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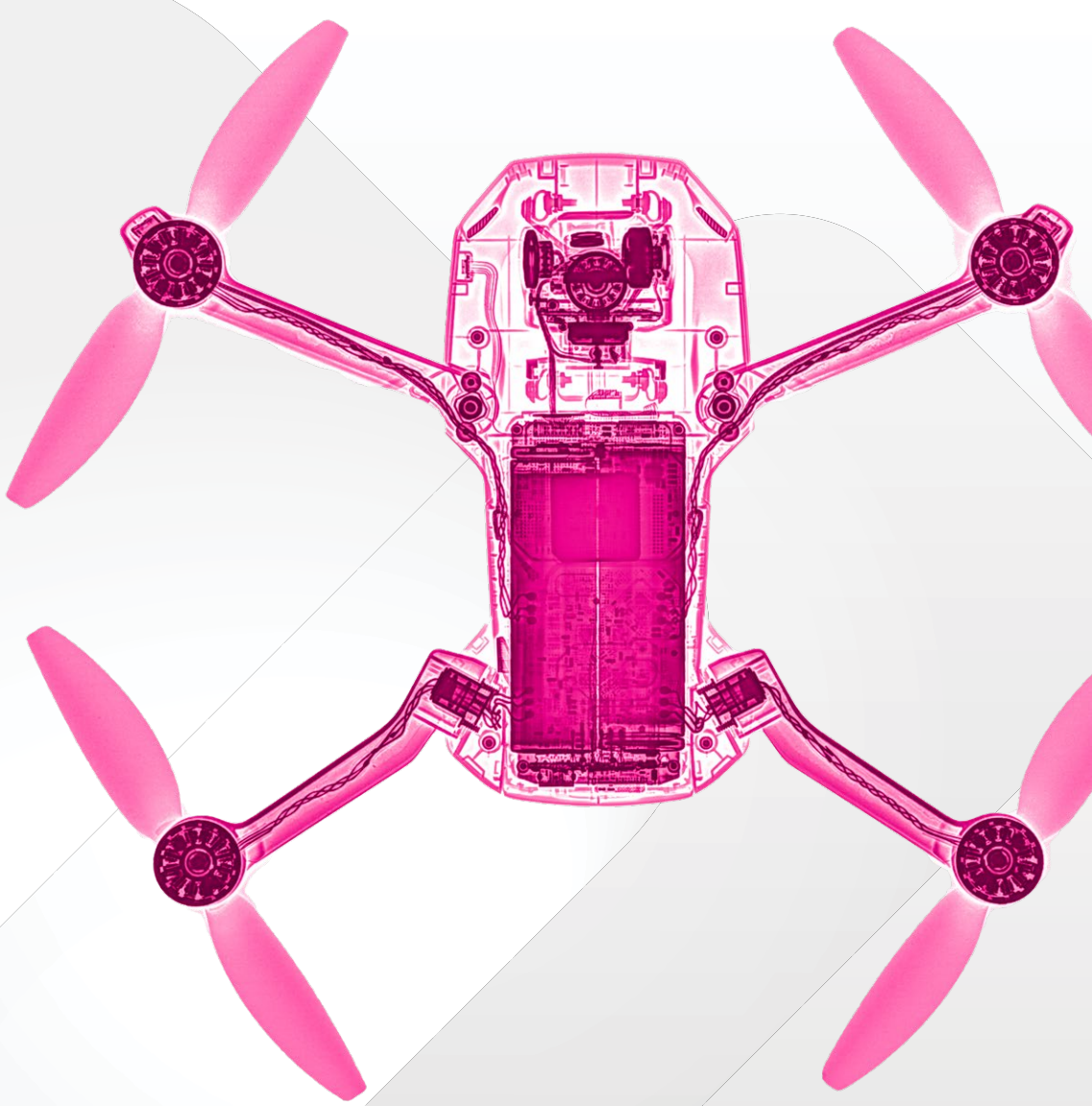
INSIGHTS FROM A SURVEY OF CLINICAL RESEARCH PROFESSIONALS

IRT Trends for Today and Tomorrow

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



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Introduction

Clinical research is complex and requires multiple teams with specialized expertise using different technologies to be executed accurately and efficiently. One of the technologies used by sponsors and contract research organizations (CROs) is interactive response technology (IRT), sometimes referred to as randomized trial supply management (RTSM), which helps clinical trial personnel manage participant randomization and allocation, drug dispensation and inventory management, and other associated tasks. IRT streamlines critical processes, significantly impacting the timeliness and data integrity of a clinical trial and the caliber of the human experience.

Since the start of industry adoption about 30 years ago, IRT has continuously evolved, taking advantage of increasingly efficient underlying technologies and expanding its impact on the speed and quality of clinical trials. Today's most innovative IRT architecture, based on microservices rather than monolithic designs, promises to address IRT users' most significant pain points. This latest technology accelerates trials and enhances data integrity with faster design, start-up, and protocol amendment implementations, as well as seamless integrations with other eClinical systems. The evolved architecture facilitates business intelligence and reporting, and its built-in flexibility enables adaptive trial design and the agility to make mid-study changes more easily and quickly.

As a leading IRT provider, YPrime surveyed clinical research professionals involved with the selection and use of IRT to better understand their perspectives and needs. This report presents the survey results and industry insights to provide context and provoke consideration.

