MEDIDATA | WHITE PAPER

Preparing for a New Data Future:

A Survey of Clinical Research Technology Decision Makers

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Introduction

The pharmaceutical industry is in an exciting state of flux that is changing the industry in fundamental ways. While these changes are converging from several fronts, technological transformation has been identified as a priority that will significantly impact the industry in the near future (Deloitte 2020a). This is a promising outlook for an industry that has traditionally been viewed as relatively slow to adapt and embrace automation (McKinsey 2020). The industry's transformation has been accelerated by the COVID-19 pandemic, which has forced biopharma to adapt and quickly adopt eClinical technologies and other innovations (McDermott 2020) which may provide significant benefits in a post-COVID environment. For example, Ken Getz, deputy director of the Tufts University Center for the Study of Drug Development (CSDD) stated:

> **"The forced use of such tech-based modifications to traditional procedures may serve to give sponsors and regulators confidence that they can be effectively deployed in non-emergency conditions." (Hinkle 2020)**

To better understand current views on technology software solutions that support clinical research and development (collectively referred to as "eClinical software solutions"), especially on a unified platform, Medidata surveyed current and former technology decision-makers representing large to mid-size pharmaceutical companies and contract research organizations (CROs). Medidata also conducted secondary research, with recent relevant industry literature, to frame the questions and answers.

The key focus areas of the survey were as follows:

- **Industry**—Better understand what the industry views as the biggest need for eClinical platforms moving forward, given the increasing volume of data collected in clinical trials
- **On-premise versus cloud**—Determine the current state and expectations going forward for how and where Clinical software products will be hosted and the rationale for any changes in approach
- **eClinical software architecture**—Determine the current state and expectations going forward for eClinical software solutions architecture (e.g., stand-alone point solutions versus integrated applications versus integrated platforms versus unified platforms [See Table 1 for Definitions of Commonly Used Terms]) and the rationale behind their approach
- **Value proposition**—Better understand the context for why, how, and when a unified platform solution could provide value in clinical trial planning and execution, which attributes are likely to drive adoption, and how success is measured for eClinical software solutions

KEY TRENDS IDENTIFIED

The following are the six key trends identified from our analysis:

1. **Market Environment Supports Unified Platforms**
   Several recent market activities were identified as drivers for increasing the value proposition of unified platforms in clinical research. These trends include expanding clinical portfolios in an environment of research and development cost reduction, high numbers of mergers and acquisitions (M&A), carve-outs, and other transactions (Jewell 2020; Alvaro 2020) that have forced new eClinical purchase decisions. Rapidly evolving trends include a desire to maximize the use of clinical data and increasing trial virtualization (McKesson 2020). Unified eClinical platforms that better facilitate data interoperability - with data collected from different applications and sources across users - will benefit from these trends.

   While customers with complex legacy architectures also embrace the value proposition of unified platforms, their shift to a new solution may be slower, since it will take time to unwind their legacy architecture (Langhauser 2019).

2. **Virtual Solutions for Clinical Trials Are Accelerating**
   The COVID-19 pandemic has been unquestionably difficult for the clinical trial industry (Spinner 2020). However, it has forced it to adapt and accelerate its adoption of virtual solutions to overcome some of the myriad of new challenges it faces, including outcome data collection, efficient recruitment and randomization, and ensuring protocol adherence by the patient and delivery of drug to patients (McDermott 2020).

3. **Cross-Application Data Availability Is Desired**
   There is an expressed need for eClinical software solutions to seamlessly connect and share data so that stakeholders can more efficiently acquire the complete picture of their clinical trials. Study teams view cross-application data availability as a way to gain better insights about how a trial is performing from planning through closeout, allowing for quicker action to mitigate potential risks.

4. **Industry Wants Cloud Deployments**
   The industry is not hesitant to consider cloud solutions, given that cloud deployments are now considered standard in areas such as compliance, privacy, and data ownership and auditing (Challener 2019).

