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Outsourcing in Clinical Trials 2026

The guide for professionals in the global clinical trials space

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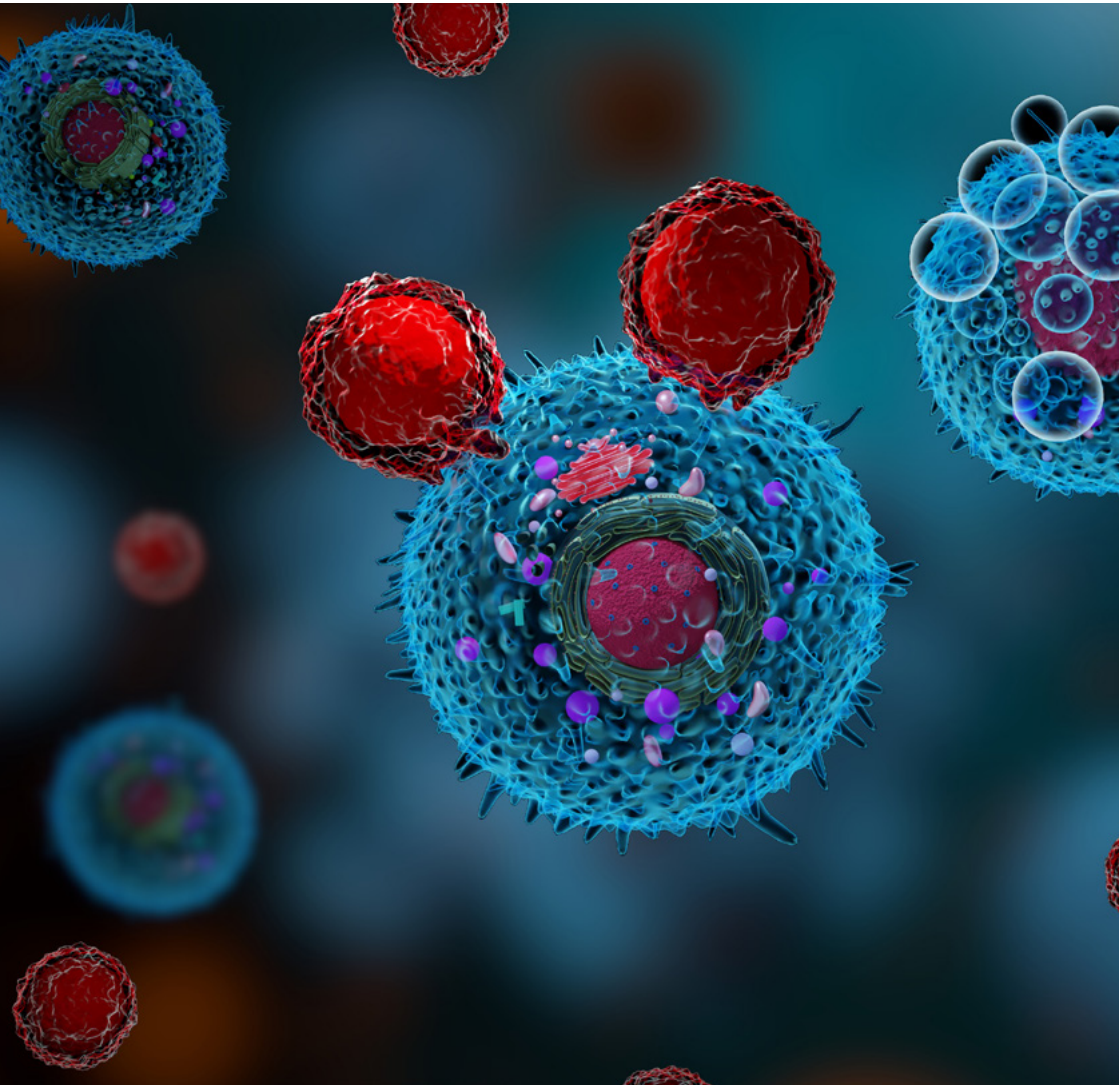

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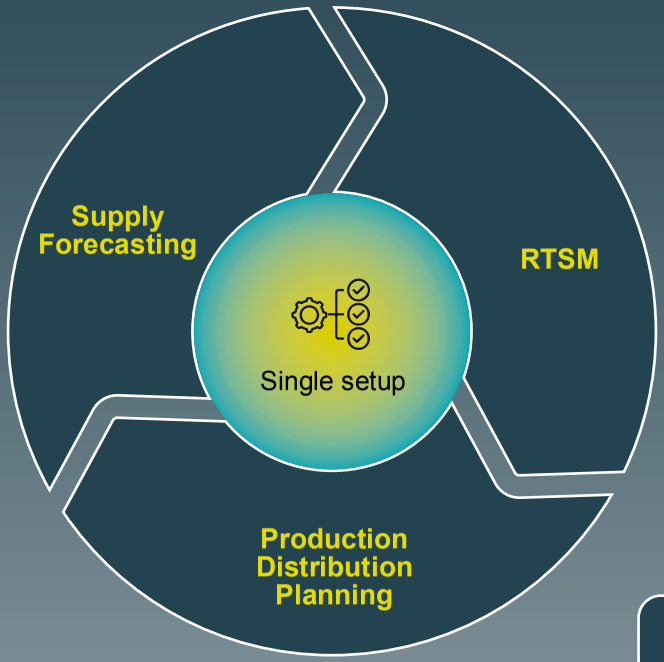

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Outsourcing in Clinical Trials 2026

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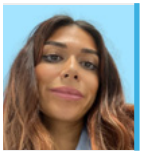

Welcome to the 2026 edition of the Outsourcing Clinical Trials Report from Arena International. Comprising both industry-written insight and specialist analysis, this report is a key tool to support you in navigating the year ahead.

2025 saw significant change. MFN, drug pricing, the introduction of IRP to the US, new legislation and pressures to address environmental, social, and governance (ESG) issues continue to provide challenges and opportunity for the Clinical Trials Sector.

2025 also saw a significant increase in emerging technologies, with advancements in AI and automation to drive operational and efficiency challenges offering a new competitive edge to early adopters.

This year's report, available in both digital and print formats addresses key themes including:

- Navigating and thriving in the ever-faster pace of change
- AI – its real impact and opportunity
- True patient- centric trials
- Buyer guide directory from leading suppliers globally.

Arena International organises over 25 events in the world's leading biotech hubs in US, Europe, APACand now including China. For more information www.arena-international.com. Arena International is part of GlobalData Healthcare – a world leading solutions provider in the clinical trials space. www.globaldata.com www.clinicaltrialsarena.com

Best wishes,

Niki Khoshkbary, Editor, Outsourcing in Clinical Trials

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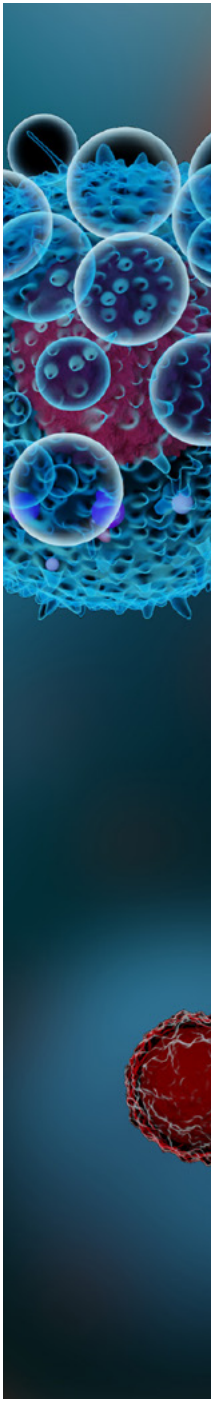

OUTSOURCING IN CLINICAL TRIALS EVENT SERIES

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Chapter 1
Clinical Operations & Outsourcing

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Smart and Efficient RFPs: A Vendor's Plea for Better Questions

By **Douglas Fiebig**, Senior Partner at Trilogy Writing & Consulting and **Evija Kuemmel**, Head of Corporate Communications at Trilogy Writing & Consulting

When outsourcing services, designing and issuing a Request for Proposal (RFP) is an important step for establishing successful partnerships with vendors. The RFP process helps pharmaceutical companies, Contract Research Organizations, and other healthcare organizations assess potential vendors, compare their capabilities, and shortlist the most suitable partners. When done well, RFPs streamline selection and set the stage for productive collaborations.

As medical writing consultants, we have responded to dozens of RFPs for over 20 years. Many have been thoughtful, strategic documents that helped both sides manage expectations. Unfortunately, others have been lengthy and filled with irrelevant questions, making the process inefficient for both issuer and vendor.

The consequences of inappropriate and lengthy RFPs are not only a challenge for vendors in terms of the time needed for their completion. We suspect that poorly designed RFPs also disadvantage the issuers. They are likely to generate superficial or inappropriate responses, delay decision-making, and lead to vendor selection based on incomplete or irrelevant criteria. After years of receiving frequently ineffective RFPs, we are using this article to share a few ideas for designing effective RFPs. We explore why so many RFPs miss the mark and how they can be smarter, more efficient documents that serve the issuer's needs. We provide examples from our service line – medical writing – but believe these principles are equally applicable across all services.

What We Encounter: The Reality of Poor RFPs

Before exploring ideas about what can make the RFP process more effective, it's worth highlighting some characteristics of ineffective RFPs that we have received.

The kitchen sink approach. These RFPs involve 50-80 questions, asking everything from founding year to office square footage to the history of the company. Buried within are the few questions that matter to the service needed.

The copy-and-paste problem. Many RFPs are generic templates applied across service areas and project scopes. As a medical writing vendor, we've been asked about experience running Phase 2 studies – irrelevant to writing services. This generic approach shows little thought about the specific services needed and makes it harder for vendors to demonstrate their fit.

Questions that lack differentiation or create confusion. Asking "What are your staff's hours and days of operation?" adds little value to assessing medical writing credentials. More importantly, the responses are unlikely to vary substantially among vendors. It would be more pertinent to ask whether the vendor has resources in different time zones and to ask for evidence of how these resources can be leveraged to optimize timelines of the envisaged project.

Similarly, another real-life question like "Provide a price for writing a CTD submission" is meaningless without details about the product, indication, development program, and CTD modules within the scope. This is about as effective as asking a builder "Provide a price for building a building". Without context, issuers receive a wide range of prices based on assumptions made by vendors.

Questions that mislead. A question like "What is the average length of service for your employees?" can elicit a skewed response if a company is growing and has many recent new hires. If you compare a company that is growing with a company that is not, then a meaningful comparison cannot be made. A better approach is to categorize employees by predefined ranges for the length of service.

Likewise, "How many reports have you authored in neurology?" may appear relevant due to its specificity but ignores experience in other therapeutic areas. In medical writing, broad experience is often more valuable than narrow specialization. The best medical writers will have honed their skills over time through having worked on a broad range of document types and therapeutic areas.

The narrative trap. RFPs relying too heavily on open-ended questions invite lengthy responses that are hard to analyze and compare.Instead of structured data points, issuers sift through pages of subjective storytelling, slowing decision-making and increasing bias. Ultimately, no one gains from this approach – vendors invest time crafting narratives, while issuers struggle to extract meaningful information and compare vendors.

What Makes a Good RFP: A Vendor's Perspective

Having experienced both excellent and deficient RFPs over time, we have gained insight into what works well and the characteristics of effective RFPs that benefit issuers and vendors alike. The list below is not exhaustive, but when RFPs feature these traits, they are easier to respond to and yield productive interactions. Here are our recommendations from a vendor's perspective.

Good RFPs are focused on decision criteria. Every question in a well-designed RFP should answer one fundamental question: "Can the vendor successfully deliver on our specific project?" Issuers should identify 5 to 7 key decision criteria before drafting questions. Examples include therapeutic area expertise, experience with specific regulatory authorities, resources for tight timelines, quality management systems, and pricing structure. If price matters, acknowledge it; if regulatory experience is critical, prioritize it. Validate questions internally and ask: "Will this help us make a decision?" If not, revise or delete. This ensures vendors provide focused responses to questions that influence decision-making.

Good RFPs are specific to your project. Generic questions yield generic answers; specific questions yield useful information. Instead of asking "Do you have experience with Marketing Authorisation Application (MAA) dossiers?", ask "How many MAA dossiers have you written in the past 2 years, and which modules did you author?" Instead of "Provide details on your staff," ask "How many medical writers with MAA expertise are available for a project starting in Q2 20xx?" Specificity tells vendors exactly what you need and prevents vague responses.

Good RFPs enable meaningful comparisons. To compare vendors objectively, RFPs should favor structured formats over open-ended questions. Use checkboxes for yes/no questions, tables for capacity, timelines, and pricing, and implement word limits for open-ended questions. Structured formats guide vendors and facilitate assessments. If every vendor responds with lengthy narratives, issuers end up comparing writing styles rather than capabilities. A balance between structured and open-ended questions ensures comparability and context.

Good RFPs speak the vendor's language. Using terminology and frameworks familiar to the service area being procured clarifies scope and fosters trust. By aligning the language and concepts with the service being requested, the likelihood of receiving relevant, actionable insights rather than generic responses is

"As a vendor responding to RFPs, we aim to provide clear, accurate information to help issuers make the best decisions but all too often, project scopes are vague and the questions asked are not directly relevant to our service offering, making it hard to see how comparisons between vendors can be made."

increased, ultimately leading to better decision-making and stronger partnerships.

