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INSIGHTS FROM A SURVEY OF CLINICAL RESEARCH PROFESSIONALS

Decreasing the Burden of Oncology Clinical Trials with eCOA

A survey report revealing the need for flexible technology that aids clinicians, patients, and sponsors

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Introduction

While there are similarities between all clinical trials, no matter the therapeutic area, certain elements make oncology clinical trials unique. These include the heterogeneity of cancer types, the diversity of treatment modalities, the state of the patient populations, the complexity of endpoints and assessment criteria, and the long duration of follow-ups.

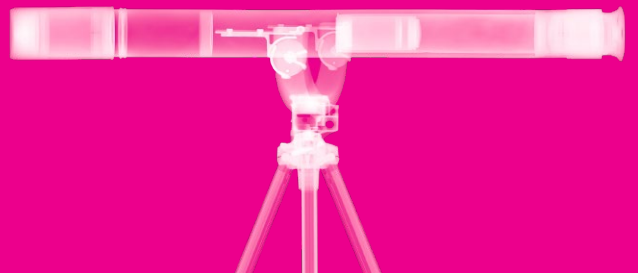
Electronic clinical outcome assessment (eCOA) is a valuable technology tool for a diversity of therapeutic areas and can address the specific requirements of oncology studies. It is widely recognized for improving data accuracy, reducing errors, enhancing patient engagement, and streamlining data collection. eCOA's heightened adoption and acceptance by regulatory agencies is underscored by certain aspects of oncology clinical trials. These include:

- Patient-reported outcomes (PROs) in oncology trials, critical for capturing subjective experiences related to symptoms and treatment tolerability, are efficiently managed by eCOA platforms.
- The complexity of oncology trial endpoints is streamlined through eCOA, ensuring accurate measurements.
- eCOA's real-time data capture capabilities are well suited to collect dynamic and time-sensitive safety data in oncology trials.
- Longitudinal monitoring and remote data collection, essential in oncology due to the chronic nature of the disease, are facilitated by eCOA.
- eCOA's integration with other electronic clinical systems and connected devices/sensors is crucial for the multidisciplinary context of oncology clinical trials.

As an eCOA provider committed to addressing the needs of patients, clinical sites, and sponsors, YPrime conducted a survey among oncology research specialists. The primary goal was to glean current perspectives on eCOA within oncology clinical trials and uncover insights into future expectations. This report presents the survey results and a discussion of each finding.

Integration of eCOA into clinical research methodologies over the past 20 years has transformed how data is collected, managed, and used to advance medical knowledge and enhance patient outcomes. We take pride in contributing to the pivotal role of eCOA in modern clinical trials.

> "We recognize the unique challenges faced by oncology researchers and are committed to providing tools to help them navigate trial complexities.
>
> Through our support of oncology studies, we help sponsors transform the experiences of site staff and patients in their quest to deliver new cancer treatments to market faster.
>
> **Mike Hughes**
> **Chief Product Officer,**
> **YPrime**



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Executive summary

YPrime executed the *eCOA Trends in Oncology Clinical Trials* survey in December 2023. The aim was to discover perspectives on eCOA technology platforms from clinical trial professionals at biotechnology and pharmaceutical companies who specialize in oncology research. This report presents the responses of 100 survey participants, all of whom work in the US, and indicate they are very (55%) or extremely (45%) familiar with eCOA. The pool of respondents comprises therapeutic area leaders (30%), clinical operations professionals (24%), and other professionals with roles in clinical research. Survey participants were involved in Phase II (91%), Phase I (71%), and Phase III (59%) clinical studies at pharmaceutical and biotechnology companies. 30% were manager level, 30% were director level, and the remaining 40% were vice president level and above.

The *eCOA Trends in Oncology Clinical Trials* survey results revealed persistent concerns regarding patient recruitment and retention as well as managing complex, oncology-specific study design and protocol amendments. To the right are some key survey results, with detailed findings on the following pages.

What are the top three issues keeping you up at night when conducting an oncology clinical trial?

81%

Patient recruitment and retention

68%

Timelines/delays

50%

Managing complex study design and protocol deviations

What are the top three issues keeping you up at night related to your eCOA platform in your oncology clinical trials?

67%

Managing the complex design and unique requirements

47%

Managing eCOA measures
(including licensing, translations, and getting the measures to the eCOA provider)

36%

- Systems too difficult for patients to use
- Integration with other eClinical systems

What are the top three ways an eCOA platform helps your oncology studies?