5. **Industry Is Moving to Platform Builds**
   Most companies do not want to take on the complexity or cost of managing their eClinical system architecture; where feasible, those with legacy architecture would like it to be vendor managed. Most architectures have evolved as a mix of best-in-class eClinical software solutions with internal integration/development, but companies with this type of architecture are willing to consider opportunities to establish a unified platform architecture (Deloitte 2018). The clear preference is for products built by eClinical solution providers, but legacy internal architecture takes time/effort to unwind. Cross-application data availability is considered the most critical attribute, while ease of integration, interoperability, and a simple and consistent user experience/interface (UX/UI) are considered justifications for a platform approach.

6. **Surfacing Clinical Data Is Now Critical**
   An increasing number of technologies—such as wearables, sensors, smartphone data—are generating large volumes of data that sponsors, CROs, and other clinical trial stakeholders want to better surface, view, and analyze. As more benefits are identified from the ability to leverage data across applications, trials and sources, the capability to ingest, structure and report on data is now a top priority for the industry.

   This white paper discusses the key results of this survey, which was designed to gain the industry's current view on and future vision for eClinical software solutions in general and unified platform solutions, specifically.

Methods And Definitions

Medidata conducted in-depth interviews of current and former senior and/or executive technology decision-makers representing large to mid-size pharmaceutical companies (n = 9) and CROs (n = 3). Collectively, their current and past experiences represent twenty-two manufacturers and nine CROs.

Subject matter experts were identified and recruited, and the survey was conducted during July and August 2020. The survey was sponsored and funded by Medidata. A third-party market survey company recruited the experts and conducted the phone interviews.

For the benefit of our readers, Table 1 provides definitions for commonly used terms throughout the white paper.

Table 1: Definitions of Commonly Used Terms Associated with eClinical Software Solutions

Definitions of Commonly Used Terms
eClinical software platforms are integrated suites of cloud-hosted technologies connected in a platform architecture that provide services and solutions to manage clinical trial planning and execution.
eClinical software applications (or application suites) are distinct in that they are modularized and defined as one or a number of point solution offerings. They exist to support clinical trial setup and operation, but may be installed on-premise or cloud hosted and often do not have or require significant configuration to allow for interoperability, collaboration, security, etc.
Stand-alone point solutions are applications intended to fulfill the needs of individual clinical departments, and they are often specialized to fulfill a specific need by trial type or indication.
Integrated applications are sets of software applications that clinical vendors link together to create tighter process integration and elimination of middleware. These are often sold in modularized components.
Integrated platforms are enabled by the cloud, allowing vendors to piece together multiple solutions and link them through a common access point, allowing clinical teams the ability to manage the identity of both sponsor users and site users and to transmit and receive data and triggers. These have the flexibility for a platform vendor to combine other solutions.
Unified platforms aim to create a single system made up of multiple subsystems that mimics how clinical trials are a single process made up of many subprocesses. The key is that unified platform solution providers must develop each eClinical point solution individually for their platform to maintain a unified architecture and data model. This allows faster integration between point solutions, holistic platform performance metrics, and reduced support complexity.

Findings

This section provides a summary of the results from the survey's four key focus areas:

- ✓ Industry Outlook
- ✓ eClinical Software Architecture
- ✓ On Premises Versus Cloud
- ✓ Value Proposition

INDUSTRY OUTLOOK

The following is a representative sample of the key questions posed to respondents:

- What are some of the biggest changes impacting eClinical software solutions over the last five years?
- What are the main areas of expected technology investment over the next five years?
- What are the biggest expectations for eClinical software solutions in the next five years?

HIGH-LEVEL TAKEAWAYS:

Trial optimization will be analytics driven
It is anticipated that artificial intelligence (AI) and machine learning (ML) will increasingly be applied to optimize decisions related to clinical trials, such as study design and site selection (Deloitte 2020b).

Further, as the number of data streams increases and better analytical methods become available to draw insights across clinical trials, unifying clinical data will be a key factor to reduce trial time, optimize study design, and allow for new virtualization methods.

Clinical trials will incorporate more virtual elements
The industry has seen an increasing trend toward virtualizing clinical trials in the past few years, which has been accelerated by the COVID-19 pandemic. While some parts of trials cannot be done remotely, the pandemic has forced companies to get even more creative around what can be accomplished virtually.

