
# THE NEW GOLD STANDARDS OF IRT

## *WHAT SPONSORS SHOULD EXPECT FROM NEXT-GENERATION SYSTEMS*

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## Introduction

From the beginnings of automation in clinical trials, Interactive Response Technology (IRT) has been the operational workhorse for the management of patient randomization and drug supply. Early IRT systems centralized the randomization event with increasing capabilities as clinical trials grew in size and complexity though the 1980s and expanded globally through the 1990s and 2000s. During that expansion, IRT allowed for more sophisticated clinical supply packaging designs which in turn led to the use of IRT beyond the initial randomization and dispensation visits. In today's data-driven research environment, the new IRT gold standards support state-of-the-art study designs and research technologies, helping to achieve the biopharma industry's greatest needs—to improve patient safety and data quality while reducing time and cost.

New-generation IRT systems go beyond the fundamentals 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. They provide real-time data functionality and sophisticated analytics in systems that are fully configured and customized for specific trial needs, from Phase I to late phase research.

Evolving IRT technology continues to advance clinical trial management. This overview summarizes what sponsors may expect from the newest IRT systems and points to trends for emerging capabilities.


## From Workhorse to Race Horse

Long accustomed to traditional systems, drug developers are not always quick to embrace the latest IRT capabilities and efficiencies. From simple voice response systems to speed subject enrollment in the 1980s, IRT systems have evolved to meet the increasing demands of large global studies that can involve more than 10,000 subjects in hundreds of sites spanning multiple regulatory jurisdictions.

In addition to study size and global operations, growing IRT capabilities have been driven by increasingly complex protocols. The demands of complex inclusion/exclusion criteria, visit schedules, dosage schedules, and numbers of measurements required greater IRT functionality to support enrollment, randomization and supply chain processes. Today's sophisticated IRT systems integrate electronic data capture (EDC) and multiple data streams with real-time data capabilities and built-in analytics and business intelligence.

The latest advances—like those being engineered by YPrime—deliver these expanded capabilities in ways that give sponsors more visibility into their study data and more flexibility to make changes while a study is ongoing. YPrime employs a modified "agile" approach to quickly customize and configure IRT functions tailored to the needs of the study. This approach puts the sponsor at the center of the system design process, shortening time to delivery and ensuring that the system meets the sponsor's expectations.


## Agile vs. Waterfall Development: Faster, Cleaner and Flexible

Traditionally, IRT systems are built using the linear "waterfall" approach. This process moves step by step through seven major tasks to deliver a customized system configured to meet the operational needs of a protocol:

1. Requirements gathering

2. Specification & Design

3. Development

4. Validation

5. User Acceptance Testing (UAT)

6. Go-Live

The waterfall approach involves extensive programming and typically requires from six to eight weeks for development. In most cases, the sponsor does not see the system until user acceptance testing (UAT), at which point changes tend to be larger in scope and involve significant delay, unneeded expense, and unnecessary stress.

An agile approach improves on this process in a number of important ways. At YPrime, our modified agile approach begins with a robust base system, then uses a streamlined, iterative process to configure and customize it for the sponsor. The agile process merges the pre-validation steps (requirements gathering through development), typically reducing the traditional six- to eight-week development timeframe to two weeks. Validation and testing typically span two weeks, resulting in an overall 4 week timeline. Key to this streamlining is the early involvement of the sponsor. Working with the IRT project manager and design manager, the sponsor confirms the direction of the design, making small corrections along the way. This ensures delivery of a clean, high-quality system, virtually error-free, at the UAT stage.

Once the basic requirements are understood, system developers configure basic functions. The project manager (PM) invites the sponsor to view this first iteration. The sponsor is


asked whether the study needs have been understood as they pertain to transactional, informatics, and integration functions. With the help of the design manager, the PM and sponsor configure the screen functions together—on the spot—and the sponsor views the configured screens immediately with the click of a button. After the configuration phase is complete, the system enters a one-week finalizing period, undergoing small, iterative changes and validation to produce the UAT-ready system.

The emergence of the agile approach is changing the role of the IRT system project manager. In this iterative model, configuration takes place in parallel with design. The PMs and their team work at the interface, interpreting and implementing the sponsor's requirements on the spot to produce immediate views of the developing system. PMs must be nimble IRT experts to guide sponsors through design and configuration considerations.

Consulting at this design/development interface requires deeper and broader expertise and new skill sets. PMs need to understand protocol requirements and anticipate needs and risks. For example, they need to identify potential conflicts between protocol design and IRT functionality. They need to ask appropriate questions to anticipate possible protocol amendments and other changes that may occur after the system goes live.


# 2017 IRT GOLD STANDARDS

In 2017, sponsors can expect faster, cleaner system development based on an agile-type approach, as well as more functionality and more flexibility and control to implement IRT changes during the course of a clinical trial.

