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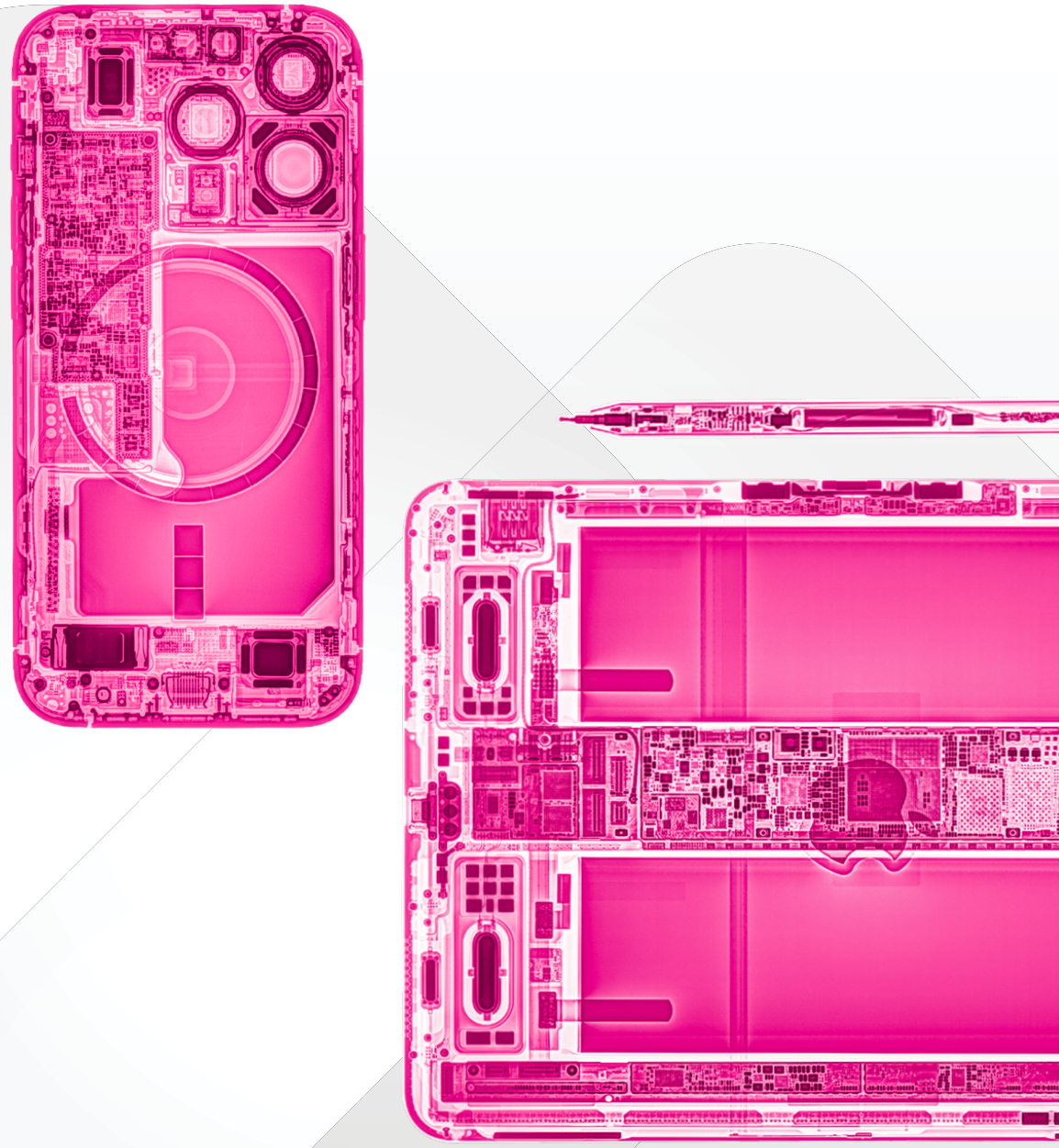
INSIGHTS FROM A SURVEY OF CLINICAL RESEARCH PROFESSIONALS

eCOA Trends for Today and Tomorrow

Keeping patients, sites, and sponsors at the forefront of eCOA innovation



Mike Hughes
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Introduction

Electronic clinical outcome assessments (eCOA) in clinical studies offer a range of benefits, including improved data accuracy, enhanced participant engagement, greater site personnel productivity, and streamlined study processes. All these benefits ultimately contribute to more efficient and effective clinical research that accelerates the delivery of new therapies to patients. This is why eCOA adoption continues to increase despite some growing pains already being addressed by advanced technologies and enhanced user training.

eCOA leverages digital platforms and electronic devices to collect critical data on the outcomes of various patient assessments. Although particularly transformative in collecting data directly from patients (electronic patient-reported outcomes or ePROs), eCOA also encompasses data collection from clinicians (clinician-reported outcomes or ClinROs), observers such as caregivers (observer-reported outcomes or ObsROs), and performance testing such as measurable physical or cognitive tasks (performance-reported outcomes or PerfOs).

The most important element of clinical trial management is protecting participants' safety and quality of life. eCOA captures subjective experiences and symptoms, providing valuable insights into the impact of treatments from the patient's perspective. eCOA also allows for real-time data collection and remote monitoring, providing immediate access to patient-reported outcome measure data. This in turn enables researchers and clinicians to monitor patient progress more closely, make timely decisions, and respond promptly to symptom reports that may require adverse event evaluations.

eCOA platforms are poised for continual transformation to effectively address the evolving needs of patients, clinical sites, and sponsors. As the landscape of medical innovation progresses, especially with the integration of advanced medical devices like wearables and sensors, eCOA platforms are adapting to seamlessly incorporate these cutting-edge technologies and integrate seamlessly with other eClinical systems. The growing acknowledgment and acceptance of data generated by eCOA platforms by regulatory agencies contribute to a valuable advantage for sponsors—enabling faster regulatory approvals and expediting time-to-market in an inherently competitive environment.

In our role as an eCOA platform provider, dedicated to delivering technologies and services attuned to the genuine requirements of patients, clinical sites, and sponsors, YPrime conducted a comprehensive survey among clinical professionals. This survey aimed to capture their current perspectives on the state of eCOA and shed light on their aspirations for the future. This report not only presents the insightful findings from the survey but also includes commentary to illuminate the significance of each discovery.

eCOA's integration into clinical research methodology has marked a paradigm shift in how data is collected, managed, and used to advance medical knowledge and improve patient outcomes. We are pleased to be involved with making eCOA a cornerstone of modern clinical trials.

