YPrime

Clinical Trials Run on Certainty

The Biotech Sponsor's Playbook for IRT Success

Designing for Speed, Flexibility, and Trial Integrity

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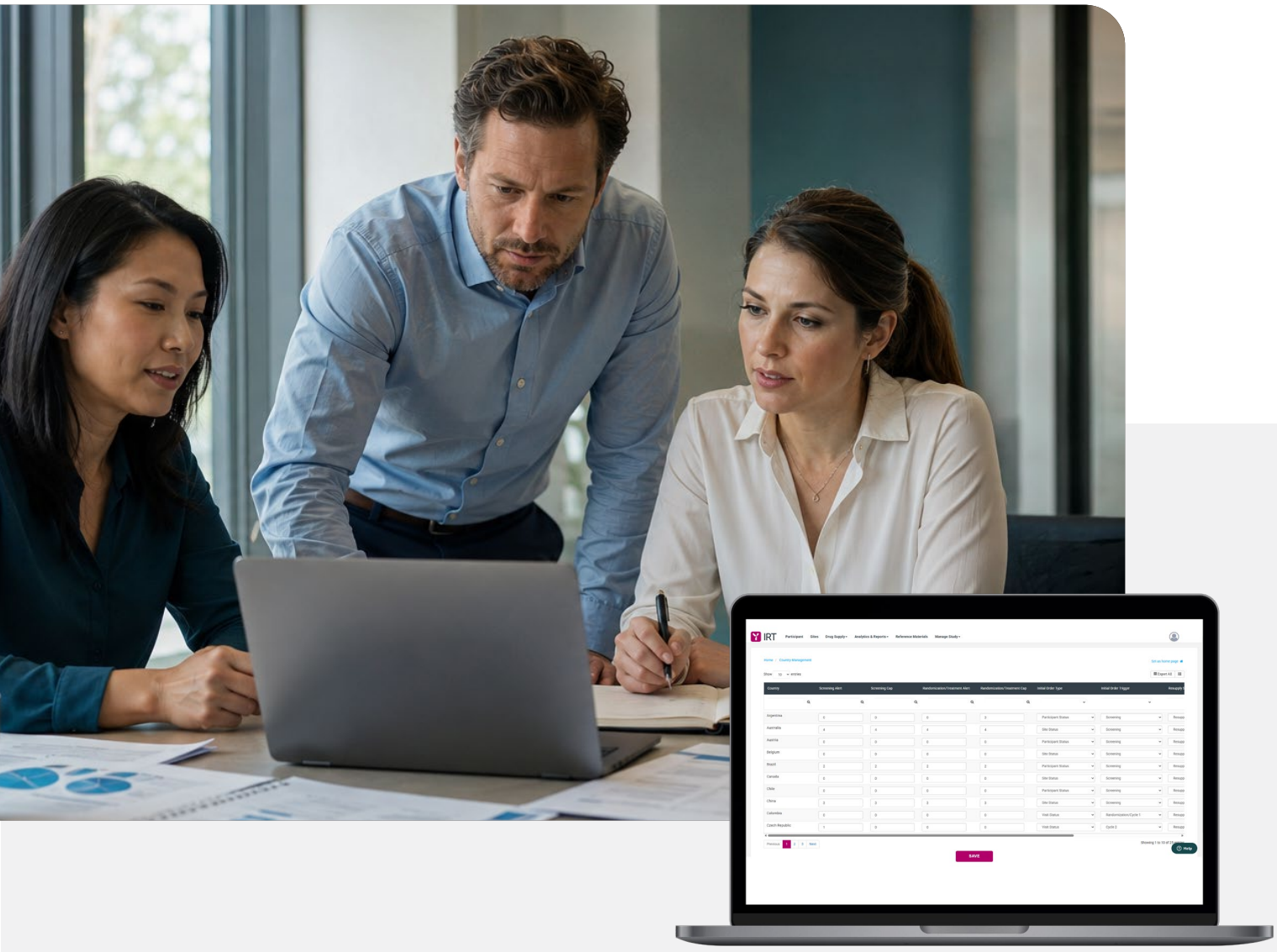
Introduction

For many biotech companies, an IRT system is implemented only a handful of times across the organization's lifecycle. Unlike large pharmaceutical companies with dedicated RTSM and supply specialists, emerging and mid-sized biotech sponsors are often managing study startup, supply planning, enrollment oversight, and vendor management with lean teams and limited internal IRT expertise.

As a result, the decisions made during IRT design can have a disproportionate impact on trial execution. A poorly designed system can create delays, introduce unnecessary complexity, increase drug waste, and make protocol amendments difficult to implement. A well-designed system becomes invisible—enabling sites, patients, and study teams to focus on the trial itself rather than the technology supporting it.

