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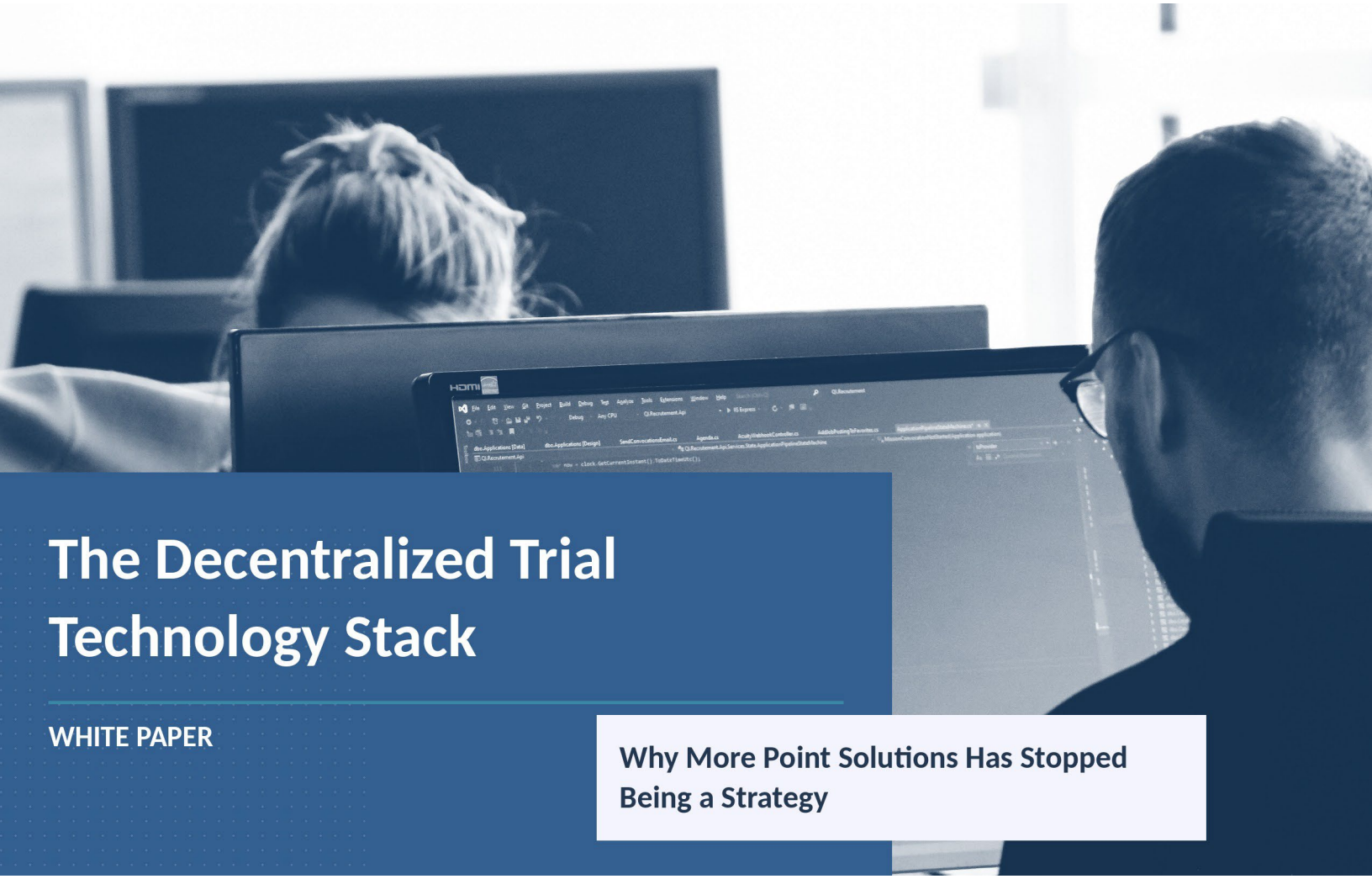

The Decentralized Trial Technology Stack

WHITE PAPER

Why More Point Solutions Has Stopped Being a Strategy

Abstract

Decentralized and hybrid trials now run on an average of four distinct point-solution technologies per study, telehealth, ePRO, home health coordination, direct-to-patient shipment, each selected independently and rarely designed to talk to the others or to the core EDC and CTMS systems underneath them. Site staff feel the consequence directly: a clinical research coordinator survey identified consolidating disparate DCT technologies into a single platform experience as a top recommendation for reducing site burden, citing the multiple separate logins a fragmented stack requires as a genuinely cumbersome part of daily study conduct. The pattern extends to data ownership as well, with the large majority of data-capture platforms sponsor-owned rather than site-owned, a structural mismatch that compounds integration friction. The market has begun to notice. A pure-play decentralized trial technology vendor that reached a billion-dollar valuation in 2021 was acquired for a fraction of that figure three years later, a data point in a broader shift away from standalone point solutions toward consolidated platforms. This white paper applies established connected trial systems and data integration best practices to the decentralized trial technology stack specifically, giving clinical operations and technology leaders a practical approach to choosing and connecting DCT technologies as a coherent system rather than a growing collection of separately excellent parts.