Good RFPs are concise and crisp.
Concise RFPs respect the time of issuers and vendors, focusing only on essential information. Direct, well-structured questions allow quick, accurate responses, reducing ambiguity and expediting assessment. Brevity done well signals professionalism and purpose. If you cannot shortlist vendors based on 15 focused questions, adding more will only create unnecessary complexity. The challenge for an issuer when drafting an RFP should be to set a limit of 10 to 15 relevant questions.

A Partnership Mindset

As a vendor responding to RFPs, we aim to provide clear, accurate information to help issuers make the best decisions but all too often, project scopes are vague and the questions asked are not directly relevant to our service offering, making it hard to see how comparisons between vendors can be made. Poor RFPs make it harder for an issuer to make sound procurement decisions. They waste the vendor's time crafting responses to irrelevant questions and waste the issuer's time assessing information that is likely not pertinent to the service being sought.

Good RFPs form the foundation of successful partnerships. They identify vendors with the right expertise, capacity, and approach. They signal that the issuer values efficiency and clarity and set the tone for collaboration based on mutual respect and meaningful communication. Good RFPs may take more time to prepare than ill-considered RFPs – recall Blaise Pascal's quote: "I have made this longer than usual because I have not had time to make it shorter" – but they provide meaningful insights and save time during assessment. When issuers select the right vendor, everyone benefits: issuers receive quality deliverables on time, and vendors gain successful projects and happy clients.

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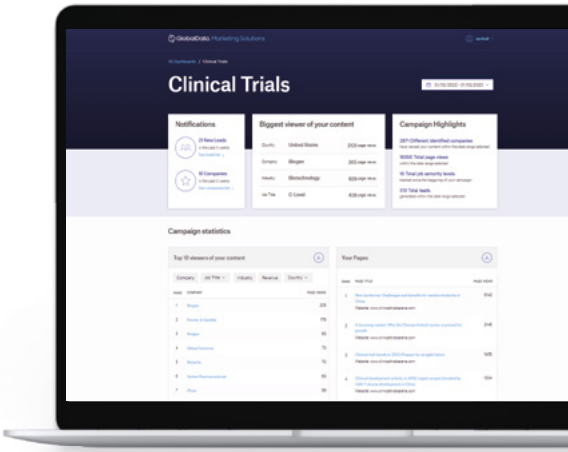

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Andrew Waiton, Abacus Medicine Pharma Services

Free to download now, the 2026 Clinical Research Report. Showcasing AI breakthroughs, diversity, and innovation for 2026.

A Strategic Guide to Becoming a Sponsor of Choice

By **Carrie Lewis**, Executive Director, Clinical Program Optimization at Keenova Therapeutics

Have you ever wondered what truly sets a Sponsor of Choice apart in the eyes of clinical research sites? As a leader in the industry, this is a question worth reflecting on every day. At Endo, we once launched a theme called "The Year of the Site"—a theme that had such an impact on what we did, it continues because of its importance..

In the complex landscape of clinical research, sites play a pivotal role. Sponsors cannot run successful studies without strong site partnerships. Behind every success story lies a solid relationship, and while we often focus on internal and vendor relationships, the connection with our sites has historically been overlooked.

According to some published industry surveys the inclusion of site feedback in protocol design dropped. Satisfaction with overall site payment amounts fell, indicating that compensation may not be keeping pace with rising costs. These numerous statistics highlight the challenges sites face—getting up and running, staying operational and retaining skilled staff. In an industry that depends on site success to ensure high-quality studies, Sponsors must actively support their sites.

A key change to be a Sponsor of Choice for Endo was the addition of our **Site Relationship Manager** who plays a crucial role in strengthening site partnerships. This role serves as a liaison between the site and Sponsor, ensuring the site's perspective is considered. For example, after we receive site feedback on the protocol draft, we do a protocol walkthrough. During this meeting, our Site Relationship Manager assumes the role of a Study Coordinator while another team member is a potential participant, helping us identify and address issues before finalizing protocols and ensures the protocol is logistically aligned with site practice. While perfection is elusive, this proactive approach helps us integrate site feedback and point of view early in the process.

Additionally, the Site Relationship Manager collaborates with the Clinical Operations team to review site-facing documents such as email blasts, newsletters, Informed Consent Forms, and more to ensure they are clear, engaging, and actionable. Her experience as a former Site Director helps us improve our communications with sites. This is ever present when she collaborates internally with Data Management team on queries and CRF guidelines. Places where sites can sometimes struggle with guidance, so we work to have the site point of view in those processes as well. Lastly, the Site Relationship Manager engages with sites both in person and virtually to cultivate strong, trust-based relationships. This strategic engagement ensures sites have a dependable advocate and partner throughout the trial.

Another area we try to succeed at is simply **listening!** That sounds easy but can be surprisingly difficult at times. We are mindful of their concerns and make a conscious effort to implement meaningful change on their behalf. For example, we have had internal meetings where we address site frustrations that were shared directly, or just from online forums. Then revamped processes such as outlining our training expectations more directly in advance or streamlining communication to sites to be more effective.

Listening has also brought change to our query process. We use direct outreach to ensure we pick up the phone instead of re-querying and are cautious to avoid simply querying to confirm what is already stated. We actively seek input from our sites through an annual survey, which they can choose to complete anonymously. When a site provides constructive feedback and identifies themselves, we follow up with a personal call to better understand their experience and explore ways we can provide meaningful support.

Site teams are not a one-size-fits-all, thus we have spent time internally training our clinical operations team to **get to know their sites**. Know what works for each site and doing our best to customize our work flow per each site's needs. For example, ask the site if they prefer paper or electronic files, phone calls or emails. That may also mean making personnel changes based on personalities. In any partnership, you must get to know each other. Sometimes the simple things can have a huge impact on a relationship.

Fair payments are another critical factor to becoming a Sponsor of Choice. Work to pay on time and pay fairly, including paying for screen failures. At the end of the day, sites are businesses and many of them operate on small margins where keeping the doors open can be difficult. Lastly, listen to them if they need to re-negotiate at any point. I look at paying sites the same way as paying vendors, and we pay all vendors for the work done so why do we continually tell sites that is part of business? We need to listen and compromise in ways that are reasonable and beneficial for both organizations.

Another strategy to become a Sponsor of Choice is **supporting naïve site staff**. While it's tempting to rely on familiar sites, embracing new ones is essential. High turnover among Principal Investigators (PIs) can disrupt trials and cause delays. Expanding our pool of sites to include diverse locations and new faces strengthens our research infrastructure. Recognizing the challenges faced by naïve sites is key to effective engagement. By offering tailored support, we empower these sites to contribute meaningfully to clinical trials. Implementing targeted strategies fosters stronger collaboration and improves trial outcomes.

"Site teams are not a one-size-fits-all, thus we have spent time internally training our clinical operations team to get to know their sites."

Finally, one of my favorite initiatives we implemented to better listen to our sites, and drive internal and vendor improvements, was the creation of a **Site Operational Advisory Board**. Each year, we bring together approximately ten sites to provide feedback on key topics such as startup and feasibility, contracts and budgets, training, and vendor interactions. We welcome all feedback and genuinely seek areas for improvement. One area where I personally gained valuable insight from this board was site expectations around detailed budgets. We discovered that despite our good intentions, some internal practices inadvertently made site budget review more difficult. These open and sometimes challenging conversations helped us understand site needs and allow us to explain our processes—leading to mutual understanding and improvement.

In conclusion, becoming a **Sponsor of Choice** requires intentional effort, open communication, being adaptable, self-reflection, and a strong commitment to site success. By valuing our site partnerships and continuously seeking improvement, we pave the way for more effective and impactful clinical research.

Mind the Gap Why Knowing the Guidance Isn't Enough

By **TRI** www.tritrials.com

2024 was the year ICH E6(R3) entered the conversation. 2025 is the year it demands execution. Awareness is strong: 87% of stakeholders now report familiarity and optimism is high, with four in five expecting quality improvements. Yet only 19% say significant change has occurred. The gap between knowing and doing remains.

Why? Because understanding guidance is easy. Embedding it into processes and culture is harder. And that's where the industry is stuck.

Awareness Isn't Alignment

Sites still trail sponsors and CROs in familiarity, and that matters. E6(R3) is a shift toward collaboration and designing for critical-to-quality factors from the outset.

Early alignment is essential. Sponsors and CROs should meet at RFP stage to harmonize risk tolerance and outline monitoring strategies: central, remote, or site, with clear budget implications. This proactive approach reflects the intent of E6(R3): quality by design, not by correction.

And let's clarify CtQ. "Critical data" and "critical processes" are examples, not synonyms. Eligibility criteria can be CtQ too. Precision here avoids semantic confusion and ensures proportionate controls.

Risk-Based Approaches: Priority and Pain Point

Risk-based approaches rank as the top implementation priority (44%), and for good reason. They enable sponsors and CROs to focus resources where they matter most, improving efficiency without compromising quality.

Centralized monitoring is a cornerstone of RBQM. It's a hybrid role, part project manager,

part data analyst, with authority to act on risk signals. KRIs feed into weighted site-risk scores, which drive interventions. On-site visits? Now the exception, reserved for foundational issues like IP storage failures. Remote reviews come first, supported by platforms that visualize trends and root causes. Transparency is non-negotiable. Monitoring plans must define KRIs, thresholds, and escalation steps. Platforms should show site trends over time to justify decisions during audits. RBQM provides the structure to make these decisions defensible and data-driven.

Promise Meets Paradox

Quality by Design earns the strongest vote for positive impact, and when paired with RBQM, it becomes transformative. Together, they reduce site burden by focusing on what matters most. Yet half the industry fears E6(R3) will increase site burden, a perception RBQM can chang Sites support RBQM and dislike unnecessary visits, but they want inclusion, not imposition. Their message: "Do it with us, not to us."

To deliver on QbD's promise, involve sites early in defining CtQ and feasibility. Clarify SDV expectations: risk-based, not blanket 100%.
Technology: Enabler, Not Obstacle
"Innovative trial design & technologies" tops the challenge list. Barriers include cost, integration complexity, validation, and uneven regulatory comfort, but these are solvable with the right RBQM platform. Technology should simplify oversight, not add burden.
Data governance compounds the challenge. Organizations need frameworks that connect processes and systems, a reminder that E6(R3) is as much an operating-model transformation as a compliance update.

Turning Guidance into Action

ICH E6(R3) sets the principles; OPRA makes them operational. OPRA embeds RBQM into every stage of the trial lifecycle:

- **CtQ Alignment Tools** – Define and document critical-to-quality factors with clarity and compliance.
- **Dynamic Risk Scoring** – Monitor KRIs and KPIs in real time to prioritize interventions proportionately.
- **Centralized Oversight** – Visualize site trends, root causes, and thresholds to justify decisions during audits.
- **Integrated SDV Logi**c – Apply risk-based source data verification where it matters most.

For organizations navigating the shift from awareness to action, OPRA offers a proven framework to operationalize E6(R3), without adding unnecessary complexity.

Six Moves to Close the Gap

If your organization "knows" E6(R3) but struggles to live it, start here:

1. **Run early alignment workshops.**
   Align risk tolerance, define CtQ factors, and preview monitoring strategies and budgets.
2. **Codify centralized monitoring.**
   Publish KRIs, weightings, thresholds, and escalation steps. Require trend analysis and root-cause hypotheses before on-site visits.

"For organizations navigating the shift from awareness to action, OPRA offers a proven framework to operationalize E6(R3), without adding unnecessary complexity."

3. **Upskill CM talent.**
   Hire hybrids with PM, monitoring, and data expertise, and empower them with decision rights and SOPs.
4. **Invite sites into QbD.**
   Co-define CtQ and feasibility to reduce deviations and amendments.
5. **Right-size SDV.**
   Document CtQ data, independent sources, and risk triggers. Align sponsors and CROs on rationale.
6. **Invest in enablement.**
   Provide role-specific training, R2 vs R3 comparisons, checklists, and case studies. Build an internal hub for proportionality scenarios and audit-ready evidence.

The State of Play, and Why Optimism Is Justified

Organizations are starting with process changes, then technology, and people, a logical sequence for cultural and infrastructural shifts. Stakeholders agree the prize is worth it: improved quality and better participant experience.

But challenges persist. Sites haven't budged on perceived burden since 2024, and ambiguity around "proportionality" remains. The fastest path forward? Align early. Explain the why. Make thresholds visible. Empower those closest to the signals.

E6(R3) isn't asking us to do more. It's asking us to do less of what doesn't matter, and to prove it. The sooner we embed that mindset, and the tools to support it, the sooner awareness becomes action.