There is no doubt that clinical research is becoming more complex. If sponsors and CROs want to compete and get their therapies to patients faster, they must adopt innovative technologies to help make it happen. But first, let's look at today's insights and outlooks

> "Assisting site staff with technology in clinical trials is like providing top-notch equipment to athletes before a championship game. It's about giving them the best tools, streamlining their performance, and ensuring they have the winning edge in the pursuit of groundbreaking discoveries. In the realm of clinical trials, our goal is not just success, but a record-breaking triumph for the future of healthcare.
>
> **Mike Hughes**
> **Chief Product Officer,**
> **YPrime**

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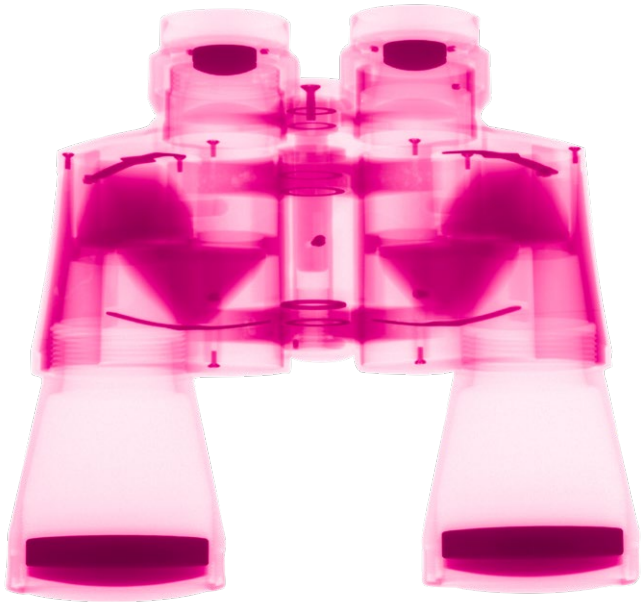
Executive summary

YPrime conducted its *Interactive Response Technology (IRT) Technology Trends* survey via email in the fourth quarter of 2023. The survey respondent pool is comprised of IRT development, drug supply, clinical operations, and research and development professionals, all of whom indicated they are extremely or very familiar with IRT platforms in clinical trials. The survey participants are director level and above, involved with Phase I, II, and III clinical studies in pharmaceutical and biotechnology organizations.

The survey results pervasively pointed to timelines/delays as a major challenge. Respondents also indicated data quality is a significant concern. They realize there are technological solutions to help with the issues identified but face obstacles in implementing a new platform. Below are some of the most revealing statistics, with full results in the next section of this report.



- When asked to rank **the top three (3) issues keeping them up at night when conducting a clinical trial,** 61% indicated timelines/delays, 55% specified patient recruitment, and 40% designated data quality.
- **Explicitly related to their IRT platforms, the top issues keeping respondents up at night** are timelines/delays (62%), lack of tech flexibility (41%), and trust in their IRT provider (41%).
- **Survey participants ranked the top three (3) most important benefits they seek in a new IRT provider,** with 61% indicating quick study start-up, 58% prioritizing faster protocol amendment implementation time, and 48% specifying platform cost-effectiveness.
- When asked to rank the **top three (3) most important provider attributes when selecting an IRT platform,** respondents indicated data quality (88%), user interface/ease of use (85%), and the ability to handle changes quickly (81%).

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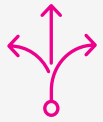
Five key takeaways

1.
Adhering to timelines and ensuring data integrity are among the top concerns of clinical professionals.

Timelines/delays and data quality are critical components of clinical trial efficiency and, therefore, prevalent concerns.

2.
Clinical pros who focus on IRT point to timelines, delays, and lack of tech flexibility as primary issues.



Study managers rely on IRT for study flow and efficiency, seeking a trustworthy provider who can address their challenges.

3.
Study start-up and protocol amendments are primary hindrances in adhering to timelines.

Study teams are seeking help with accelerating study start-up, protocol amendments, and other mid-study changes.

4.
Research pros seek an IRT provider who delivers data quality assurances as well as tech flexibility and ease-of-use.

IRT provider must-haves: Ability to ensure data quality, system ease of use, and the capability to handle changes quickly.

5.
IRT innovation adoption requires trust in advanced technologies and provider.

Clinical research projects will benefit not only from a trustworthy IRT partner, but also innovative technology.

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Survey findings

What's keeping execs up at night on clinical trials

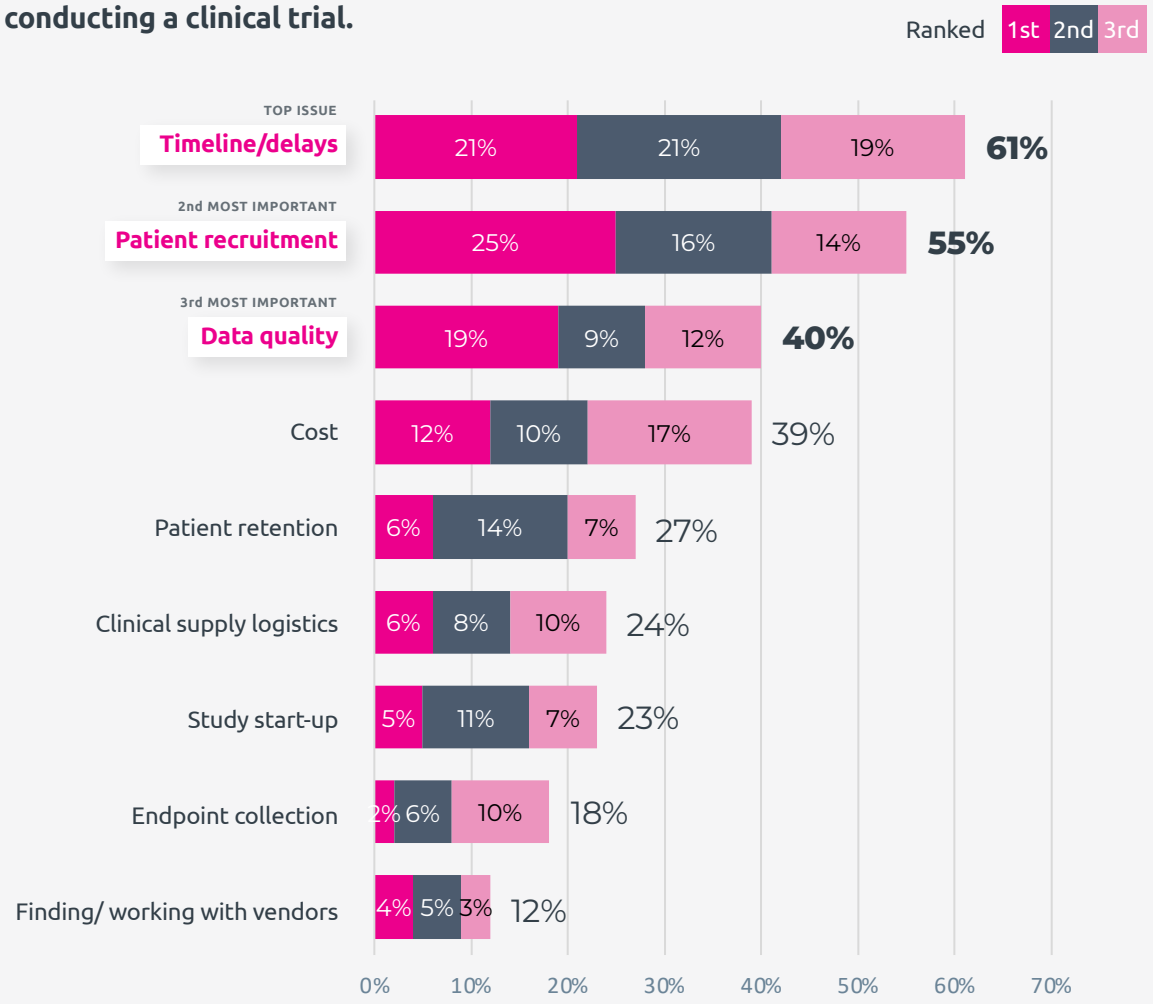
Timelines, delays, and patient recruitment are the greatest causes for concern.