**Full patient management.** Sponsors should look for full control and simplified management of patient enrollment and randomization, dosing scenarios and treatment schedules, with real-time capability for data access and reporting to support adaptive trial designs and rapid decision-making.

Systems designed specifically to manage complex Phase I studies—for example, those in oncology that involve complex dose-finding regimens—can be configured to provide critical safety alerts and reporting. User-friendly, intuitive designs can help minimize site training needs.

New systems provide full visibility and easy workflows. For example, YPrime provides a landing page for patient management with patient demographics and their individual next available transaction(s) based on their status. In another advancement, YPrime offers a unified platform that combines IRT and electronic clinical outcome assessment (eCOA) systems to help align interdependent study operations—for example, a dose that must be administered following an eCOA entry.

**Reporting and analytics.** Today's IRT systems integrate multiple data streams to manage patient interactions and supplies globally, from a single platform, across functions and stakeholders. Real-time integration enables the sharing of multiple data streams to support real-time reporting. Screens display aggregate data and individual data points allowing users to track patients, sites and drug supply status, and to identify operational trends. Embedded analytics and business intelligence let users graph trends based on selected data, such as projections of patient visits and drug demand. Reports are accessible through web portals and mobile devices to support global management.


**Flexibility and control.** Sponsors should look for flexible systems that provide for quick and efficient changes to the system as the study progresses. Data changes—for example, adding a new study site or changing common site entry errors—used to require contacting a held desk and a day of turnaround time. New systems can be designed to give the sponsor or CRO the ability to change specified data points themselves as needed. System changes still require intervention of the system developer. But using a configurable IRT system, PMs and designers can anticipate potential study needs during development. They can plan in advance for the possibility of a new study arm or new dose scenario and make such variables configurable to avoid costs and study delays associated with traditional system changes.

## Emerging Capabilities

IRT capabilities continue to advance, and sponsors can look forward to faster, more flexible system development and more operational efficiencies in more advanced systems.

**Customization libraries.** Many IRT providers are now streamlining customization by building libraries of customized features common to clinical trials. Customized functions such as returns and accountability processes, informed consent forms and partial dispensing workflows, are stored in growing archives and applied to build new systems. As the library expands, the archived resources are used to reduce time and cost to tailor IRT systems for a given protocol.

**Full supply chain capability.** Sponsors expect complete visibility into the supply chain, with end-to-end management from drug release through reconciliation and destruction. More sophisticated IRTs offer uncomplicated pooled and bulk material management solutions. Pooled solutions, for example, are successful in reducing packaging and distribution expenses and, with improvements to make their administration less time-consuming, promise to deliver significantly better cost efficiencies.

**Mobile apps.** Several IRT vendors offer downloadable apps which provide visibility and analytics from the convenience of a smartphone. Graphs and reports are available through the YPrime mobile app, YPGO, which allow a user to monitor current site enrolment versus


planned targets in real time. In addition, users can access unblinded or blinded drug inventory reports, review global study alerts, and pull up email messages previously generated by the system.

**Clinical supply forecasting**. IRT systems drive clinical supply inventory. When clinical supply forecasting is available directly in an IRT, this functionality allows study teams to create more supply chain efficiencies by projecting drug supply needs from enrollment performance. Teams can also schedule repackaging and labelling based on actual use patterns.

**Unified platforms.** A select few providers are offering unified platforms to deliver faster and more capable joint IRT & eCOA system builds. In these platforms, the use of a unified portal and joint database eliminates the need for complicated, complex system integrations between these two commonly used systems. With all the data in one location and visible in one study portal, study teams and site users have the benefit of increased efficiencies in system functionality, new possibilities for patient and clinician assessments and more complete reporting capabilities.

**Patient communications.** Select IRT systems can keep patients engaged and informed in a blinded and protected way. When a patient is screened, email is securely stored and can be used for a number of event-specific and timely follow-up communications, including:

- Instructional emails triggered by individual visits (i.e., dosing instructions)
- Newsletters, information about managing their condition, access to visit schedules
- Post-study updates, such as information about study results or treatment approval
- Content can be dynamically populated by specific triggers, ensuring timeliness and relevance to study participants

This feature is particularly useful for extension studies. It also provides ongoing touchpoints when there are several months between visits, a period when patients are most likely to drop out of a study.


## The Future

The new IRT gold standards will continue to evolve as advancing technologies offer new solutions to reduce time and cost in clinical research. Ahead, real-time data capabilities coupled with mobile health technologies will have increasing impact on clinical trial operations, enabling more patient-centric approaches and virtual trial designs. IRT will continue to support emerging research methodologies in this innovative biopharma landscape.