Powering Your Digital, Hybrid, and Decentralized Clinical Trials with a Next-Generation R&D Platform
Table of contents

1. Executive summary
2. Introduction
3. The problem with first-generation eClinical platforms
5. The promise of next-generation solutions
6. Clinical One: The most modern eClinical platform
9. Conclusion
10. Next steps
Executive summary

Historically, the pharmaceutical industry has been slow to implement digital technologies that could propel clinical trials forward. Paper-based processes and individual point solutions have dominated the clinical research landscape for years. In addition, patient participation has traditionally been in person, with the average patient living more than 30 miles from the trial site. This limits patient diversity and access and places a heavy burden on the patient. As the clinical trial landscape has become more competitive and these factors have contributed to higher costs and lower returns, leaders are demanding changes to reduce the time and cost required to bring life changing and saving treatments to patients faster.

Sponsors and clinical research organizations (CROs) have responded to these pressures by introducing digital, hybrid, and decentralized clinical trial (DCT) methods designed to enhance patient access and diversity, drive down costs, and condense time frames. However, most eClinical platforms don’t have the capabilities to support these methods, resulting in segmented technology solutions inefficiently patched together, complex workflows between systems, and the inability to effectively manage emerging data sources generated by DCTs.

Oracle Health Sciences Clinical One Cloud Service (Clinical One), a next-generation platform for conducting digital, hybrid, and decentralized clinical trials, has emerged as a leading solution for improving workflow efficiencies, increasing speed to market, broadening patient access, boosting engagement and diversity, and reducing clinical trial costs. This highly interoperable approach enables the clinical development organizations to embrace change while looking to the future with confidence.

“The current rate of trial cost increase is unsustainable, and clinical leaders must challenge the existing model and enable new approaches to take hold.”

Gartner®, Industry Vision: Life Science CIOs Must Transform Clinical Development With Digital Trials, Jeff Smith, 7 September 2021

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Introduction

Already spurred by industry pressures to address rising costs and a competitive, time-sensitive landscape, the COVID-19 pandemic ignited a momentous shift toward the adoption of new clinical trial approaches and technologies at a scale not seen before.

While this forced change was disruptive, its impact on clinical trials has been seen as overwhelmingly positive. Informa Pharma Intelligence and Oracle surveyed professionals involved in clinical trials at biopharmaceutical companies, medical device companies, and CROs around the world to understand pandemic-driven clinical trial adaptations and their ongoing impact.

At the time of the pandemic in 2020, a decisive majority of respondents (84%) reported implementing alternative approaches to existing clinical trials or to the start of new trials. Since then, many have indicated that these newly adopted approaches have positively impacted clinical trials with more timely data, improved flexibility for patients, and increased speed.

These newly adopted clinical trial methods have taken hold and many believe they will continue to evolve in a post-pandemic world.

It’s clear that study teams are confident that the right technology will help them survive—and thrive—in an ever-changing landscape. The challenge now is to maintain the momentum sparked by necessity and fully embrace next-generation solutions that improve processes and the patient experience while preparing clinicians for what lies ahead.

97% of respondents who implemented new clinical trial methods during the pandemic indicated their organization will continue using at least one of these new methods.
The problem with first-generation eClinical platforms

Despite the confidence and desire to forge ahead, challenges with existing technology and adoption make it difficult for organizations to move forward with advanced hybrid and DCT methods. Many of today’s so-called “all-in-one” first-generation eClinical platforms are the sum of pre-selected solutions for study start-up (SSU), electronic data capture (EDC), clinical trial management system (CTMS), and randomization and trial supply management (RTSM) patched together by a layer of complex integrations. These platforms remove the ability for sponsors and CROs to choose best-of-breed technologies that fit their particular situations and may lead to further issues such as:

- Complex, costly, and time-consuming integrations between systems
- Data-related issues across systems like synchronization, redundancy, and access to high-quality data in real time
- Redundancy among study setup and configuration, security, and data access
- Lack of genomics and patient-engagement applications
- Aging and inflexible infrastructure

These issues have resulted in a number of troubling challenges. First is the ability to support complex hybrid and DCT methods effectively at scale. To do this, systems must be free from burdensome data redundancy and quality issues, and access to data must be real time across applications to provide higher quality insights. Because users of first-generation eClinical systems often work in silos, their work can be negatively impacted by a lack of data integrity and synchronicity, which slows down overall clinical trial progress and critical decision-making processes.

Furthermore, systems that are difficult to work with will continue to propagate patient engagement challenges. Study designs that employ hybrid and DCT methods attempt to place the patient at the center of the trial, but systems that are inflexible and difficult to use don’t allow for the collection of patient data where patients live and work, making true patient-centric approaches nearly impossible.

Fewer than 4% of people are actively enrolled in clinical studies. Historically, 60% to 70% of clinical trial participants have been white males because they were the ones who could afford the cost of travel and the time off work to participate.