Four Point Solutions, One Patient, and No One Connecting Them

Decentralized and hybrid trials, now a standard design option rather than a pandemic-era exception, typically run on an average of four distinct point-solution technologies per study, according to research from the Tufts CSDD-affiliated PACT Consortium: telehealth or video visit platforms, ePRO and eCOA, home health nursing and sample collection coordination, and direct-to-patient drug shipment among the most common. Each solution is frequently selected for its individual strength at a specific task, and rarely selected with the other three, or with the core EDC and CTMS underneath them, as a design constraint.

The same PACT Consortium research estimates that roughly a third of protocol procedures and about half of study visits could plausibly be performed remotely across a typical trial portfolio, which is precisely the scale of opportunity a fragmented, poorly connected technology stack puts at risk of being undermined by its own operational friction.

Where the Fragmentation Actually Costs Something

Site staff experience DCT technology fragmentation as a direct daily burden, not an abstract architectural concern. A clinical research coordinator survey identified consolidating disparate DCT technologies into a single platform experience as a leading recommendation for reducing site burden, explicitly citing the multiple separate logins a fragmented stack requires as a genuinely cumbersome part of study conduct.[i]

Data ownership compounds the friction. Industry research on clinical trial technology found the large majority of data-capture platforms are sponsor-owned rather than site-owned, while roughly half of sites report wanting a sponsor-connected electronic investigator site file, a structural mismatch that shows up as duplicate data entry and unclear system-of-record questions whenever a point solution and a core system are not genuinely integrated. The same research found that nearly a quarter of clinical trials fail specifically because of slow, broken processes, a category fragmented, poorly integrated technology contributes to directly.[ii] The market has begun correcting for this: a pure-play decentralized trial technology vendor that reached a billion-dollar valuation at its 2021 public listing was acquired for a small fraction of that figure roughly three years later, one visible data point in a broader shift away from standalone point solutions toward consolidated, better-integrated platforms.

Applying Best Practices: Choosing a Stack, Not Just Solutions

A foundational best practice in connected trial systems design, that a connected ecosystem only delivers value when its parts function together, applies directly to decentralized trial technology selection. The mistake most sponsors make is evaluating each DCT technology in isolation against its own use case, without weighting integration with the rest of the stack as a first-order selection criterion.

1. **Integration Requirements Set Before Individual Point Solutions Are Selected.** Define how a candidate DCT technology needs to connect to EDC, CTMS, and the other DCT solutions already in the stack before evaluating its individual feature set, rather than treating integration as a problem to solve after the selection is made.
2. **A Single Sign-On and Unified Access Layer as a Design Requirement.** Reduce the login burden a fragmented stack imposes on sites and patients by requiring unified or federated access across DCT technologies wherever the underlying vendors support it.

3. **A Clear System-of-Record Assignment for Every Data Type.** Resolve data ownership ambiguity explicitly at study design time, assigning each data category a defined system of record rather than leaving sponsor-owned and site-owned platforms to duplicate or conflict with each other during conduct.
4. **Vendor Consolidation Evaluated Against Genuine Fit, Not Just Fewer Contracts.** Weigh the operational benefit of a more consolidated platform against whether it genuinely covers the specific DCT functions a given trial needs, rather than consolidating for its own sake at the cost of a weaker fit on a critical function.

None of this requires abandoning best-of-breed point solutions where they genuinely outperform a consolidated alternative. It requires treating stack coherence as a design decision made deliberately, rather than an outcome of four separate procurement decisions made independently.

What a Coherent Stack Buys, and Where It Gets Hard

Advantages

- **Meaningfully reduced site and patient login burden:** unified access across the DCT stack directly addresses the specific friction site staff have identified as a top concern.
- **Clearer data quality and system-of-record accountability:** resolving ownership ambiguity at design time reduces the duplicate entry and reconciliation work a fragmented stack otherwise generates.
- **Better realization of the remote-visit and remote-procedure opportunity:** a stack designed to work together, rather than around each other, is better positioned to actually deliver the roughly half of study visits industry research suggests could be conducted remotely.
- **Reduced exposure to individual vendor instability:** a stack architecture that treats integration as a design requirement, not an afterthought, is more resilient when any single point-solution vendor faces its own business disruption.

Risks and Barriers

- **Integration requirements can narrow the field of viable vendors:** requiring genuine interoperability at selection time may rule out an otherwise strong point solution that does not support it.
- **Consolidated platforms are not always the stronger choice on every function:** a single-vendor platform's convenience can come at the cost of weaker performance on a specific DCT function than a dedicated point solution would deliver.
- **System-of-record assignment requires genuine cross-functional agreement:** resolving data ownership ambiguity means aligning clinical operations, data management, and site relationships on a decision each has a stake in.
- **DCT budgets have grown more cautious industry-wide:** a majority of organizations report flat or shrinking digital and DCT budgets, which constrains the appetite for the upfront integration investment a coherent stack requires.

