The Worst Case Scenario Survival Handbook for IRT Users

A handy guide for overcoming common challenges

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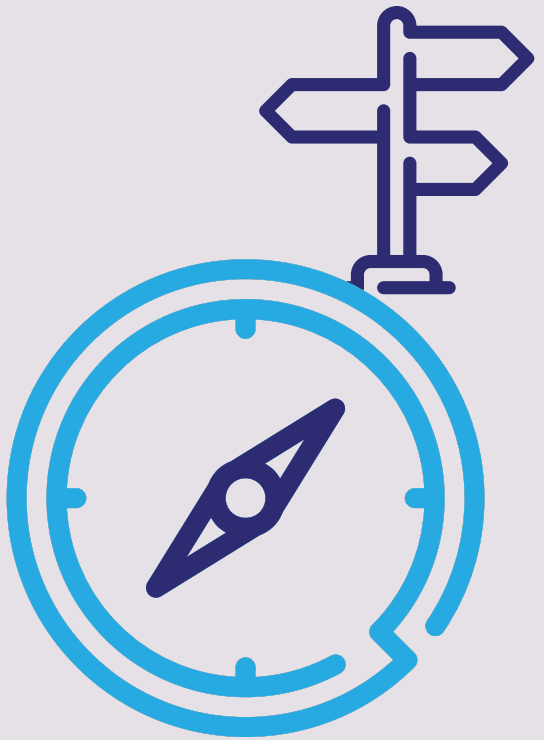
While interactive response technology (IRT) has been a standard part of clinical research technology for years, recent advances have transformed IRT systems from workhorse to racehorse.



New-generation IRT systems go beyond the fundamentals of randomization and drug supply to offer more functionality, visibility, flexibility and quality. Today's advanced systems allow sponsors to fully control materials management, site and patient interactions, dosing scenarios, and treatment schedules down to individual patient and material unit levels. But are you fully aware of how your IRT can work harder for you?

The IRT Worst Case Scenario Survival Handbook was built from YPrime's knowledge gained, lessons learned, and creative solutions used to overcome study challenges and keep projects on track, no matter what.

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When your protocol is amended

Protocol amendments are a fact of life in today's clinical trials. They're also a headache for site users and study managers. It can mean downtime for your IRT system. Configurable and customizable systems are your ally when protocol amendments threaten your study timelines, as well as patient recruitment and retention potential.

Modular components of configurable systems can be quickly updated, based on the needs of the new protocol. Cycle time to go into production is much shorter because the modules are pre-validated.

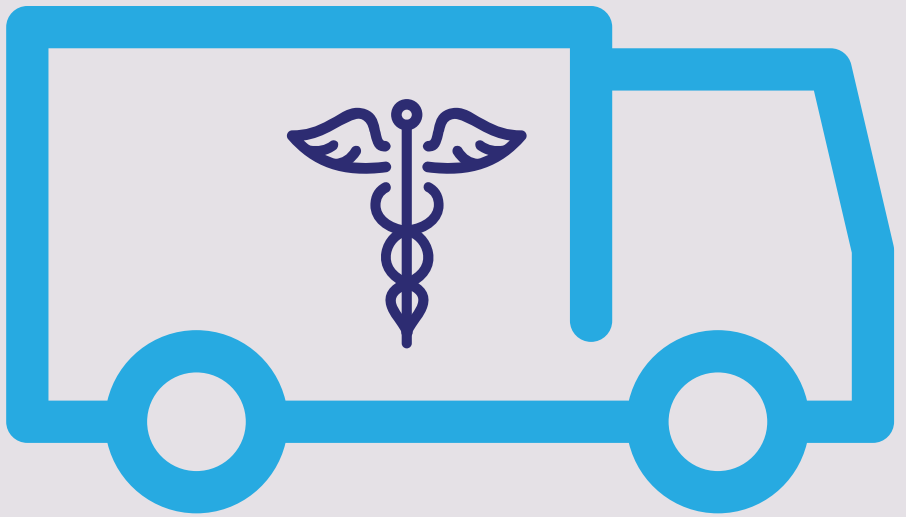
Configurability is particularly valuable for adaptive trial designs with open-ended protocols. You can update dose scheming from patient-to-patient and visit-to-visit. What's more, this functionality is controlled by the end user, eliminating the need to get the IRT vendor involved or generate a change order.