For more information contact us at info@tritrials.com

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10-11 March | Raleigh, NC, USA

MAY

Outsourcing in Clinical Trials Europe
6-7 May | Barcelona, Spain

Outsourcing in Clinical Trials East Coast
12-13 May | New Brunswick, NJ, USA

JUNE

Outsourcing in Clinical Trials: Medical Devices USA
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Outsourcing in Clinical Trials UK & Ireland
9-10 June | London, UK

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Outsourcing in Clinical Trials New England
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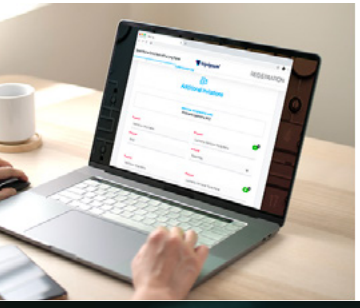
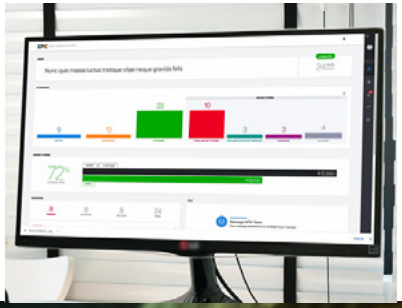
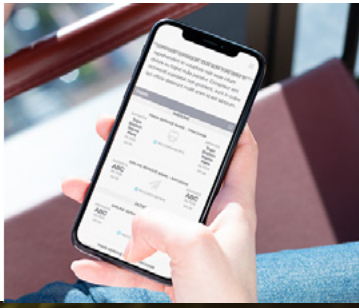

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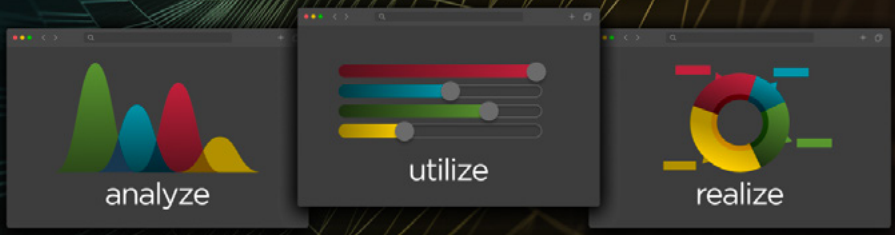

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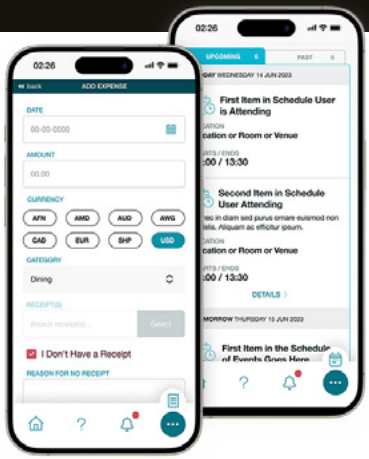

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Transforming Clinical Trials Through Event Technologies

5 Lessons Learned from Experienced Event Planning Professionals

By **Miller Tanner Associates**

Understanding the Increasing Complexity of Clinical Trials

Clinical trials have never been more complex—or more demanding.

Today's studies span numerous global sites across multiple time zones. High staff turnover means you're constantly retraining new team members. Protocol amendments move at lightning speed. Documentation and compliance expectations continue to rise. And through it all, there's relentless pressure to deliver studies faster without compromising quality.
Traditional methods—emails, spreadsheets, static agendas, and paper documentation—simply can't sustain this level of complexity anymore.

All of these factors also impact any events involved in a trial, threatening to compromise the efficacy of training and — ultimately — the overall study performance.

The answer? Event technologies that offer structure, oversight, and a truly connected experience for all stakeholders.
Over our almost 30 years planning events in the life sciences space, we've learned what works (and what doesn't). Here are five lessons that can transform how you approach clinical trial events.

1. Use an Event Management Platform

Think of an event management platform as your operational command center for investigator meetings and study-wide events. It's where chaos becomes coordination.

Look for these important features:

- **Digital registration** that captures the right data from the start
- **Automated communication** so nothing falls through the cracks
- **Logistics and travel management** that actually makes sense
- **Real-time dashboards** giving you visibility when you need it most
- **Budgeting and cost analytics** that keep spending in check
- **Issue tracking & support** to address problems before they escalate
- **Post-event reporting** that tells the full story
- **A holistic overview** of all your events and data—attendance, financials, performance, and feedback in one place

“Investigators and site teams are juggling multiple studies, patient care, and administrative demands.”

The Result: Significant reduction in administrative burden and improved global process consistency. Your team stops firefighting and starts leading.

2. Put the Experience in the Attendees’ Hands

Investigators and site teams are juggling multiple studies, patient care, and administrative demands. The last thing they need is to hunt through email chains for basic event information.

Simplify their experience with technology that puts control where it belongs—in their hands.

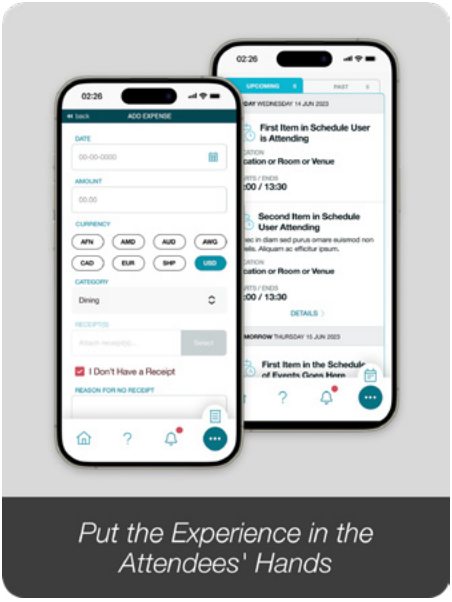
Make sure attendees can:

- View **personalized agendas** and receive **automated reminders**
- Get **real-time schedule updates** (because things always change)
- Access **speaker and session details** instantly
- Experience **paperless event execution** (yes, it’s possible)
- Submit expenses digitally
- Use **on-site check-in systems** that actually move quickly

What This Means: Higher engagement, reduced confusion, and a more polished, professional event experience. When attendees feel supported, they show up ready to learn and contribute.

3. Track Training & Achieve 100% Compliance

Training is essential in clinical trials—and must be thoroughly documented to meet regulatory requirements. Yet many organizations still



struggle to track who completed what, when, and whether they understood it.

Find a solution that delivers:

- **Role-based training paths** customized to each participant’s responsibilities
- **Real-time compliance dashboards** showing exactly where you stand
- **Audit-ready certification records** that inspectors will appreciate
- **Version control for protocol amendments** so everyone’s always working from the latest information
- **Mobile and asynchronous learning** options for busy professionals
- **On-demand resource libraries** accessible when questions arise

The Payoff: Stronger training consistency, improved readiness for inspections, and better support when staff turnover hits. Compliance stops being a source of anxiety and becomes a competitive advantage.

4. Extend the Engagement

Here’s the challenge: achieving 100% training compliance is tough when healthcare professionals aren’t available to attend live events. Even when they do attend, engagement

often drops off once everyone goes home. The solution? Technology that keeps the conversation going and the relationships strong.

Look for a technology or product that:

- **Drives HCP engagement** with sponsor medical experts beyond the event
- **Strengthens relationships** between HCPs and study teams over time
- **Re-emphasizes the importance** of the study, keeping it top of mind
- **Spotlights high-performing sites** to recognize excellence and motivate others
- **Fits within your existing meeting budget** (because resources aren't unlimited)

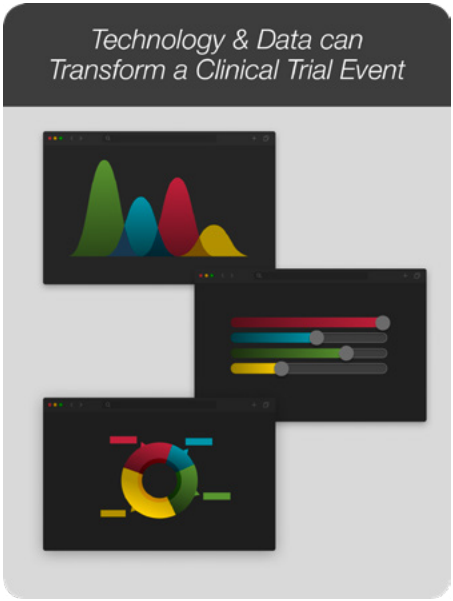
Why It Matters: Extended engagement transforms one-off training events into ongoing partnerships. Sites feel supported, questions get answered promptly, and study performance improves across the board.

5. Leverage a Technologically Experienced Event Professional

Technology alone won't solve your problems. The most powerful support comes from partners who can anticipate pain points, minimize logistical stress, and free your team to focus on what only they can do: ensuring safe, high-quality conduct of the study. This comes from experience—and the right products to back it up.

At Miller Tanner Associates, we've spent nearly three decades perfecting our approach to life sciences events. We've developed proprietary technologies like EPIC™ (our event management platform), ATTEND™ (our attendee experience app), and ALEX™ (our training and engagement solution) specifically to address the unique challenges clinical trial teams face.

But technology is only part of the story. Our team brings the expertise to make these tools work seamlessly within your specific study design, therapeutic area, and organizational culture.



See our OCT handbook ad to learn how MTA leverages technology and experience to transform clinical trial events. Please visit www.millertanner.com for more information.

The Bottom Line

Event technologies are reshaping how clinical trials operate—from planning and logistics to training and long-term site engagement. By integrating these technologies thoughtfully, organizations significantly improve knowledge retention, compliance, readiness, and overall study performance.

The result? A more connected, informed, and empowered network of clinical trial sites—ultimately accelerating timelines and improving data quality.

Because in clinical trials, every day matters. And every site deserves the tools and support to succeed. Miller Tanner Associates is a WBENC-certified, full-service life sciences event planning company with nearly 30 years of experience delivering exceptional face-to-face, virtual, and hybrid meeting experiences. **www.millertanner.com**

Chapter 2
Innovation & Technology

Credit: Shutterstock.com

Cybersecurity in Service Providers Selection and Qualification: A Critical Aspect of Modern Clinical Research

By **Martin Rodriguez,** Medical Strategy & Operational Effectiveness Head at Opella

"A Company's level of cybersecurity is only as good as the cybersecurity of its vendors"

In today's rapidly digitalizing world, the importance of cybersecurity in clinical research cannot be overstated

As we increasingly rely on digital tools and third-party service providers for critical processes, the risks associated with cybercrime have grown exponentially. Even more, recently Artificial Intelligence (AI) solutions deliver real-time data and insights through a modern, integrated experience, enabling drug developer companies to make decisions faster and reduce study timelines by 50% and bring therapies to market faster. So we can see that digitalization of our world is a reality that we have to cope with. This article explores the current landscape of cybersecurity in the context of service provider selection and qualification, with a particular focus on the pharmaceutical industry and clinical research organizations (CROs).

Introduction

The digitalization of clinical activities, including electronic Case Report Forms (eCRFs), electronic Clinical Outcome Assessments (eCOAs), and cloud-based databases, and recently applications based on AI have revolutionized the way we conduct clinical research. However, this digital transformation has also opened up new avenues for cybercriminals to exploit with critical impact for the companies. The challenge is how to benefit the digital world and to minimize and mitigate the risks generated. The objective of cybersecurity is to reduce the risks weighing on the information system, in order to limit their impact on operation and business activities of organizations.

The Current Situation

The landscape of cybersecurity in the pharmaceutical industry does not scape of the reality of continuous cyberattacks. Consider these statistics as examples:

1. 98% of organizations have at least one third-party vendor that has experienced a data breach.
2. 73% of organizations have faced at least one significant disruption caused by a third party in the past three years.
3. Data breaches cost organizations an average of $4.88 million and increasing every year.
4. Network or data breaches are the top security breach impacting organizations, affecting 51.5% of companies.

These figures underscore a critical reality: cybersecurity is a business of all the companies, sponsors and services providers as the it is only

as strong as that of its weakest vendor. Data is the core asset nowadays.

In the clinical research environment, the dependence on third-party service providers is particularly high. From Interactive Voice Response Systems (IVRS) providers to eCOA platforms and Data Management teams, for functional and even for full-service outsourcing, the exchange of sensitive data is constant, volumes are considerable, and the criticality of data is high as we transfer sensitive personal data. This high level of interdependence makes the industry particularly vulnerable to cyber threats at different levels of the system.

Regulatory Landscape

Recognizing the critical nature of health data, regulators have stepped in to ensure its protection. The regulations are not standardized and very different form one country to another, which makes the situation more complex. Europe, for example, has one of the most regulated environment regarding data security and privacy. In France, for instance, the Hébergeurs de Données de Santé (HDS) certification is required for entities that host personal health data. This certification, governed by Decree No. 2018-137 of 26 February 2018, covers five key hosting activities:

1. Provision and maintenance of physical sites
2. Provision and maintenance of virtual infrastructure
3. Provision and maintenance of the application hosting platform
4. Administration and operation of the information system
5. Backup of Heath data

That's the reason why companies and service providers need to continuously to get and maintain international certifications such as ISO 27001 that provides a framework for information security management systems. These regulations and standards form the backbone of cybersecurity efforts in the industry, and we will not be able to work with companies that cannot ensure the security of data that they collect or manage for other companies.

Vendor Information Risk Process

To address the cybersecurity risks associated with third-party vendors, many companies, have implemented vendor Information risk processes. This process evaluates vendors based on three key criteria:

1. Relation to critical business functions. (eg Research & Development)
2. Type of data stored or managed (e.g., confidential product information or personal data)
3. Criticality of the service to the company and level of access to internal systems
4. CROs, given their critical role and access to sensitive data, typically meet all these criteria and are thus subject to rigorous cybersecurity assessments.