"For those navigating the digital landscape of healthcare, optimizing electronic clinical outcome assessment (eCOA) is not just a choice—it's a strategic advantage. In the hands of those already harnessing its power, eCOA becomes the compass guiding precision, efficiency, certainty, and patient-centricity in the journey toward optimal clinical outcomes.

Jim Corrigan
CEO, YPrime

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Executive summary

YPrime executed the *eCOA Trends Survey* in October of 2023 to discover clinical professionals' perspectives on eCOA technology platforms within clinical research. This report presents the responses of 100 survey participants. The pool of respondents is comprised of clinical operations professionals, eCOA subject matter experts, and other professionals with roles in clinical research at pharmaceutical and biotechnology companies, all of whom indicated they were extremely or very familiar with eCOA tools in clinical trials. 94% of respondents were director level and above, involved primarily with Phase I, II, and III clinical studies in pharmaceutical and biotechnology organizations.

Results revealed concern about the challenges of adhering to timelines, minimizing delays, and ensuring data integrity. Respondents look to eCOA providers to address these issues and offer tech flexibility that facilitates streamlined integrations with other eClinical systems, incorporating expanding wearable technologies and accelerating protocol amendments.

The findings in this report can help steer the many stakeholders within the clinical research ecosystem in their selection or development of technology solutions. Here are a few highlights, with detailed findings in the next section of this report.

- When asked to rank **the top three (3) issues related to their eCOA technology platform that keeps them up at night**, 62% of respondents indicated timelines/delays, 50% highlighted data change capabilities, and 41% specified protocol amendments.
- 97% of respondents marked data quality as the most important factor in **selecting an eCOA technology platform provider**. 90% indicated user interface/ease of use as important or very important, and 88% pointed to faster study start-up.
- When asked to rank their **top three (3) measurements of success in eCOA endpoint collection**, 79% indicated visit compliance status, 77% noted diary/scale compliance status, and 65% pointed to patient enrollment status.
- Establishing new third-party integrations is considered a **top three (3) burden of switching eCOA providers** for 65% of respondents. 64% pointed to the burden of procurement qualification of the new provider, and 61% ranked losing customizations with the incumbent eCOA provider.

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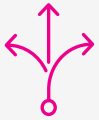
Five key takeaways

1.
eCOA continues to expand in adoption and integration with other health technologies.

eCOA adoption is growing because it improves data quality as well as the participant and site experience. It also integrates with advanced technologies like wearables and sensors.

2.
The biggest challenges clinical pros expect eCOA to address include timeline adherence and the need to make changes.



Clinical professionals seek eCOA technology that addresses timelines/delays and offers flexibility to make data and protocol changes quickly.

3.
The most critical eCOA features include an easy-to-use interface and the ability to ensure data quality.

Data quality is of utmost importance to clinical professionals, as is faster start-up times and a user-friendly interface to increase adoption and compliance.

4.
Top eCOA providers are keeping pace with advanced technologies.

Adoption of e-Consent, BYOD, and multimedia continues to grow, as eCOA providers address concerns and take a patient-centric approach.

5.
Collaboration among all stakeholders will drive accelerated research.

eCOA providers must lead partnerships with all stakeholders to advance the common goal of more quickly delivering new therapies to patients.

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Survey findings

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Top eCOA issues keeping execs up at night

Managing timelines and delays is a major challenge for clinical professionals.

> ***We asked survey participants to indicate the top three (3) issues keeping them up at night as it relates to their eCOA platform.***

The issue most frequently ranked as the respondents' number one concern was timelines and delays, with 62% of respondents ranking this challenge among their top 3. This is not surprising given the pressure on clinical teams for speed and efficiency as well as the impact delays have on time-to-market and budget. 50% rated data change capabilities in their top 3, which tracks back to the requirements of data accuracy. The third and fourth most frequently occurring items in the respondents' top 3 were protocol amendments (41%) and lack of tech flexibility (39%), which both point to the need to make changes in a timely manner.

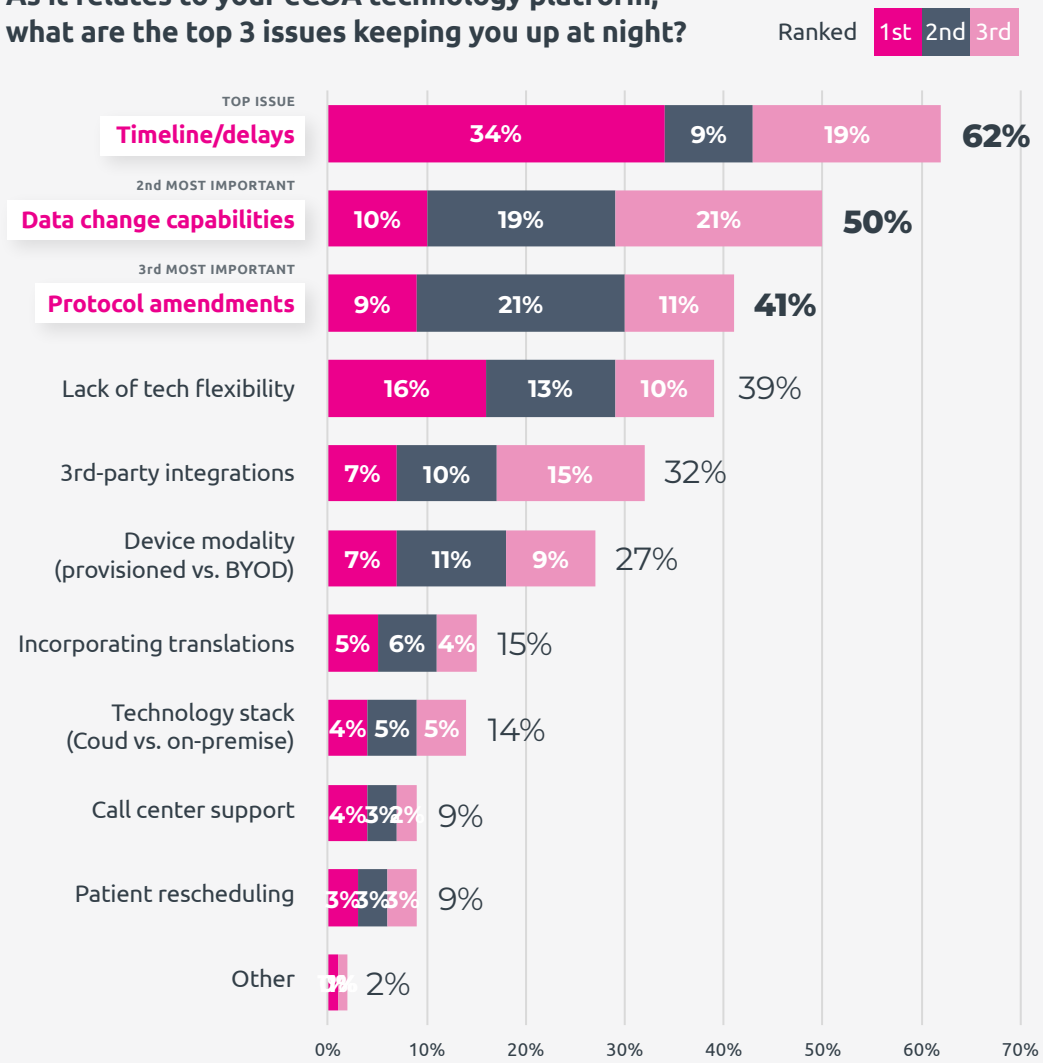
Timelines & delays: A pervasive challenge!

