient
- Drug integrity and chain of custody
- Schedule of drug
- Surveillance required post-drug administration

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Key Considerations in Decentralized Clinical Trial Design

Generating insights that drive patient centric solutions

A comprehensive understanding of study design and patient population plays a critical role in selecting an optimal patient centric delivery model. However, data also plays an essential role in identifying eligible patients, accelerating recruitment and increasing retention.

LabCorp, the parent company of Covance, has amassed longitudinal real-world data sets for both individual, de-identified patients and populations of patients. These populations of interest are compiled by using a predefined combination of laboratory testing and/or ICD codes from LabCorp data. By analyzing ICD codes, Covance can help sponsors gather insights into a disease, define the applicability of key inclusion/exclusion parameters and even identify geographical clusters of specific patient populations with certain laboratory characteristics. These data are critical for identifying patients as patient catchment areas will expand for virtual trials. The LabCorp Patient Direct program provides Covance with access to consented and interested patients along with the lab result values to enable direct-to-patient recruitment. Finally, the Covance Patient Intelligence Database, with more than 70,000 patients from 30 countries, enables surveying potential trial participants to obtain guidance in designing trials that reduce patients' needs and allows them to participate in a real-world environment, which will, in turn, accelerate recruitment and increase retention.

The challenge of creating a seamless solution

Getting the most out of decentralized clinical trials requires seamless interplay of technology, services, regulatory strategy, operational elements and clinical data (such as safety data as well as primary and secondary endpoints) that are all designed to best meet the need of study participants. An optimal solution must manage the ecosystem of patient-centric services and include a framework to integrate rapidly evolving technologies into internal systems and processes in order to enhance patient experience, streamline execution and accelerate development timelines.

Depending on study design, the cost of decentralized clinical trials may be higher than site-based studies. In such cases, the long-term benefits realized by reducing patient burden should be a key decision driver. As traditional studies increasingly face recruitment and enrollment challenges, expanding patient access and reach through decentralized delivery modalities can offer a paradigm shift for designing the trials around patients. These approaches are likely to boost return on investment by expediting recruitment timelines, increasing retention and engagement as well as improving data quality and patient compliance. Taken together, these elements can ultimately accelerate the speed of bringing new therapies to market.

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