66%

- Collects vital patient-reported outcomes
- Manages complex questionnaires and diaries

60%

Reduces patient time at site

55%

Measures quality-of-life indicators

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Survey findings

Top issues keeping stakeholders up at night

There are many reasons why recruiting and retaining participants for oncology clinical trials can be difficult.

> ***We asked survey participants to indicate the top three issues that keep them up at night regarding the conduct of oncology clinical trials.***

Patient recruitment and retention (81%) was identified as the issue most likely to cause sleepless nights for clinical trial professionals involved with oncology studies. Timelines/delays were cited by 68%, and managing complex study design and protocol deviations was ranked by 50%.

To gain broader industry insights, we replicated the "top three concerns" question among clinical trial professionals in six other therapeutic areas. While the specific concerns varied across therapeutic areas, the top concern for each area was:

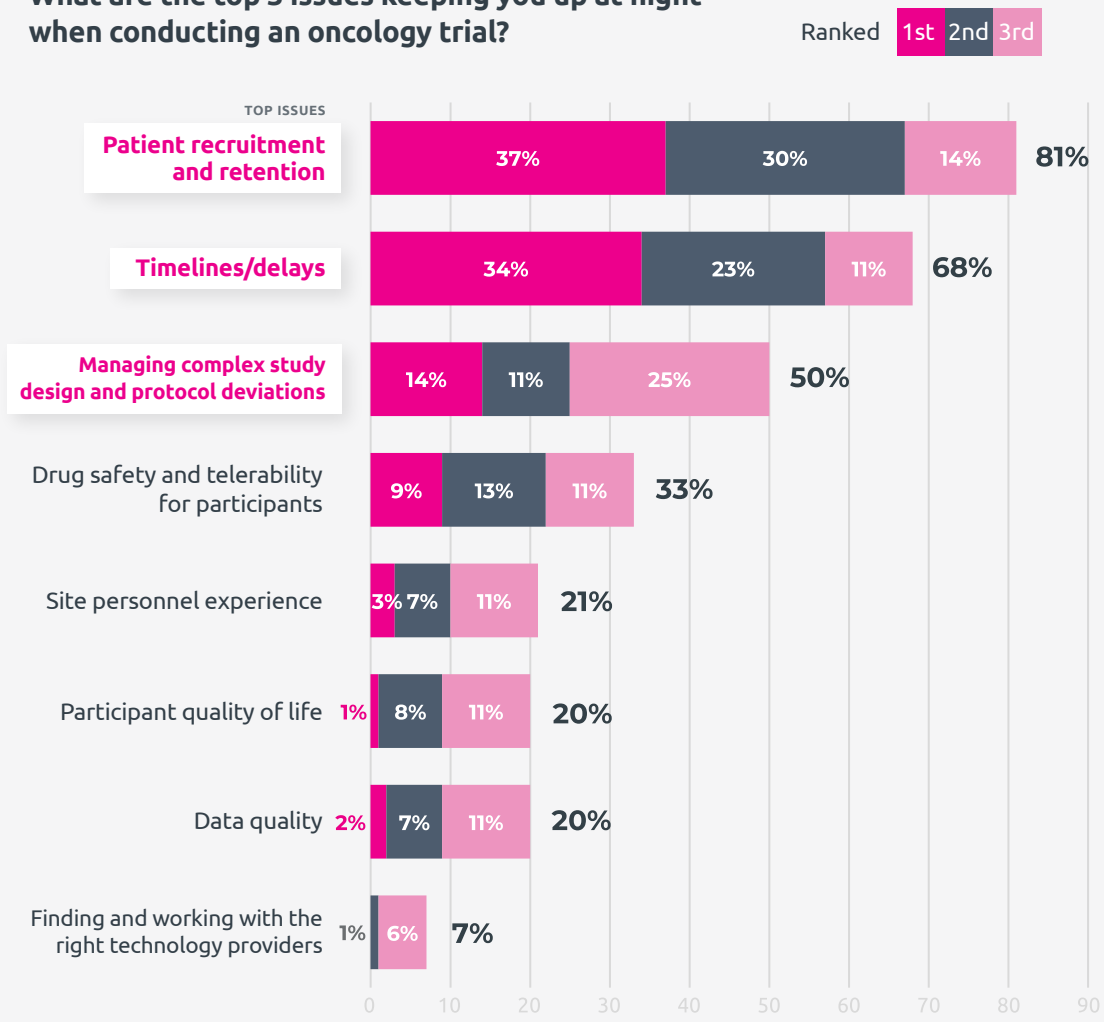
Recruitment & Retention
cited as #1 by:
71% of Dermatology Execs and
68% of Endocrinology Execs