The most successful sponsors do not view IRT as a randomization tool. They view it as a critical layer of trial infrastructure that protects trial integrity, manages investigational product, and provides operational visibility throughout the study.



Start with Operational Risks, Not System Features

IRT discussions often begin with functionality: randomization methods, supply algorithms, reports, dashboards, and integrations.

A better starting point is risk.

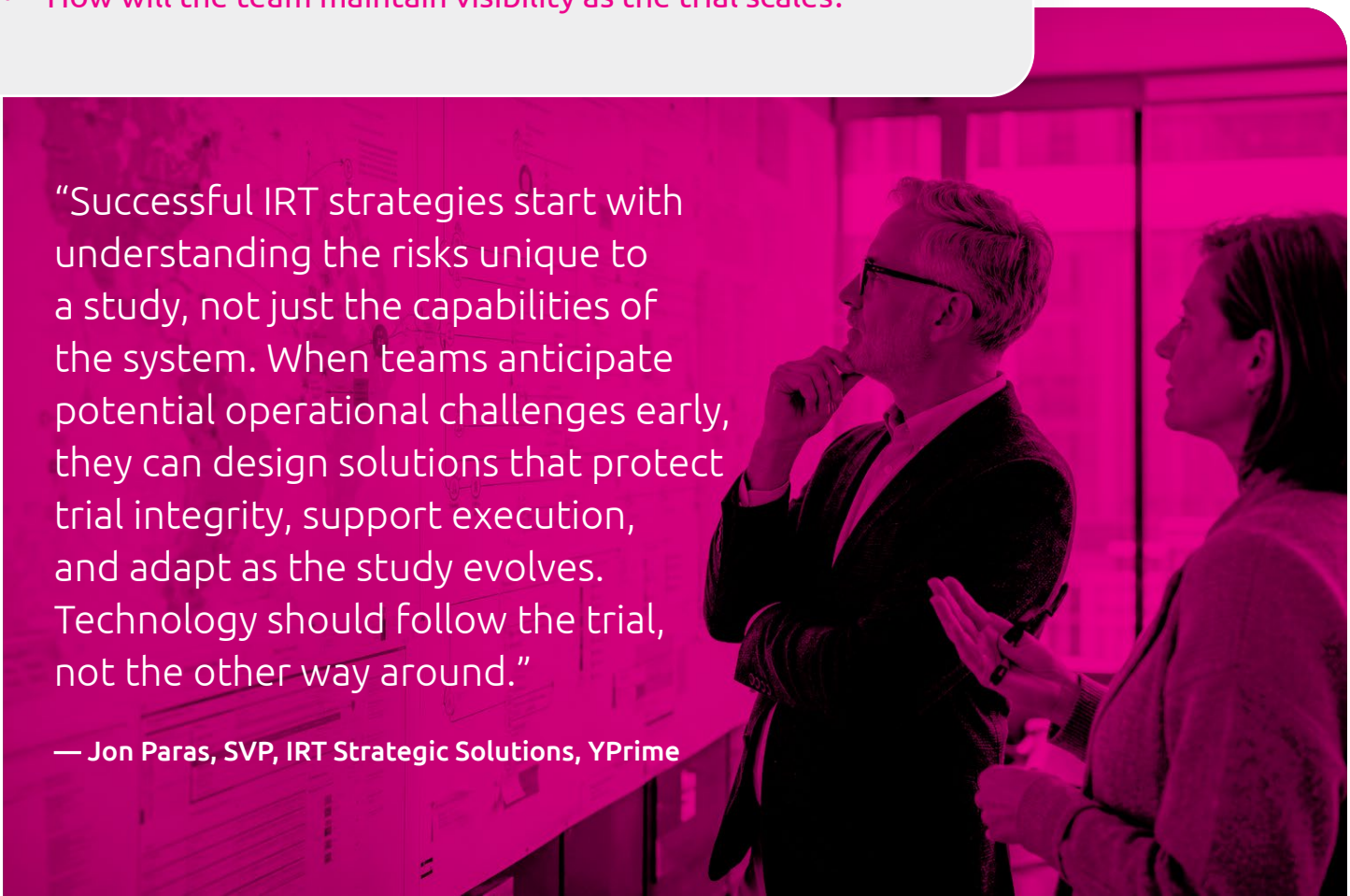
Before defining requirements, sponsors should identify the operational challenges most likely to affect study execution. Will enrollment occur in waves? Is the investigational product expensive or supply constrained? Could the protocol evolve as data emerges? Is accidental unblinding a significant concern?

These questions are more important than any specific system feature because they determine how the IRT must behave to support the study.

A strong IRT strategy is built around preventing operational failures before they occur. Technology should follow trial design—not the other way around.

Consider:

- What events could disrupt patient dosing?
- Where are supply shortages most likely to occur?
- What aspects of the study are most likely to change?
- How will the team maintain visibility as the trial scales?