Amendments pose another logistical challenge when IRB and ethics committee approval timelines vary by country. In advanced systems, IRT functionality can be customized to streamline amendment roll-out and help you avoid countless hours of country and site-level management efforts. YPrime can work with you to build out functionality in advance of approval that automates the transition to amended functionality. Once activated by a designated user, sites who have received approval are immediately associated with the new functionality.

How to prevent clinical supply shortages

Effective IRT development needs to be aligned with clinical supply strategy from project outset. A properly set-up IRT system will prevent clinical supply shortages, reduce shipping costs and remove headaches from manual efforts. A full-featured IRT system will also give you the tools to efficiently manage clinical supplies throughout a trial.

When you are in the planning stage of a trial, clinical supply guidance on the front end can go a long way in optimizing a supply chain throughout the study. This type of expertise is required for mapping investigational product movements, planning against shortages and forecasting resupply needs through automation in your IRT settings. During the trial, a clinical supply specialist should perform a periodic review of IRT settings and adjust for enrollment patterns, to avoid potential oversupply and shortages.



When drug reconciliation becomes a full-time job

When drug reconciliation is not built into your IRT system, it can add considerable hours to your clinical supply team's workload.

To provide proper context, a recent clinical study involving approximately 1300 patients and 220 sites required 225 hours of manual efforts to reconcile paperwork with study files. The effort required coordination with CRAs, depot representatives, and clinical teams. A built-in reconciliation module could have prevented these efforts.

YPrime can customize your IRT system to perform full reconciliation of your study drug. Our reconciliation reporting feature makes it easy to monitor compliance on a site level. This function not only automates a time-intensive process; it also eliminates the potential for manual data entry error.

Prevent Unblinding

Although uncommon, unintentional patient unblinding happens. Even the most innocuous events may potentially cause the entire trial to fail. When an IRT system is involved, ensuring the blind goes beyond clinical and technical know-how. It requires a mix of extensive clinical and IRT system knowledge.

At YPrime, we not only protect the blind through system design and operating procedures. Our experienced project managers look for potential unblinding scenarios and advise clients before go-live. Key considerations include:

- Careful planning of user accounts and role-specific access is essential, from customer care to the project management level. Critical items such as unblinded reports should be flagged to eliminate the possibility of a blinded user receiving it.
- Risk management techniques are integral to day-to-day operations. This begins with ensuring there's a valid reason for an unblinded user in the system, and then limiting the exposure and circumstances where trial information is shared.
- The devil is in the details when ensuring control of the chain of custody. For example, in the event of unblinding emergencies, allowing on-screen views is preferable to sending information to impacted users via email.

Avoid Randomization Errors

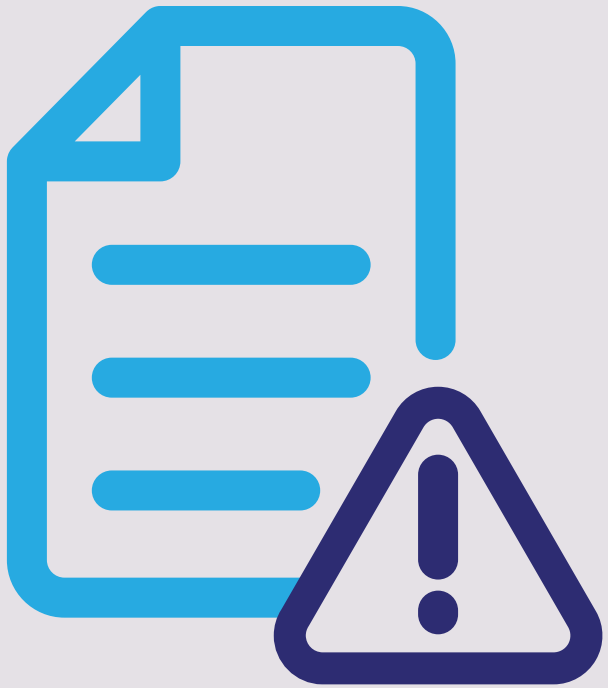
Randomization ensures methodically sound practice in a clinical trial. While IRT intelligently maintains the balance throughout the study, the smallest missteps in study design and conduct can quickly add up and put your whole trial at risk.