Decentralized trials—also referred to as virtual, hybrid or digital trials—where one or more trial activities that typically take place on-site are conducted off-site through digital methods, now make up an increasing percentage of all studies. Approximately 35% of healthcare experts are using decentralized trials and 67% planned to use them in the future (GlobalData June 2020). Notably, while decentralized trials – where on-site components are still required – are making up a greater percentage of all trials, studies that are conducted entirely off-site using fully virtual methods remain rare.

Trial virtualization offers several benefits for both sponsors and patients, including increasing the size of patient pools, decreasing patient burden, and enhancing patient retention (Khozin 2019). As more clinical trial workflows become remote for patients, software capabilities will need to quickly evolve and adapt to meet these changing needs. However, headwinds to virtualization exist, and many eClinical solution providers do not yet have optimal virtualization capabilities.

> **"[Growth in virtualization capabilities] was being done methodically, [but] COVID, as you can imagine, has given us a good, swift kick in the rear to ensure that we are moving at a heightened pace."**
>
> Former Director, Health Outcomes and Market Access, Large Life Sciences

IT overhead costs will decrease through outsourcing
Industry sees more of their legacy IT overhead and maintenance costs being replaced by vendors' cloud-hosted software as a service (SaaS) and there will be more outsourcing of either individual trials or specific clinical functions.

Clinical data will be better unified
Due in large part to poor cross-application data sharing, data analysis and reporting remains a challenge for companies that are ingesting data from different sources with different system architectures and data structures. In large part, data are not unified because sponsors tend to cherry-pick best-in-class point solutions (e.g., eCOA, ePRO, EDC, etc.) for different parts of a clinical trial, and end up with several disparate applications that do not work together or cross-share data.

As a result, stakeholders are not able to view data across their trial from start to finish and are not able to unify disparate data streams to generate novel insights. In fact, 75% of respondents assessed the "availability of data across all clinical products" as a 9 or 10 on a 10-point scale intended to measure the most important drivers of adoption for unified platforms. Survey results suggest that the advantage of the "best-in-class" for eClinical software applications is narrowing and the opportunity for platform solutions that can unify cross-application data is growing.

> **"Clinical data [availability] is really the gold dust… if you [are able to] access that data, however big or small you are, the sooner you can make decisions on next phase, next regulatory approval process, reporting out to publications… all of those things."**
>
> Former Head of Biometrics, Mid-Sized CRO

The need for "best-in-class" will decrease
According to multiple respondents, eClinical solution providers with reputations for single or specialized applications are seeing their market advantages shrink. This is because "best-in-class" offerings in individual eClinical categories are becoming less important due to fewer differences in features and capabilities in products across eClinical solution providers. This indicates that the value of a "best-in-class" solution is becoming less relevant and the ability to connect individual applications is of higher importance and can be achieved with a unified platform. Respondents indicated that companies choose the best point solution for their needs, with 70% of respondents saying they consider the "strength of a specific eClinical solution" as a 9 or 10. However, this is changing based on responses that indicate sponsors are thinking about factors that go beyond a specific application—such as data unification, data surfacing, and interoperability—which suggests that companies are balancing application strengths with unified platform capabilities.

> **"No matter which vendor we pick, it is challenging for the vendors to differentiate themselves. And [that] is a good sign, because industry-wide, [there are] the same parameters or similar standards or similar ways of doing something."**
>
> VP of Clinical Development, Mid-Sized Life Sciences

PERCEPTIONS OF DEPLOYMENT STRATEGY

The following is a representative sample of the key questions posed to respondents:

- How are buyers now deploying their suite of eClinical software solutions and why?
- Are there any expected changes to the deployment setup of potential buyers?

HIGH-LEVEL TAKEAWAYS:

Companies are increasingly deploying eClinical software solutions via the cloud
Based on data from several interviews, ~70–80% of large life science companies' eClinical software capabilities are cloud-hosted. The prevailing theme across interviews was a general acceptance of cloud hosting as fit for purpose and acceptable in terms of compliance, privacy, and data ownership and auditing. The primary factor restricting its use is the complexity of replacing legacy architecture.