"Successful IRT strategies start with understanding the risks unique to a study, not just the capabilities of the system. When teams anticipate potential operational challenges early, they can design solutions that protect trial integrity, support execution, and adapt as the study evolves. Technology should follow the trial, not the other way around."

— Jon Paras, SVP, IRT Strategic Solutions, YPrime

Speed Matters. Design Matters More.

Every biotech sponsor wants to reach first patient in as quickly as possible. Startup timelines are scrutinized by leadership teams, investors, and study stakeholders.

However, speed without sufficient design rigor often creates larger problems later.

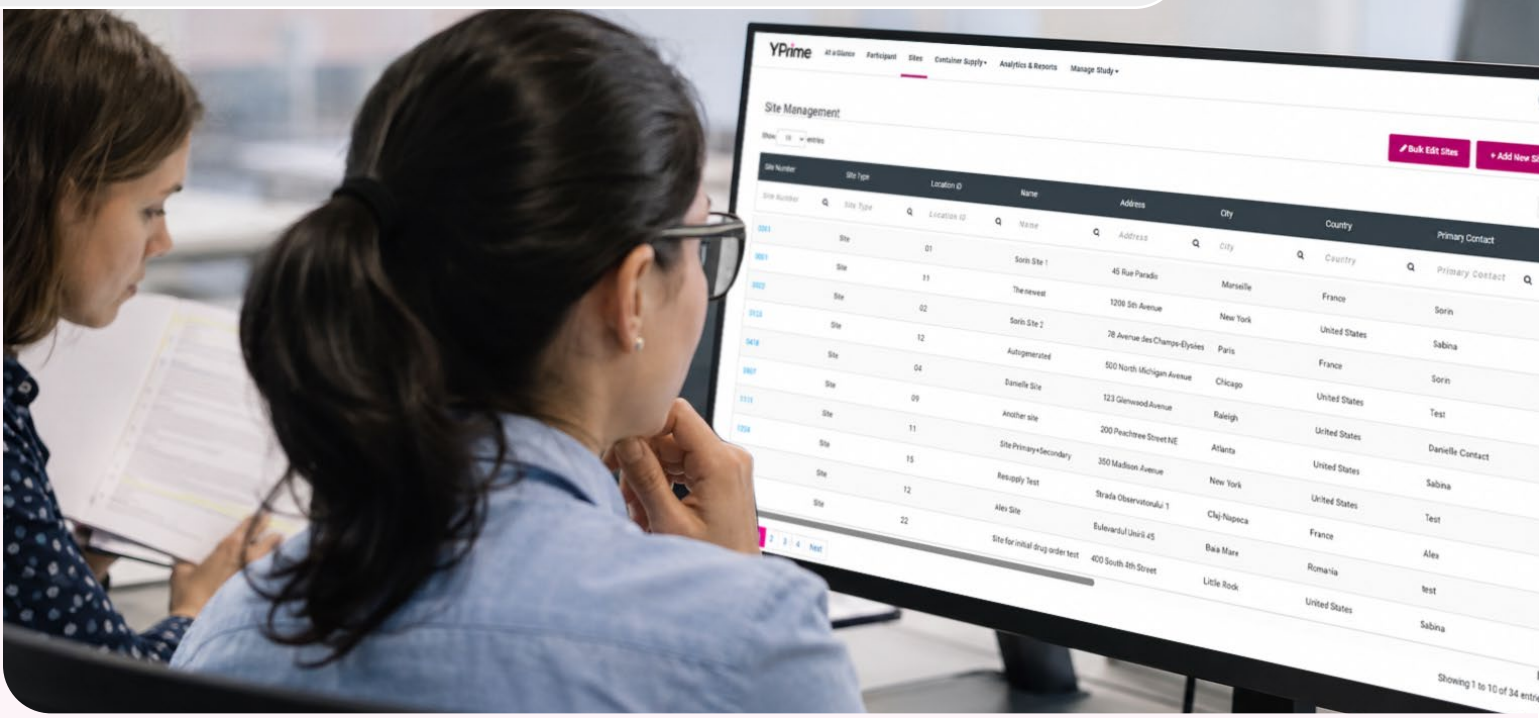
Many of the costliest IRT issues emerge not during development but during user acceptance testing or after study launch. These issues frequently stem from assumptions made during requirements gathering that were never adequately challenged.

The best implementations provide opportunities for sponsors to review participant journeys, randomization workflows, supply strategies, and screen designs long before formal testing begins. Early visibility allows teams to identify concerns when they are easiest—and least expensive—to address.

A fast deployment is valuable only if it is built on a solid foundation.

Questions to Ask:

- How will protocol assumptions be challenged during design?
- Can the study team review workflows before UAT?
- Are supply simulations conducted prior to launch?
- How much visibility will the sponsor have throughout testing?



