ALMAC

Connected Trial Execution

Why Integrating IRT, eCOA and Clinical Supply Matters More Than Ever

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Executive Summary

Clinical trials are no longer constrained only by protocol design, recruitment performance, or technology selection. Increasingly, they are constrained by the quality of the connections between the systems, services, data flows and decisions that keep a study moving.

For sponsors running complex global trials, particularly in oncology and other operationally demanding therapeutic areas, the operational challenge is no longer simply to randomise participants, capture outcomes, and distribute investigational product. It is to ensure that these activities work together as one coherent trial-execution model.

A participant is enroled. Treatment is assigned. A visit is scheduled. A kit is dispensed. A symptom is reported. A dose is modified. A shipment is triggered. A site requires clarity. A sponsor needs oversight. Each event may appear discrete, but in practice each depends on the others. When these workflows are disconnected, complexity increases for sponsors, CROs, sites and patients. When they are connected by design, trial execution becomes more responsive, visible and controlled.

Connected trial execution is therefore not just a technology issue. It is an operational, quality, supply, site-experience and patient-continuity issue. A trial may have best-in-class individual systems, but if those systems do not work together effectively, sponsors are often left managing the gaps between them.

This is why the integration of Interactive Response Technology, electronic Clinical Outcome Assessment, and Clinical Supply is becoming strategically important.The value is not created by bundling services together under a single commercial wrapper.

The value is created when specialised capabilities are connected deeply enough to reduce interface risk, improve visibility, accelerate operational response, strengthen inspection readiness and simplify participation in complex clinical research.

In this model, IRT/RTSM, eCOA and clinical supply do not simply coexist. They form a connected operating environment where randomisation, treatment assignment, patient-reported outcomes, visit and event triggers, drug availability, forecasting, resupply logic, and trial continuity are intelligently aligned around the realities of the live study.

For sponsors, the benefit is better control over complex trial execution. For CROs, it is reduced reconciliation burden and clearer operational accountability. For sites, it is a simpler and more coherent workflow. For patients, it is the potential for fewer avoidable disruptions and more responsive trial participation.

This paper argues that the future of clinical trial execution will not be defined by monolithic platforms, nor by disconnected best-of-breed systems operating in isolation. It will be defined by integrated specialist ecosystems with clear governance, validated workflows, interoperable data flows and unified accountability.

Almac Clinical Technologies is positioned at the intersection of IRT, eCOA, trial coordination and clinical supply.

The strategic opportunity is not simply to provide technology, but to help sponsors connect critical workflows that drive patient experience, supply continuity, operational efficiency, and trial oversight.

The Fragmentation Problem in Modern Clinical Trials

Clinical trial technology has advanced significantly over the past decade. Sponsors now have access to powerful systems for randomisation, electronic data capture, eCOA, eConsent, clinical trial management, safety reporting, supply forecasting, and remote participant engagement.

Yet many studies still operate as a collection of adjacent workflows rather than a connected execution model, resulting in operational friction across teams and systems where responsibilities, data flows, and operational triggers intersect.

This matters because some of the most critical trial decisions occur between systems. A randomisation event affects treatment assignment. Treatment assignment affects dispensing. Dispensing affects site inventory. Site inventory affects resupply. Resupply affects participant continuity. Participant-reported symptoms may affect visit schedules, dosing decisions, safety review, or retention risk. Protocol amendments may affect all of these at once.

When IRT, eCOA and clinical supply are managed separately, sponsors and CROs often compensate through manual reconciliation, spreadsheets, status meetings, custom reports, and issue escalation. These workarounds may be familiar, but they introduce delays and variability. They also push complexity onto the very teams least able to absorb it: sites, monitors, supply managers, and study teams managing live trial pressure.

The result is not always dramatic failure. More often, it is operational drag that results in data delays, duplicated efforts, and manual adjustments. In these cases, the trial remains functional, but less responsive, efficient, and inspectable than intended.

Best-of-breed systems can work well when integration governance is strong. However, where integration is weak, the sponsor or CRO effectively becomes the systems integrator. In complex multinational trials, that model is increasingly difficult to defend.

Key takeaway: Trial fragmentation rarely appears as a single failure point. It usually appears as cumulative operational drag; slower decisions, more reconciliation, greater site burden and reduced visibility across the study.

Why IRT/RTSM, eCOA and Clinical Supply Belong in the Same Strategic Conversation

IRT/RTSM, eCOA and clinical supply are often procured and managed as separate categories. This reflects historical operating models more than current trial reality.