Cloud solutions remove IT overhead
IT departments seeking to eliminate unnecessary costs are removing large and complex infrastructure and instead deploying in the cloud, solutions which are primarily hosted/supported by external vendors.

The shift is tougher for large incumbents
Cloud-hosted SaaS solutions are now the expectation, though larger sponsors will take time to make the shift, since they have legacy infrastructure that supports point solutions. They will need significant change management, SOP updates, and new vendor and data management processes to move over to a fully outsourced cloud-hosted SaaS solution.

New organizations looking first to the cloud
Cloud-based solutions allow for easier cross-organization working and tighter control of data flow for newly formed or smaller, more nimble organizations.

PERCEPTIONS OF eCLINICAL ARCHITECTURE

The following is a representative sample of the key questions posed to respondents:

- What does the architecture of respondents' eClinical software solutions look like today and why?
- What changes or eventual architecture do respondents expect for their eClinical software solutions and why?

HIGH-LEVEL TAKEAWAYS:

The biggest barrier is resistance to change
The overall expectation is that there will be a slow convergence to a unified platform architecture. However, there is a general sentiment that it remains a challenge to convince organizations to make a platform change in a business-as-usual scenario, given interruptions to ongoing studies, the complexity of changeover, and familiarity with current systems.

Organizations see the benefits
Respondents cited several business-case benefits for using platform systems, including lower total cost of ownership, increased study speed, easier access to relevant data and reporting capabilities, and fewer manual processes.

The best organizations take advantage of change
The organizations that have shifted to an external eClinical solution provider-based platform have sought opportunities to make the case for a change (e.g., contract renewal, step-change in studies, business event/transaction).

eClinical software solutions architecture will take on different forms

eClinical software solutions architecture for pharmaceutical/biotech companies is likely to come in one of two forms:

Large Legacy Companies

- Platform architectures are often entirely or mostly built internally, with a mix of cloud-hosted solutions and internal integration. The cost of updating and maintaining the complex ecosystem is high and burdensome. A new application purchase often requires reconsideration of the existing architecture.

New Companies

- A precipitating event (such as M&A or a new venture) often leads to considering a new or modified architecture. Few businesses in this situation will invest in internal IT development; they consider either outsourcing their studies to CROs or procuring an eClinical platform that covers all or most of their needs. SaaS solutions that offer end-to-end coverage and easy integration to other needed capabilities are critical factors.

Similarly, eClinical software solutions architecture for CROs is also likely to come in one of two forms:

Preferred Tech

- These are typically large CROs that go to market selling their outsourced services in addition to their own technologies. These technologies may be the result of internal development, acquisition, or exclusive vendor partnerships. These CROs may prefer to rely on their own technologies, but they also use and sell others.

Agnostic

- These CROs have not built large internal infrastructures, but they can typically manage data integrations. These companies may have a preferred eClinical solutions provider they recommend but will typically follow the client's preferences.

VALUE PROPOSITION OF UNIFIED PLATFORMS

The following is a representative sample of the key questions posed to respondents:

- Does your organization have a preference between building your own internal architecture versus vendor built?
- What are the key attributes driving adoption of unified eClinical platforms?