Build for Change from Day One

Protocol amendments are no longer exceptional events. They are a normal part of modern clinical development. New cohorts may be added. Dosing schedules may change. Enrollment criteria may evolve. Randomization strategies may need refinement as new information becomes available.

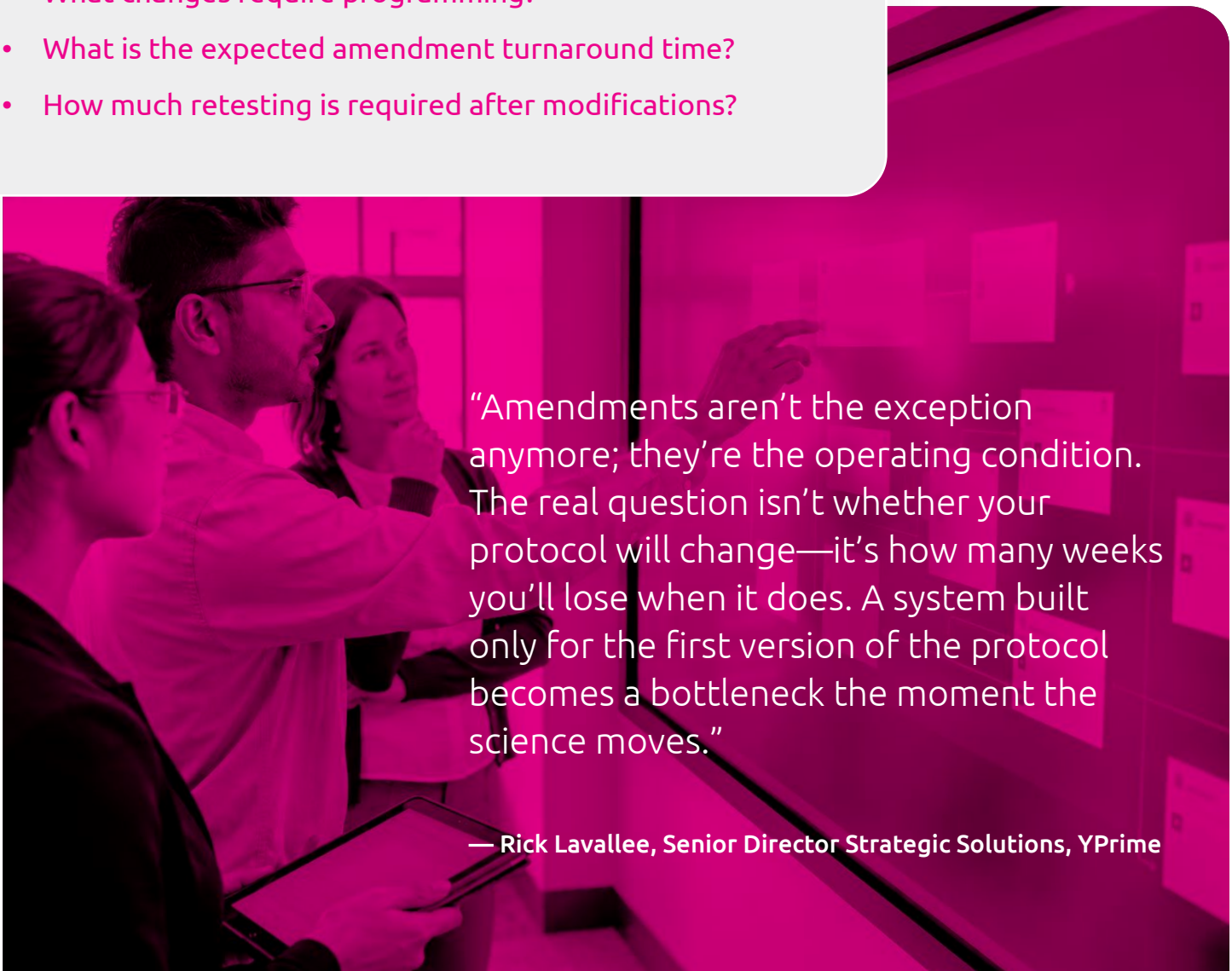
The question is not whether changes will occur. The question is whether the IRT can adapt quickly when they do.

IRT platforms have shifted away from heavily customized approaches toward flexible architectures that allow sponsors to implement many changes without extensive redevelopment. This flexibility is particularly important for biotech sponsors operating in fast-moving development programs.

An IRT strategy should account for uncertainty from the beginning. Systems designed only for the initial protocol often become bottlenecks as the study evolves.

Evaluate Your Flexibility:

- What changes can be made quickly?
- What changes require programming?
- What is the expected amendment turnaround time?
- How much retesting is required after modifications?



"Amendments aren't the exception anymore; they're the operating condition. The real question isn't whether your protocol will change—it's how many weeks you'll lose when it does. A system built only for the first version of the protocol becomes a bottleneck the moment the science moves."