IRT is central to participant enrolment, randomisation, treatment assignment, stratification, cohort management, emergency unblinding, visit-driven dispensing, drug accountability, and resupply logic.

eCOA supports the capture of participant-reported, clinician-reported, observer-reported, and performance-based outcomes. It enables symptom diaries, quality-of-life instruments, compliance reminders, decentralised data capture, and participant-facing engagement.

Clinical supply covers packaging, labelling, comparator sourcing, depot strategy, distribution, temperature management, forecasting, inventory control, returns, reconciliation, expiry management, and supply continuity.

Each of these functions is important on its own, but their full value emerges when they operate together.

Here, connected data becomes just as important as connected technology. The strategic value lies not only in linking systems, but in helping study teams see what is happening across the execution layer of the trial; participant activity, treatment allocation, visit adherence, eCOA compliance, supply status and operational exceptions.

In this model, the trial can respond to what is actually happening, rather than what the original forecast assumed would happen.

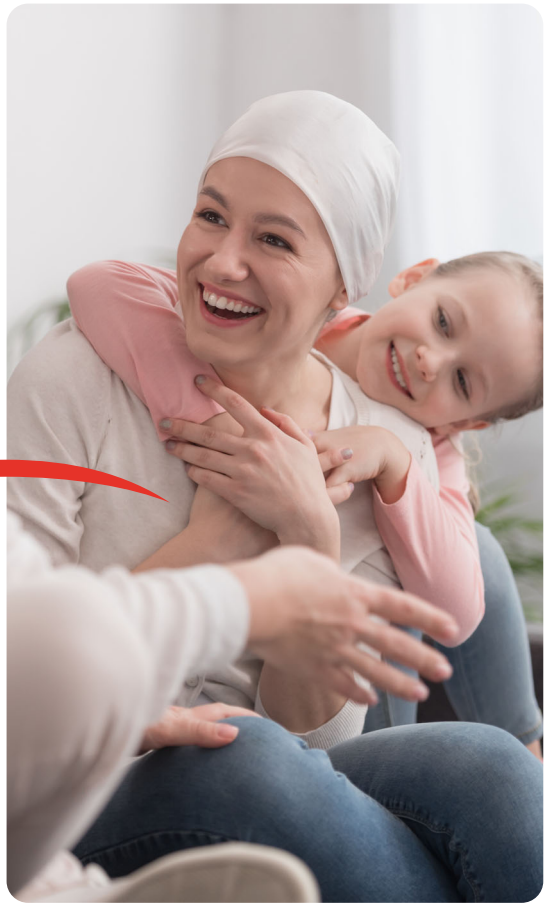
The strategic case is therefore not “one supplier is easier than three.” That may be true, but it is not the deeper argument. The deeper argument is that trial execution improves when the systems responsible for participant status, participant experience, treatment assignment, and drug availability are connected by design.

Key takeaway: IRT, eCOA and clinical supply should not be viewed only as separate functional systems. They are interdependent execution workflows that determine how effectively a trial operates in real time.

Why Oncology Raises the Stakes

Oncology provides the clearest case for integrated IRT, eCOA and clinical supply because operational complexity, participant burden, treatment variability, and supply sensitivity are often present at the same time.

Modern oncology studies may involve stratified randomisation, biomarker-defined populations, adaptive designs, dose escalation or optimisation, cohort expansion, comparator constraints, protocol amendments, complex visit schedules, imaging windows, safety monitoring, and participant-reported outcome requirements. Many studies are multinational, with uneven enrolment across countries and variable site activation timelines.



The clinical supply challenge is equally demanding. Oncology products may be expensive, scarce, temperature-sensitive, short-dated, or difficult to replace quickly. Comparator sourcing can be complex. Demand may vary significantly by region, cohort, dose level, or recruitment performance. Small forecasting errors can create meaningful operational consequences: excess waste in one country, shortage risk in another, or avoidable shipment urgency.

At the same time, the participant experience is central. Oncology participants may experience fluctuating symptoms, dose modifications, treatment interruptions, or high visit burden. Participant-reported outcomes are increasingly important for understanding tolerability, function, quality of life, and treatment burden.

This creates a natural convergence point.