It's not just in the realm of eCOA. Here's what we learned when YPrime polled clinical professionals with interactive response technology (IRT) expertise in late 2023:

- **61%** indicated timelines/delays was the top issue keeping them up at night regarding their studies overall
- **62%** pointed to timelines/delay as the biggest issue keeping them up at night related specifically to their IRT platform

→ Read the full report on IRT trends. (URL to follow)

As it relates to your eCOA technology platform, what are the top 3 issues keeping you up at night?



Burdens in switching eCOA providers

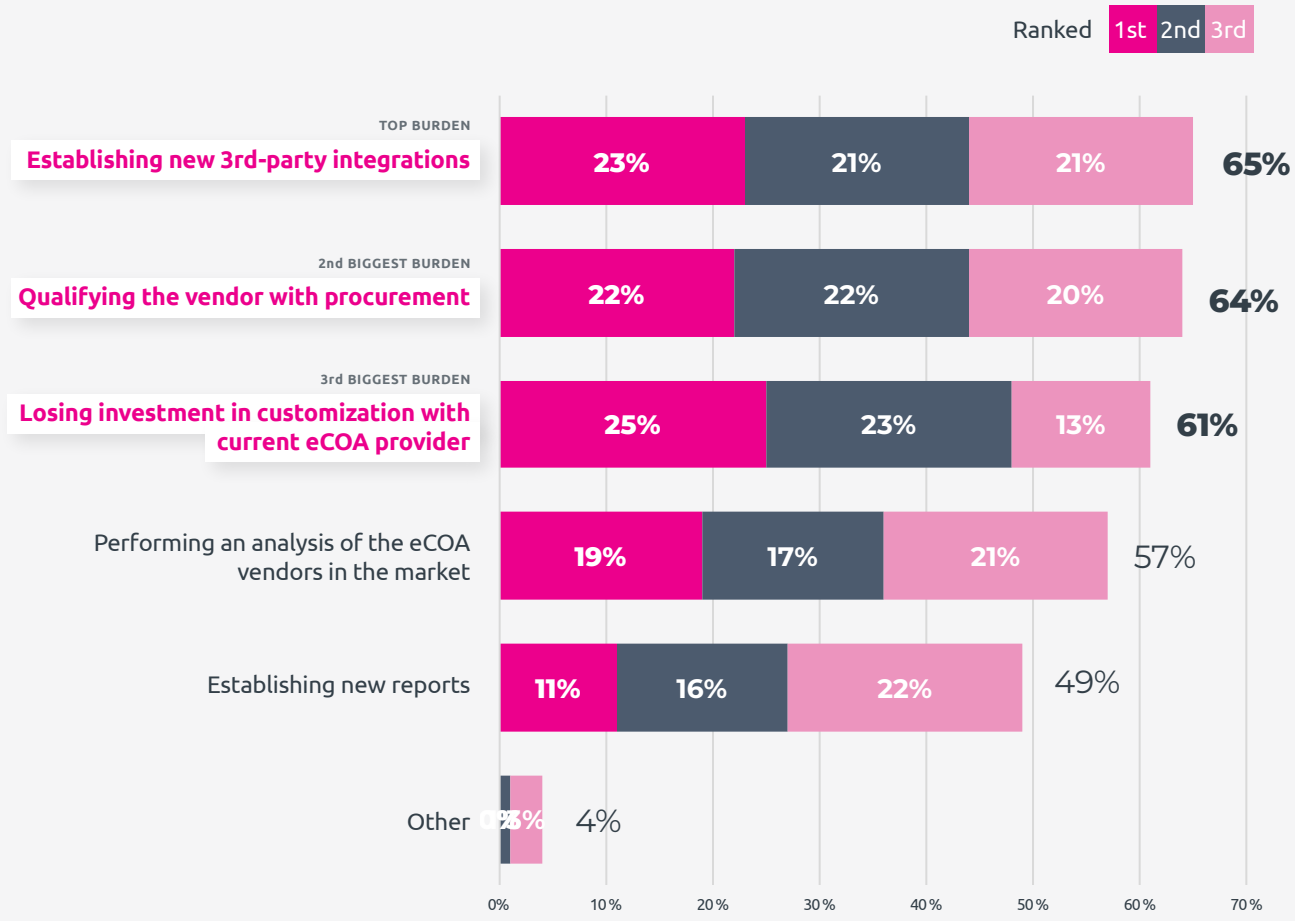
Changing eCOA providers is never easy, especially when there are 3rd-party integrations, software customizations, and procurement qualifications to consider.

> ***We asked survey participants to report the top three (3) burdens in switching eCOA vendors.***

Study teams already using an eCOA platform may wish to change but take pause because of some of the obstacles involved with switching providers. The top hindrances point to the difficult and time-consuming tasks they performed in implementing their existing eCOA provider's platform. 65% are concerned about having to set up new third-party integrations. 64% indicated the process of qualifying a new vendor with procurement, and 61% noted the loss of the investment in customizations done within the incumbent provider's system.

The top-3 difficulties in changing eCOA providers are nearly neck-in-neck.

What are the top 3 burdens in switching eCOA providers?



Top eCOA provider attributes

An eCOA provider's ability to ensure high-quality data is a key consideration.