— Rick Lavallee, Senior Director Strategic Solutions, YPrime

Clinical Supply Is Where IRT Delivers Its Greatest Value

When sponsors evaluate IRT solutions, randomization typically receives the most attention. Yet one of the greatest opportunities for operational and financial impact lies elsewhere: supply management.

Investigational product is often among the most valuable assets in a clinical trial. Every unnecessary shipment, expired kit, or emergency resupply event has implications for cost, timeline, and patient experience.

An effective IRT strategy helps sponsors balance two competing priorities—ensuring product availability while minimizing waste. Achieving that balance requires thoughtful forecasting, inventory controls, and proactive monitoring throughout the study.

For biotech organizations with constrained budgets and limited product availability, these decisions can materially influence trial performance.

Key Supply Considerations:

- Enrollment uncertainty
- Country and depot strategy
- Predictive resupply approaches
- Expiry management
- Drug waste reduction
- Emergency shipment risk

The goal is not simply moving product through the supply chain. The goal is getting the right product to the right patient at the right time.

Visibility Enables Better Decisions

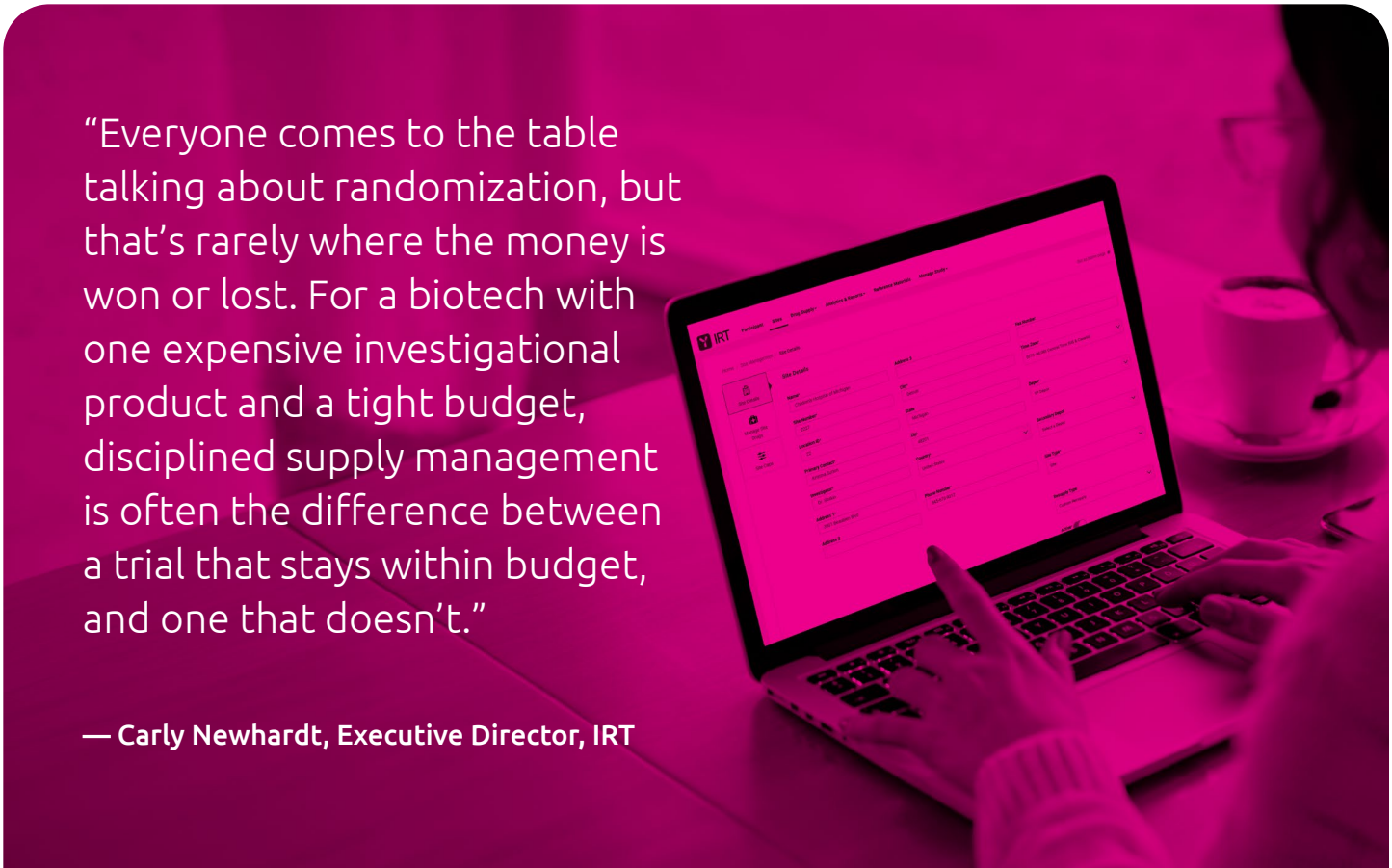
Historically, IRT reporting was largely retrospective. Study teams reviewed reports after events occurred and reacted to issues that had already impacted the trial. Today, trial execution requires something different.