Data Quality
cited as #1 by:
55% of Immunology Execs and
55% of Vaccine Clinical Trial Execs

Timeline / Delays
cited as #1 by:
60% of CNS Clinical Trial Execs

Drug Safety and Tolerability
cited as #1 by:
50% of Musculoskeletal Execs

What are the top 3 issues keeping you up at night when conducting an oncology trial?



Top eCOA issues keeping stakeholders up at night

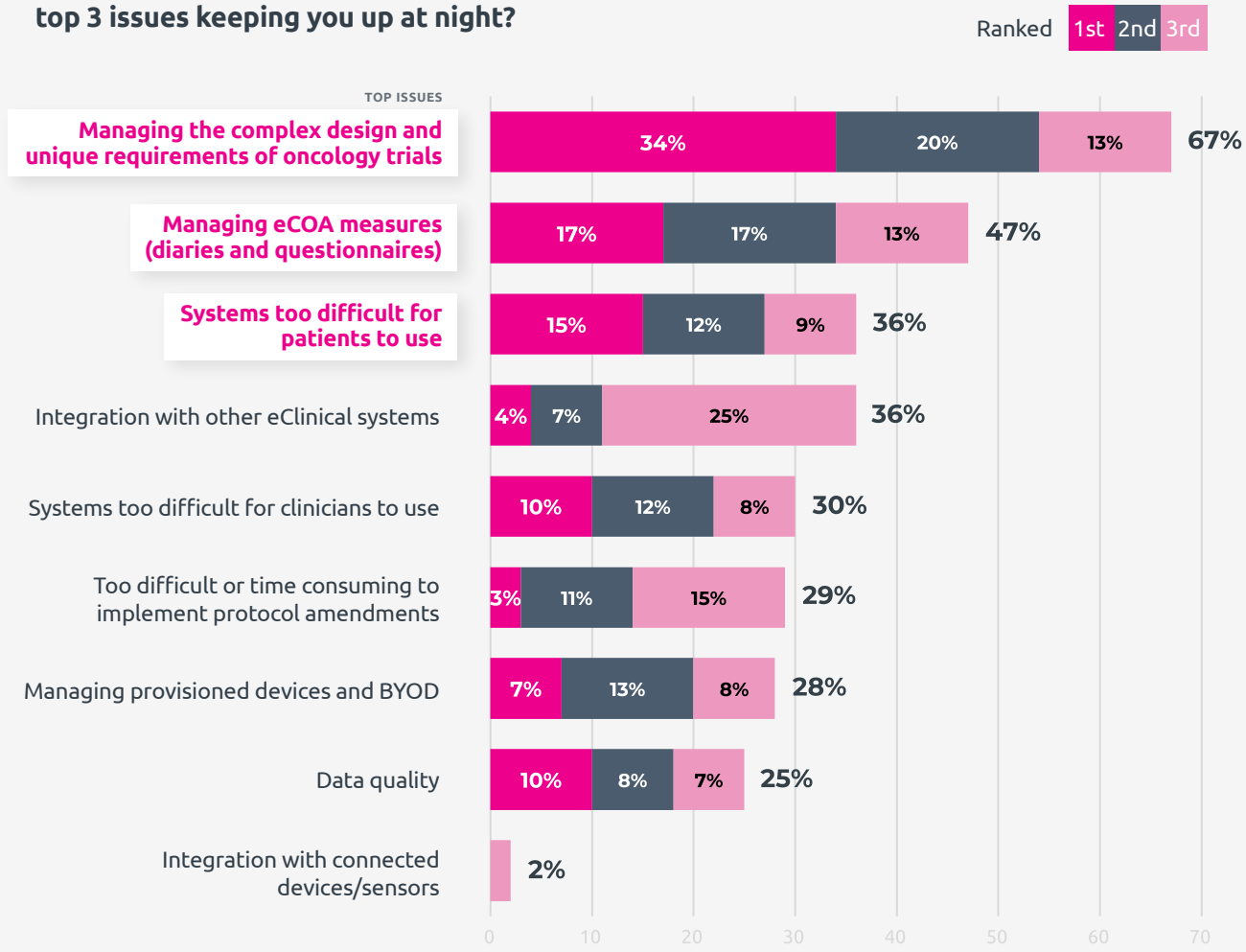
eCOA technology must be flexible enough to manage cancer studies as well as patients' unique and frequently changing requirements.