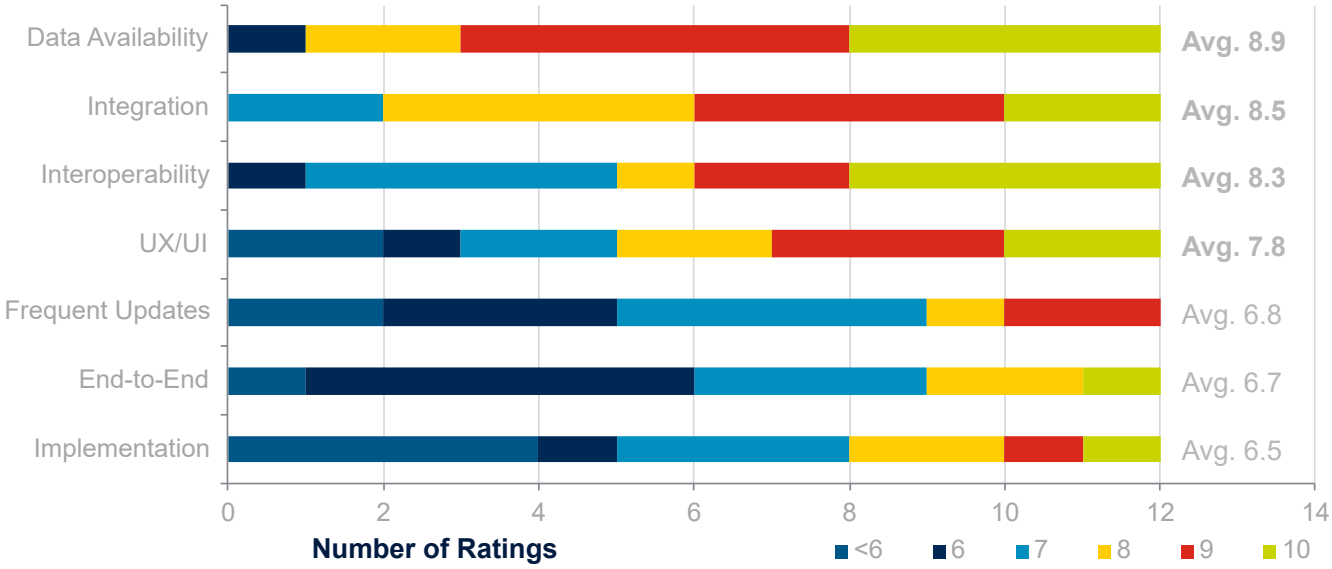
HIGH-LEVEL TAKEAWAYS:

eClinical solution providers expand from core products
Respondents indicated that eClinical solution providers generally have a core product they are best known for, which they expand from and establish a platform around. For instance, an eClinical solution provider known for their Clinical Trial Management System (CTMS) adding a Randomization and Trial Supply Management (RTSM), and an Electronic Data Capture (EDC) provider adding an electronic Clinical Outcomes Assessment (eCOA) or eConsent offering, or an eCOA provider adding on an imaging product.

Product disparities are decreasing
Respondents indicated they tend to prefer applications from specific eClinical solution providers, but since differences between point solution products are narrowing across eClinical solution providers (i.e., products and features are beginning to look more and more alike between different solutions), the appeal of a full platform offering or solutions that are part of a unified platform are increasing.

Demonstrated cross-app data availability and integration drives unified platform adoption
Companies considering unified platforms care less about end-to-end application coverage than the ability to integrate and manage data across applications. As Figure 1 below shows, the high scores weighted on a 10-point scale intended to measure the most important drivers of adoption for unified platforms are data availability, integration, interoperability, and UX/UI underscore an expectation for unified platforms to eliminate some of the traditional boundaries across eClinical applications. Even though the attribute “end-to-end” was ranked lower than other attributes, a prevailing theme across the interviews was an expressed preference for data availability and integration across a clinical trial. The best way to achieve these functionalities is to have a single unified platform that connects as many eClinical solutions as possible so that cross-application data sharing can occur seamlessly.

Figure 1: Attributes important for driving adoption of a unified platform for clinical research



As one would expect, larger impact of professional services in eClinical solution provider selection comes down to customer need

CROs generally have some professional service capabilities outside of their core services. Their customers may look to them to perform these services, such as study build, study process consulting, and technology strategy.

Larger biopharmaceutical companies often do not need much professional service support because they have most if not all of the professional service support they need in-house. However, they still view customer service and helpdesk capabilities as important.

Small and mid-size biopharmaceutical companies and CROs indicated a desire to purchase additional professional services from eClinical solution providers, noting a lack of existing in-house expertise in these areas.

