What does good look like? Cutting uncertainty to unlock the tech-enabled future of clinical trials

Market Report

March 2022

DILIGENT® QUALIFICATION PLATFORM

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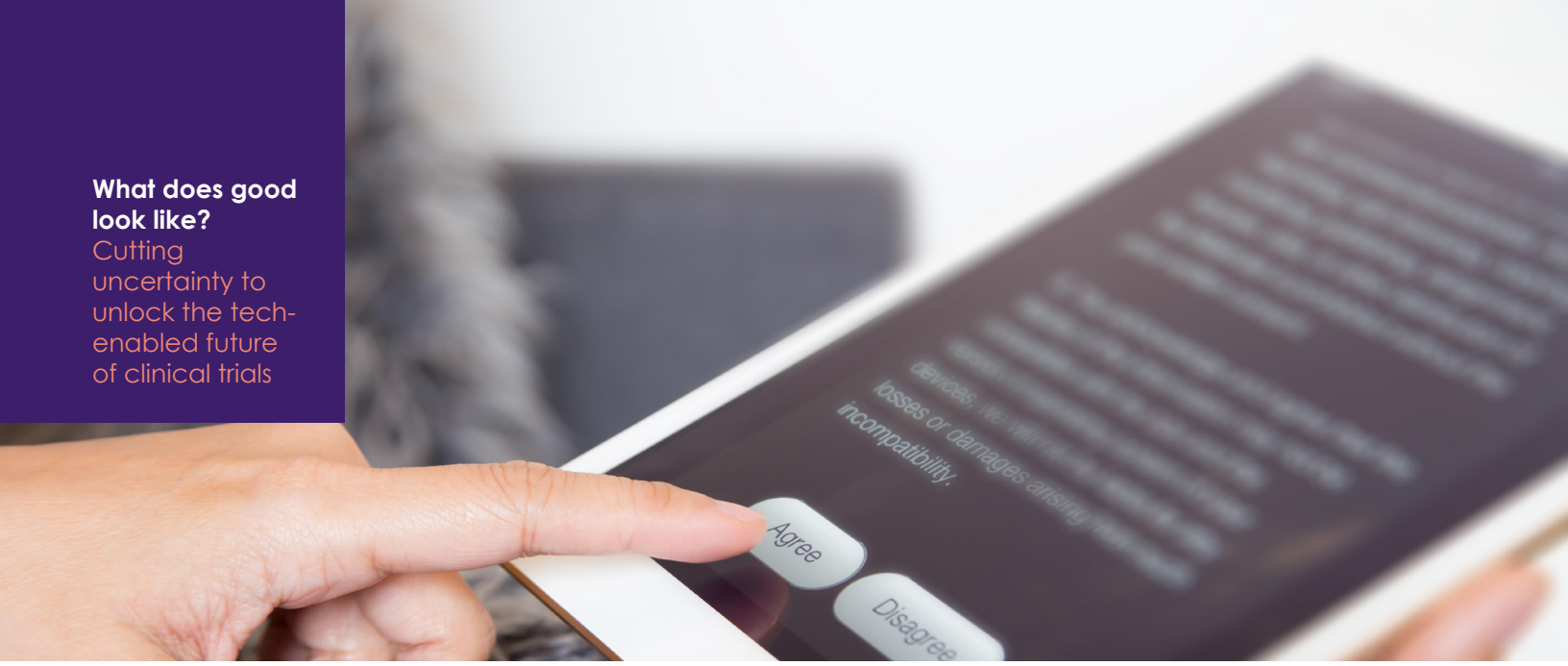
Technology is transforming clinical trials. By deploying new systems to find patients and monitor them remotely, pioneering sponsors are tearing down barriers to the efficient execution of clinical research. Yet, early movers face the risk and uncertainty associated with breaking new ground. Our industry knows what good looks like when qualifying established vendors. But how can sponsors be confident of suppliers of e-Technologies such as eConsent, wearables, home care providers or Telemedicine?

Diligent Pharma is reducing the uncertainty with a qualification process that thoroughly evaluates providers, empowering sponsors to accelerate adoption of new approaches including decentralized clinical trials (DCTs), confident in the knowledge that they are using effective, leading-edge technology that will meet the expectations of the biopharma industry and regulatory agencies.

The need for better ways to evaluate e-Technologies is clear. COVID-19 has permanently reshaped the clinical trial environment, turning technologies that were promising but partly unproven before the pandemic into essential enablers of a new, more decentralized approach to drug development that brings benefits to patients and industry alike.



How clinical development is changing

90%
of sponsors and CROs used DCTs during the pandemic

Use of DCTs rose steadily in the 2010s before taking off as COVID-19 prevented in-person interactions.[1] Almost 90% of sponsors and CROs used DCTs in the pandemic, up from 28% pre-pandemic, and there were more confirmed DCT starts in June 2020 than any prior month on record.[2] The emergency switch to decentralized and hybrid trials is having lasting effects, with almost all sponsors and CROs predicting COVID-19 will permanently boost DCT use.

The prediction reflects how the pandemic has validated DCTs and changed the expectations of patients. Most sponsors and CROs have found DCTs improve the patient experience. Patients, having welcomed aspects of the switch to Telemedicine in the pandemic, and want virtual options. Half of patients are interested in virtual-first healthcare and Telemedicine use remains up on pre-pandemic levels.[3] Patients prefer in-home visits by study staff, when possible.

Sponsors stand to benefit from patients' embrace of DCT technologies. With technology lowering geographic barriers to participation, patients who live hours away from research centers can now be recruited into DCTs accelerating study enrollment and drug development timelines. Researchers are starting to quantify those benefits, with one study finding Phase 3 DCTs generate savings of up to 14 times the upfront investment by cutting timelines.[4]

With the pandemic validating DCTs and still disrupting in-person trials, now is the time to adopt. To do so, sponsors need to learn how to remotely recruit, monitor and treat patients. That will require the effective deployment of technologies that are new to most people.

