DESIGNING IRT FOR MODERN TRIALS:

Configurable vs. Customizable IRT Platforms and How to Choose the *Right* Approach for Your Study

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CLINICAL RESEARCH

5 Key Takeaways You'll Find in this Paper

When it comes to IRT/RTSM platforms, configurability and true customization are not the same. Many modern clinical trial protocols require more than a configurable or 'plug and play' system can realistically provide. pg 5

IRT/RTSM technology should adapt to the protocol. Ensuring that operational systems enable protocol innovation—rather than constrain it—should be a critical consideration during study planning. pg 7

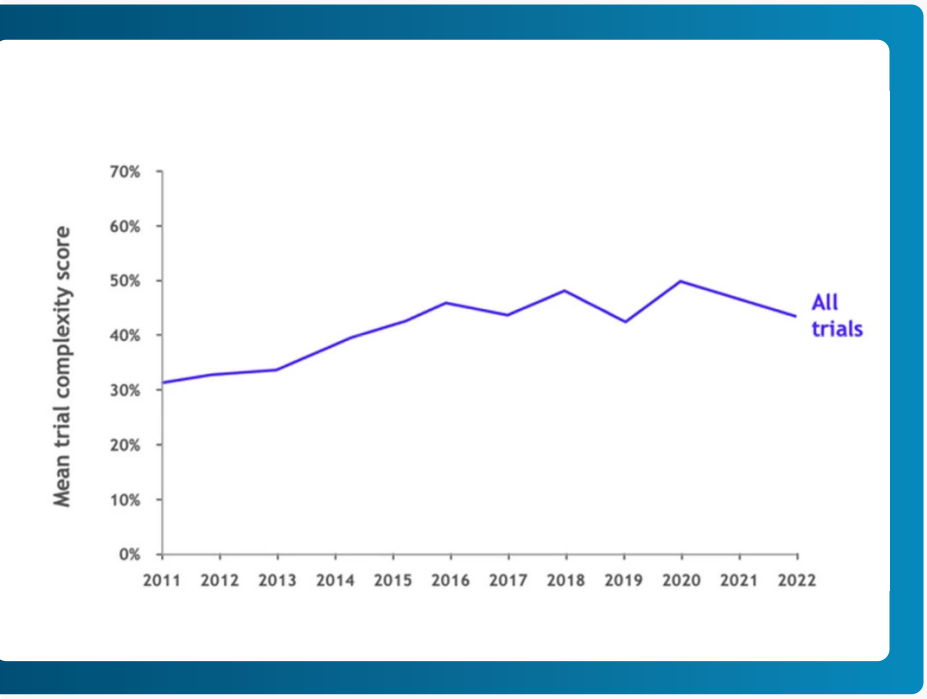
Customizable and flexible IRT/RTSM platforms can improve operational resilience. IRT/RTSM systems built around protocol intent are often better positioned to support mid-study changes without disrupting randomization, dosing logic, or supply workflows. pg 8

Artificial intelligence is narrowing the historical trade-off between flexibility and speed. AI-assisted development tools are making it easier to build and deploy protocol-specific execution logic efficiently. pg 9

Technology alone is not the solution. Successful execution of complex trials requires both flexible systems along with an active, hands-on approach via operational oversight. pg 12

01 Introduction and Industry Context

Clinical trial design is undergoing a profound transformation. Protocols that were once relatively straightforward have steadily grown in complexity, driven by scientific ambition, regulatory expectations, and evolving patient needs. Sponsors today are increasingly combining adaptive methodologies, decentralized trial components, advanced therapies, and global execution strategies within a single protocol. While these innovations enable more sophisticated science, they also introduce significant operational challenges.



Source: https://doi.org/10.1038/s41598-024-53211-z

This rising complexity affects nearly every aspect of clinical trial execution, but few functions experience it as directly as randomization and trial supply management (RTSM).

Historically, Interactive Response Technology (IRT)/ RTSM systems served a relatively narrow purpose: randomizing patients and tracking drug inventory.