> ***We asked survey participants to rank the top three issues keeping them up at night related specifically to eCOA in their oncology clinical trials.***

By a wide margin, 67% of survey respondents ranked managing the complex design and unique requirements as the top issue keeping them up at night in terms of their eCOA platform(s). Coming in a full 20 points below, at 47%, is managing eCOA measures, including licensing, translations, and getting the measures to the eCOA provider. Both systems too difficult for patients to use and integration with other eClinical systems were ranked in the top three by 36%.

Two thirds identified
"Managing the complex design and unique requirements of oncology trials"
as a top challenge.

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



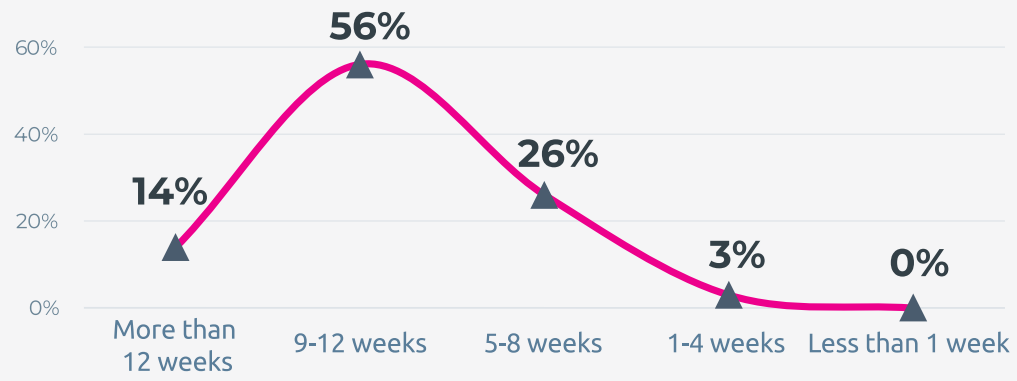
Analyzing time and change

Study start-up and protocol amendments are major considerations when estimating and managing timelines.

> ***We asked survey participants how long it takes to start an oncology study, how many protocol amendments they typically have, and how long it takes to implement a protocol amendment in their current eCOA platform(s).***

More than half (56%) of survey respondents indicated that it takes 9 to 12 weeks to start up an oncology study. 14% stated it takes longer than 12 weeks, and 26% reported 5 to 8 weeks.

How long does it take to start up an oncology study on your current eCOA platforms?



Oncology clinical trials have some of the longest start-up times, according to YPrime therapeutic area (TA)-focused research. 70% report 9 weeks or more.

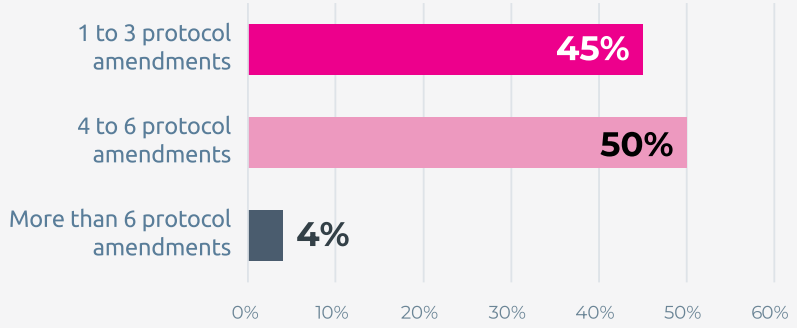
It is estimated that up to
80% of clinical trials fail to finish on time.*

*Accelerating clinical trials to improve biopharma R&D productivity, McKinsey & Company, January 2024.