Sponsors need visibility into enrollment, inventory, dosing activity, cohort progression, and site performance as events unfold. Operational intelligence allows teams to identify risks early and intervene before those risks affect patients or study timelines.

The most valuable dashboards are not those that provide the most data. They are the ones that allow teams to answer critical questions quickly:

- Which sites are at risk of stockouts?
- Which cohorts are progressing slower than expected?
- Where is inventory accumulating unnecessarily?
- Are enrollment trends aligning with forecasts?

Real-time visibility transforms IRT from a transactional system into a strategic decision-support tool.



"Everyone comes to the table talking about randomization, but that's rarely where the money is won or lost. For a biotech with one expensive investigational product and a tight budget, disciplined supply management is often the difference between a trial that stays within budget, and one that doesn't."

— Carly Newhardt, Executive Director, IRT

Integration Is No Longer Optional

IRT does not exist in isolation. Sponsors increasingly rely on connected ecosystems that include EDC, eCOA, eConsent, CTMS, safety systems, data platforms, and supply chain technologies. When these systems are disconnected, operational inefficiencies quickly emerge.

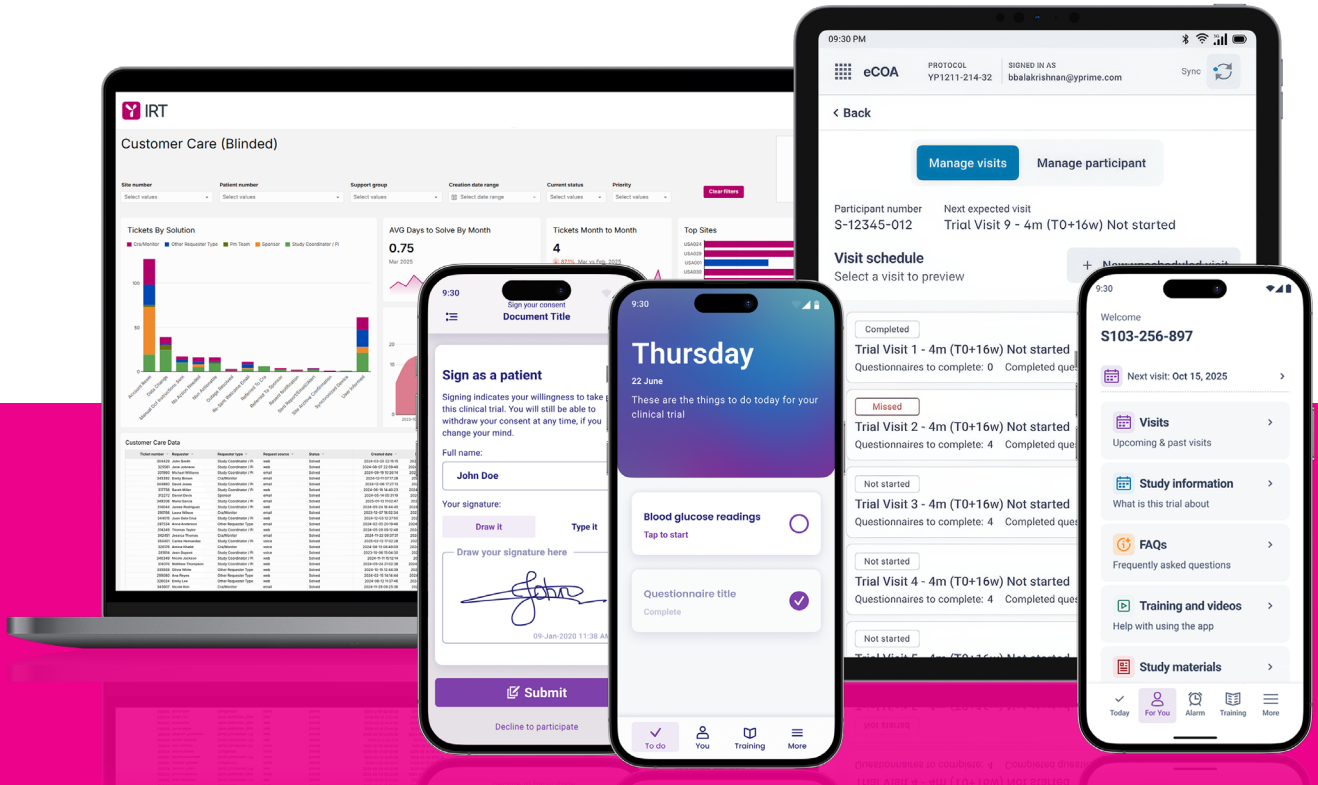
Manual data reconciliation consumes resources. Reporting becomes fragmented. Decision-making slows.