Cybersecurity Assessment in CRO Qualification

The cybersecurity assessment has become an integral part of the CRO qualification process for clinical studies. The assessment typically involves the following steps:

1. Verification of valid and recognized cybersecurity certifications
2. If certifications are lacking or invalid, a detailed assessment via a specialized platform
3. 3. Evaluation of the assessment results, (Accepted/ Accepted with corrective actions/ Rejected)

The assessment covers various areas, including Data Privacy, Data Protection, Third Party Management, and Business Continuity. It also evaluates the CRO's capacity to Identify, Protect, Detect, and React to cyberattacks.

Risk Management

The cybersecurity of the service providers is a question of risk management, and it should be adapted to the needs of the sponsor. In cases where a CRO's cybersecurity assessment is insufficient but business needs to evaluate the risks that they would be exposed if they select the vendor. While this approach should be used sparingly, it provides a mechanism for balancing business needs with cybersecurity requirements.

CRO Selection and Qualification Process

The CRO selection and qualification process is a multi-step journey that integrates cybersecurity considerations:

1. CRO Identification
2. Service Qualification (including Data Privacy)
3. Cybersecurity Assessment
4. Evaluation of Qualification and Cybersecurity Results
5. Contract Signature
6. Start of Services

This process ensures that cybersecurity is considered from the outset and remains a key factor throughout the engagement with the CRO.

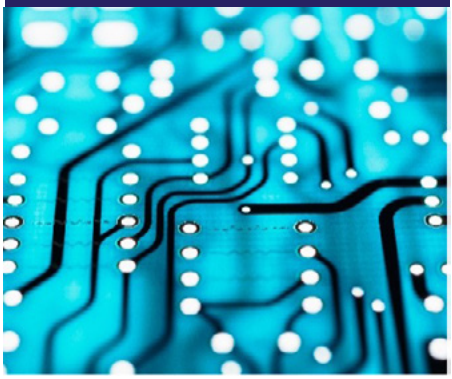
Conclusion

As the digital landscape of clinical research continues to evolve, so too must our approach to cybersecurity. The integration of cybersecurity assessments into the CRO selection and qualification process represents a critical step in protecting sensitive data and maintaining the integrity of clinical trials and it should be integrated into the standard qualification process.

To conclude, the key takeaways I would like to provide:

1. Collaboration between Digital and Business Teams is essential to ensure comprehensive cybersecurity.

"As the digital landscape of clinical research continues to evolve, so too must our approach to cybersecurity."



2. Cybersecurity assessments should be a standard part of CRO selection, qualification, and ongoing audits.
3. The criticality of data managed in clinical studies necessitates robust cybersecurity measures.
4. Continuous work with service providers to develop improvement plans and mitigate risks is crucial.

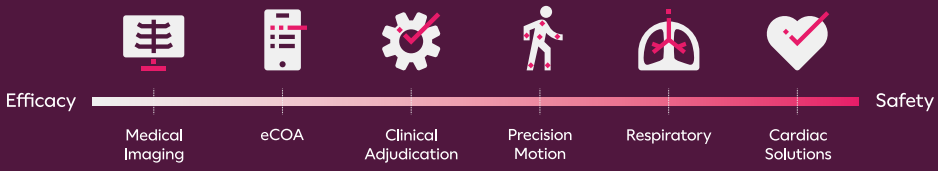
Our responsibility is to ensure data protection of consumers and patients." In an era where cyber threats are increasingly sophisticated and frequent, this responsibility has never been more important.

The pharmaceutical industry, with its wealth of sensitive data and critical research, must remain at the forefront of cybersecurity efforts. By integrating cybersecurity considerations into every aspect of vendor selection and management, companies can better protect themselves, their research, and most importantly, the patients they serve.

CLARIO.

The digital endpoint data partner that leaves no room for doubt

Data you can trust – every therapeutic area, every trial phase.



Operational clarity and data harmonization in clinical trials with oomnia

Wemedoo AG is a Swiss company streamlining clinical trials through its unified clinical research information system, oomnia.

Every phase of a clinical trial generates massive amounts of data, from patient enrollment and consent to drug supply management, safety reporting, and outcome data collection.

Yet, for most organizations, this data remains trapped within disconnected systems and databases. What should be a continuous, streamlined process often becomes fragmented and reactive.

At Wemedoo, we've changed the way clinical data moves across systems. Our clinical research information system, oomnia, unifies the full clinical trial lifecycle, combining scattered clinical data to a unified, real-time overview. Built upon CDISC standards and semantic interoperability principles, oomnia enables automated data harmonization, reducing manual mapping and ensuring regulatory readiness.

The challenge: Fragmented and delayed clinical data management

Clinical data management has evolved rapidly, but not necessarily cohesively. Each stage of trial execution often depends on separate digital systems; each built for a specific task. These systems require extensive data transformations and "translational" services from third parties, including data transformations, cleaning, and management. A single study update can trigger weeks or months of manual work. Each change must be replicated and validated across all systems, a process that not only consumes time but also increases errors and rework.

Raw data must first be collected from multiple systems, verified for quality, and standardized before any analysis can begin. This is followed by data mapping and formatting information for regulatory or statistical use, and then by separate steps for analysis, visualization, and reporting.

By the time a trial team reaches the point of decision-making, the data they are analyzing is already outdated. Any late-stage data correction or protocol change can reset the process, which demands repeated validation steps and further delaying access to actionable insights.

From fragmentation to flow: Months reduced to days

oomnia was designed to solve this problem, not by adding another tool, but by unifying them all into one intelligent system.

The system architecture is based on a semantic foundation that ensures consistency across all modules, including EDC, RTSM, CTMS, eTMF, eConsent, ePRO, eCOA, and eSource.

With oomnia, all trial data points exist within one unified environment. Information is available instantly to all modules, removing the need for traditional integration and manual synchronization. Because oomnia supports real-time data validation, any update made within one model is instantly propagated across the entire ecosystem.

Where traditional systems require months to align after each change, oomnia performs the

same process in days. By linking all data points within a unified semantic framework, the system ensures consistent interpretation, real-time synchronization, and transparent data flow throughout the study's lifecycle.

Teams gain immediate access to analytics and visualizations directly within the system. Oversight becomes an integral part of the workflow, not a separate step. Sponsors and CROs can monitor site performance, patient progress, and supply management in real time.

The core difference: Semantic interoperability

Most integrated systems rely on APIs that connect platforms, but do not really speak the same language. oomnia's innovation lives deeper. It is built on semantic interoperability that ensures that every piece of information carries the same standards, context, and meaning. This semantic foundation enables automated alignment of clinical data across modules and supports direct export in CDISC-compliant SDTM format.

This means that a patient's consent form or a clinical outcome record isn't just connected; they are understood as part of the single semantic framework. This reduces manual mapping and guarantees consistency across the entire ecosystem.

The result is a unified, transparent environment where data can be automatically validated and analyzed without delay.

Semantic alignment also brings significant regulatory and operational benefits:

- Faster SDTM preparation and submission readiness
- Reduced risk of discrepancies across modules
- Continuous audit trail and real-time traceability
- Improved compliance through standardized data definitions that align with key regulatory frameworks, including ICH GCP, 21 CFR Part 11, and EU Annex 11.

From oversight to insight: Real-world impact

In traditional setup, oversight is retrospective; teams analyze what has already happened. oomnia changes that dynamic entirely. By providing real-time visibility across all processes, it enables proactive decision-making.

Trial managers can detect deviations as they occur. Data managers can monitor study health without waiting for periodic exports. Regulatory teams can access harmonized datasets ready for reporting, while executives can visualize progress through automated dashboards that reflect the live state of their portfolio.

The outcome is measurable:

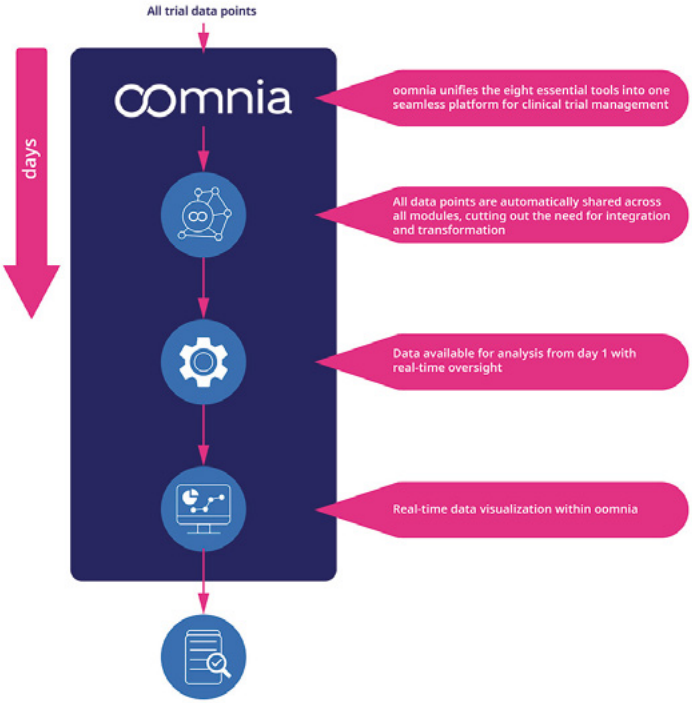
- Study launch reduces from months to days
- Reduction in manual data reconciliation
- Early detection in data inconsistencies
- Collaboration across departments and sites

For organizations running multiple trials, these improvements extend across trials, turning what used to be a slow and fragmented process into a streamlined strategic advantage.

Clients using oomnia report measurable improvements in data operations, including:

- 50% increase in operational efficiency, driven by automation and semantic standardization.
- Up to 80% reduction in manual work, particularly across SDTM mapping and randomization workflows.
- Up to 83% faster clinical trial set-up, achieved through unified modules and automated configuration.
- Up to 73% cost reduction, reflecting less vendor management and tool maintenance.
- 100% real-time oversight and data standardization, ensuring continuous visibility and quality consistency across all modules.

Modern data management with oomnia



Supporting clinical and decentralized trials: A unified approach

The success of clinical trials increasingly depends on how well we manage and interpret data. As research becomes more decentralized and focused on the patient, the ability to bring together data from different technologies and locations becomes essential. oomnia's architecture supports decentralized trials by enabling remote data capture, semantic harmonization, and real-time monitoring across distributed sites.

oomnia's unified approach is not just a technological upgrade, it's a redefinition of clinical data management itself. By aligning with ICH E6 (R3) and CDISC standards, oomnia ensures that data is not only unified but also compliant and submission-ready from the start.

The success of clinical trials increasingly depends on the ability to operationalize data in real time, combining technological efficiency with clinical relevance. As trials become more decentralized and patient-centric, the competitive advantage will not be in the number of tools used, but in the ability to unify them into a coherent, interoperable system.

About Wemedoo

Wemedoo AG is a Swiss company streamlining clinical trials through its unified clinical research information system, oomnia.

oomnia unifies EDC, CTMS, eTMF, RTSM, eConsent, ePRO, and eSource and eCOA into one cohesive system for real-time data collection, analysis, and exchange.

Designed to manage multiple trials, sites, and organizations under a single login, oomnia is adapting to the specific demands of any study. Its flexibility, intuitive design, and efficiency make it a reliable foundation for modern clinical operations.

Rooted in Swiss precision and quality, Wemedoo delivers cost-effective solutions that combine reliability with innovation. Alongside its technology, the company provides expert services in clinical advisory, protocol development, data management, medical writing, and biostatistics, supporting excellence across every stage of clinical trials. These services are aligned with regulatory expectations and industry best practices, ensuring that clients receive both technological and scientific support throughout the trial lifecycle.

Wemedoo
Clinical Information Specialists

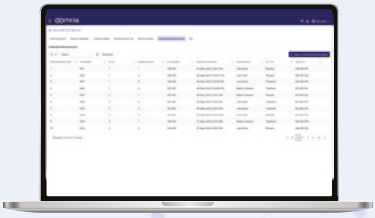
All-in-one clinical research information system

Streamline your clinical trials with oomnia

Wemedoo's **oomnia** offers solutions for smarter, faster, and more efficient clinical trials.

One system. Complete control.

- EDC
- RTSM
- eTMF
- ePRO
- eSource
- eCOA
- eConsent
- CTMS



Why choose **oomnia**?

AI-powered | Real-time insights | Full control and oversight

Reach us at **info@wemedoo.com** or visit **wemedoo.com**

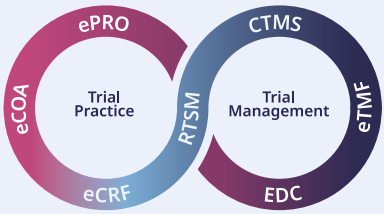
Smarter trials begin with oomnia: Trusted by clinical teams worldwide

- Up to **83%** Faster clinical trial set-up
- Up to **80%** Manual work reduction
- Up to **73%** Cost reduction
- **100%** Real-time trial oversight
- **100%** Data standardization
- **>50%** Operational efficiency increase

Real impact. Real efficiency.

- **Audit-ready** and CDISC-compliant
- **0% need** for tool integration
- **One** system. **One** login.

Complete trial management in **one system**



Turn complexity into clarity with **oomnia**.