> ***We asked survey respondents to rate attributes they may consider when evaluating an eCOA provider.***

Survey respondents overwhelmingly indicated that an eCOA provider's ability to support data quality is important, with 97% ranking it among their top 3 and 82% designating it as number 1. Other high-ranking attributes include user interface/ease-of-use (90%), functionality for faster start-up time (88%), and ability to handle changes quickly (86%).

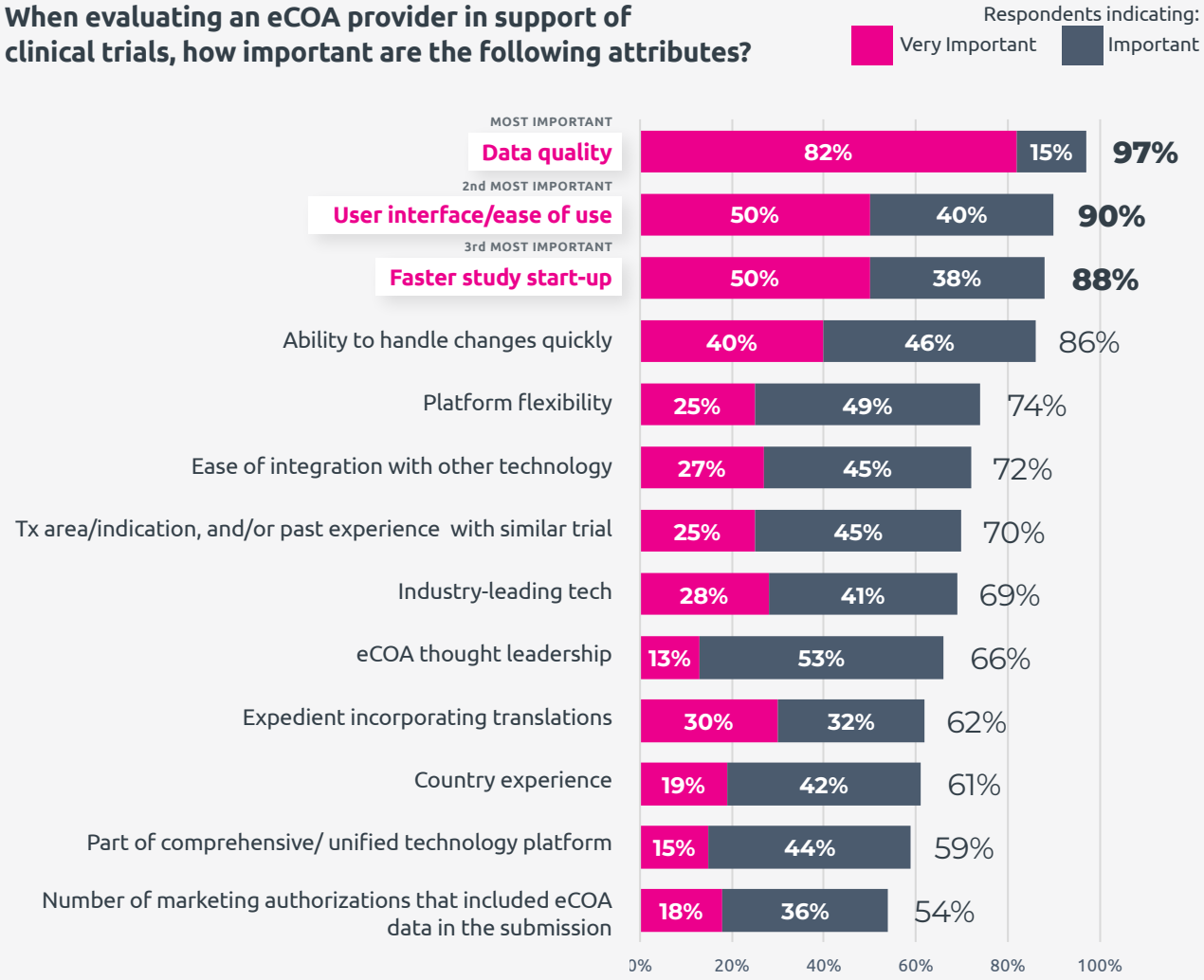
These eCOA provider attributes intertwine to deliver a better experience for patients, sites, and sponsors. Easy-to-use technology increases adoption and compliance by all user types, which contributes to data quality.

A powerful platform promotes data integrity and aids overall study acceleration.

And tech flexibility enables quicker and more accurate third-party integrations, customizations, and mid-study system changes due to protocol amendments.

The key is for sponsors and CROs to be aware of the technology available so they can take advantage of it.

When evaluating an eCOA provider in support of clinical trials, how important are the following attributes?



Managing protocol amendments & eCOA system changes

80% of respondents reported that it takes four weeks or longer to implement changes, and 26% indicated it takes seven weeks or more.

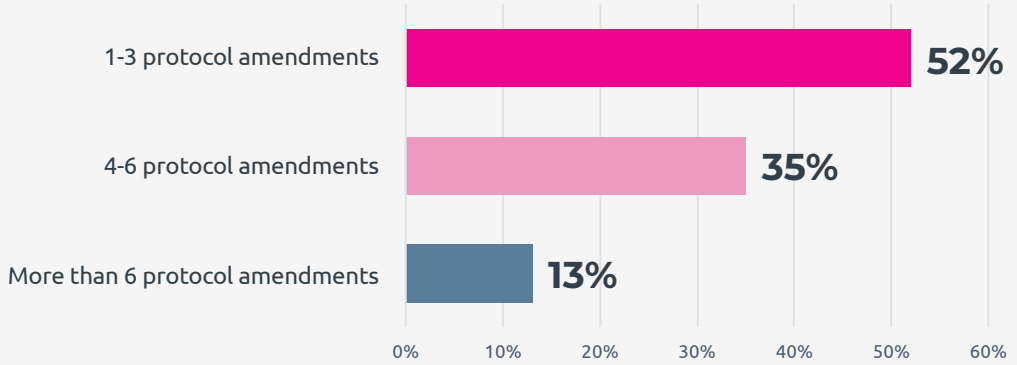
> ***We asked survey respondents two questions around mid-study changes seeking to understand their impact on a study's timeline.***

The first question asked the average number of protocol amendments in a study, and the other was the average length of time it takes to implement changes in the organization's eCOA platform.