If a participant's treatment status changes, supply planning should understand it. If a dose is held or modified, dispensing and forecasting logic should reflect it. If eCOA data indicate a pattern of symptom burden or missed completion, the study team should be able to see that signal in the broader context of visit adherence, treatment continuity, and operational risk.

Example scenario: dose modification in an oncology trial
A participant moves to a reduced dose level following a protocol-defined clinical decision. In a fragmented model, that update may need to be reconciled across the IRT, eCOA schedule, supply forecast, and site inventory view. In a connected execution model, the operational impact of that change can be reflected more coherently across treatment assignment, dispensing requirements, future kit demand and site-level visibility.

No technology model should imply that integration alone improves clinical outcomes. That would be an overclaim. But integration can improve the operating conditions that make high-quality oncology trial execution possible: timely data, reliable supply, clearer workflows, stronger oversight, and fewer avoidable discontinuities.

Key takeaway: Oncology amplifies the value of connected execution because treatment decisions, participant status, outcome data and supply requirements are highly interdependent.

The Sponsor Benefit: Control, Visibility and Accountability

For sponsors, the central benefit of integrated IRT, eCOA and clinical supply is improved control over the execution layer of the trial.

This is especially valuable in global Phase II and Phase III studies, where sponsors must manage complexity across regions, vendors, depots, CRO teams, study managers, and sites. In disconnected models, the sponsor may have visibility into each functional area but limited visibility across the full chain of operational cause and effect.

A deeply integrated model provides sponsors with clearer visibility across patient activity, supply status, and trial performance. By connecting these workflows, teams can make more informed decisions, identify emerging risks sooner, and manage amendments with greater confidence because fewer disconnected workflows need to be coordinated separately.

The sponsor benefit is not simply more data. Sponsors already have access to large volumes of trial information. The greater value lies in more actionable visibility: the ability to understand what is happening, where risk is emerging, and which operational decisions require attention.

This does not remove the need for governance. It increases the importance of governance. Sponsors still require robust vendor qualification, validation evidence, change control, data privacy review, role-based access, blinding controls, audit trails, and inspection readiness.

However, integration can make governance more manageable. Rather than overseeing multiple disconnected vendors and then reconciling their outputs, sponsors can work through a more unified operating model with clearer accountability.

The commercial implication is meaningful. Sponsor organisations are under pressure to run faster, leaner, more participant-centric studies without compromising quality. The ability to reduce interface risk and improve decision latency should therefore be viewed not merely as a technology benefit, but as a strategic execution capability.

Key takeaway: For sponsors, connected execution supports better oversight by helping transform fragmented operational data into clearer, more actionable trial visibility.

The CRO Benefit: Less Translation, More Delivery

CROs sit at the operational center of many trials. They manage study start-up, site training, monitoring, issue resolution, data cleaning, amendments, country-level coordination, and sponsor reporting. When trial systems are disconnected, CRO teams often become the human integration layer.

This creates unnecessary burden.

A CRA or study manager may need to check one system for participant status, another for eCOA compliance, another for dispensing, another for inventory, and another for shipment exceptions. When a site raises a question, the answer may require cross-vendor escalation. When an amendment is introduced, the CRO must help ensure that IRT logic, eCOA schedules, supply assumptions, site training, and participant-facing materials remain aligned.

Integrated models reduce this translation burden.

For CROs, the benefit is not simply improved integration, but greater operational clarity. Connected workflows reduce ambiguity, improve coordination, and make it easier to manage study start-up, issue resolution, and protocol changes throughout the life of the trial.

This is particularly important in oncology, rare disease, and decentralised or hybrid trials, where protocol complexity and participant burden already place pressure on delivery teams.

The CRO benefit is not that integration removes the need for expert project management. Instead, it allows expert project management to focus on trial delivery rather than systems reconciliation.

Key takeaway: For CROs, connected execution reduces the burden of translating between systems, vendors and workflows - allowing delivery teams to focus more time on study execution.

The Site and Participant Benefit: Simpler Participation in a Complex Trial

Sites experience trial complexity in practical terms. They must enroll participants, manage visits, confirm eligibility, complete assessments, dispense treatment, support eCOA use, answer participant questions, respond to queries, and maintain documentation.

When systems are fragmented, sites often bear the burden through duplicate effort, disconnected workflows, inconsistent subject information, and delays in the support needed to keep the study running smoothly.

An integrated IRT, eCOA and clinical supply model can reduce this burden by making the site workflow more intuitive. The site should be able to understand what the participant needs, what treatment action is required, what outcome assessment is due, and whether supply is available without navigating a maze of disconnected systems.
For participants, the benefit is more indirect but still important.