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Clinical Trials in the Age of AI: Promise vs. Pragmatism

By **Piotr Maślak,** Senior Director, Head of Emerging Technologies at AstraZeneca

Artificial Intelligence marks its presence among more activities day by day, proving to be a reliable companion that supports people globally. But pharmaceutical industry faces another challenge:

Investment required to develop a single medicine requires approximately 2.6 billion US dollars, up to 15 years of research and success rates below 10% . A question naturally arises: can we leverage technology advancement to improve these odds and deliver medicines to patients faster and more efficiently? Should we embrace it in regulated environments, or be cautious about the risks?

How AI has expanded across drug development.

The mark of AI is present across the whole process of drug development – from discovery, with molecular design and target identification, through preclinical, with AI-driven toxicity predictions, to clinical trials, where AI enables protocol design and optimization, streamlines patient recruitment and explores real-world data.

Promise: what are the key advantages of AI in clinical trials?

AI's advantage is where people's weakness sits – manual, repeatable tasks, that are relatively straightforward, yet time consuming. Large language models are trained on comprehensive datasets – drafting a clinical study protocol while having thousands of documents in the memory, along relevant assumptions from the clinical team, takes minutes instead of weeks, while considering a plethora of sources and prior knowledge. This allows clinical development experts to focus on the viability and alignment with research goals, limiting the risk of future protocol amendments. Wealth of past experiences captured in real-world databases and internal data sources prevents repeating mistakes that might delay the study or risk the integrity of data collected.

Automating clinical site feasibility assessment suggests best performing sites, relevant equipment and expertise in specific disease areas, along with proposed country allocation that considers global differences, like disease seasonality, incidence and prevalence, helping locate and reach the patients that are looking for a treatment via clinical studies. Oversight of AI models over in-flight trials can proactively suggest focus areas and flag risks and issues in the data, providing data-based recommendation, limiting the burden on clinical staff. This shifts attention from identifying potential signals across immense landscape of available data to identifying which signals flagged by AI are important, and which are false positives.

Insights that are the result of AI-powered analysis and AI-assisted oversight have the potential of providing plenty of benefits – from suggestions for protocol amendments, through site selection and monitoring to identification of duplicate patients and irregularities in trial conduct. Pulling the data sources and insights together allows clinical professionals to leverage predictive analytics that forecast trial performance, randomization rates, risk stratification and even patient drop-out rates in trials that are yet to start. This is an enormous opportunity for a strategic shift from reactive to proactive approach in how pharmaceutical companies operate, allowing simulations of

alternate scenarios and data-driven decision making before the trial even starts.

Pragmatism: how to navigate risks?
While with the growing landscape there is a promise of automation and productivity increase that was impossible to achieve with traditional methods, there are several risks to consider in implementation of AI. Emerging regulations, such as EU AI Act or FDA framework for use of AI in clinical trials indicate that there are concerns about the use of AI in decision making processes, stressing the need of human in the loop, assessments of implementation risk with certain use cases and requirements for explicit consent to process and utilize the patients' data using AI. Systems increasingly rely on AI augmentation, and this mandates robust risk governance and model explainability to ensure processes are transparent and auditable.

AI solutions are inherently biased due to the training datasets – one of the stark examples is the case of heart attack symptoms – due to data collection happening in 20th century, the sample is overwhelmingly (70%) biased towards male population, leaving female-specific symptoms out of the picture. If such AI solution was to create a set of health screening recommendations to the general population, it would have omitted crucial symptoms for half of potentially impacted patients. This requires careful oversight to ensure the sample is balanced and the insights are considering algorithmic bias.

Healthy dose of scepticism is required to successfully deliver AI solutions: there's a positivity bias in the published research on its use in drug development, which obscures failed pilots and unsuccessful outcomes. Additionally, there's little evidence on AI-assisted drugs advancing beyond phase 2.

How it informs outsourcing strategies?
Strategic alliances in the AI space require careful consideration of multiple factors, when setting up successful partnerships. Due diligence process is required to ensure service providers adhere to the existing and upcoming regulations and guidelines, AI models are explainable, and underlying data is robust and ethically sourced. Interconnection of systems between sponsor and vendor requires real-time data integration, continuous auditing capability and mutual validation, providing a competitive edge to the organizations that are tech-savvy and open to integrate own pipelines into the comprehensive and complex data infrastructures of pharmaceutical companies, often carrying the burden of technical debt. Contracts must consider 'human-in-the-loop' clauses, ensuring that decision-making processes are ultimately including a human, as delegating it to a machine raises the risk profile of the system dramatically. This also implies robust training requirements and a new, digital-first talent approach that requires upskilling in technical acumen and regulatory complexity navigation. Key differentiators will include sophistication of developed systems: bias prevention, compliance record and digital capabilities aligned to the priorities of the industry: acceleration of drug development process, realised efficiencies, safety of the patients and compliance to the expanding regulatory landscape.

"AI solutions are inherently biased due to the training datasets – one of the stark examples is the case of heart attack symptoms – due to data collection happening in 20th century, the sample is overwhelmingly (70%) biased towards male population, leaving female-specific symptoms out of the picture."

Beyond the Basics: Navigating the Complexity of Modern Clinical Trial Supply Chains

By **www.s-clinica.com**

Sponsors today face ever increasing costs in running clinical trials, making every opportunity for efficiency and savings critical. A major contributor to overall trial cost is the production and management of the Investigational Medicinal Product (IMP)—from manufacturing and storage to temperature controlled logistics and site level distribution. These challenges are amplified by the inherent uncertainties of clinical research, often resulting in significant waste. McKinsey reports an alarming average of 50% medication waste across the industry.

Investment required to develop a single medicine requires approximately 2.6 billion US dollars, up to 15 years of research and success rates below 10% . A question naturally arises: can we leverage technology advancement to improve these odds and deliver medicines to patients faster and more efficiently? Should we embrace it in regulated environments, or be cautious about the risks?

As studies grow more complex and IMP costs rise, the need for smarter, more adaptive supply strategies becomes undeniable. Supply managers must not only stay informed but anticipate risks and mitigate them proactively. Dr. Irena Seredina and Jasvinder Osan, Executive Director and VP of Business Strategy at S Clinica, explain how the company's deep understanding of clinical operations—combined with advanced mathematical algorithms and predictive technologies—is helping clinical supply teams plan more accurately, reduce waste, and ultimately lower costs.

RTSM System: The Nerve Center of Clinical Supply

Randomisation and Trial Supply Management (RTSM), also known as IRT, sits at the heart of clinical trial operations. As trials become more expensive and operationally demanding, study teams increasingly expect RTSM systems not only to manage supply availability but also to forecast, plan, and optimize supply strategies throughout the study lifecycle.

While experienced supply planners often rely on complex spreadsheets, this approach has a major flaw: it oversimplifies reality. High level metrics alone cannot capture the nuances that drive accurate forecasting.

"The devil is in the details," says Seredina. "Successful supply chain management requires a granular understanding of every study parameter. That's why we developed an algorithm capable of integrating multiple variables—something spreadsheets simply cannot achieve."

A Unified Algorithm: Speaking the Same Language

Seredina, a medical doctor and health care economist, recalls the origins of S Clinica's forecasting platform:
"S-Clinica developed ClinVision with a biotech partner who needed a portfolio level forecasting tool and wanted to leverage our unique drug supply algorithm. The key is that both forecasting and supply management use the same algorithm—they speak the same language."

This unified approach eliminates inconsistencies and ensures that planning and execution remain aligned.

Is Real Time Sufficient? The Case for Preventive Control

ClinVision, S Clinica's RTSM platform, is founded on a central operational principle: real time detection occurs downstream of the actual problem event. By the time a deviation is

visible, it has already generated operational, financial, or logistical consequences. As Seredina notes, "**Real-time is too late** - real time indicates that the deviation has already manifested. Effective operational control requires preventing such deviations before they arise." This shift from reactive monitoring to preventive control is not only operationally advantageous—it is economically essential. Every unanticipated stock out, overage, or misaligned shipment carries measurable cost implications, from expedited manufacturing to site level delays.

ClinVision supports decision making from the earliest phases of study planning—even prior to protocol finalization—by enabling quantitative estimation of supply requirements and facilitating early production pre orders. This early stage modeling reduces financial exposure by minimizing unnecessary manufacturing commitments while ensuring adequate buffer capacity. As the trial progresses, the system integrates newly available data, allowing teams to reassess risk profiles, update forecasting assumptions, and plan subsequent operational steps with greater precision.

This continuous recalibration is not merely a forecasting exercise—it is an optimization engine. By dynamically balancing demand uncertainty, production lead times, depot capacity, and site level consumption patterns, ClinVision helps teams converge on the most cost efficient supply strategy at each stage of the study. The ability to simulate alternative scenarios, quantify their cost risk trade offs, and select the optimal path forward reduces both operational volatility and budgetary waste. Such dynamic adaptability is critical in clinical research environments characterized by protocol amendments, variable recruitment trajectories, and persistent uncertainty. In these conditions, preventive control is not a luxury—it is the only sustainable approach to minimizing risk, controlling cost, and optimizing supply performance across the study lifecycle.

AI or Not AI? Cutting Through the Noise

With AI dominating industry conversations, many vendors promise "AI powered accuracy." But what does that really mean for clinical supply?

Jasvinder Osan references a recent research paper noting that **AI is fundamentally mathematics, probability, and statistics**—disciplines that have long underpinned S Clinica's work.

Built on a foundation of biostatistics and advanced mathematics, S Clinica pioneered the **predictive probabilistic adjusted real time supply management algorithm**. "We've been refining our algorithm for over 20 years," Osan says. "It remains the secret sauce behind ClinVision."

The algorithm has been validated in 1,200+ clinical studies across all phases and therapeutic areas, proving its robustness in real world conditions.

Adaptability: The Key to Reducing Waste

"The key to reducing waste and saving costs is the ability to adapt supply strategies immediately during a trial," Seredina emphasizes. Achieving this requires breaking down silos—not only between departments but also between the systems they use.

When S Clinica's full platform is deployed, forecasting and RTSM operate seamlessly together. Supply managers can evaluate real time study data, adjust strategies, and implement changes instantly within the same system. Study teams can collaborate, explore scenarios, and identify optimal paths forward during complex situations.

A Practical Solution for Biotech and Smaller Sponsors

S Clinica's integrated approach is particularly attractive for midsize and smaller biotech companies—or sponsors tied to third party IRT providers but still relying on spreadsheets for forecasting.

"S Clinica offers an easy to use forecasting solution," Osan explains. "By integrating forecasting with IRT, we deliver a cost effective, tailored option for smaller and midsize organizations."

Chapter 3
Patient Centricity

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Placing Trial Participants at the Center of Clinical Trials

By **Ros Cheetham**, Vice President, Clinical Operations at MacroGenics

Without clinical trial participants there would be no new drug development. Although substitutes are being found for animal research, and the FDA has announced a roadmap for phasing out animal testing for certain drug classes1, there is no alternative to clinical trials that involve those with the diseases our potential new therapies target.

We know that our clinical trials are not always representative of ultimate users. An article in the Lancet reported trial participants to be almost 80% White2. So, if trial participants are the key to success, how do we increase our focus on them in drug development?

Some key times for connecting with patients are:

- Early in drug development to understand the Patient Journey
- Input into the protocol and consent form
- Mid-way through the trial, if it is long or there are significant changes
- At trial conclusion.

Understanding the Patient Journey is key to understanding how people will access and learn about clinical trials and at what point in their treatment a clinical trial may be an option. What do we mean by the Patient Journey? It is the road that a patient travels from the first time they have symptoms, get diagnosed and

receive treatment through to maintenance, cure or re-treatment. It sounds so simple but for many people the road is full of potholes that can include:

- Lack of belief from the medical community that there is a medical issue
- Misdiagnosis
- Lack of access to the appropriate specialties and second opinions
- Inadequate information about treatment options including clinical trials
- Lack of understanding what is important to the patient
- Information delivered in medical jargon and the patient feels unable to ask for clarification.

The best source of information about the Patient Journey is patients and those are often accessed through Patient Advocacy Groups (PAGs).

It is crucial to contact relevant PAGs early in the development of a new therapy. PAGs have different aims, commonly government advocacy, patient support and/or research. Research PAGs in your therapeutic areas and find a small number whose aims fit with the aims of your company. PAGs expect a pharma or biotech company to establish a long-term relationship with them and so making contact with PAGs early in the development of a new therapy is key to establishing that relationship.

PAGs can help you with fleshing out the Patient Journey, providing patient contacts to interview at various times during your drug development, assisting with establishing a Patient Advisory Board, reviewing protocols and Informed Consent Forms (ICFs) as well as disseminating information about your clinical trial.

Protocols that are overburdened with tests, blood draws, extensive visits, long lists of exploratory objectives and multiple patient outcomes assessments or diaries, are not going to be patient friendly. There are several tools that measure protocol complexity and assign a score, however, simply challenging each of the items in the above list and asking whether the data will be used and is crucial to the outcome of the trial is a good approach. Anything where the answer is “it’s nice to have” should be scrutinized and potentially omitted.
We are quick to get scientific and medical input into our protocols, but patient input is also crucial to have a protocol that is realistic, meaningful and doable. The best time to gather patient input is once there is a protocol concept document that includes a time and events table. This activity can be done in the context of a patient advisory board (virtually or in person) or individual patient interviews. If you want to use the same group several times, then forming a patient advisory board may be a good option.

You should have a confidentiality agreement with each participant/PAG, a participation agreement and reimburse the participants. Seek advice on the current IRS legislation regarding reportable amounts and ask participants if they want to receive remuneration as it could have undesirable tax implications for some people.