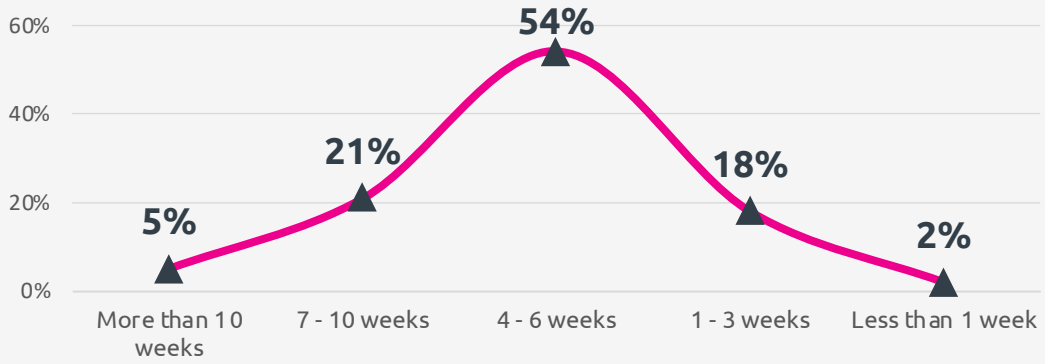
YPrime's ongoing marketing research shows that protocol amendments consistently rank high as an area of challenge for study sponsors. In the current survey, more than half (52%) of the respondents reported that their studies average one to three protocol amendments. Over one-third (35%) indicated four to six amendments, and 13% reported more than six. Regarding the time frame for implementing changes in their eCOA platform, 54% reported four to six weeks, 21% indicated seven to 10 weeks, and 18% reported one to three weeks.

More than half of respondents indicated it takes a month to a month and a half to implement changes in their current eCOA platform.

What is the average number of protocol amendments per study in the last 18 Months?



How long does it take to implement changes into your company's eCOA platform?



BYOD trends

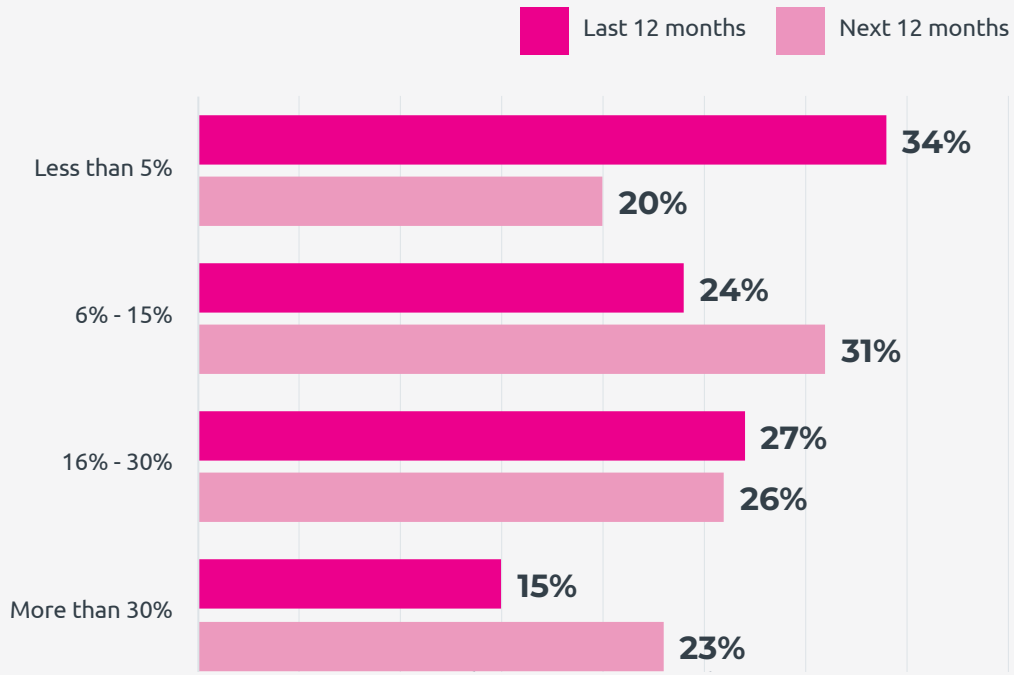
Use of Bring Your Own Device (BYOD) for eCOA will continue to increase.

> ***We asked survey respondents about the use of Bring Your Own Device (BYOD) in their eCOA studies in both the previous and upcoming 12 months.***

Use of Bring Your Own Device (BYOD) for eCOA continues to be a topic of debate because of the inherent benefits and obstacles, both of which vary based on therapeutic area and protocol design. Survey data reveal that in almost all cases, BYOD usage will increase in the 12 months following the survey versus the 12 months prior.

- There will be increased usage by 14% for the group that indicated "use BYOD in less than 5% of studies."
- There will be increased usage by 7% for the group that indicated "use BYOD in 6% to 15% of studies."
- There will be decreased usage by just 1% for the group that indicated "use BYOD in 16% to 30% of studies."
- There will be increased usage by 8% for the group that indicated "use BYOD in more than 30% of studies."

What percentage of your trials have used Bring You Own Device (BYOD) in the last 12 months/will use BYOD in the next 12 months?



Multimedia trends

Most respondents are using multimedia for eCOA in a small percentage of their studies.

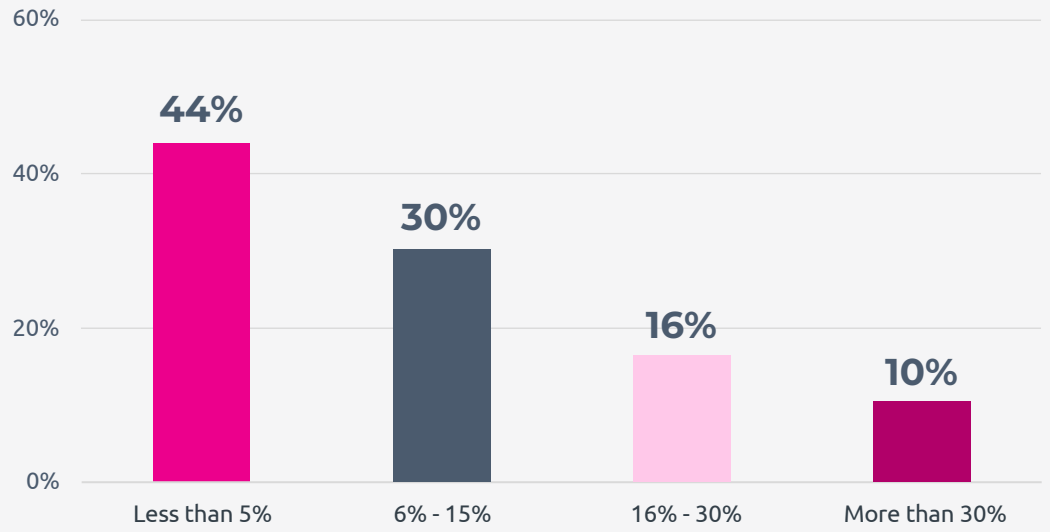
We asked survey respondents about their use of multimedia as a tool for outcome measurements.