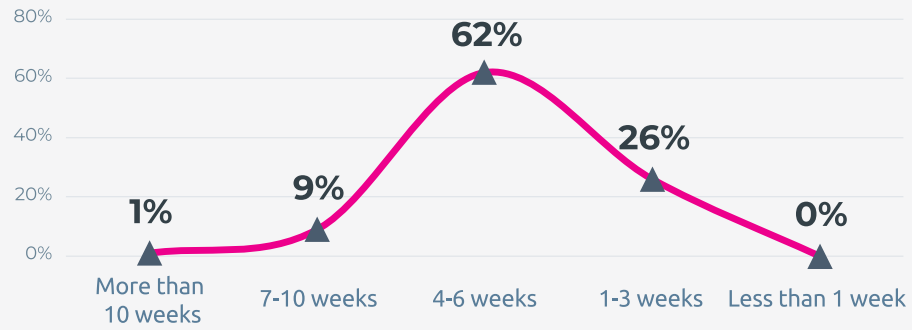
Analyzing time and change (continued)

Regarding protocol amendments, another time consumer, the majority (62%) indicated it takes 4 to 6 weeks to implement changes in their eCOA systems, with 26% stating 3 weeks or less and 10% responding 7 weeks or more.

On average, how many protocol amendments per study have occured during the last 18 months?



On average, how long does it take your preferred eCOA provider to implement protocol amendments?



A key finding from the survey revealed that **a significant portion (50%) of respondents experienced 4 to 6 protocol amendments per study** within the past 18 months.

72% report that it takes 4 weeks or more to implement a protocol amendment.

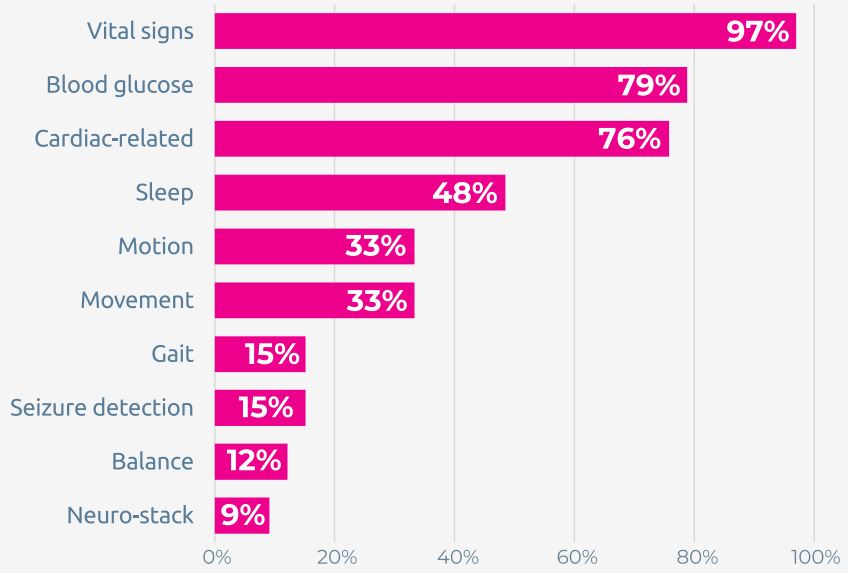
Leveraging other technologies

With concern for patient experience and data quality, clinical trial professionals cautiously adopt adjunct technologies.

> ***We asked survey participants what endpoints they measure with connected devices/sensors in their oncology clinical trials, and in what percentage of their studies they use multimedia/video in eCOA assessments.***

The oncology clinical trial professionals who participated in the survey indicated the most common endpoints they collect from connected devices/sensors are vital signs (97%), blood glucose (79%), and cardiac-related measures (76%).

Which endpoints do you measure using connected devices/sensors?



Commonly Used Connected Devices/Sensors Across Therapeutic Areas

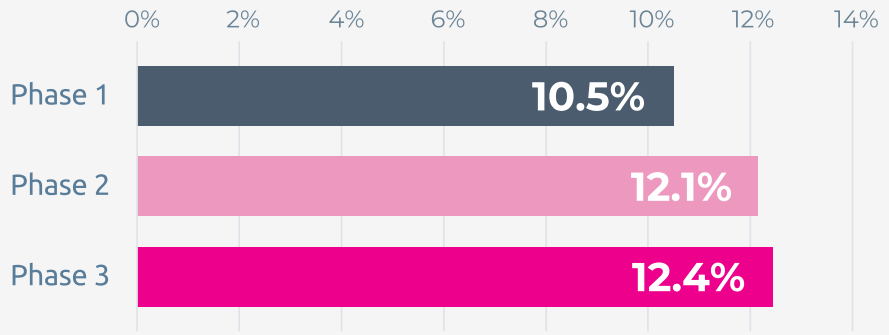
Depending on the nature of the clinical trial and the parameters being measured, study teams may use connected devices/sensors to collect valuable data. The devices may be used to collect data passively, in-clinic, or outside-of-clinic. Here are some of today's more commonly used connected devices/sensors.