Sharing the background of the therapeutic agent and protocol, inclusion, exclusion criteria and the time and events activities in simple, non-medical terms is key to helping your patient advisors understand the proposed protocol. Provide this information in advance of the meeting and ask them to have read through it beforehand. In the meeting be clear about what you are looking for. Asking specific questions will result in higher quality information, for example:

- Would you have any issues joining this trial? If so, what?
- What could we do to minimize the burden of having to go into the clinic every day for 3 days?
- Would not being able to take drug A during the trial be a problem for you? If so, what do you recommend?

It is essential to take minutes of meetings or interviews. Once you have considered all the input, give written feedback to all the participants, thanking them for their time and explaining what feedback you were and were not able to implement. For the things you

were not able to implement it's very helpful to explain the rationale. For example: "We know advisors were concerned about all the clinic visits. We were not able to reduce the number of times participants must come to the clinic for blood draws. The reason for that is because this is a first in human study and we must collect blood samples every day to be able to understand how the drug is absorbed."

The ICF is the first formal interaction that a potential trial participant has about the trial and patient engagement starts with the ICF. They will form an opinion about whether the trial will be welcoming for them, will it meet their needs and whether they would be comfortable participating, based on the ICF. Consent forms need to be written in everyday language and utilize call out boxes, tables and possibly color to make them more understandable. It is important to test an ICF with a group of patients who have the disease or similar disease to the one under study, to find out if it is comprehensible and meets their needs. If you are running your trial in the UK, it is mandatory to have sought patient input into the ICF. This requirement may spread to other countries.

"The ICF is the first formal interaction that a potential trial participant has about the trial and patient engagement starts with the ICF. They will form an opinion about whether the trial will be welcoming for them, will it meet their needs and whether they would be comfortable participating, based on the ICF."

If your trial is long, or if there are significant changes to the protocol and/or ICF, then checking back in with the patients who helped you earlier in the process is important. It is a good way to ensure that the changes have not adversely affected how patients view the trial. Often overlooked is communicating the outcome of a study. There could be reticence to communicate a negative outcome, however PAGs and patients understand that not all trials are positive or result in a new therapy coming to market. In addition to posting on government websites, some suggestions for communicating the trial outcomes are:

- Meet with the PAGs
- Meet with the patient advisory board/ patients or send a summary of the findings and next steps.
- Provide an IRB approved summary of the trial outcomes to the participating investigators to give out to participants.

External communications would likely require input from your company legal and/or communications groups.
If we place trial participants at the center of our thoughts at each stage of drug development and the development of each trial, then our trials will be more realistic, the patient community will support them and there will be an improved chance of timely completion.

1 U.S. Food and Drug Administration. (2025, April 10). FDA announces plan to phase out animal testing requirement for monoclonal antibodies and other drugs. FDA Press Announcement

2 Turner, B. E., Steinberg, J. R., Weeks, B. T., Rodriguez, F., & Cullen, M. R. (2022). Race/ethnicity reporting and representation in US clinical trials: A review of published studies. The Lancet Regional Health – Americas, 11, 100252. https://doi.org/10.1016/j.lana.2022.100252

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The Heart of Clinical Research: Why Community Engagement Is Essential

By **Justine Holleran**, Manager of Community Development & Engagement, and Hope Ventricelli, Senior Manager of Community Events & Programs at CISCRP

Clinical research is often portrayed as a highly technical endeavor, an intersection of science, regulation, and innovation.

Yet, beneath the protocols and data points lies a deeply human narrative. Every trial involves real people making consequential decisions about their health, their time, and their trust. Therefore, community engagement is not just a nice-to-have; it's a moral, strategic and practical imperative. To ensure clinical trials are truly inclusive, effective, and ethical, we must prioritize meeting people where they are. That means, building trust through community advocates, maintaining continuity, and embracing the slow, deliberate process of relationship-building.

Meeting People Where They Are

Community engagement begins with a simple but powerful principle: go to the people. Too often, clinical research is presented in sterile environments or online portals that assume a baseline level of health literacy and digital access. However, real communities gather in places that feel familiar and safe: churches, mosques, farmers markets, local clinics, community centers, and neighborhood events. The CISCRP team has found that these spaces foster organic trust, encourage natural conversations, and empower people to ask questions without judgment.

Engagement efforts must also be tailored to each community. That means translating complex medical jargon into plain language, offering materials in multiple languages, and using formats that resonate. At CISCRP that may look like hosting a panel discussion with locals that represent the diverse population of the community or presenting educational information in a new and engaging way like our Journey to Better Health (JTBH) mobile exhibit. Survey results from our JTBH visit to Newark, NJ highlighted that visitors' understanding of clinical research increased after viewing the exhibit compared to before viewing (from 39% understanding clinical research 'very well' beforehand to 57% after viewing.) In addition, 75% of community members said that they would consider participating in a trial after having spoken to CISCRP staff or listening to a panel discussion at an AWARE for All Event. It also means recognizing that engagement isn't just about delivering information; it's about listening. A guiding principle for CISCRP is to begin dismantling historical barriers to participation by collaborating with the very communities that have been mistreated and misrepresented.

Community Advocates and Partners Are Key

Trust is the currency of clinical research, and it must be earned. Trust grows through community advocates: people within the community who share their values and experiences. These can be health workers, faith leaders, educators, or former trial participants. Their voices matter because they speak with shared understanding.
Partnering with advocates is not just smart;

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it's respectful. When local advocates shape outreach strategies, co-host events, or provide feedback on trial design, the research becomes more relevant to the community they represent. Survey results from our JTBH visit to Baltimore, MD highlighted that 54% of visitors most appreciated the interactions with local Community Educators. These partnerships bridge cultural gaps and encourage participation when it's clear that the community voice is taken into account. A trusted advocates message can reach people more powerfully than any brochure or website ever could.

Continuity Matters

Community engagement cannot be a one-off event. Researchers often visit communities with a flurry of activity, only to disappear after meeting their goals. This approach breaks trust and reinforces the perception that clinical research is extractive, not collaborative. True engagement requires ongoing commitment. Promoting lasting impact and collaboration through our community educators and offering opportunities to amplify the community voice through patient advisory boards, review panels and medical hero stories. These approaches allow us to continue the conversation about clinical research with these communities for years to come.

When communities see lasting involvement and continued investment, they become more willing to participate, advocate, and even co-create studies.

Slow and Steady Wins the Race

In a deadline driven world the slow work of relationship-building can feel odd. But in community engagement, patience is a strength. Building authentic relationships takes time, steady presence, and humility. It requires showing up consistently, listening deeply, and being willing to adapt based on what you learn. Communities are rich with knowledge and lived experience that improve clinical research. When we approach engagement as a two-way street, we create a more equitable and effective research ecosystem.

Community engagement is the heart of ethical and inclusive clinical research. It's what transforms trials from abstract protocols into human-centered partnerships. Meet people where they are, partner with trusted advocates, commit to continuity, and invest in the relationship to reflect the diversity and wisdom of the communities we serve.

If we want research to serve everyone, then everyone must be invited in, and that door can only open with trust.

Next-Level Patient Engagement: From Intention to Operational Impact

By **T.J. Sharpe,** Patient Advocate

There is no secret sauce to patient engagement. The recipe is fairly simple and well-known—but like any good recipe, it requires two things to truly stand out: the right ingredients and the knowledge of how to put them together.

At its core, effective patient engagement is a deliberate investment in bringing the right patient and caregiver expertise into the development process early, often, and meaningfully—and then operationalizing what is learned in ways that drive real change. Organizations that consistently generate better patient insights do so intentionally, with a clear purpose and articulated goals, both for individual engagements and as part of a broader, sustained program.

These organizations build systems, expectations, and capabilities that treat patient engagement as a core operational function rather than a one-time activity or a regulatory checkbox. The result is not only better trials, but better technologies, stronger research programs, and ultimately better outcomes for patients.

Patient Engagement Is Not About Representation—It's About Expertise

One of the most common misconceptions about patient engagement is that interaction equals engagement. Finding a patient and asking for feedback can create a sense of inclusion, check internal boxes, and introduce a degree of patient centricity into the organization. But at the end of the engagement, a critical question remains: did the information gathered generate new, actionable insight—or did it simply validate assumptions that already existed?

Next-level patient engagement depends on finding the best right advocates—patients and caregivers who can speak not only from their own lived experience, but who also understand the broader patient population, disease heterogeneity, care pathways, and the (often competing) scientific, operational, regulatory, and business drivers inherent in clinical development.

When lived experience is paired with this broader perspective, patient advocates become trusted translators between program development and patient reality. They bring informed challenge, contextual nuance, and the ability to connect individual experience to population-level impact. Build a team of these advocates, and you create a group that actively contributes to the success of the business, the trial, and the patients.

Build a Sustainable Advocate Model, Not a One-Time Panel

The strongest patient advocates function much like subject matter experts. They bring pattern recognition, context, and the ability to elevate feedback beyond personal anecdote. These advocates should not be treated as one-off contributors, but as long-term partners who are consistently engaged across programs and phases.

Operationalizing patient engagement begins with how organizations identify, engage, and retain patient and caregiver experts. Rather than assembling a new panel for each study, mature organizations invest in developing a team of well-versed advocates who can be engaged repeatedly over time.

Consistency matters. When advocates

understand an organization's role in the ecosystem—whether as a sponsor, CRO, or service provider—along with its development strategy, operating model, and constraints, the quality of insight improves dramatically. Feedback becomes more nuanced, more actionable, and better aligned to organizational goals, regardless of where the organization sits in clinical research.

Capturing Meaningful Insights

Even the most experienced advocates cannot—and should not—cover everything. Their expertise must be intentionally supplemented with additional subject matter experts and external sources of insight. This includes published literature and white papers, peer-reviewed journal articles, survey data, patient-reported outcome research, and publicly available patient community insights.

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This triangulation of perspectives allows organizations to ground lived experience in broader evidence, reducing the risk of over-emphasizing any single voice while still preserving the authenticity and value of patient input. When done well, it increases confidence in the insights generated and meaningfully improves the likelihood that those insights will be acted upon.

Triangulation is also achieved through multi-modal engagement design. As patient insight teams grow, the time allocated for live meetings rarely expands at the same pace. The result is less "air time" per participant—a particularly challenging dynamic for a group whose greatest strength is their willingness to speak candidly and often. Rather than allowing louder voices to dominate by default, effective facilitation introduces structure: round-robin discussion formats paired with asynchronous or offline input. Whether through written exercises during in-person sessions or virtual collaboration tools for remote engagements, this approach creates space for broader participation while allowing advocates to capture thoughts in real time—without waiting in line behind colleagues who may unintentionally steer conversations away from the original stimulus.

Engage Early—and Stay Engaged

One of the clearest indicators of mature patient engagement is when it occurs. Too often, patients are brought in after protocols are largely finalized, technology decisions have already been made, and timelines leave little room for meaningful change.

Next-level engagement happens early—during concept development, endpoint selection, visit schedule design, and technology planning—and continues throughout the trial lifecycle. Patients and caregivers can meaningfully inform protocol feasibility, patient, caregiver, and site burden, informed consent design and readability, site and visit logistics, technology usability and accessibility, recruitment and retention strategies, and return-of-results planning.

Engagement should be mapped to decision points rather than milestones. If there is no clear decision to influence, engagement risks becoming performative versus productive. Rather than gathering patient input for the sake of gathering, reset the internal team expectations to articulate why we are engaging our patient experts. Oftentimes, rethinking to this level of clarity will drive more specific and targeted engagements, leading to more impactful output from the engagement session.

Translate Insight Into Action

Operational excellence in patient engagement requires clear pathways for translating insight into action. This means planning for who owns patient insights once they are collected, how insights are documented and prioritized, how conflicting priorities are evaluated, how decisions are made and communicated, and what happens to insights that are not—or not yet—integrated.

Establishing this structure creates clarity and transparency throughout the engagement process and strengthens trust in the feedback loop. It also enables patient insights to be effectively evangelized across the organization and with external stakeholders. Too often, patient input is blended into a broader stew of information, losing the nuance that makes it valuable.

“Striking the right balance between active listening and purposeful facilitation is critical. Skilled patient advocates adapt to structured conversations, and strong facilitators guide discussions efficiently without diminishing lived experience.”

Imagine an environment where site teams understand broader patient preferences, clinical operations teams gain first-person insight into burden and feasibility, development teams understand the rationale behind protocol or technology adjustments, and business development teams can articulate how a trial or platform affects real people. Organizations that complete this cycle successfully build credibility not only with patient engagement teams, but for patient engagement teams across the enterprise. Over time, patient insights become a critical input alongside scientific, regulatory, technical, and operational considerations.

The “RSTLNE” Principle and Conversation Momentum

Fans of the game show Wheel of Fortune know that certain letters—R, S, T, L, N, and E—are so common that they eventually became a given in the bonus round. Patient engagement conversations often follow a similar pattern. As organizations build a growing knowledge base, certain themes and insights recur repeatedly. While these recurring insights are valuable, they can slow momentum or cause conversations to feel repetitive.

To avoid this, organizations should continuously evolve their baseline assumptions, documenting and distributing them in advance of engagements. Starting meetings with these assumptions clearly articulated allows participants to acknowledge what is already understood and focus their time on generating new insights. The goal is not to dismiss foundational themes, but to recognize when they are sufficiently understood and intentionally move the conversation forward.