> ***We asked survey participants to rank the top three (3) issues keeping them up at night when conducting a clinical trial.***

Nearly two-thirds (61%) of survey participants indicated that timelines/delays are a significant challenge in running clinical trials. Over half (55%) specified patient recruitment, which can be a major factor in adhering to timelines. Other high-ranking issues include data quality (40%) and cost (39%).

Pressure to keep things on track: 61% of respondents report timelines/delays are a top challenge

Rank the top 3 issues keeping you up at night when conducting a clinical trial.



Top IRT issues keeping execs up at night

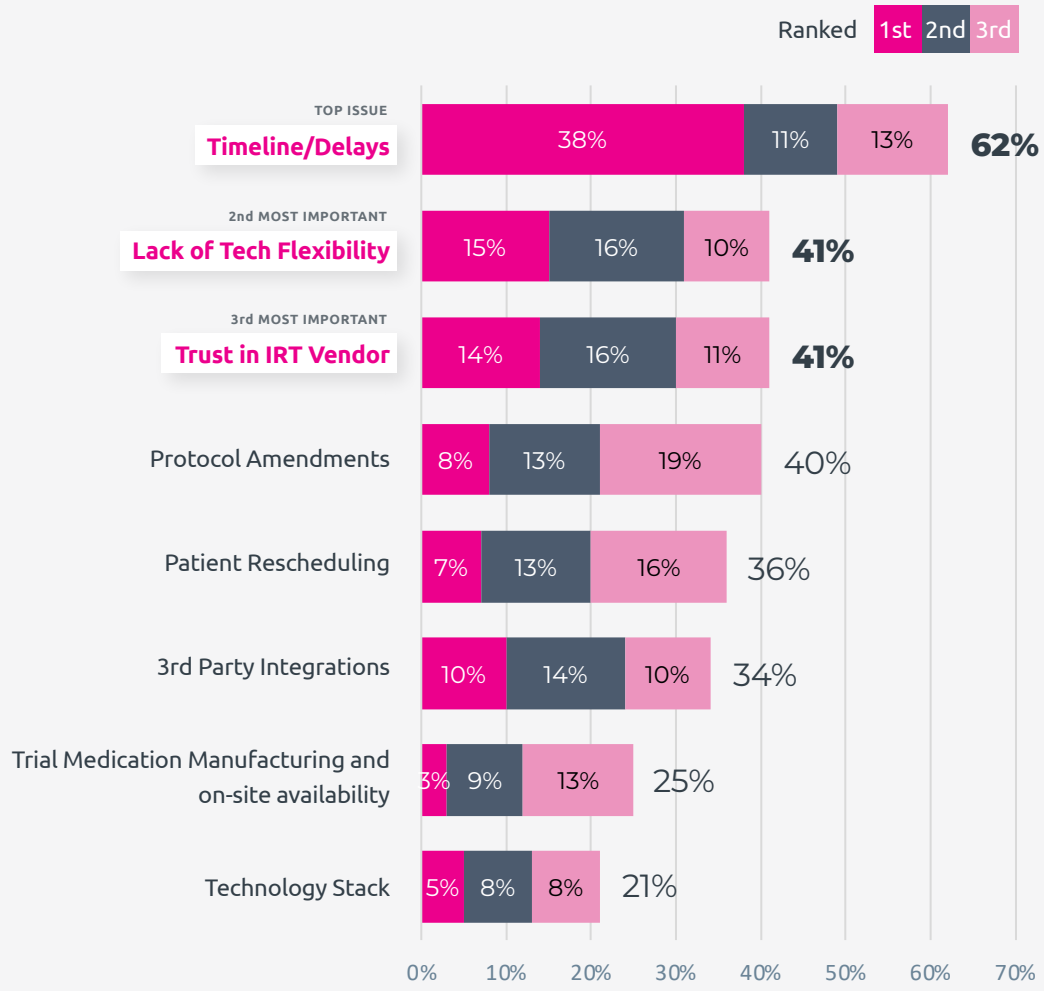
Once again, timeline adherence and unexpected delays are ranked as top stressors.