The use of multimedia/video for eCOA, like BYOD, is often debated for reasons of accessibility, compliance, and therapeutic area concerns. This could, at least in part, explain why most respondents reported infrequent multimedia use. 44% reported using it in less than 5% of studies. 30% indicated they leverage available technologies in 6% to 15% of their studies, and 16% denoted they use it 16% to 30% of the time. Only 10% signified they use it in more than 30% of their clinical trials.

Multimedia in eCOA can improve data accuracy, participant engagement, and study efficiency, contributing to the success of a clinical trial. Here are some multimedia elements that can enhance eCOA.

- Interactive surveys and questionnaires
- Visual Analog Scales (VAS)
- Audio and video diaries
- Educational videos
- Multimedia instructions for assessments
- Adaptive questioning
- Integration with mobile apps and wearables
- Real-time feedback during assessments
- Data visualization

In what percentage of your clinical trials are you using multimedia/video in your eCOA assessments?



Other important trends

eConsent use is common among the survey respondents, and nearly 80% noted the value of a web diary.

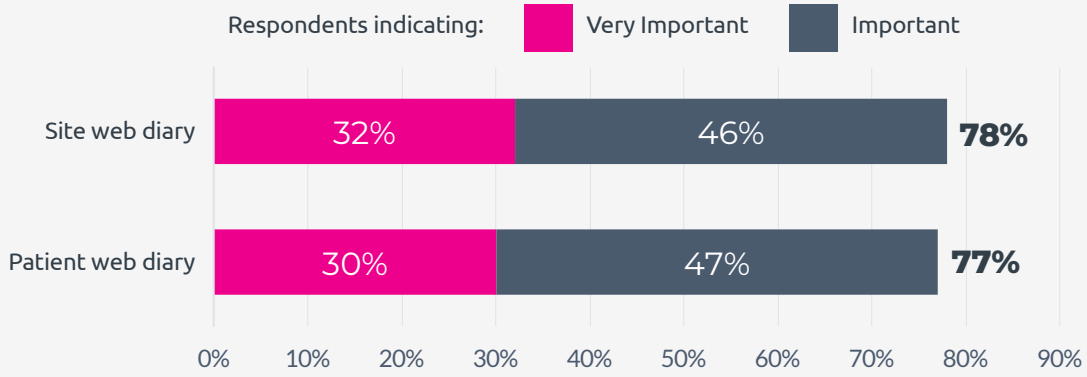
> ***We asked survey respondents about two other clinical trial technology tools: web-based eCOA data collection (referenced here as "web diary") and eConsent.***

More than three-quarters of respondents indicated the importance of a web diary as part of their eCOA platform, with 78% reporting that this functionality is important or very important for site personnel, and 77% responding that it is important or very important to offer to patients.

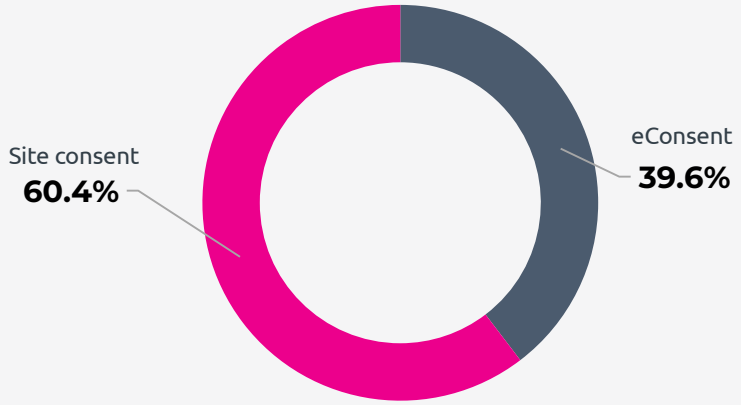
eConsent is becoming more common in clinical trials, and 40% of our respondents reported having used it.

These results reflect some of the priorities of survey respondents, namely, the need for tech flexibility and eCOA integration with advanced technologies.

How important is it to offer web diary entry to patients and clinicians?



What percentage of your trials are using eConsent vs. site consent?



Optimal use of eCOA

Respondents reported that visit and diary compliance are the greatest measures of eCOA endpoint collection success.

> ***Our survey explored how pharmaceutical and biotech study teams are using and measuring eCOA by asking about types of endpoints and definitions of success.***

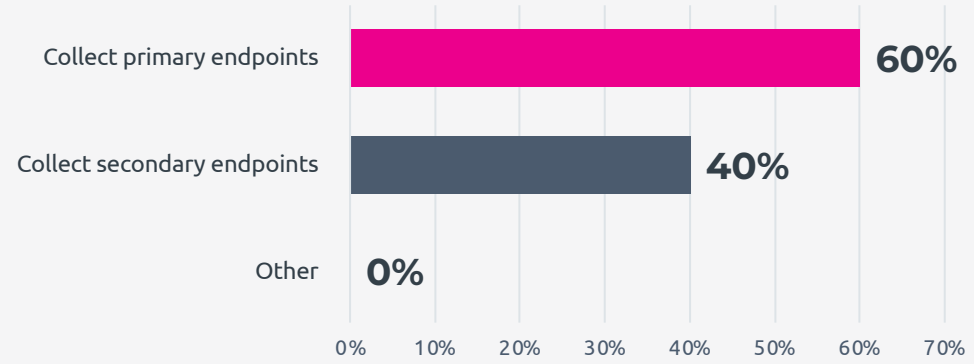
eCOA is valuable for multiple types of endpoints, with survey respondents indicating they use eCOA 60% of the time to collect data to support primary endpoints and 40% of the time to support secondary endpoints.

Respondents gauged the success of their eCOA endpoint collection in several ways. 79% indicated visit compliance status was a measure of eCOA success, while 77% reported diary/scale compliance status and 65% pointed to patient enrollment status.