An analysis of more than

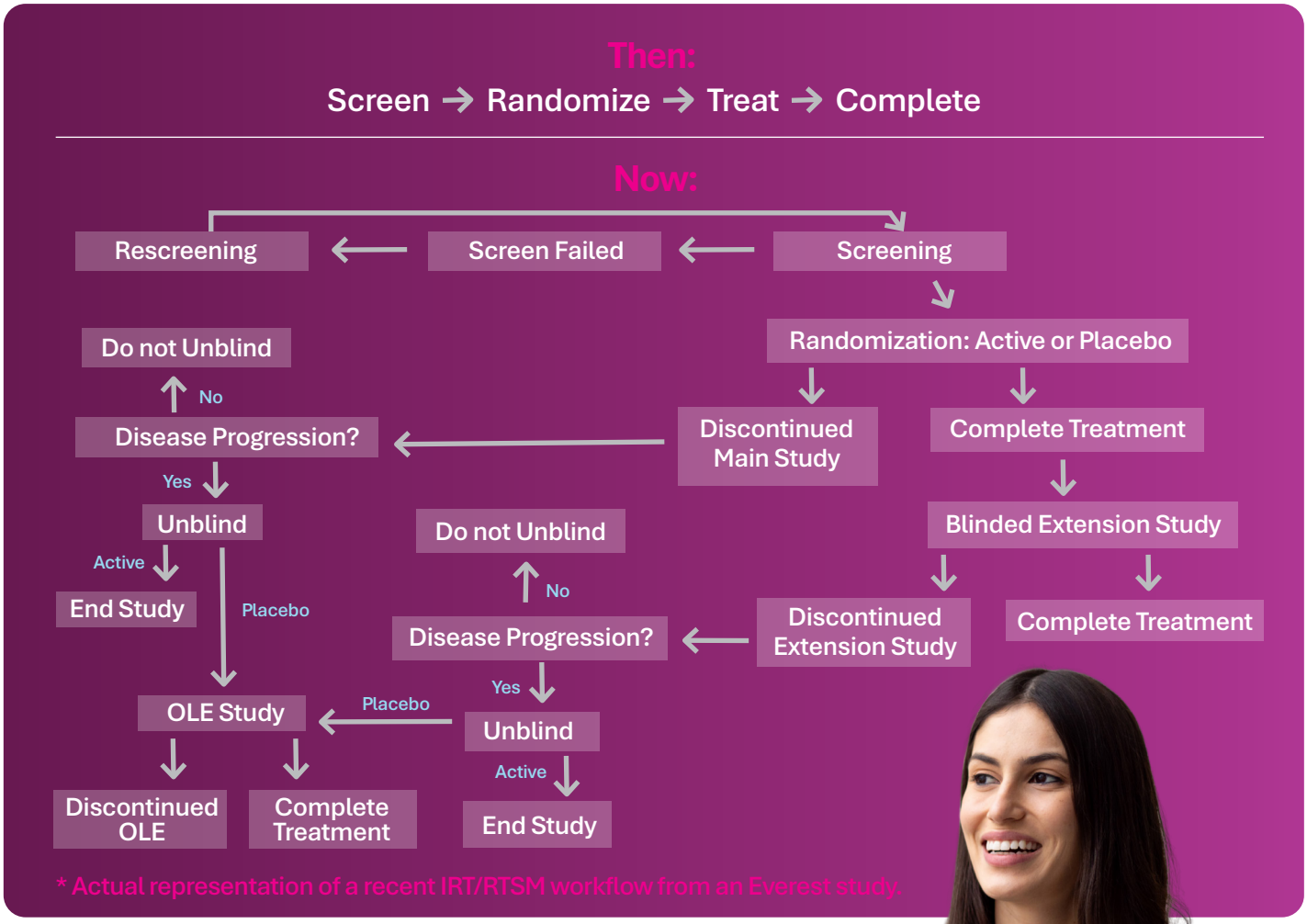
16,000

clinical trials

found that overall trial complexity—measured across endpoints, design structure, and operational elements—has increased on average 10 percentage points over the past decade. [1]