Striking the right balance between active listening and purposeful facilitation is critical. Skilled patient advocates adapt to structured conversations, and strong facilitators guide discussions efficiently without diminishing lived experience. Developing these skills requires investment—both in defining what contributions are most valuable and in clearly articulating engagement goals. A shared understanding of assumptions, objectives, and boundaries benefits both patients and internal teams.

Make Patient Engagement an Organizational Capability

Ultimately, next-level patient engagement cannot live within a single function. It is an organizational capability that requires executive sponsorship, cross-functional alignment, and sustained investment. While leadership support is essential, patient engagement truly flourishes when teams across the organization independently seek patient input early and often. When done well, patient engagement shapes more than individual trials. It influences how organizations think, how teams collaborate, and how decisions are made.

Great patient engagement isn’t a secret. It isn’t accidental. And it isn’t symbolic. It is the choice to invest in the right expertise, engage consistently and early, supplement lived experience with broader evidence, and operationalize insight in ways that lead to meaningful change. In an industry tasked with developing medicines and technologies that change lives, this shift—from listening to leadership—is not optional. It is essential.

Quotient Sciences: Integrated strategies for rapid first-in-human to proof-of-concept clinical programs

First-in-human (FIH) studies represent a critical inflection point in drug development where missteps in trial design, CMC, or regulatory planning can lead to costly delays and derail timelines.

Accordingly, it is important to apply proven and practical strategies to accelerate molecules efficiently through early clinical assessment – such as innovative single ascending dose/multiple ascending dose (SAD/MAD) designs, diverse patient recruitment tactics, and sound CMC approaches.

These measures help drug developers avoid common development pitfalls and enable a confident fast-tracked path to proof-of-concept (PoC) validation.

In today's environment, biotech companies are currently facing significant funding challenges making rapid, de-risked early-stage development more essential than ever. Advancements in artificial intelligence and machine learning have also contributed to an increase in candidate compounds emerging from discovery. As a result, sponsors must be even more selective when advancing molecules for early development.

De-risking the FIH pathway

Drug developers must de-risk and simplify decision-making before FIH trials by obtaining robust data to support fundraising and designing FIH trial protocols that address key needs. Reducing the gap between protocol design and patient enrollment is also essential. An increasingly common way to enable more robust data generation and time-savings in Phase I research is the application of hybrid approaches that tighten the gap between Phase I and Phase II.

In practice, this strategy comprises an effective FIH study design with meticulous attention to basic considerations, an understanding of options that could expand or enhance the data generated and, when possible, the inclusion of patients. Initial FIH trial-planning considerations include:

- **Regulatory and geographic factors** that must align with the developer's go-to-market strategy
- **Preclinical data** to guide FIH trial decisions, such as starting dose, formulation strategy and exposure cap
- **Safety monitoring** concerns, including whether sentinel dosing will be used and which stopping criteria will be followed
- **Dose escalation pattern** decisions, including the size of dose escalation steps and how SAD/MAD are interwoven (i.e., sequential or overlapping)
- **Adaptive design approaches** to save time and avoid costly protocol amendments by adding predefined spaces to the original protocol submission that allow for adjustments as the trial progresses
- **Molecule specifics** to ensure an appropriate FIH trial design, as the fundamental differences between small molecules and biologics require distinct strategic approaches

In addition to basic FIH study considerations, trial enhancement options should be applied wherever possible. Examples include:

- **Food effect evaluation**, essentially a standard inclusion in modern FIH trials, incorporated into the SAD or as a standalone cohort in parallel with the MAD
- **QT data collection** to collect data early, and to potentially avoid running a thorough QT (TQT) study later in development.
- **Pharmacokinetics (PK)** to address differences in gender, ethnicity, and age early in development, making early formulation adjustments to prepare for later trials
- **Pharmacodynamics (PD) and early patient data collection** in healthy volunteers to support earlier proof of mechanism of action (MoA)
- **Molecule and therapeutic area-specific data**, allowing for the capture of valuable information even when not strictly necessary to support specific clinical endpoints.

Case study: Development of a new treatment for a rare genetic disorder

At Quotient Sciences, we are experts in early clinical research, and we know that drug developers need fast, reliable supply of the appropriate drug product to quickly generate understanding within the Phase I human trial and reach FIH clinical endpoints.

In a recent case study, we helped a customer navigate a new molecular entity for rare genetic disorder within the category of immunologic/inflammatory diseases through early clinical trials. As an orphan indication, patient recruitment for the clinical trial was a known challenge.

To overcome the client's challenges, the study comprised three components: SAD and MAD conducted in healthy volunteers, MAD also in healthy patients, and finally, under a single protocol, and dosing of HAE patients under a separate protocol. Because of the relatively small patient numbers and difficulty in enrollment, the manufacturing supply chain needed to be capable of delivering capsule formulations for all three components in near-real time. In this case, a manufacturing process was established that fulfilled a 14-day lead time for shipment to patients in both the UK and in Germany (Fig. 4).

Using Translational Pharmaceutics®, Quotient Sciences' integrated drug development platform that combines drug product manufacturing with clinical testing, greatly helped overcome the challenges the client initially faced. In this case, Translational Pharmaceutics®, streamlined the process from SAD initiation to positive PoC in patients in just 18 months.

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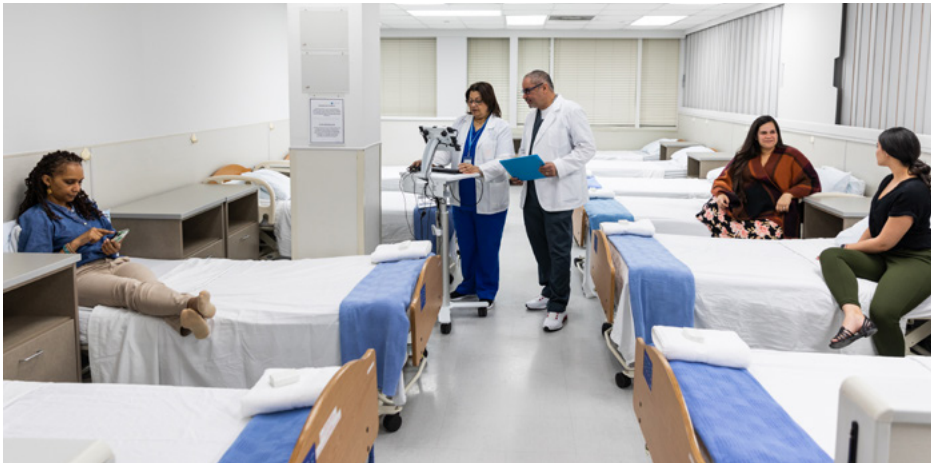

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In today's competitive landscape, drug developers face mounting pressure to advance studies deeper into clinical development while managing limited financial resources. Achieving faster, cost-effective generation of reliable data is a significant challenge.

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How can pharma manage rising trial costs?

With trial costs rising over the past decade and concerns they'll keep climbing, companies are seeking ways to manage expenses.

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Clinical trial costs have been rising year-on-year, with companies working to balance the scales and keep studies running despite declining investment.

The pharma and biotech sector appeared to be jumping into action during the 2021 financial boom, however, this was followed by a drought of financing in the three years since. At the same time, costs have been rising for research, meaning companies who are yet to market a product are caught in the middle of a perfect storm.

GlobalData research, using its proprietary Trial Cost Estimates model, shows the cost to run single-country and multi-country trials has risen annually over the past decade (2014-2024). This, coupled with a variety of global political shifts, means these prices are likely to continue rising according to experts, meaning the sector may have to start rethinking strategies to keep trial costs manageable.

Adequate staffing is a major trial cost

One of the main drivers of rising trial costs is personnel, experts agree. Jeff Fischer, CEO of Longhorn Vaccines & Diagnostics, notes that contract research organisation (CRO) costs are increasing, largely driven by rising staffing costs.

As a result, Longhorn has been focusing on pre clinical and Investigational New Drug (IND) research to keep costs in-house and reduce the number of patients and data needed. He adds that having a good understanding of what a drug is doing and the best patient population

before going to the clinic is helpful in managing expenses.

While helping reduce the cost of Phase I and Phase II research, these investigations are unlikely to have a great impact on Phase III studies, Fischer concedes. For Longhorn specifically, Fischer says that the increase in vaccine speculation means that clinical trials must include all patient groups to ensure that safety signals and efficacy can be more effectively evaluated before approval to avoid post-approval signals, such as the blood clots which were associated with Covid-19 vaccines. As a result, large-scale studies with certain therapeutics are unavoidable.

While personnel costs are increasing, material costs are also on the up says Jason Jones, global business development lead for Cellular Origins, a technology company looking to drive more scalable and efficient manufacturing of cell and gene therapies. Jones hopes that now several cell and gene therapies have received approval, companies will be more flexible and supportive of sponsors to get therapies over the line.

These material increases are not limited to pharmaceuticals or raw materials, with a rise in costs for instruments and devices associated with the manufacturing of these therapies. Jones agrees that personnel costs are a huge contributor to rising trial costs but says that automation in the manufacturing space could help drive these down.

In cell and gene therapies, due to a limited patient population and the utilisation of natural history/real-world data, costs are generally lower than large-scale studies for more prevalent diseases, but they often require more trained staff.

“You have to coordinate the patient in the hospital itself, especially with autologous therapies, then you may be flying the cell product around the world after it’s been frozen to get it to the manufacturer. It then goes back into the logistics chain and back to the hospital to return it to a patient. That means we’re likely to see more price increases,” Jones says.

Heather Purvis director of operations at Title21 Health Solutions, agrees that staffing is a big part of the cost and can see this only worsening as various National Institutes of Health (NIH) grants are culled.

“You need highly skilled individuals who can pivot and be critical thinkers. That takes a lot of experience and training, so these staff members are highly sought after,” explains Purvis. “Not only this but now, staff are being asked to do more with less because of the cuts in the funding. With the funding removal, the cost of staff is going to increase even further. I believe that is one of the biggest issues that we’re seeing within the space currently.”

Simplifying trial designs

Often, trial designs can be made more complicated than needed. Reducing the number of endpoints being evaluated and limiting it to just those that are necessary is a way to reduce trial cost, says Meri Beckwith, co-founder of Lindus Health, an “anti-CRO”. Beckwith notes that over-optimising can be dangerous financially and can elongate the planning process, when two smaller, less complex trials with different endpoints could save both time and money.

“People just aren’t thinking rationally about the purpose of the clinical trial and the endpoints they need to get from the study. Instead, they’re getting caught up in optimising every endpoint to collect more data which draws them into a spiral that leads to bloated trial designs that are more expensive. Just keep it simple and focus on what matters.”

Beckwith suggests that one way to achieve this is by asking more from a CRO when it comes to designing a study, requesting more milestone-based studies.

Biomarker adoption

More sponsors are evaluating biomarker-based endpoints in their studies, which experts agree will assist in bringing early-stage trial costs down as it can signal efficacy and drug targets at an earlier stage. They can also be used in healthy volunteer studies to determine a variety of indications in which the therapy could

be efficacious.

They can also be used to shorten trial length as they can, in certain cases, establish efficacy earlier than physical symptoms. Fischer uses sepsis as an example, stating that Longhorn's antibody therapies are using a biomarker to detect early stages of bacterial infection. This can help to establish earlier signs of efficacy in a drug and reduce the trial length, saving sponsors money.

"We believe that biomarkers are going to play a huge role in the Phase I and Phase II arena, and I think that more studies are going to be done at these stages because being able to do your safety and immunogenicity studies in populations that you can gain efficacy information from too is going to become more important," Fisher says.

Fischer acknowledges that this could increase risk but believes it will be outweighed by reward due to the abundance of data it will provide.

Tariffs expected to significantly drive up study costs

Unsurprisingly, Trump's tariff announcements are at the top of the list of considerations by the clinical trial sector right now when evaluating trial costs. While pharmaceuticals were granted a temporary reprieve, Trump has stated they are coming soon. Pharmaceuticals have normally been excluded from tariffs because of a 1994 World Trade Organization agreement.

The second largest cost rise in the clinical trial sector is from supplies, says Purvis, who adds that a colleague has already said they are pivoting away from specific clinical trials because of tariffs. "These could have been potentially promising lines of clinical trials, but unfortunately, they've had to limit themselves because they just couldn't afford to handle that with the impending tariffs. We're only going to see an increase in costs unless US-based companies re-imagine manufacturing but that takes time," Purvis explains.

Another concern is that tariffs could lead to longer development times, especially given that companies will be trying to do more with less. Sponsors may consider reducing patient numbers, but this would have a knock-on effect on the quantity of data for a sponsor to use when seeking approval, Purvis adds.

"Trump's tariff announcements are at the top of the list of considerations by the clinical trial sector right now when evaluating trial costs."

To try and avoid tariff costs impacting clinical trials, some European-based sponsors/biotechs may consider avoiding the US when running studies, Jones believes. The importance of the US market however cannot be underestimated, which could mean that companies feel an obligation to run studies in the US to provide a substantial package for approval to the US Food and Drug Administration (FDA) when seeking approval. While European data is considered by the FDA, as long as the data is applicable to the US population and is of sufficient quality, there is the possibility that this opinion could shift under the Trump administration and the changes in the FDA, Jones adds.