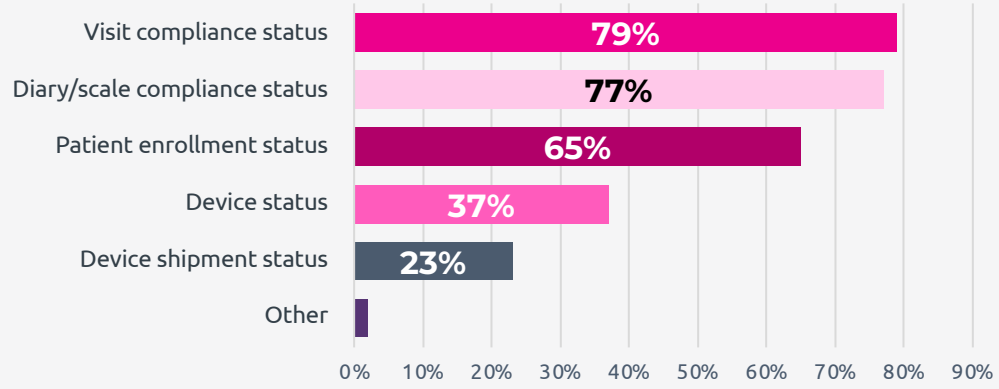
FYI, this is a valuable eCOA resource recently co-authored by YPrime's VP of eCOA Science on behalf of Critical Path Institute's eCOA Consortium:

Best Practices for the Electronic Implementation and Migration of Patient-Reported Outcome Measures

What type of endpoints do you typically collect with eCOA?



What are your measurements for successful eCOA endpoint collection?



Selecting the best technology for your study

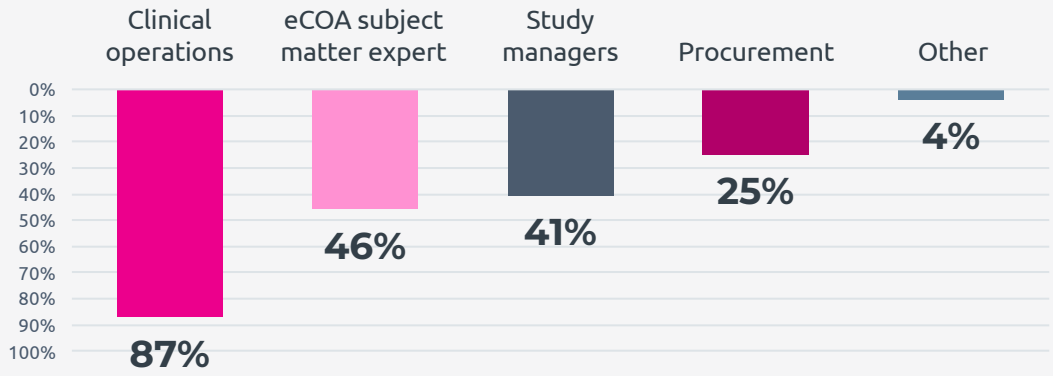
In most cases, the Clinical Operations team drives eCOA provider selection.

> ***To get a clear view of clinical eCOA environments, we asked survey respondents about the number of eCOA providers they worked with in the past year, as well as the primary decision maker(s) in selecting an eCOA provider.***

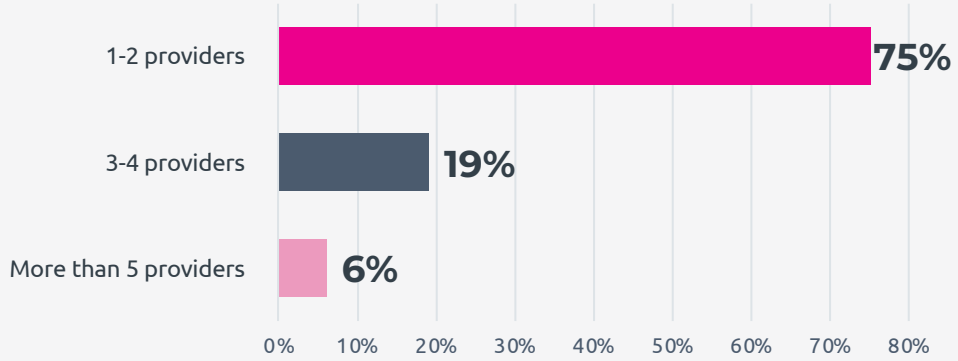
Other YPrime research has shown that eCOA platform selection is typically a team effort, and that is likely the case with the organizations represented in this report. In terms of making the final choice, most respondents (87%) indicated that the primary decision maker(s) is a clinical operations staff member(s). 46% indicated the eCOA subject matter expert(s), and 40% highlighted the study manager(s). Three-quarters (75%) of respondents reported that they have worked with one or two eCOA providers in the past year, 19% indicated three or four, and 6% said five or more. compliance status and 65% pointed to patient enrollment status.

While study teams tend to utilize multiple eCOA providers, three quarters of survey participants reported that, in the past year, they worked with just one or two.

Who are the primary decision maker(s) on selecting your eCOA provider?



How many eCOA providers have you worked with in the last year?



Conclusion

Navigating challenges related to digital and electronic data collection requires stakeholder collaboration, ongoing technological advancements, and a commitment to refining processes based on real-world experiences and feedback from the many parties involved in clinical research.

YPrime can help pharmaceutical and biotechnology clinical teams with the increasingly complex tasks involved with capturing, reviewing, and presenting clinical outcomes data throughout the course of a clinical trial. YPrime's development team keeps patients, sites, and sponsors at the forefront when designing our eCOA platform and works with project managers to incorporate feedback from these key stakeholders.

eCOA continues to expand with innovation shaping its future. In accordance with the industry's patient-focused drug development effort, eCOA is becoming more patient-centric and is seamlessly integrated with other technologies such as wearables, sensors, and other eClinical systems. It is built with site staff in mind so they can focus more on science and health and less on administration.

It's an exciting time for the intersection of technology and clinical research.

For more information on how YPrime's eCOA platform can help you achieve your goals, please contact **marketing@yprime.com**.

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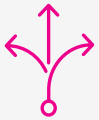
Five key takeaways

1.
eCOA continues to expand in adoption and integration with other health technologies.

eCOA adoption in clinical studies continues to grow due to its benefits, such as improved data accuracy, enhanced participant engagement, greater site personnel productivity, and streamlined study processes. eCOA platforms are evolving to meet the needs of patients, sites, and sponsors, integrating with advanced technologies like wearables and sensors.