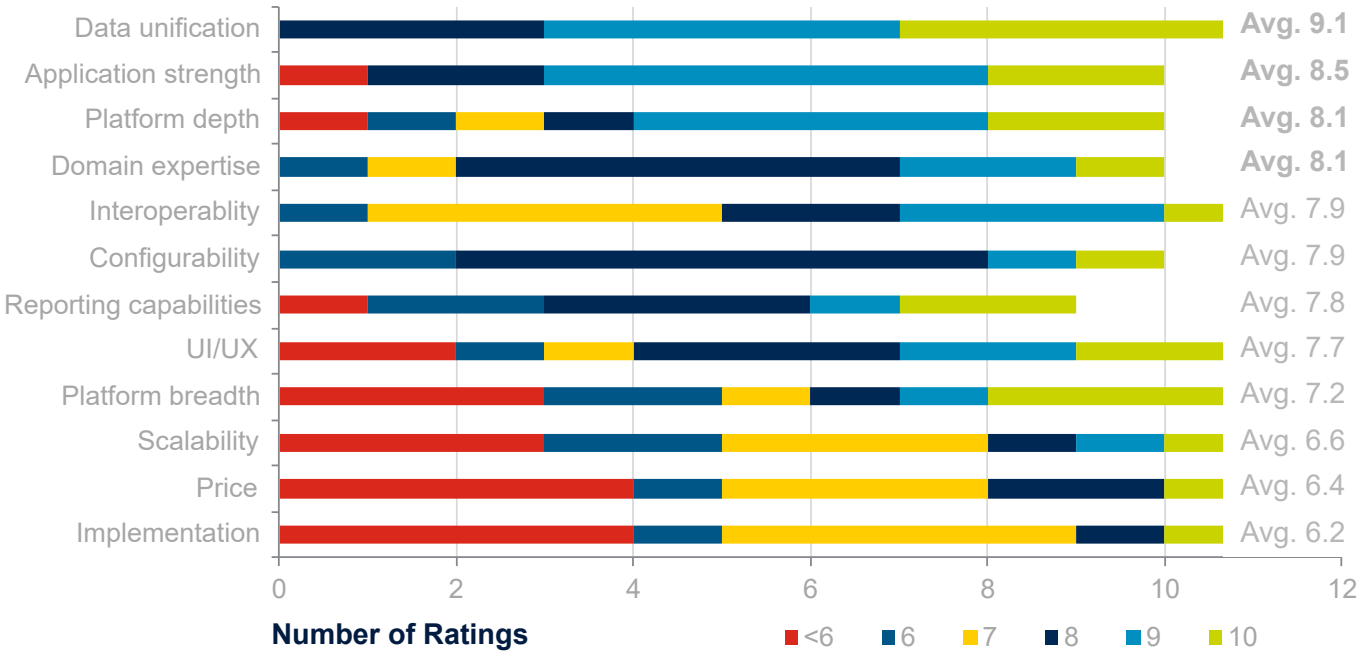
> **"Especially for a mid-sized [company] or a startup, you don't want to rely on 100 different consultants. [Professional services] really help to offer expertise where we do not have any internal capacity."**
>
> VP of Clinical Development, Mid-Sized Life Sciences

Biopharmaceutical and CROs expect domain expertise
Domain expertise was a consistently high-rated criterion (See Figure 2), and the respondents that viewed it as most important were most likely to consider buying eClinical solution providers' professional services.

CRO software tends to trail in capability depth
Respondents indicated that some CROs offer their own internal eClinical software for specific functions whereas others maintain a broader eClinical product offering. These solutions were viewed as trailing in software capabilities in comparison to established eClinical solution providers. However, it was also noted that these CROs provided strong professional support services for their eClinical software products, which was consistent with their strong service offerings in general.

Unified means unified
Respondents indicated that a key and expected factor in adopting unified platforms is the availability of data across eClinical applications to support clinical trial workflows. Other types of approaches, such as point solutions and integrated applications, simply do not provide the same level of data unification and cross-application data availability as a unified platform. As shown in Figure 2, platform capabilities, especially cross-application data availability (i.e., data unification), were vital proof points for respondents. Figure 2 also shows that traditional eClinical software solution buying criteria, such as the strength of individual point solutions and domain expertise, remained highly important to respondents. The survey results also show that successful growth may come from demonstrated capabilities, especially data unification, that a platform can provide underneath the application suite.