Today, the operational considerations these systems must address are far more complex, including but not limited to:

- Screening Pathways, Re-Screening & Special Populations
- Randomization & Cohort/Arm Management (Adaptive Designs)
- Drug Supply Strategy, Forecasting & Blinded Logistics
- Dosing Algorithms, Titration, & Visit Schedule Complexity
- Unblinding, Emergencies, Deviations & Governance Controls



These challenges reflect a broader shift in the role of IRT—from a transactional tool to a core operational engine supporting modern clinical trials. As a result, the technology used to manage randomization and supply must now support increasingly complex decision logic, dynamic patient pathways, and evolving protocol requirements.

At the same time, sponsors face competing organizational pressures. On one hand, protocol complexity demands increasingly sophisticated operational execution. On the other, internal and market pressures emphasize reducing study startup timelines and controlling upfront technology costs.

In response, the industry has increasingly adopted execution platforms designed to be “configurable,” “modular,” and “plug-and-play.” These systems aim to balance flexibility with rapid deployment by allowing sponsors to configure studies using predefined workflows and parameter settings.

> However, configurability and true customization are not the same—and many modern protocols require more than configurable systems can realistically provide.

02 Configurable vs. Customizable Platforms

A simple metaphor illustrates the distinction.

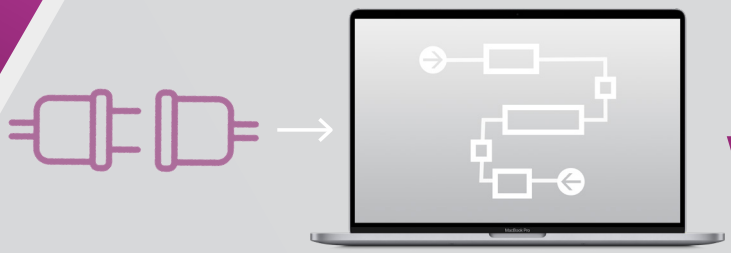
A configured system is like a do-it-yourself IKEA kitchen: cabinets, appliances, and fixtures can be purchased and rearranged within fixed boundaries, but the plumbing, overall layout and infrastructure are constrained.

Custom design, by contrast, resembles working with an architect. Standard materials may still used, but the layout and infrastructure are arranged around how the space will actually function.

Importantly, customization does not mean building systems from scratch. Modern development environments allow teams to assemble validated components and modular logic while tailoring workflow architecture to the protocol itself. The key difference is whether the system adapts to the protocol—or the protocol must adapt to the system.

Plug and Play

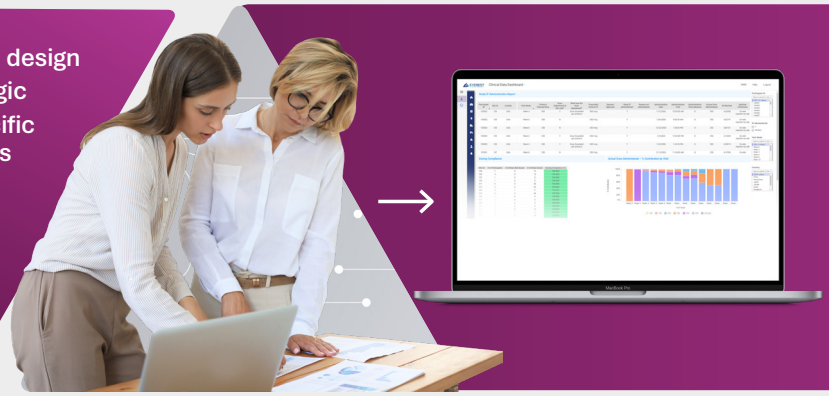
Predefined modules
Fixed workflows
Limited configuration



Configured Within Limits

Customizable

Protocol-driven design
Flexible logic
Study-specific workflows



Built to Your Exact Needs

03 The Benefits of Customization

No Study Design Restrictions

One of the less visible but increasingly important challenges in modern clinical trials is the risk that execution technology begins to shape protocol design, rather than support it.