2.
The biggest challenges clinical pros expect eCOA to address include timeline adherence and the need to make changes.



The survey results reveal significant concerns among clinical professionals regarding timelines and delays, the flexibility to quickly update eCOA systems due to protocol amendments, and ensuring data integrity. There's a clear demand for eCOA providers to address these challenges by offering technology that facilitates streamlined integrations and quick adaptation to changes.

3.
The most critical eCOA features include an easy-to-use interface and the ability to ensure data quality.

The survey results indicate data quality is a key criterion for clinical professionals when selecting an eCOA technology platform, followed by the importance of a user-friendly interface and the capability for faster study start-up.

4.
Top eCOA providers are keeping pace with advanced technologies.

The report discusses emerging trends like the increasing use of BYOD (Bring Your Own Device) and multimedia/video in eCOA assessments. These trends are expected to evolve further, reflecting the need for more patient-centric and adaptable solutions in clinical trials.

5.
Collaboration among all stakeholders will drive accelerated research.

The evolution of eCOA necessitates ongoing collaboration among stakeholders and continual technological advancements. eCOA processes should be refined based on real-world experiences and feedback to ensure the technology remains effective and relevant in the ever-changing landscape of clinical research.

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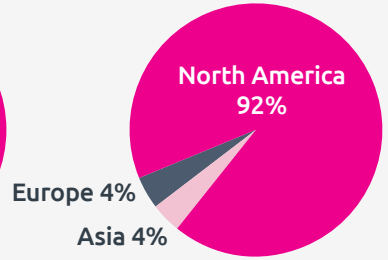
About the survey

YPrime executed this survey in October of 2023 with responses submitted via online questionnaires. This report presents the responses of 100 qualified survey participants, comprised of clinical operations professionals, eCOA subject matter experts, and other professionals with roles in clinical research, all of whom indicated they are extremely or very familiar with eCOA tools in clinical trials. 94% of participants are director level and above, involved primarily with Phase I, II, and III clinical studies in pharmaceutical and biotechnology organizations.

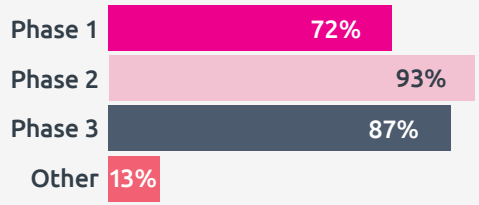
Country in which respondents work:

Region of company headquarters:

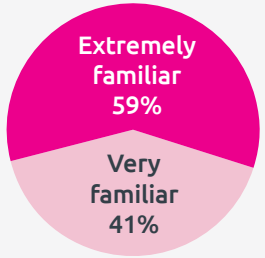


Sector:

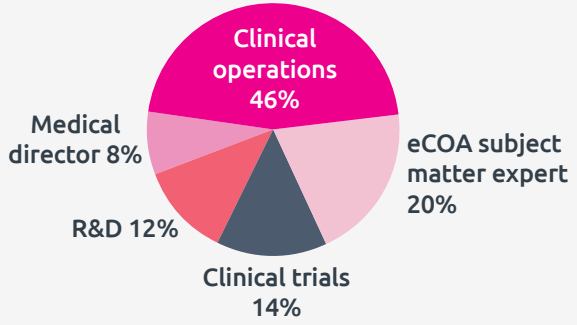
Phases of clinical trials in which respondents work



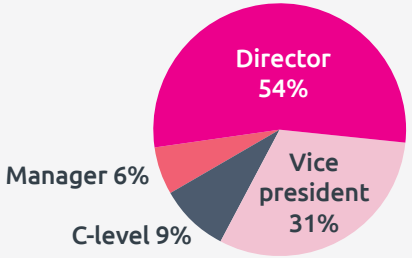
eCOA familiarity:



Job function:



Seniority level:



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About the authors

Mike Hughes
Chief Product Officer, YPrime

Mike has been a leading driver in the evolution of mobile health solutions for clinical outcome assessments for the past decade. Today he utilizes his extensive expertise in eClinical technologies to lead the engineering, development, and product management functions for all YPrime offerings. He is highly skilled in the design, development, and delivery of cutting-edge, patient-focused electronic clinical outcome assessment (eCOA) technology.

Drew Bustos
Chief Marketing Officer, YPrime

Drew stands at the forefront of innovation and design thinking as he directs Global Marketing at YPrime with an unyielding commitment to technological advancement. His strategic vision and leadership have been instrumental in pioneering patient-centric technology solutions in the life sciences sector. Drew's approach is not only strategic but also analytical and data-driven, resulting in a proven track record of substantial growth and market expansion.

About YPrime

YPrime's eCOA Solutions

YPrime's eCOA solutions are protocol-tailored to meet the unique needs of each therapeutic area. Our advanced eCOA platform is designed and implemented by a team that is passionate about improving the daily lives of patients, sites, and sponsors. We combine our know-how and technology to deliver cleaner data, enhanced clinical trial efficiency, and increased site satisfaction. Our advanced technology, flexible modalities, and expert scientific consultation ensure you focus on the most crucial endpoints and timepoints to answer the most important research questions, withstand regulatory scrutiny, and improve patient compliance and retention.

About YPrime

At YPrime, we pioneer solutions that streamline the clinical trial journey, increasing certainty from study design to data lock. With a foundation built on decades of industry insight and expertise, we are inspired by the life-altering outcomes unlocked by clinical trials. Our dedication to quality is pivotal in propelling the groundbreaking endeavors of our partners, researchers, and investigators. With a technology platform that enables speed, flexibility, and certainty for large and emerging pharma companies alike, we provide eConsent, eCOA, IRT, and patient engagement solutions that solve for certainty in clinical research. To learn more, email marketing@yprime.com or visit www.yprime.com.

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Let’s talk!

At YPrime, we pioneer solutions that streamline the clinical trial journey, increasing certainty from study design to data lock. Our approach to each clinical trial is based on a deep understanding of the medicine, your objectives, and the target patient population. There’s no one-size fits all at YPrime—our technology platform and expertise allow us to customize an approach that works best for you.

To find out why top pharma leaders and emerging biotech companies continue to choose YPrime for eConsent, IRT, eCOA, and patient engagement solutions, email **marketing@yprime.com** or visit **www.yprime.com**.

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