The strongest IRT strategies acknowledge that data must flow across the broader clinical technology landscape. Integration planning should begin during study design, not after deployment.

Integration Readiness Checklist:

- Have all required systems been identified?
- Are data ownership responsibilities defined?
- What happens when integrations fail?
- How quickly are discrepancies detected and resolved?

A connected ecosystem improves not only efficiency but also confidence in the accuracy of trial data.



Protecting Trial Integrity Must Remain the Priority.

No matter how sophisticated the technology becomes, the primary responsibility of an IRT system remains unchanged: protecting patients and maintaining study integrity.

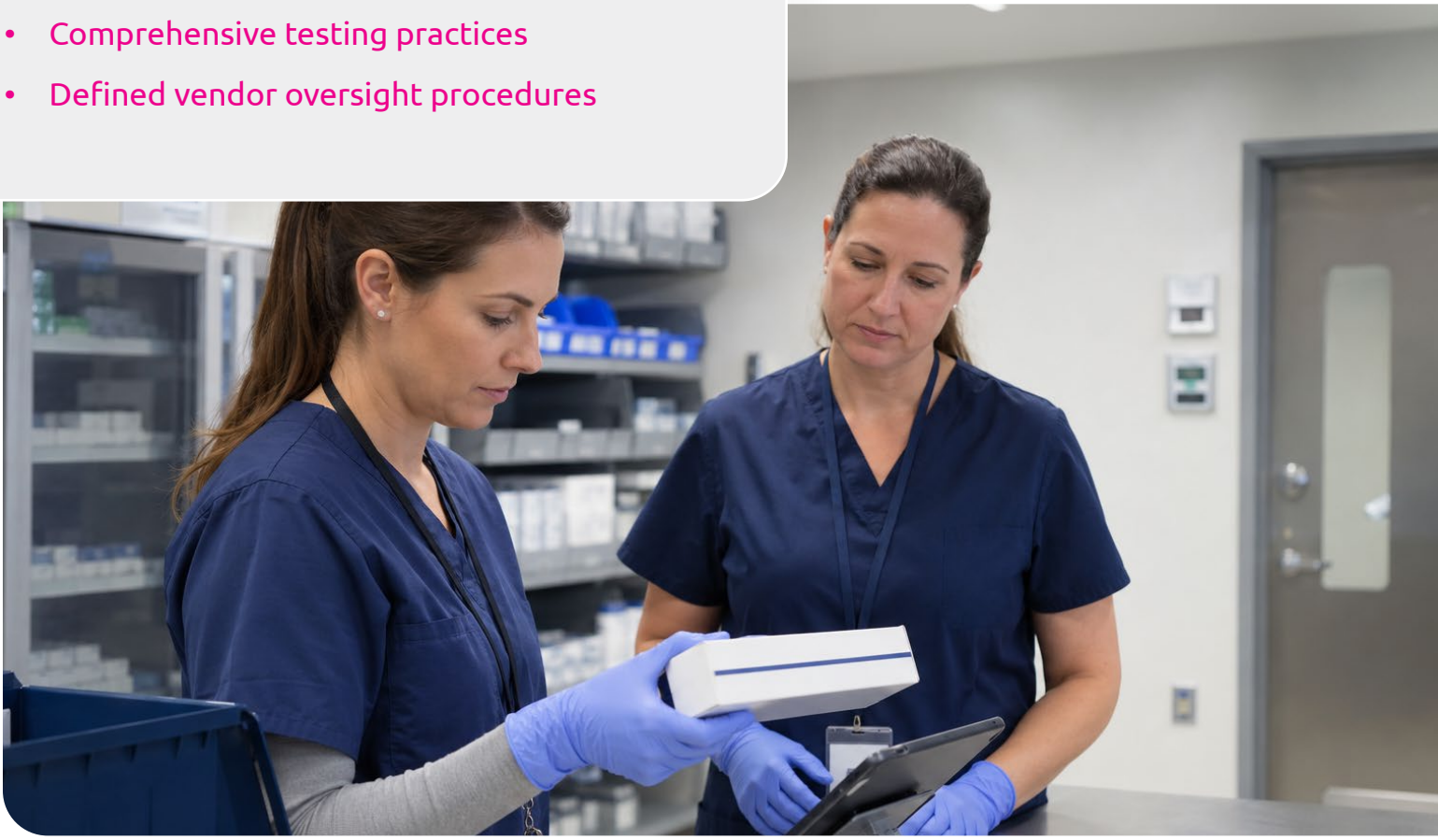
Randomization errors, dosing mistakes, and accidental unblinding can have significant implications for data quality and study outcomes. Preventing these events requires thoughtful design, rigorous testing, and disciplined operational controls.