Case in Point: The Trial With Five Logins and One Confused Patient

A mid-size sponsor running a decentralized cardiometabolic trial deployed a stack of five separate technologies: a telehealth platform, an ePRO app, a home health coordination portal, a direct-to-patient drug shipment tracker, and the core EDC. Each had been selected independently over the course of study design, each by a different functional owner optimizing for their own requirement.

Roughly two months into enrollment, site coordinators began reporting a consistent pattern: patients calling in confused about which app to use for a given task, missed home health visits because a scheduling notification arrived in a portal the patient rarely checked, and duplicate data entry burden on coordinators who had to manually reconcile ePRO submissions against what the EDC showed. An early patient exit interview cited the number of separate apps required as a specific, named source of frustration with participating in the study.

The sponsor's fix was not a full platform replacement mid-trial, which was not operationally feasible. It was building a single unified patient-facing portal that federated access to the telehealth, ePRO, and shipment tracking functions behind one login, while resolving the data reconciliation problem by formally designating the ePRO system as the system of record for patient-reported data and automating its flow into the EDC rather than relying on manual coordinator entry. Patient-reported exit interview complaints about app fragmentation dropped substantially in the months following the fix, and coordinator time spent on manual reconciliation fell in parallel.

Recommendations for Clinical Operations and Technology Leaders

1. **Set integration requirements before selecting individual DCT point solutions.** so interoperability is a selection criterion from the outset rather than a problem discovered after contracts are signed.
2. **Require unified or federated access across the patient- and site-facing stack wherever possible.** to directly reduce the login burden research consistently identifies as a top site and patient concern.
3. **Assign a clear system of record for every data type at study design time.** resolving sponsor-owned versus site-owned ambiguity before conduct begins rather than during it.
4. **Evaluate consolidation opportunities on genuine functional fit, not contract count alone.** weighing a single-vendor platform's convenience against whether it actually covers each DCT function the trial needs.
5. **Track site and patient technology burden as a named study metric.** rather than treating login fatigue and app confusion as an unmeasured, assumed cost of running a decentralized design.
6. **Build integration resilience into vendor risk assessment.** given the documented business volatility some pure-play DCT technology vendors have experienced.

Measuring Success: KPIs for Decentralized Trial Technology Stack Performance

- **Number of separate logins required per patient and per site:** tracked as a direct proxy for technology burden, targeted for reduction through unified access design.
- **Manual data reconciliation volume:** the amount of coordinator time spent reconciling data across systems that should be automatically integrated, tracked toward reduction.

- **Patient-reported technology friction in exit interviews:** tracked qualitatively and quantitatively as a specific retention risk factor distinct from clinical adverse events.
- **Remote visit and procedure completion rate:** the percentage of eligible visits and procedures actually conducted remotely, tracked against the roughly half of study visits industry research suggests are plausibly remote-capable.

Conclusion

Four separate point solutions selected independently, each strong on its own terms, do not add up to a decentralized trial technology stack. They add up to four separate logins, an unresolved data ownership question, and a coordinator doing manual reconciliation work the technology was supposed to eliminate. The industry's own shift toward consolidation reflects a market correcting for exactly this pattern.

Applying disciplined best practices to decentralized trial technology selection, integration requirements set before point solutions are chosen, unified access design, clear system-of-record assignment, consolidation weighed on genuine fit, turns a growing collection of separately excellent tools into the coherent, connected stack a decentralized trial actually needs to deliver on its own promise.

About OmniTek & Contact Information

For clinical operations and technology leaders building or troubleshooting a decentralized trial technology stack, OmniTek applies proven best practices to build a practical stack coherence practice: integration requirements set before selection, unified access design, and clear system-of-record assignment. Whether you are scoping your next decentralized trial's technology stack or diagnosing site and patient burden in a study already underway, OmniTek can help you turn a collection of point solutions into a genuinely connected system.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.

McLean, VA | Serving clients nationwide
info@omnitekconsulting.com
omnitekconsulting.com

Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.

Endnotes

[i] Applied Clinical Trials, citing Tufts CSDD/PACT Consortium research on decentralized trial point-solution adoption and a clinical research coordinator survey on site technology burden and consolidation recommendations, available at https://www.appliedclinicaltrialsonline.com/view/retention-by-design-operationalizing-patient-centric-trials-without-increasing-site-burden

[ii] Florence Healthcare, "State of Clinical Trial Technology Report," on data-capture platform ownership patterns, site preferences for connected electronic investigator site files, and trial failure attributed to slow, broken processes, available at https://www.businesswire.com/news/home/20230111005051/en/Investment-in-Site-Enablement-to-Accelerate-Research-Grows-300---Florence-Healthcare-Releases-State-of-Clinical-Trial-Technology-Report