Some common scenarios include:

- Dosing schedules that partially unblind the study drug
- Deletion of accidental subject randomizations
- The placement of unused study drug back into inventory during a doubleblind trial
- While permissible in certain situations, forced randomization into a specific treatment to preserve clinical trial supplies is not always acceptable

Avoiding bias and maintaining deliberate element of chance is critical for success. YPrime recommends familiarizing yourself with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH E9 section 2.3.2) to ensure compliance with statistical principles and clinical trial randomization.

Most important, an experienced IRT project manager can help you avoid known pitfalls and scenarios with potential unintended consequences throughout a trial.



Time lost due to data corrections

In clinical trials, there's a standard way to handle data correction forms (DCFs). It involves a series of approvals across the project team, manual updates from helpdesk or project support, and spans up to five days. Or you could bypass that manual process entirely. With YPrime's IRT platform, the whole process can be completed in minutes.

YPrime's DCF tool allows specific types of changes related to demographics and visit dates to be raised by the investigator site.

An automated workflow advances data change requests through the approval process, beginning with the site user. The completion of the initial request advances the data correction to a second level review, typically a sponsor representative, who can approve, reject, or request more information from the site user who raised the data correction. Once the final reviewer approves the data correction, database values are automatically updated.

Project managers work with the sponsor to identify those data points that should be editable. Each data point can have an independent approving workflow, driven by user roles. With configurable workflow, additional reviewers can be added as needed.

The DCF tool improves data quality by reducing the cycle time from data entry to the completion of data review, and eliminating the possibility of human error involved with manual data entry of the final values into the database. What's more, it's super easy to use.

When IRT helpdesk experiences feel like your cable company's customer service

There's an art and science to providing customer care in clinical research. It starts with recognition that technology support needs knowledgeable people who are trained on the protocol, and a culture that supports those people's best efforts.

Technology can automate and bring efficiency to customer care, but quality training and exceptional customer service at the front end will prevent end user frustration with the helpdesk when requests for assistance come in. It's important for the support teams to know about the visit schedule, as well as implications of the technology and time sensitivity.

YPrime's customer care is designed to bridge technical expertise with the finer skills of problem solving. Three tiers of support help resolve issues in real-time, so patients are never kept waiting too long, *and* potential safety issues are minimized. Exceptional customer care is a strategic mix of relatively simple things:

- Prompt response and resolution, no matter what
- The knowledge to anticipate and resolve issues related to users' experience with the technology
- A willingness to go the extra mile whether it involves patience, troubleshooting or treating the user as you want to be treated

Reports in your pocket that aren't made of paper

Does your team want to access essential IRT data remotely from their own mobile devices and reports that incorporate responsive web design — so you can read and respond while on the go?

YPrime's IRT+ can send clinical supply status updates, global alerts and enrollment milestones to each team member's personal device, available via an app. Downloadable reports let you see the big picture and the finer details. This feature gives you more visibility into site level performance and the ability to monitor a variety of study-related milestones in real-time on an Apple and Android-compatible application.

Thanks to the extended suite of offerings provided with our IRT+ solution, our clients often ask "What else can we do?" With the most advanced configuration platform available in the eClinical space, YPrime can now extend its functionality to meet the specific needs of any clinical study — no matter how complex. This means that IRT+ will continue to evolve with each clinical trial it supports.

About YPrime

YPrime offers more than a decade of focused work with eClinical systems to expedite and improve the quality of patient management, clinical supplies, drug accountability and clinical data. Cloud-based IRT+ and electronic clinical outcome assessment (eCOA) platforms enable greater speed, precision and integration in clinical trial management. Our data services tools help sponsors bring together fragmented clinical research data into contextual information they can act on. YPrime's technology and service offerings enable sponsors to move faster and more efficiently to their next development milestone.

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