When operational systems impose structural limitations on what is feasible, study teams may face a difficult choice: simplify the protocol to fit the technology or implement complex workarounds that introduce operational risk. Many contemporary protocols incorporate design elements that extend beyond simple configuration settings. These may include dynamic patient pathways, conditional treatment logic, or hybrid supply strategies that combine depot distribution with direct-to-patient delivery. Systems designed primarily around fixed workflows can struggle to accommodate these elements without introducing manual processes or operational exceptions.

Protocol-driven customization addresses this challenge by aligning system behavior directly with the logic embedded in the protocol. Rather than forcing complex study designs into predefined templates, execution models can be structured around the decision points, pathways, and contingencies defined by the protocol itself.

As clinical research continues to evolve toward more adaptive and personalized study designs, this capability becomes increasingly important. Ensuring that operational systems enable protocol innovation—rather than constrain it—is becoming a critical consideration during study planning.

Startup Speed vs. Study Resilience

Due to the constant pressure to reduce study activation timelines, accelerate first-patient-in milestones, and control initial costs, execution models that promise rapid deployment often receive significant attention during IRT/RTSM technology selection.

> However, focusing exclusively on startup speed can obscure another critical dimension of execution success: the ability to maintain stability and flexibility over the full lifecycle of a study.

Modern clinical trials rarely proceed exactly as originally designed. Protocol amendments have become a routine component of clinical research. These amendments often involve more than minor adjustments and the operational impact can be significant. Changes to eligibility criteria, dosing regimens, cohort structure, or treatment pathways can require updates across multiple operational systems, including randomization algorithms and supply management rules. This reality highlights a critical trade-off in execution strategy.

Configurable systems are optimized for speed and standardization. However, when protocols evolve—as they often do—these systems may struggle to accommodate structural changes without introducing disruption.

The rise of protocol amendments

Between 57% and 76% of clinical trial protocols require at least one substantial amendment. [2]

The average protocol experiences more than 3 amendments during its lifecycle. [2]

The average number of amendments per protocol has increased by nearly 60 percent since 2015. [2]

Approximately one-third (33%–34%) of protocol amendments are considered avoidable. [2]

> Customizable RTSM/IRT systems might require more alignment effort during study setup, but they often provide greater resilience once the trial is underway.

When execution logic reflects the underlying structure of the protocol, amendments can be implemented more predictably, and operational integrity can be maintained more effectively.

For complex studies involving adaptive cohorts, biomarker-based patient routing, or dynamic dosing pathways, this resilience becomes essential.

AI Is Changing the Economics of Customization

Much of the early focus on AI in clinical research has centered on drug discovery, patient recruitment, and trial design optimization. However, the same technologies are beginning to reshape how operational systems are built and maintained, too.

Artificial intelligence-enabled clinical development platforms can improve productivity across trial operations by 15–30 percent while accelerating certain aspects of study planning and execution by up to 20 percent. [3]

Tools such as AI-assisted code generation platforms now allow engineers to build and validate complex logic structures far more efficiently than traditional development methods. AI-assisted development environments can rapidly generate conditional workflow logic, data validation structures, and automated test frameworks—capabilities that previously required extensive manual coding effort. As a result, the time required to build customized platforms specific to each unique protocol and operational logic can decrease significantly and fundamentally change the economics of customization.

This does not eliminate the need for rigorous validation. Even with AI capabilities, comprehensive validation testing remains essential, especially for complex, regulatory-sensitive IRT/RTSM systems used within clinical trials. Engineering oversight, quality assurance, and system validation remain essential.

04 Practical Guidance for Sponsors Evaluating IRT/RTSM Systems

Selecting the appropriate execution technology strategy begins with understanding the specific needs and risk profile of a study. Sponsors should evaluate the level of complexity, the likelihood of protocol evolution, and the operational risks associated with the study.