- Activity trackers
- Smartwatches
- ECG monitors
- Blood pressure monitors
- Glucose monitors
- Pulse oximeters
- Smart inhalers
- Sleep trackers
- Medication adherence sensors
- Temperature sensors
- Smart clothing

Leveraging other technologies (continued)

Regarding multimedia/video, survey participants reported using photos, videos, audio, and other technologies in about 12% of their clinical trials. The percentage is slightly higher in Phase III (12.4%) and Phase II (12.1%) studies as compared to Phase I (10.5%).

What percent of your trials are using multimedia/video in your eCOA assessments?



Multimedia/video lends itself to some therapeutic areas more than others.

While the average use in **oncology** is **12%**

the average use in **dermatology** is **21%**

We examined the utilization of multimedia and video elements within eCOA to understand what percentage of trials incorporate this technology.

How eCOA helps patients and clinicians

The clear consensus from clinical trial professionals is that eCOA is powerful because it promotes patient-centricity in many ways.

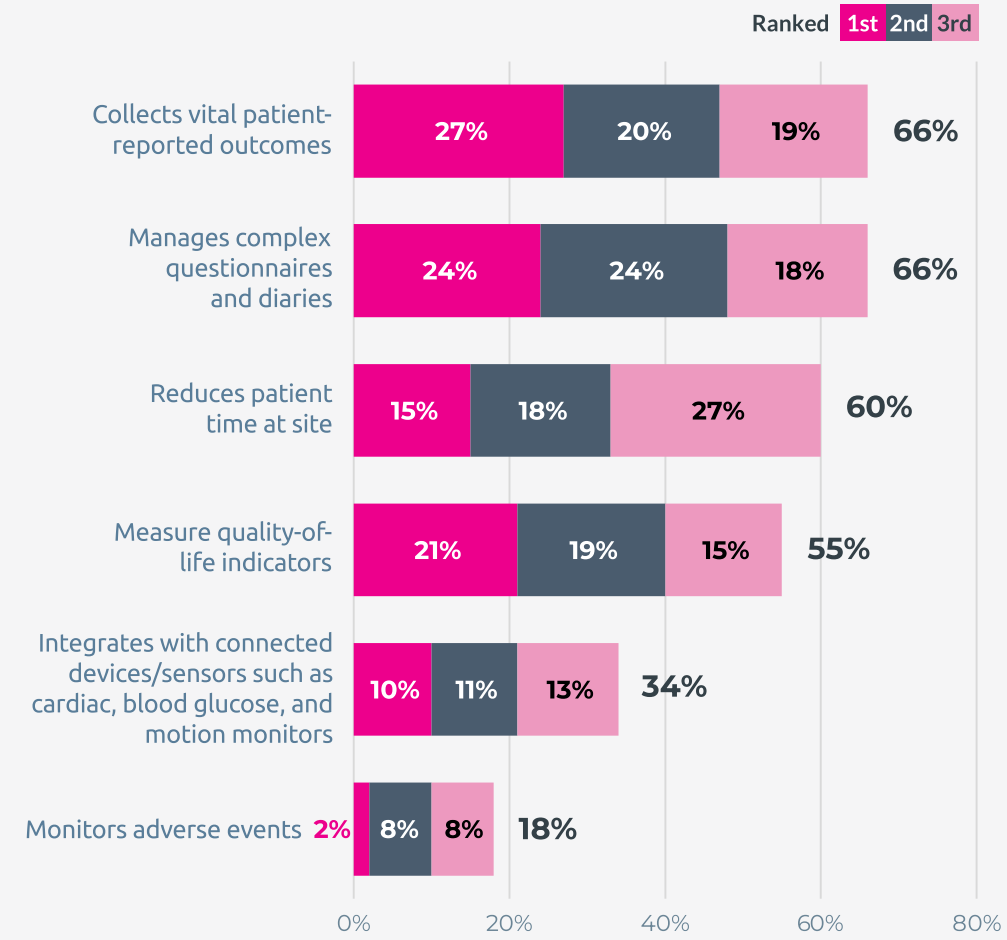
> ***We asked survey participants to indicate what they consider to be the top three benefits of an eCOA platform.***