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Why uncertainty delays adoption

A lack of familiarity with e-Technologies is a big barrier to their use in site-based and decentralized trials. Sponsors need to know what good looks like for a technology or service provider to adopt it in a study. Many people have direct experience of what good looks like for established services. If not, they can ask colleagues for appropriate questions or criteria to develop a suitable qualification Request for Information (RFI) template to elicit relevant and important details and be able to determine the best option. That makes it relatively easy for sponsors to adopt established services.

In contrast, very few people have direct experience of the technologies that enable DCTs. E-Technologies have only been used in a tiny fraction of studies, so the technologies themselves, as well as the ways they are deployed, are continuing to evolve.

Trial sponsors lack RFI questionnaires and clarity about what questions to include. Similarly, sponsors are unsure how to qualify vendors effectively; they need the right standards and experienced auditors who can evaluate effectively. Failing to get the qualification step right could have dire consequences later. As such, sponsors need a knowledgeable and adaptable risk-based approach to qualify new technologies.

In the absence of such an approach, the uncertainty could make pharma, an understandably risk-averse industry, slow to adopt e-Technologies. With human health and vast sums of money resting on each study, sponsors need to know that a technology is accurate, reliable and compliant before adopting it in their clinical trials. That may deter some drug developers from embracing e-Technologies, but sponsors that find a way forward will be rewarded with faster clinical trials.

How Diligent accelerates uptake

The lack of in-house experience with e-Technologies means drug developers need external input to manage uncertainty. Diligent has responded to the need by adapting the latest industry standards to develop appropriate RFI questionnaires that will help to accelerate adoption of novel clinical trial technologies. The list of standards covers an array of technologies that enable DCT and more efficient trials, including systems for:

- Electronic Trial Master Files (eTMFs)
- Interactive Response Technologies/Interactive x{Telephone/Voice/Web} Response System (IRT/IxRS)
- Electronic Informed Consent (eIC)
- Electronic Regulatory Binders/Electronic Investigator Site Files (eISF)
- Mobile cardiac monitoring
- Mobile HCP visits
- eHealth Records
- Wearable Devices/sensors
- Telemedicine
- Electronic Clinical Outcomes Assessment (eCOA)
- Electronic Health Records (EHR) to Electronic Data Capture (EDC) Connector Apps
- Electronic Health Records (EHR) to Patient Recruitment Feasibility Apps

Ready to use qualification standards for 10 eClinical technologies and services

175
organizations developed the qualification standards used by Diligent

The standards used in this solution have been developed since 2015 by the Avoca Quality Consortium drawing on its base of more than 175 member organizations to understand the latest thinking about what "good providers" look like. The resulting standards form comprehensive benchmarks that enable in-depth qualification of novel technologies. For example, eTMF providers are rated against 82 industry standards.

Example eTMF Standard Topics:

- eTMF Organization and contents
- eTMF Verification/Validation (TMV)
- Indexing and Metadata (TMM)
- Security and Control (TMC)
- Access (TMA) and Permissions (TMP)
- Archival/Storage/Retention (TMS)
- Reports (TMR)

How Diligent accelerates uptake (Cont.)

Confidence lowers barriers to adoption

Those standards are specific to eTMF. Diligent uses other technology-specific standards for everything else it assesses. In addition, Diligent scrutinizes all providers against a set of core standards covering:

- Quality control/Quality Assurance
- Document management
- Physical and Data Security
- Computer systems/21 CFR Part 11 Compliance
- Data Management & Transfer
- HR, training processes and record keeping
- Financial stability and insurance
- And much more

Diligent ensures the answers to RFI questions it obtains can be trusted, by reviewing and validating the details given by providers before release. The process has further advantages: answers to RFI questions from each service or technology provider are stored on the Diligent Qualification Platform. They are then made available for multiple trial sponsors, subject to authorization by the service provider for each trial. This means trial sponsors can access a comprehensive set of RFI answers in just a couple of days, rather than weeks. Furthermore, providers benefit by avoiding the need to respond to a new RFI for every trial sponsor that it seeks to engage with.

On request by trial sponsors, Diligent will also use the appropriate qualification standards to assess vendors. The Vendor Qualification Assessments (VQAs) are conducted by a global network of experienced expert auditors. Once complete, VQA reports can be saved in a library system, making them rapidly available to sponsors using the Diligent Qualification Platform, saving time and money.

By qualifying vendors against leading standards, Diligent empowers companies to adopt DCTs quickly, rather than slowly building experience of which providers or technologies can be trusted, and even what questions to ask to understand supplier risk. The result is a step change in the pace of progress toward a new era of technology-enabled clinical trials. That acceleration is sorely needed.

How Diligent accelerates uptake (Cont.)

Newer technologies have enabled increased use of DCTs, with benefits for patients and sponsors. But the uptake of new technologies has been slower than it could have been as sponsors' assessment of the quality of these new technology providers often does not adequately identify all potential risks. Diligent's unique solution utilizes a comprehensive set of qualification standards specifically compiled to assess newer technologies, and gives sponsors access to details of each vendor against those standards.

References

1. Chancellor, D. Decentralized Clinical Trials In 2020: A Global Survey. (2020).

2. Veeva Digital Clinical Trials Survey Report.

3. Bestsennyy, O., Gilbert, G., Harris, A. & Rost, J. Telehealth: A quarter-trillion-dollar post-COVID-19 reality?

4. New study: Decentralized clinical trials can achieve net financial benefits of 5X to 14X, due to reduced trial timelines and other factors.

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