> ***We asked survey participants to indicate the top three (3) issues keeping them up at night related to their IRT platform(s).***

The top cause for concern around IRT is the same as for the study overall: timelines and delays. 62% of the professionals surveyed identified this as the number one issue because IRT has such a major impact on the trial flow. Lack of tech flexibility, trust in the IRT provider, and protocol amendments all came in at around 40%.

IRT users seek help managing timelines and delays with more flexible technology

Top IRT Issues Keeping Execs Up Night



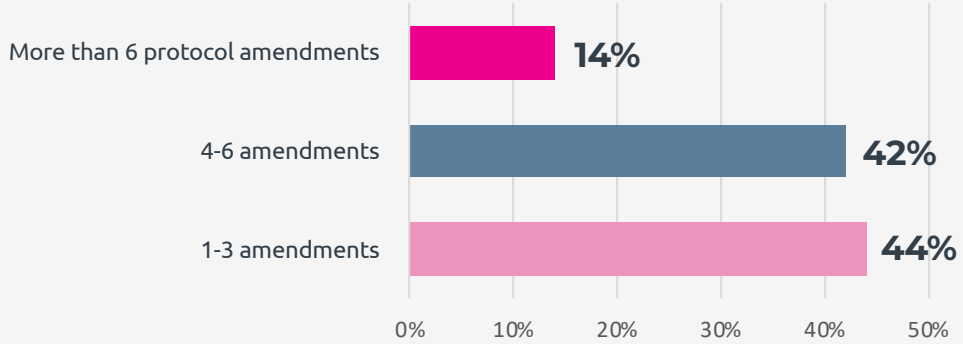
Study start-up and protocol amendments

Consumers of time: study start-up and implementation of protocol amendments.

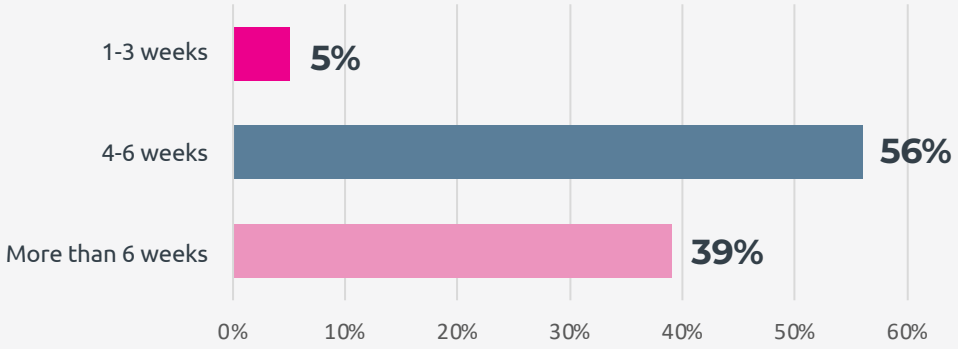
> ***The survey asked three (3) operational questions designed to help drill down on expenditures of time: length of study start-up, number of mid-study protocol amendments, and the time it takes to implement the amendments into the organization's IRT system(s).***

It takes at least a month to start a study on the current IRT platform for more than half (56%) of the respondents, with nearly 40% reporting it takes more than six weeks. 44% indicated their trials typically have one to three protocol amendments, and virtually the same number (42%) cited four to six. 45% stated it takes four to six weeks to implement protocol amendment changes on their current IRT system(s), with one-third estimating one to three.

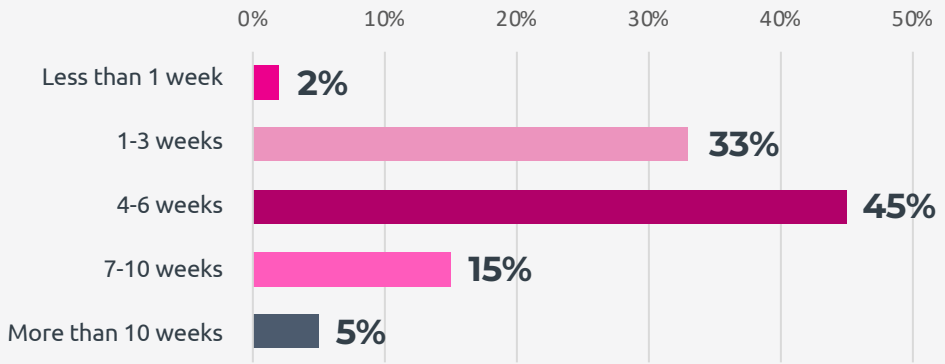
How many protocol amendments per study have occured in the past 18 months in the studies that you have been involved in?



Length to start-up a study on your current IRT platform?



Length to implement protocol amendment changes into your company's current IRT platform?



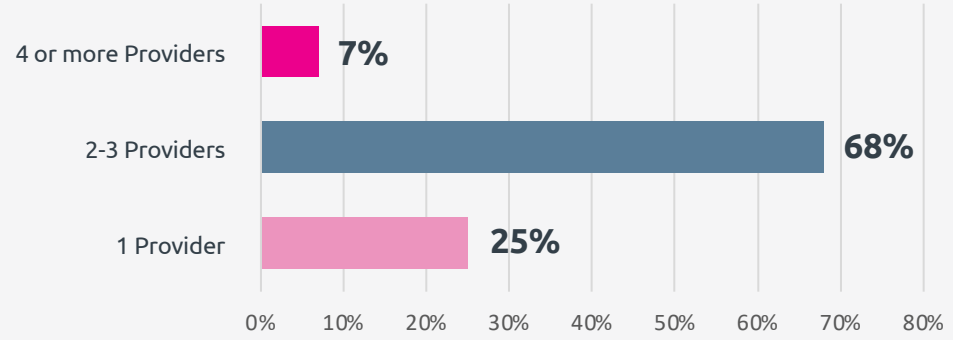
The right IRT partner makes all the difference

Most respondents require a variety of services from their IRT provider.