A participant-centered trial is not created merely by adding an app or allowing remote completion. It is created when the operational model respects the participant's time, condition, and continuity of care. Better reminders, clearer visit coordination, timely eCOA completion, fewer avoidable supply-related delays, and more responsive support can all contribute to a better participation experience.

This matters because participant experience is shaped not only by clinical interactions, but also by operational reliability. A missed supply shipment, unclear visit requirement or poorly coordinated assessment can create unnecessary burden for participants and site staff.
Connected execution helps reduce avoidable friction in the moments that matter.

Regulators have rightly cautioned that digital tools must not create exclusion or unnecessary burden. Integration must therefore be designed around usability, accessibility, language, device strategy, and site support. The goal is not to digitise complexity. The goal is to simplify participation in a complex clinical trial.

Key takeaway: Connected execution should ultimately support simpler participation, for sites managing complex workflows and for participants navigating demanding trial requirements.

Regulatory and Quality Considerations

Regulatory expectations increasingly support the case for connected, well-governed trial systems.

FDA guidance on participant-reported outcomes emphasises the importance of reliable instruments, appropriate documentation, and careful use of PRO data in medical product development. FDA's guidance on decentralised elements highlights the need for clear sponsor and investigator oversight when trial activities occur beyond traditional sites. 21 CFR Part 11 establishes expectations for trustworthy, reliable electronic records and electronic signatures.

EMA guidance on computerised systems and electronic data in clinical trials is particularly relevant because it explicitly addresses system validation, audit trails, user management, security, data integrity, ALCOA++ principles, direct access, and the interdependencies between systems used in clinical trials. It also recognises eCOA and IRT as specific system types within the broader computerised-systems environment.

The regulatory message is clear: integration is valuable only when it is controlled.

An integrated IRT, eCOA and supply model must preserve data integrity, blinding, role-based access, investigator oversight, auditability, and inspection readiness. It must include validated interfaces, documented requirements, test evidence, change control, training, access reviews, and defined responsibilities.

Poorly governed integration creates risk. Well-governed integration reduces risk.

This distinction is important. The value of an integrated model should not be presented as automatic. It depends on the maturity of the supplier, the clarity of the implementation model, the quality of validation, and the sponsor's oversight framework.

For sponsors, this means connected execution should be evaluated not only through a technology lens, but also through a quality and governance lens. The right model should make it easier to understand system dependencies, document decision pathways, manage amendments, and demonstrate control during inspection.

Key takeaway: Integration should not be treated as a shortcut. It should be treated as a governed operating model that strengthens control, traceability, and inspection readiness.

Risks and Balanced Considerations

It must be acknowledged that integration is not always the answer in every trial

There are studies where a separate best-of-breed model may be appropriate. A sponsor may have a mature enterprise architecture, established integrations, existing preferred systems, or highly specialised requirements that justify a multi-vendor approach. In simpler open-label trials, manual or semi-manual supply planning may remain proportionate.

There are also risks in relying too heavily on a single supplier. Sponsors should evaluate service levels, business continuity, integration flexibility, data-export options, governance structures, cybersecurity, and the supplier's ability to work with other sponsor and CRO systems such as EDC, CTMS, eTMF, safety databases, analytics platforms, and enterprise data lakes.

The strongest model is therefore not a rigid monolith. It is a deeply integrated ecosystem of specialist capabilities, delivered with unified accountability but designed to remain interoperable.

That distinction is central to Almac Clinical Technologies' strategic relevance. The opportunity is not to claim that one platform can or should replace every other system in the trial. The opportunity is to connect the trial-critical workflows that most directly affect participant randomisation, treatment allocation, participant experience, supply continuity, and operational oversight.

This balanced position is important commercially. Sponsors do not need another broad platform claim. They need confidence that specialist capabilities can work together in a controlled, flexible and accountable way.

Key takeaway: The goal is not to replace every system. The goal is to connect the workflows that matter most to trial execution, while preserving flexibility and governance.

What Good Looks Like

An effective integrated operating model begins before technology configuration.

It starts with joint study design and configuration workshops that bring together clinical operations, supply chain, data management, biostatistics, participant engagement, CRO delivery teams, and site-facing stakeholders. IRT logic, eCOA schedules, visit windows, dosing rules, resupply assumptions, language needs, country rollout plans, and amendment pathways should be discussed as one operating model, not as separate workstreams.