Figure 2: Most important proof points for respondents



PLATFORM NEEDS DIFFER BY COMPANY SIZE

In general, respondents indicated that the larger and more siloed the organization, the more difficult the shift to an eClinical solution provider's platform, given that there may be different eClinical software solutions by therapeutic area and/or region. Smaller or emerging companies are much more willing to consider unified platform solutions that provide integration capabilities across the organization.

While technology leads understand and may push for more platform-based solutions, the challenge is convincing clinical department leads that individual applications on those platforms meet their needs.

> **"At a small company, [e-clinical software solutions are] integrated across the company. At a large company, it's siloed into either regions or therapeutic areas, and the others do not even know or care about what they use."**
>
> Former Technical Operations Product Lead, Mid-Sized Life Sciences

> **"I try to drive technology efficiencies throughout the organization, and the platform approach lends itself to that; [it's a] question... to always put on the table. It's challenging because a lot of [users] have preferences, and they're biased from their historical usage."**
>
> Former Technical Operations Product Lead, Mid-Sized Life Sciences

Large, Established Companies

These companies are more likely to consider eClinical solution providers that can integrate with existing architecture and expand platform-like capabilities to their existing point solutions.

Individual solutions must meet an "acceptable level" – beyond that, demonstrating unification of clinical data across applications holds strong appeal. Overall, these larger companies are slower to shift trial design or systems to align with new trends or best practices.

Mid-Sized, Newer Companies

With a new set of trials and limited or no legacy technology and data to manage, the aim is to simplify, centralize, and minimize the cost of managing their clinical trial data. There is broad appeal in solutions that allow them to minimize the number of vendors they manage and not invest in large internal IT resources, while still maintaining control and oversight of their clinical data. They are also less likely to have a procurement-driven set of pre-approved vendors, which gives these newer, mid-sized companies greater flexibility than large, established companies when selecting eClinical solution providers.

These type of companies may or may not use CROs to own whole trials or functions. If not, a platform with a broader portfolio that can meet an "acceptable level of functionality" is more appealing. These mid-size companies are more likely to shift trial design to align with emerging trends (e.g., virtualization).

Summary

The results of this survey confirm that multiple market trends—a rapid shift towards virtualization due to the COVID-19 pandemic, larger volumes of data collection from an increasing number and diverse set of data sources, and the need for sponsors and CROs to gain more complete pictures of trials and to act on data quickly—are forcing the industry towards eClinical software solutions that are on unified platforms. This is because unified platforms centralize data and allow for users to more rapidly surface and report on key data, while also allowing sponsors to easily virtualize components of their trials and reduce internal IT costs. However, there remain some challenges that may slow the widespread adoption of platform solutions, such as the unwinding of legacy architecture at large life science companies.

While the COVID-19 pandemic has presented significant challenges to the clinical trial industry, there has also been great growth since companies have been forced to adapt and accelerate their adoption of solutions that virtualize key aspects of study conduct. These forced adaptations will undoubtedly teach many important lessons for how trials can be made more virtual in a post-pandemic environment for an increasingly digital future.

Respondents also expressed a need for eClinical software solutions to seamlessly connect and share data, and they are willing to embrace cloud solutions given that cloud deployments are now considered standard in many areas relevant to clinical research. A clear preference for architecture built by eClinical solution providers was also identified, and cross-application data availability was considered the most critical attribute. Lastly, respondents also pointed to a critical need for the ability to leverage clinical data across applications and trials, while the capability to ingest, structure, and report on data is a top priority for the industry.

We expect that the pharmaceutical industry will continue to evolve and adapt to its increasingly digital environment and move from single and fragmented point solutions to unified platforms. Embracing unified platforms can ease the burden on clinical development teams, are repeatable to support large numbers of studies, and allow for sponsors to centralize their data so they can gain powerful insights across trials instead of having to deal with disparate datasets that are isolated across several point solutions.

For more information on Medidata Solutions visit www.medidata.com.

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