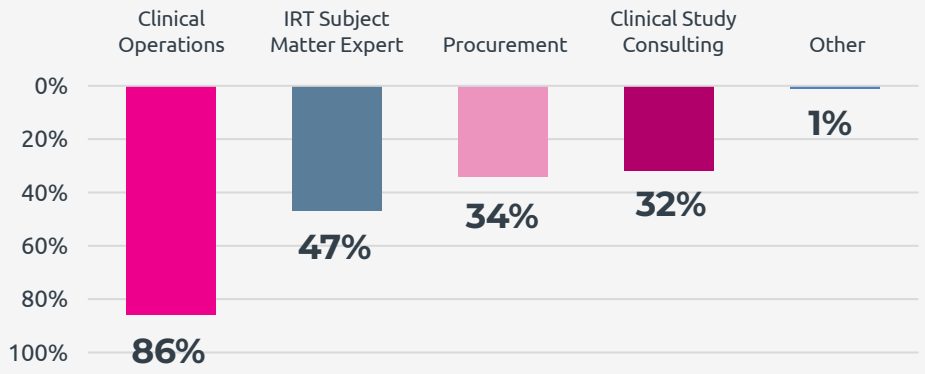
> ***These three (3) operational questions focus on the provider of the IRT platform, specifically who is involved in selecting a provider, the number of IRT providers, and the services required.***

Regarding role, the pharma/biotech survey participants indicated that a large percentage (86%) of the IRT platform selection decision makers are clinical operations professionals, and 47% are IRT subject matter experts. More than two-thirds (68%) of the survey respondents stated they worked with two or three IRT providers in the past year, and 62% specified they would prefer a full battery of services, including study build, consultative guidance, and user acceptance testing (UAT) support.

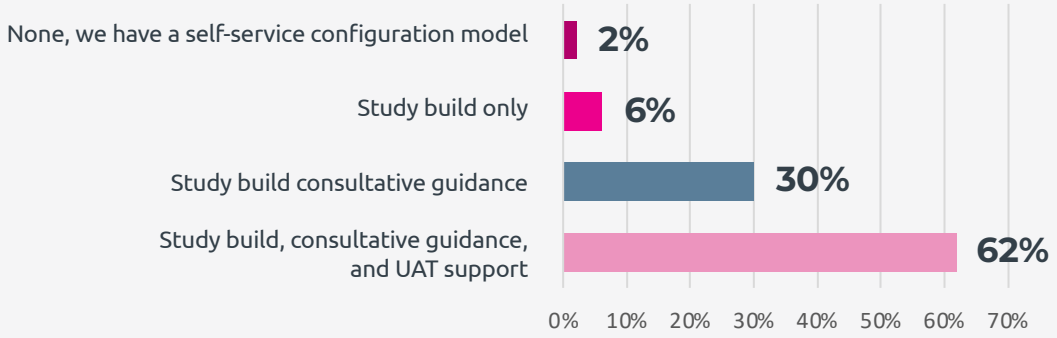
How many IRT providers have you worked with in the past year?



Who is the primary decision maker(s) in selecting an IRT provider?



What support services do you require from your IRT provider?



Top 3 perceived benefits of a new IRT platform

The top IRT benefits identified map to the top pain points, namely timelines and delays.

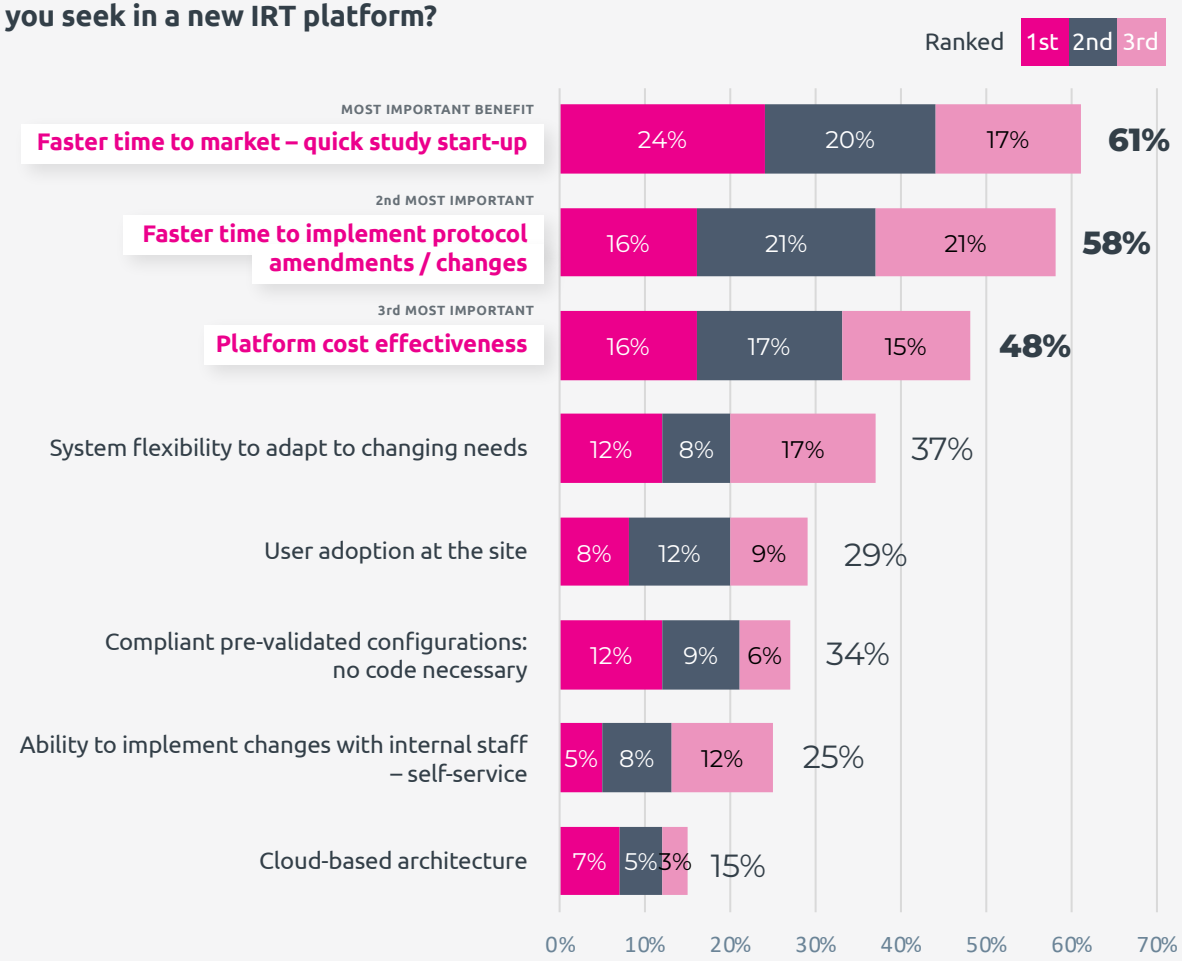
> ***We asked survey participants to rank the top three (3) most important benefits they seek in a new IRT platform.***