When Plug-and-Play Technology May Be Appropriate

Standardized IRT/RTSM platforms can be effective for studies with relatively straightforward operational requirements. This approach may be appropriate when:

1. Trial designs follow linear patient pathways
2. Randomization and dosing structures align with common industry patterns
3. Protocol amendments are unlikely
4. Supply models are conventional and predictable

In these scenarios, configurable systems can provide efficient execution while minimizing startup timelines.

When IRT/RTSM Customization May Be More Appropriate

More complex studies may benefit from an IRT model designed specifically around protocol requirements. Customization may be particularly valuable when:

1. Adaptive or response-driven designs are central to the study
2. Hybrid or decentralized trial elements are incorporated
3. Novel therapies introduce complex supply considerations
4. Protocol evolution is expected based on emerging evidence

These conditions often require operational logic that extends beyond predefined system templates.

Questions Sponsors Should Ask

Evaluating IRT solutions requires looking beyond feature lists. Sponsors should instead focus on how platforms behave when protocols evolve or operational complexity increases.

Key questions may include:

- How does your change control process work for mid study IRT updates, especially complex changes?
- What is your typical turnaround time for requirements gathering, design updates, validation, and release?
- How do you ensure continuity of blinded and unblinded operations during system modifications?
- Can you implement changes without requiring a full re build?
- How is change impact assessed on historical/randomization data?
- How do you maintain data integrity during mid study changes?
- Do you provide strategic consulting on protocol design for IRT impacts?

05 Technology Alone Is Not Enough

Execution success depends not only on the capabilities of the technology itself, but also on how that technology is supported during study conduct. Great technology may enable complex workflows, but maintaining operational integrity over the course of a study requires continuous oversight and collaboration between technology providers and clinical teams.

Some execution models focus primarily on delivering software while leaving operational oversight largely to the sponsor. This is risky, as sponsors may not have the dedicated expertise or the required time needed for real-time monitoring in order to detect anomalies.

Instead, sponsors should choose a model where the vendor provides active study oversight, especially as trials become more dynamic.

Active study monitoring support from an IRT/RTSM vendor should include:

- Continuous monitoring for operational anomalies
- Early identification of risk trends in randomization or supply
- Proactive escalation of potential issues
- Ongoing alignment between system behavior and protocol intent
- White glove approach, with hands on support

06 Conclusion

Clinical trial complexity is unlikely to decline. Advances in precision medicine, adaptive trial design, and decentralized execution will continue to expand what protocols attempt to accomplish.

As a result, execution technologies, such as IRT/RTSM systems, are no longer a purely operational consideration.

Sponsors should therefore avoid equating configurability with true flexibility and customization. Instead, execution strategies should be aligned with the complexity and lifecycle risk of the protocol itself.

In some cases, standardized platforms will remain the appropriate choice. In others, protocol-driven IRT customization may offer the resilience required to support complex, evolving study designs.

Ultimately, the goal is not to choose between configurable and customized systems in absolute terms, but to apply the execution model that best supports the scientific and operational goals of each individual study.

Citations:

1. Markey N, Howitt B, El-Mansouri I, Schwartzenberg C, Kotova O, Meier C. Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials. Sci Rep. 2024;14:3514. doi:10.1038/s41598-024-53211-z
2. Getz KA, Campo RA, Kaitin KI. Variability in protocol design complexity by phase and therapeutic area. Ther Innov Regul Sci. 2024;58(2):215-224. doi:10.1007/s43441-023-00554-7
3. Mihic A, Adabala Viswa C, Agrawal G, Yew H, Webster K. Unlocking peak operational performance in clinical development with artificial intelligence. McKinsey & Company. January 9, 2025.

Planning a Clinical Trial?

Let Everest Clinical Research Customize an IRT/RTSM Solution to Suit Your Unique Needs

Everest Clinical Research is a full-service, global CRO with end-to-end clinical trial execution capabilities. Our IRT platform is built in-house and designed to support the unique operational needs of each study. We combine our technology with an expert team that delivers white-glove service to keep your study running smoothly and efficiently.

100%
Go-live timelines met

0
Randomization errors

24/7
Helpdesk support

Seamless
integrations with EDC and other systems

100%
Customizable

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