From there, the trial should be configured around a shared logic spine.

Randomisation and stratification should align with dispensing and inventory rules. eCOA schedules should align with visit schedules and participant burden considerations. Supply forecasts should reflect actual enrolment, discontinuation, dose changes, and geography. Dashboards should give sponsors and CROs visibility across participant activity, site performance, compliance, supply status, and operational exceptions.

Change control should be designed for the realities of live trials. Oncology studies evolve. Cohorts expand. Dose logic changes. Countries are added. Translations are updated. Sites activate at different speeds. A mature integrated model makes these changes manageable because dependencies are known and governed.

A strong connected execution model should include:

1. **Shared design principles**
   IRT, eCOA and supply requirements should be considered together during study design and configuration.

2. **Connected operational triggers**
   Randomisation, visit events, dosing changes, discontinuations, eCOA completion and resupply logic should be mapped as interdependent workflows.

3. **Unified visibility**
   Sponsors and CROs should be able to view participant activity, treatment allocation, eCOA compliance, and supply status in a coherent operational context.

4. **Governed change control**
   Protocol amendments, cohort expansions, supply updates, and configuration changes should be managed through documented dependencies and validated processes.

5. **Site and participant usability**
   The model should simplify workflows for sites and reduce avoidable disruption for participants.

6. **Inspection readiness**
   Data integrity, audit trails, access controls, validation evidence and defined responsibilities should be built into the model from the outset.

This is where a provider with IRT, eCOA and clinical supply connectivity has a meaningful advantage. It can help sponsors design the execution model, not just configure the software.

Key takeaway: Connected trial execution starts before system build. It starts with designing the right operating model across participant, treatment, outcome, and supply workflows.

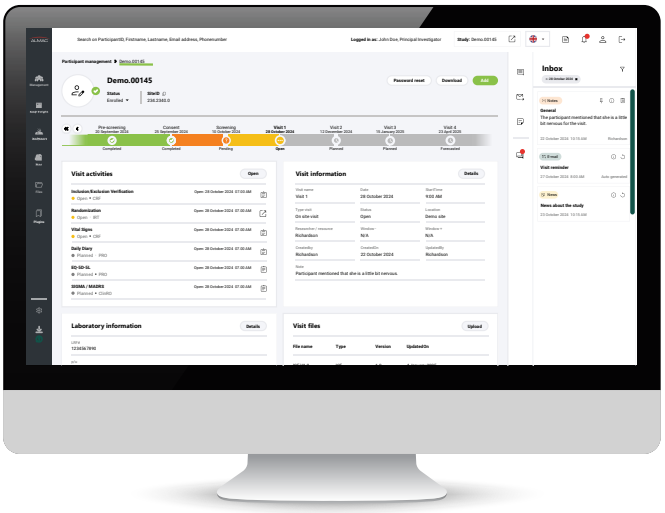
Conclusion

The industry should move beyond viewing IRT, eCOA and clinical supply as separate procurement categories.

In modern clinical trials, particularly complex oncology, rare disease, and multinational studies, these functions are operationally interdependent. Randomisation affects supply. Supply affects continuity. Participant-reported data affects oversight. Visit activity affects forecasting. Amendments affect all of them.

The unique benefit of combining IRT, eCOA and clinical supply is the ability to connect participant activity, trial execution, treatment allocation, and supply continuity into a more intelligent, responsive, and inspection-ready operating model.

This does not remove the need for good protocol design, strong governance, validated systems, or expert study management. But it can reduce fragmentation, improve visibility, support better forecasting, reduce site burden, and strengthen the operational foundations of modern clinical research.



For sponsors, this is a strategic execution question. For CROs, it is a delivery question. For sites, it is a usability question. For participants, it is a continuity question.

For Almac Clinical Technologies, it is an opportunity to articulate a clear market position: not simply as a technology provider, but as a specialist partner helping sponsors connect critical workflows across IRT, eCOA and clinical supply to support more coherent, responsive and controlled trial execution.

Sponsors evaluating future trial operating models should consider not only the capabilities of individual technologies, but also how effectively those technologies work together to support execution, oversight, participant experience, and supply continuity.

Learn how Almac Clinical Technologies helps connect critical trial workflows across IRT, eCOA and clinical supply operations to support more efficient, participant-centered and inspection-ready clinical trial execution.

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