Source: ACRP
First-generation platform study build

Many first-generation eClinical platforms are comprised of pre-selected solutions for SSU, EDC, CTMS, and RTSM and require duplicate builds of components, resulting in lost time and money.

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While some progress has been made toward implementing a more patient-centered, efficient, cost-effective, and secure clinical-trial process, it’s clear that today’s digital, hybrid, and DCT methods were largely built out of necessity and in response to outside pressures.

The industry must now consider how to put a technological approach in place that is more proactive than reactive. For many, this will mean replacing siloed legacy systems and infrastructures with unified eClinical platform solutions to ensure they have the interoperable, next-generation capabilities to continue to thrive today while preparing for future unknowns.

Next-generation platforms can address the limitations of integrated systems by delivering optimal functionality across organizations while enabling more efficient configurations as needed. Sponsors and CROs who embrace next-generation solutions will realize immediate benefits and be assured they have the future capabilities to easily adopt and adapt to new methods as they arise.
Clinical One: The most modern eClinical platform

Clinical One, hosted on Oracle’s next-generation cloud infrastructure is running on an autonomous database for maximum flexibility and scalability. This interoperable platform manages all data in one place, simplifying the site experience and improving the user experience. All technologies and tools needed to conduct a trial (EDC, RTMS, etc.) can be accessed through a single, centralized platform. This approach enables organizations to choose their own best-of-breed technologies to optimize the user experience while reducing the amount of time and duplication of effort for setup across multiple solutions. The platform also empowers organizations to easily adopt new technologies as they are released—such as wearables and patient apps—with no downtime for upgrades or study deployment and no data migrations.
Next-generation platform study build

Clinical One simplifies the build, setup, and data changes that affect the quality, cost, and timeliness of hybrid and decentralized clinical trials.

True interoperability across the platform streamlines data collection, improves data quality, and enables real-time management, analysis, and reporting. This unified platform means each study is built once, all data is entered once, and all activities can be managed from one centralized dashboard. Moreover, the platform remains functioning and accessible around the clock—even when new features or upgrades are introduced.

With Clinical One, users aren’t forced to decide between an all-in-one platform or best-of-breed technology strategy. Instead, Clinical One does both: It provides a platform strategy that breaks down silos while allowing users to choose best-of-breed applications to maximize flexibility.

Clinical One streamlines processes and data flow with shared microservices, master data, and study design, optimizing user experience and reducing data redundancy with a consolidated source of truth across all data sources.
Centralized data model

Clinical One is highly scalable and all data is centralized, so users benefit from shared security and access to real-time data through a single view. This next-generation platform enables study teams to get a complete picture of a patient’s experience through a single dashboard. Unlike existing eClinical platforms, Clinical One truly synchronizes all sources of data in real time, eliminating data-redundancy, improving quality, and enabling more accurate analysis and reporting.

Improved patient engagement

High-quality patient data can be collected remotely in real time, more closely representing the real world where patients live and work every day. Giving patients a choice about how, when, and where they will participate in clinical trials has been game-changing for speeding results and promoting diversity and engagement. Likewise, Clinical One easily interoperates with new technologies that empower patients, such as wearables, while generating more accurate and insightful data about their health.

Insightful analytics

Clinical One enables deeper insight by providing real-time data access via a single interface, delivered to the right people at the right time, enabling:

- Increased breadth and depth of insights
- Quicker, more informed decision-making that can improve trial outcomes
- Data visualizations from multiple sources, opening up new ways of seeing data patterns
- Stronger portfolio oversight with cross-study analytics
Conclusion

If there’s any takeaway from the pandemic, it’s that change is inevitable, and planning for change can keep sponsors and CROs out front when the unexpected happens. There continues to be a great deal of pressure in the industry to reduce trial time frames and costs, and many clinical leaders have committed to digital, hybrid, and DCT methods, to address these challenges. But supporting these new methods requires technology that is purpose-built to support scale and growth.

Clinical One is a fully unified, and scalable platform that brings speed and efficiency to decentralized and hybrid trials, providing sponsors and CROs the true interoperability they need to keep pace. With Clinical One, organizations can:

• Optimize the user experience with a single, consolidated user interface and shared security
• Streamline processes and data flow with shared microservices, master data, and study design
• Reduce data redundancy and quality issues with a single source of truth across all data sources
• Obtain real-time clinical insights and study oversight with built-in and ad-hoc analytics
• Implement proven solutions to drive down trial costs and reduce clinical study time frames
• Move to a platform approach to gain efficiencies while having the flexibility to choose best-of-breed technology solutions
• Move from site-centric to patient-centric processes to increase patient diversity and access
Next steps

Reduce trial time and cost today—and be ready for tomorrow with the only truly unified platform, Clinical One.

Learn more about Clinical One

View the Clinical One demo

Engage with an expert

Additional information:

Read the research report:
Clinical Trial Management in a Post-Pandemic World

Watch the webcast:
Addressing the Complexity of Decentralized and Hybrid Clinical Trials