It makes sense that the top benefits professionals seek in implementing a new IRT platform map directly to the top pain points. In addition to the benefits that would facilitate staying on schedule, survey respondents are seeking ease and cost effectiveness in making changes to both the system itself and protocols. 61% of respondents prioritized quicker study start-up, 58% pinpointed faster time to implement protocol amendments, and 48% are focused on cost effectiveness.

> It's good science to adapt trials as dictated by evolving data or circumstances. Technology should be a facilitator of these changes — not a barrier.

Evan Hahn
SVP, IRT Solutions, YPrime

What are the top 3 most important benefits you seek in a new IRT platform?



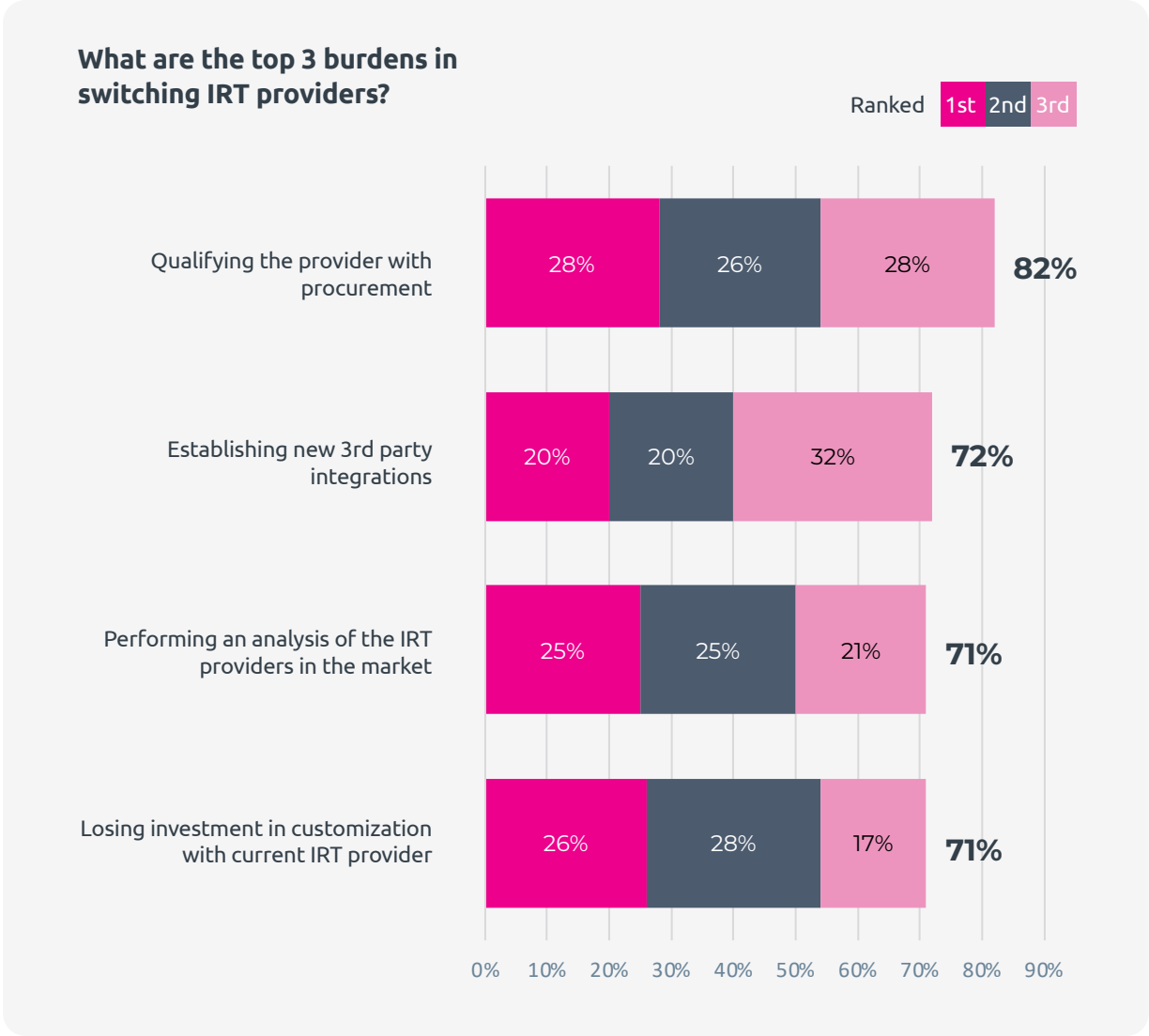
Burdens in switching IRT providers

There may be non-clinical logistics standing in the way of you making the best decision for your clinical research.