The responses to this question are quite patient-focused. 66% ranked collecting vital patient-reported outcomes as the top benefit, and the same number (66%) indicated managing complex questionnaires and diaries. 60% ranked reducing patient time at the site in their top 3, and it is worth noting measuring quality-of-life indicators (55%) ranked in the number 4 position.

Project Patient Voice

In 2020, the FDA launched Project Patient Voice, an online platform for patients and caregivers, along with their healthcare providers, to look at patient-reported symptom data collected from cancer clinical trials.

Please rank what you consider to be the top 3 benefits of an eCOA platform.



Five key takeaways

1.
eCOA helps facilitate patient-centricity in oncology clinical trials.

There is a perceived value of eCOA platforms enhancing the patient experience with simple ePROs, less patient time at sites, real-time monitoring, and quality-of-life measurements.

2.
Managing complex oncology requirements is a significant challenge.

The highly involved and variable nature of oncology studies suggests the importance of robust systems to navigate and manage the multifaceted steps effectively.

3.
Oncology clinicians require flexibility in their eCOA technology.

There is a critical need for eCOA platforms to be adaptable and responsive to the dynamic nature of oncology research, including the frequently changing requirements of cancer studies and patients.

4.
Time-consuming study start-up and protocol amendment implementations are major concerns.

Under pressure to accelerate time-to-market, clinical trial professionals are concerned about the time required for start-up and protocol amendments, which can be reduced through optimal eCOA usage.

5.
Patient recruitment and retention are top issues.

Providing patients and their care partners with easy-to-use technology will positively impact user experience and retention rates—minimizing dropouts and associated costs.

Conclusion

Integrating flexible technologies, such as eCOA, has emerged as a transformative force in cancer clinical trials. The adaptability of these technologies addresses the unique challenges posed by the dynamic nature of cancer, diverse treatment modalities, and complex endpoints. Patient-reported outcomes (PROs) are efficiently managed, and real-time data collection supports adaptive trial approaches. Flexible technology facilitates remote monitoring, ensuring patient-centricity and overcoming logistical challenges. As we navigate the future of cancer research, embracing and advancing flexible technologies will be pivotal, offering a streamlined and patient-focused approach to improving outcomes in oncology clinical trials.

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About the authors

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.

Donna Mongiello, RN, BSN
SVP, eCOA Strategy, YPrime

Donna's diverse career in healthcare began in nursing and evolved to focus on technologies that support patients in clinical research. A published author who presents at pharmaceutical industry conferences, Donna has nearly 20 years in the clinical trial space and expertise in patient centricity, improving enrollment success, eCOA, BYOD, and more. In her current leadership role at YPrime, she is the subject matter expert for eCOA, providing strategic direction that drives key partnerships through innovation.

About YPrime

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**.

About 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 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.

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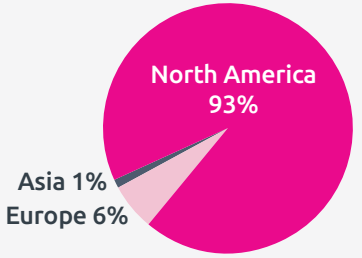
About the survey

YPrime executed the *eCOA Trends in Oncology Clinical Trials* survey in December of 2023, with responses submitted via online questionnaires. This report presents the responses of 100 survey participants who indicated they were very (55%) or extremely (45%) familiar with eCOA. The pool of respondents comprises therapeutic area leaders (30%), clinical operations professionals (24%), and other professionals with roles in clinical research. Survey participants were involved in Phase II (91%), Phase I (71%), and Phase III (59%) clinical studies at pharmaceutical and biotechnology companies. 30% were manager level, 30% were director level, and the remaining 40% were vice president level or above.