Sponsors remain accountable for trial oversight even when activities are outsourced. This responsibility includes understanding how decisions are made within the IRT, how changes are documented, and how critical study actions can be reconstructed during inspections.

Audit readiness should not be viewed as a regulatory exercise. It should be viewed as evidence that the system is operating as intended.

Indicators of a Strong Control Environment:

- Clear audit trails
- Transparent change history
- Role-based access controls
- Comprehensive testing practices
- Defined vendor oversight procedures



What Good Looks Like in an IRT Partner

Technology alone does not determine study success. The most successful sponsor-vendor relationships are built on a combination of expertise, transparency, and accountability.

Strong partners challenge assumptions, identify risks early, communicate clearly, and respond quickly when issues arise. They understand that trial execution depends as much on operational discipline as it does on system functionality.

When evaluating potential partners, sponsors should focus on three fundamentals:

Service

Does the team feel invested in your study's success?

Execution

Can they consistently deliver quality outcomes aligned with protocol requirements?

Accountability

How do they respond when challenges occur?

These qualities often become far more important than any individual system feature over the life of a study.

"Any vendor can build to spec. What matters over the life of a study is whether they challenge your assumptions early, tell you the hard things before UAT, and show up when something breaks. Sponsors should evaluate the team as carefully as they evaluate the platform."

— Grazia Mohren, SVP, Marketing and Client Engagement, YPrime

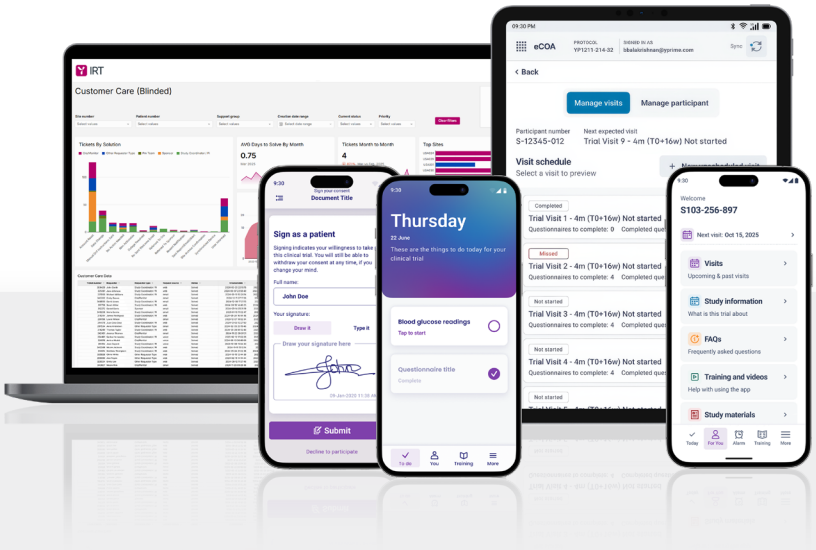
Final Thought

Biotech sponsors operate in an environment where resources are limited, timelines are aggressive, and every decision carries meaningful consequences.

An effective IRT strategy helps bring predictability to an inherently unpredictable process. It accelerates startup without sacrificing quality, supports protocol flexibility without creating operational disruption, optimizes supply without increasing risk, and provides visibility without adding complexity.

The best IRT systems are rarely the most noticeable. They work quietly in the background, protecting trial integrity, supporting clinical operations, and ensuring that patients receive the right treatment at the right time.

That is ultimately the measure of IRT success—not the technology itself, but the confidence it provides throughout the clinical trial journey.



Let's talk about what IRT success looks like for your organization.

YPrime partners with biotech sponsors to design IRT systems built for speed, flexibility, and certainty, bringing predictability to trial execution from first-patient-in through data lock.

Start the conversation at **marketing@yprime.com**.

YPrime
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About YPrime

YPrime simplifies clinical trials with eCOA, IRT, and eConsent solutions that combine speed, flexibility, and quality. The YPrime eCOA platform enhances participant compliance with an intuitive app and easy-to-use design, streamlines site workflows through a powerful eCOA portal, integrates seamlessly with connected devices, and supports sponsors with dashboards for better decision-making. AI-supported eCOA localization accelerates globalization, while pre-validated and configurable eCOA and IRT deliver faster study startup with quality metrics above industry standards. Trusted by top pharma leaders and emerging biotech companies alike, YPrime blends deep industry expertise and innovation to deliver reliable solutions. With nearly two decades of proven success, solutions in 250+ languages, and support in 100+ countries, YPrime is your partner to solve clinical research challenges with certainty. Visit www.yprime.com or email marketing@yprime.com.