> ***We asked survey participants to identify the top three (3) burdens of switching IRT providers.***

The clinical research professionals surveyed recognize the many benefits of a new IRT platform. So why not make the change? This chart shows that, in many cases, 'it's just business.' The non-clinical reality is that it can be very time-consuming to analyze and onboard a new provider. "Qualifying the vendor with procurement" was ranked in the top three (3) by 82% of the respondents, and "performing an analysis of the IRT vendors in the market" by 71%. Other critical considerations include the costs and time associated with integrations and customizations. 72% consider "establishing new third-party integrations" a top burden, and 71% indicated "losing investment in customizations with current IRT provider."

82% of respondents ranked qualifying the IRT provider with procurement as a top hindrance to change



Top IRT provider attributes

Overwhelmingly, clinical professionals seek an IRT provider who can first and foremost ensure data quality.

> ***We asked survey participants to rank the importance of several attributes they might consider when evaluating an IRT provider.***

In clinical trials, data quality is the bottom line. Researchers need to be confident in the integrity of the data that will ultimately be submitted to government agencies for drug approval. This is the same data that protects the safety of clinical trial participants as well as future users of the therapy. This is why 88% of survey respondents ranked "data quality" as important or very important.

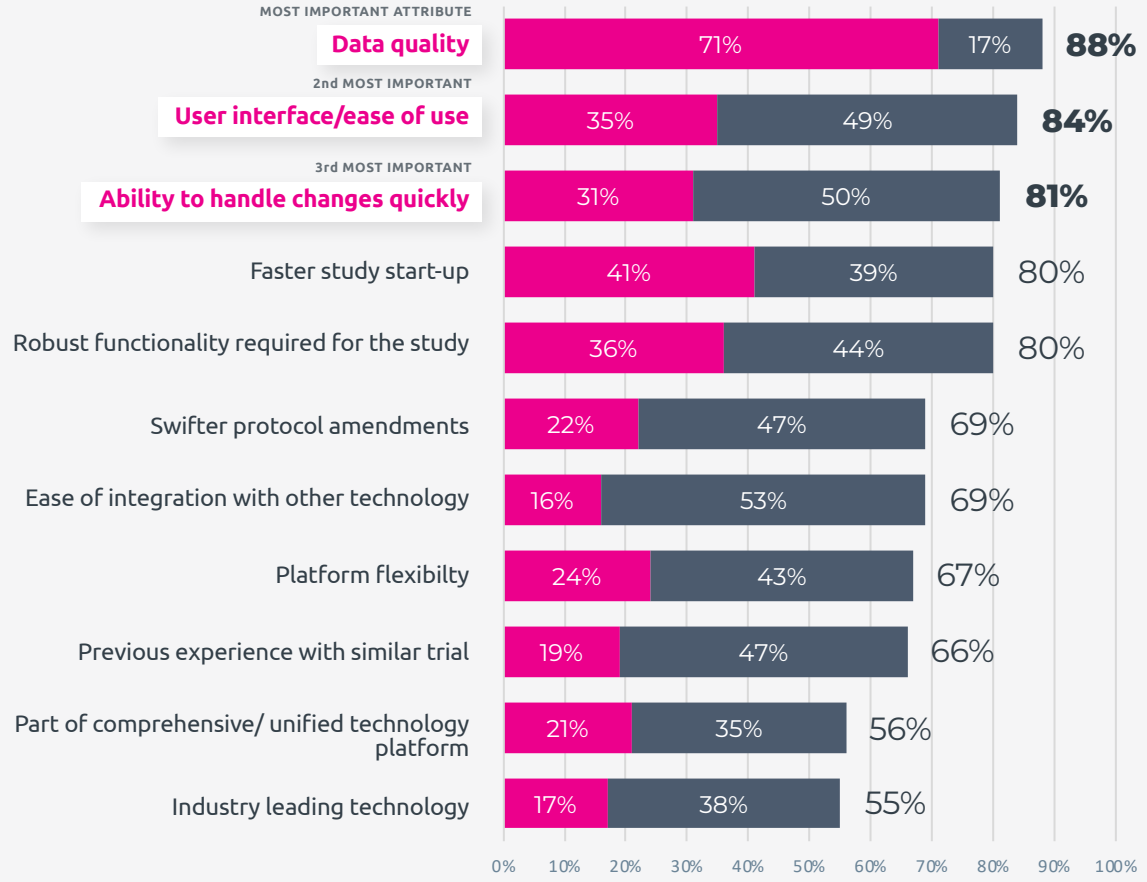
The other technology attributes identified by survey respondents point to robust, easy-to-use functionality that enables speed, flexibility, and adaptability. 84% of participants ranked "user interface/ease of use" as important or very important, with 81% doing the same for "ability to handle changes quickly."

"Technology should be a driver and not a constraint. As trials continue to become more complex, and data sources more numerous and varied, sponsors and CROs will need the technologies that can keep up with the complexity.

Ryan Ridge
VP IRT Operations, YPrime

When evaluating clinical trial IRT providers, how important are the following attributes?

Respondents ranked the following attributes either very important or important



Conclusion

The complexities of clinical trials weave a matrix of interrelated challenges. Throughout this report, issues that contribute to site burden, such as timelines, delays, amendments, and data integrity, repeatedly resurface. These and other challenges impact and exacerbate one another.

Technology is intended to unknot the tangles of the matrix; however, it can only do so if leveraged properly. This is where trust comes into play—trust that your IRT provider can guide you not just with the technology itself but also with critical components such as compliance standards, evolving regulations, data integrations, and change management. A reliable provider can help you avoid detrimental and potentially unsafe events like failed randomization and unintentional unblinding.