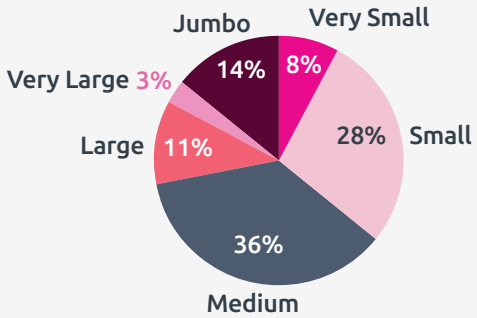
Country in which respondents work:

Region of company headquarters:



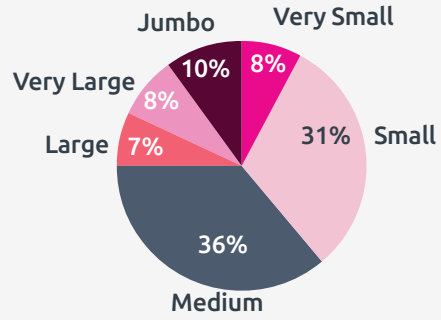
Sector:

Organization's full-time employees:



1-99 Employees (Very Small)
100-499 Employees (Small)
500-999 Employees (Medium)
1,000-4,999 Employees (Large)
5,000-9,999 Employees (Very Large)
10,000+ Employees (Jumbo)

Organization's revenue:



< $100m (Very Small)
$100m-$499m Employees (Small)
$500-$999 Employees (Medium)
$1b-$4.9b Employees (Large)
$5b-$9.9b Employees (Very Large)
> $10b Employees (Jumbo)

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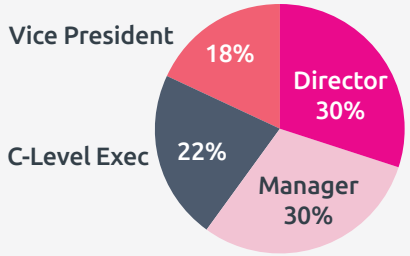
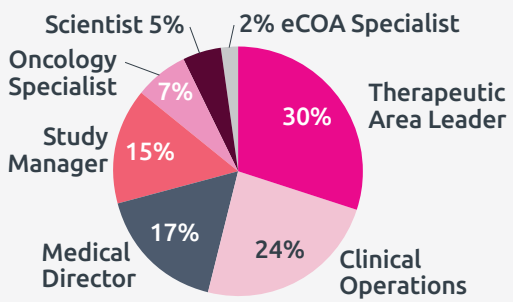
About the survey (continued)

We examined seniority level, job functions, experience with eCOA, the phase of the clinical trial, and ensured responses pertained to oncology.

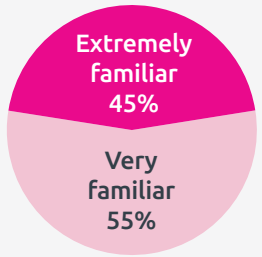
Seniority level:



Job function:



eCOA familiarity:



Therapeutic area(s) of focus:

Oncology	100%
Systemic Anti-Infectives	2%
Central Nervous System	13%
Gastrointestinal	11%
Dermatology	17%
Immunology	53%
Respiratory	12%
Cardiovascular	17%
Musculoskeletal	4%
Sensory Organs	2%
Endocrine	9%
Genitourinary	5%
Blood	39%
Other	1%

Involvement in clinical trial phase(s):

Phase I	71%
Phase II	91%
Phase III	59%
Other	2%

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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Additional reading

Access more YPrime content that focuses on reducing uncertainty and risk in clinical trials.

WHITE PAPER

Patient Perspectives on Clinical Trial Technology—Informed Consent and Patient Diaries: The Study Participants' Point of View

This report examines how clinical trial participants feel about the technologies they are being asked to use. What can we do to increase compliance and improve the patient experience?

WHITE PAPER

eCOA Trends for Today and Tomorrow

Read what clinical trial professionals report to be their greatest challenges—and how eCOA can address these issues to meet the evolving needs of patients, clinical sites, and sponsors.

WHITE PAPER

IRT Trends for Today and Tomorrow

IRT continues to evolve, expanding its impact on the speed and quality of clinical trials. This report reveals the perspectives of IRT professionals on their most demanding challenges.

CASE STUDY

YPrime in Action: A Global eCOA Rescue Study

Learn how YPrime orchestrated an urgent rescue operation for a large global pharmaceutical Phase III respiratory study. YPrime stepped in as an expert in quality data migration and management, flexible system design to accommodate amendments, validated assessment libraries, and seamless integrations.

YPrime