One of the primary keys to technology helping accelerate the timelines of clinical trials is to evolve away from the study-by-study deployment of IRT. With a flexible, scalable architecture, sponsors and CROs can more quickly launch clinical trials based on protocols from pre-built libraries, exponentially accelerating amendment implementation.

YPrime provides next generation, full-service IRT solutions with end-to-end clinical trial supply management features. We maximize confidence throughout the entire process by ensuring statistical integrity, reducing risk, and delivering submission-ready data at the end of every clinical trial. Our flexible designs can accommodate simple, early-phase studies through late-stage trials with complex protocol requirements.

For more information on how YPrime's IRT solutions can help speed development and simplify management for all your study designs, contact **marketing@yprime.com**.

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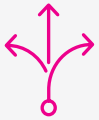
Five key takeaways

1.
Adhering to timelines and ensuring data integrity are among the top concerns of clinical professionals.

Timelines/delays and data quality emerge as the major concerns of clinical research professionals as they look at their studies overall. Solving for these pervasive challenges is critical to the management of successful clinical trials.

2.
Clinical professionals who focus on IRT point to timelines, delays, and lack of tech flexibility as primary issues.



Within the realm of IRT platforms, respondents express apprehension about timelines/delays, lack of tech flexibility, and trust in their IRT provider. These concerns underscore the pivotal role of IRT in influencing the flow and success of clinical trials

3.
Study start-up and protocol amendments are primary hindrances in adhering to timelines.

The survey delves into operational aspects, revealing that study start-up can take over a month for more than half of the respondents, and protocol amendments also consume a significant amount of time, impacting the overall efficiency of clinical trials

4.
Research professionals seek an IRT provider who delivers data quality assurances as well as tech flexibility and ease-of-use.

The attributes deemed most important when selecting an IRT provider include the ability to ensure data quality, user interface/ease of use, and the capability to handle changes quickly. These criteria reflect the industry's emphasis on safeguarding the integrity of data and accelerating research.

5.
IRT innovation adoption requires trust in advanced technologies and provider.

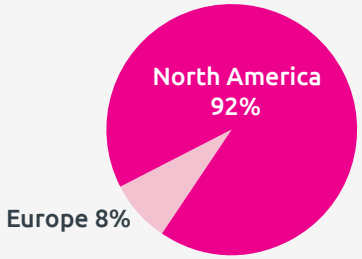
Technology can only truly benefit clinical trials when leveraged fully and correctly. The most innovative IRT solutions today utilize microservices architecture for improved efficiency and is optimally implemented with a trustworthy IRT provider who can help navigate complex aspects such as compliance, regulations, and data management.

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 primarily of IRT development, clinical operations, and research and development professionals, all of whom indicated they are extremely or very familiar with IRT platforms in clinical trials. The qualified participants are director level and above, involved with Phase I, II, and III clinical studies in pharmaceutical and biotechnology organizations.

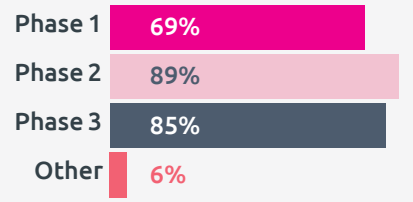
Country in which respondents work:

Region of company headquarters:

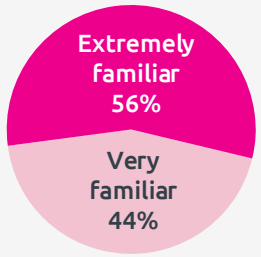


Sector:

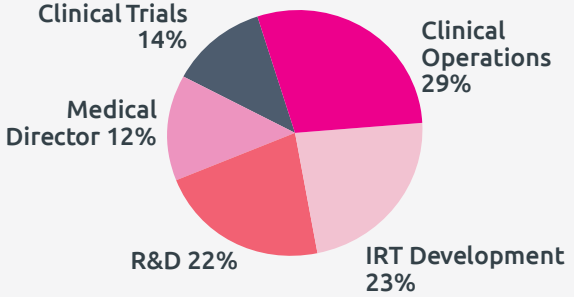
Phases of clinical trials in which respondentswork



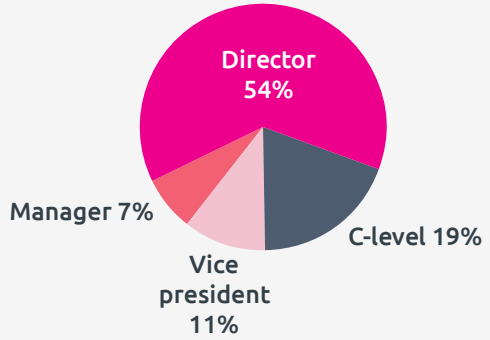
IRT familiarity:



Job function:



Seniority level:



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About the authors

Mark Maietta
President, YPrime

With more than 25 years of leadership experience within the life sciences and technology sectors, Mark fuels his ingenuities by keeping a keen eye on the evolving needs of customers. As President of YPrime, Mark directs commercial strategy and all associated functions. He is a growth catalyst who specializes in driving value globally. Mark's leadership in the clinical space includes tenures at Clariness, AdviseClinical, CRF Health, OPTUMInsight (now part of United Health Group), Pfizer, and Novartis Pharmaceuticals.

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 IRT Solutions

YPrime offers a next generation IRT platform that revolutionizes patient randomization and clinical supply management. Using modern software development approaches, YPrime's IRT solution provides the ultimate flexibility to build your own IRT experience. Minimize protocol amendments, expedite amendment implementations, streamline system builds, seamlessly integrate with other eClinical systems, improve the front-end experience, and reduce the technology burden on sites. YPrime's powerful IRT solution includes a central data repository and sponsor-level portals to access data in real time. The business intelligence analytics engine transforms operational and business data into valuable and actionable status reports.

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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