This will heavily impact the cost of running clinical trials, experts agree, but as everything is up in the air it is difficult to work out quite how much the industry will feel the impact.

Now, the constant changes make it difficult for companies to make important decisions on clinical trial design, Jones concludes. "I think we can cope with some of the changes that are happening now if we're left for a period without more changes so we can get used to it and we can strategise around it. I think we'll get calmer waters if the waters are allowed to calm, if we keep getting a series of abrupt changes, it's going to be difficult."

Building Resilient Clinical Supply Chains: From Seamless Comparator Sourcing to Last-Leg Delivery

By **Pratik Shah**, Managing Director & Head - Client Services & Project Management at Jupiter Research Services Inc

Introduction: The Fragility of Modern Clinical Supply

The landscape of drug development has undergone a **seismic shift**. The industry is moving rapidly towards complex biologics and decentralized models, creating a demand for supply chains that are **grounded in scientific rigor** rather than simple logistics. As clinical trials expand into emerging markets like APAC and LATAM, and regulatory complexities increase, the traditional supply chain has become fragile.

Today's clinical supply managers face a **"perfect storm"** of challenges:

- **Biologics Sensitivity**: The rise of biologics requires handling treatments with significant sensitivity to temperature and mechanical stress, where risks can compromise safety and immunogenicity.
- **Decentralization:** The fragmentation of "last mile" logistics and the need for precision—moving from bulk site shipments to single-patient kits—has introduced new points of failure.
- **Sourcing Bottlenecks:** Global shortages, manufacturer delays, and price volatility are causing site activation delays and mid-study stockouts.

To navigate this volatility, we must move beyond standard supply chain management to a model of Resilience. This is where Jupiter Research Services (JRS) distinguishes itself, helping numerous Sponsors, CROs, and CDMOs build effective supply chains through a unique "Glocal" strategy—combining global access with local delivery execution.

The "How": Jupiter's Integrated PSMD Model

Why do leading companies choose Jupiter Research Services?

The answer lies in our proprietary **PSMD Model**, an integrated framework designed to address the critical failure points of modern trials. Unlike fragmented providers, JRS unifies the supply chain under four key pillars:

1. **Patient Safety:** We prioritize the end-user above all. This involves rigorous pedigree verification to prevent counterfeits and ensure 100% cold chain integrity to maintain drug efficacy.
2. **Sourcing Strategy:** We move beyond high-risk local wholesaling. As a Central Specialist, JRS utilizes a vetted global network to secure comparators directly, minimizing the risk of broken pedigrees and supply interruptions.
3. **Management (Vendors & Technology):** We act as a control tower. By integrating ancillary supply and technology, we provide end-to-end visibility, allowing us to spot bottlenecks before they become stockouts.
4. **Delivery (Data Integrity & GxP Compliance):** We deliver "Solutions, Not Just Drugs." Our workflows are built on strict GxP compliance, ensuring that every shipment is audit-ready with complete documentation.

Just-In-Time (JIT): The Engine of Flexibility

In an era of high-cost comparators and unpredictable enrollment, the traditional "pre-package everything" model is obsolete. Jupiter Research Services empowers clients

with Just-In-Time (JIT) Packaging.

How We Execute JIT:
Instead of labeling all inventory upfront, we maintain supplies as "Bright Stock" (unlabeled vials) in our central hub. Labeling and kitting occur on demand, closer to the point of distribution.

Why Partners Prefer Jupiter's JIT Approach:

- **Waste Reduction:** We significantly reduce scrap and waste compared to pre-labeled batches.
- **Cost Savings:** Our clients realize direct dollar savings through reduced inventory holding costs and minimized destruction fees.
- **Extended Shelf Life:** Keeping stock unlabeled simplifies expiry date management and allows for pooling inventory across multiple protocols or countries, optimizing supply utility.

Real-World Proof: How Jupiter Builds Resilience

Theories are fine, but execution is what matters. The following case studies demonstrate why Jupiter Research Services is the preferred partner for complex, high-stakes trials.

Case Study 1: Agility in a Rare Disease Trial (US → Australia)
Challenge: A US sponsor faced a global drug shortage and tight Annex 13 labeling requirements, with delivery needed in Australia before a critical dosing deadline.
Solution: Jupiter executed accurate, regulatory-compliant labeling and delivery in just one week.
Outcome: Drug arrived before First Patient In (FPI), meeting timelines through rapid turnaround and JIT labeling.

Case Study 2: Innovation in Transit (China → Germany)
Challenge: An urgent FDA-requested clamp study required drug movement from China to Germany within four weeks.
Solution: Jupiter maintained full cold-chain compliance, designed kits during transit, and aligned early with the EU QP for dossier pre-review.
Outcome: Packaging completed in under one week, QP release in 48 hours, saving six working days on the timeline.

Case Study 3: Strategic Sourcing During a Global Shortage (Tocilizumab)
Challenge: An Asian sponsor needed long-term access to Tocilizumab during COVID-19 amid global shortages and allocations.
Solution: Jupiter sourced 12,000+ pre-filled syringes across four campaigns using its vetted supplier network.
Outcome: Continuous, temperature-controlled supply ensured uninterrupted trial progress and protected years of development.

Case Study 4: Navigating Market Variability in Oncology
Challenge: A sponsor required a US-sourced product for a Multiple Myeloma biosimilar due to EU batch variability.
Solution: Jupiter implemented a campaign-specific sourcing strategy using its Approved Supplier Network while managing DSCSA changes.
Outcome: Successful execution led to Jupiter being awarded a full Phase III program.

Conclusion: Why Jupiter Research Services?

Resilience in clinical supply chains is not accidental; it is engineered. It requires a partner who can offer end-to-end visibility, navigate regulatory minefields, and execute Just-In-Time strategies with precision. Jupiter Research Services is a preferred partner because we provide more than just logistics; we provide a "Glocal" safety net. With a strong presence in the USA, Europe, and India, and successful EU QP audits, we ensure that your trial is supported by a robust, compliant, and agile supply chain. We are committed to **Delivering Solutions, Not Just Drugs.**

Should you be interested in experiencing the excellent clinical trial supply management services, from **Comparator Sourcing to Last Mile delivery** – contact Jupiter Research Services Inc.

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- Fully Traceable Supply Chain
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- DSCSA & EU-FMD Compliant

CLINICAL TRIAL ANCILLARY SUPPLY

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- Equipment Rental Services
- Calibration Services
- Direct Rate Contract(s) with Leading Manufacturer(s), Lab Kit Assembly (Ancillary Supply Kitting)

SECONDARY PACKAGING AND LABELLING

- Kitting & Assembly
- In-house Label Designing & Printing
- Country Specific Label Translation
- Secondary Packaging
- Double Blind, Double Dummy Study Support
- QP Release Services
- Placebo Manufacturing & Absolute Blinding
- Absolute Blinding for Vials, PFS, Auto-Injectors

STORAGE AND DISTRIBUTION

- Continuos Temperature Monitoring Temperature Controlled Storage & Distribution
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- Global Depot Network
- 21CFR Part 11 Compliant
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- Project Management / Logistic Management
- IRT System Design & Management
- Bio-Repository

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Chapter 5
GlobalData Reports

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Q2 2025 Clinical Trials: CRO, Sponsor & Country Winners

This CRO Activity and Intel Report includes data analytics based on key data and insights from investigative journalism articles from Q2 2025 on the contract services sector.

This report offers an in-depth analysis of data from the contract research organization (CRO) industry, categorized by geography, therapeutic area, and phase of development for Q2 2025. Key information for the quarter includes the following:

- **ICON** (NASDAQ:ICLR) was the most active CRO in Q2 2025.
- Among large- and mega-cap sponsors, **AstraZeneca** (LON:AZN) was the most active.
- Across all regions, oncology-related trials accounted for the largest proportion of trials that started or were scheduled to start during Q2 2025.
- Solid tumors were the most widely studied oncology indication, while pain was the most studied central nervous system (CNS) indication.
- In North America, California recorded the highest clinical trial activity.
- Russia demonstrated the highest clinical trial activity among European countries.
- Apart from the US and Europe, China maintained its position as the most active country in the rest of the world (ROW).

CRO and sponsor activity in Q2 2025

ICON (NASDAQ:ICLR) was the most active CRO in Q2 2025. **AstraZeneca** (LON:AZN) was the most active company out of the large- and mega-cap sponsors during Q2 2025. **Zhejiang Huahai Pharmaceutical Co Ltd** (SHA:600521) was the most active mid-cap sponsor in Q2 2025. **Beijing Foyou Pharma Co Ltd** (SHA:601089) was the most active small-cap sponsor for the quarter.

Table 1: Most-used CROs

Rank	CRO
1	ICON
2	Parexel International
3	PPD
4	IQVIA Holdings
5	Labcorp Drug Development
=5	Clario
7	Almac Group
8	Fortrea Holdings
9	BioAgilytix Labs
=9	The Nucleus Network Pty

Table 2: Most active large- and mega-cap sponsors

Rank	Sponsor	Movement since Q2 2024
1	AstraZeneca Plc	-
2	Merck & Co Inc	-
3	Novartis AG	▲
4	Pfizer Inc	▼
=4	AbbVie Inc	▼
6	GSK plc	▲
=6	Sanofi	▲
8	Jiangsu Hengrui Pharmaceuticals Co Ltd	▼
9	CSPC Pharmaceutical Group Ltd	▲
10	Bristol Myers Squibb Co	▲

Source: GlobalData
Note: Clinical trial data is based on clinical studies involving a drug/biologic.

Table 3: Most active mid-cap sponsors

Rank	Sponsor	Movement since Q2 2024
1	Zhejiang Huahai Pharmaceutical Co Ltd	▲
2	Shanghai Henlius Biotech Inc	▼
=2	Shanghai Junshi Biosciences Co Ltd	▲
4	Haisco Pharmaceutical Group Co Ltd	▲
5	Arrowhead Pharmaceuticals Inc	▲
6	ImmunityBio Inc	▲
=6	Sichuan Kelun Pharmaceutical Co Ltd	▼
8	Gan & Lee Pharmaceuticals Co Ltd	▲
=8	Ono Pharmaceutical Co Ltd	▲
=8	Suzhou Zelgen Biopharmaceutical Co Ltd	▲

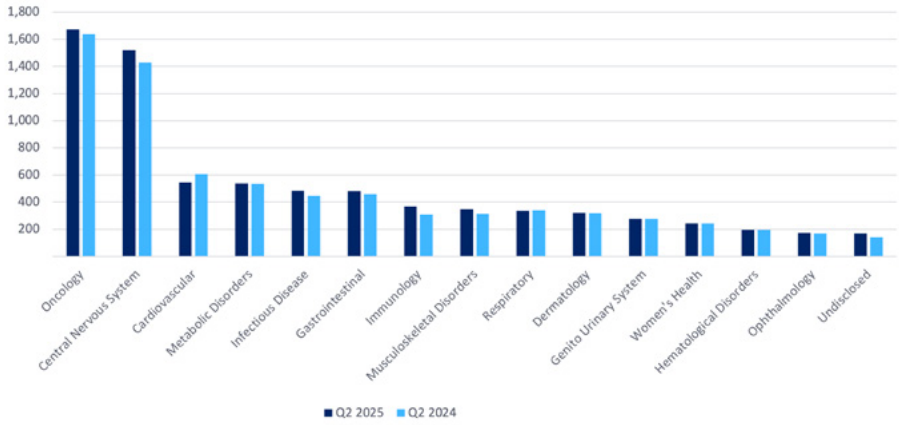
Source: GlobalData
Note: Clinical trial data is based on clinical studies involving a drug/biologic.

Table 4: Most active small-cap sponsors

Rank	Sponsor	Movement since Q2 2024
1	Beijing Foyou Pharma Co Ltd	-
2	KeyMed Biosciences Inc	▲
3	Atea Pharmaceuticals Inc	▲
=3	Boryung Pharmaceutical Co Ltd	▲
=3	Chong Kun Dang Holdings Corp	▲
6	ALX Oncology Holdings Inc	▲
=6	Asan Medical Center	▲
=6	BioAge Labs Inc	▲
=6	Day One Biopharmaceuticals Inc	▲

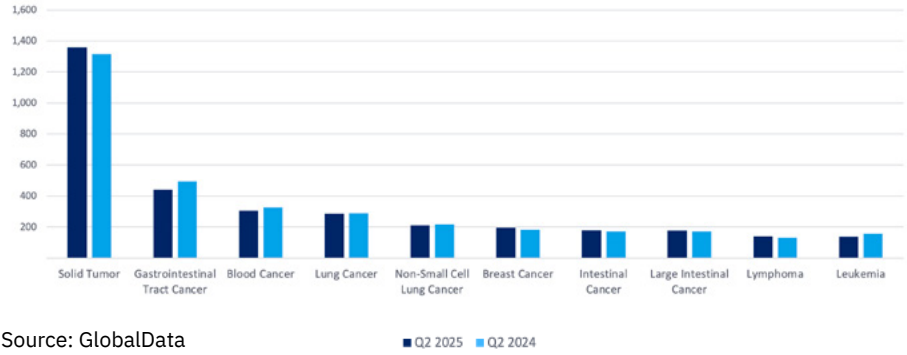
Source: GlobalData
Note: Clinical trial data is based on clinical studies involving a drug/biologic.

Therapeutic area breakdown of clinical trials initiated in Q2 2025 vs. Q2 2024



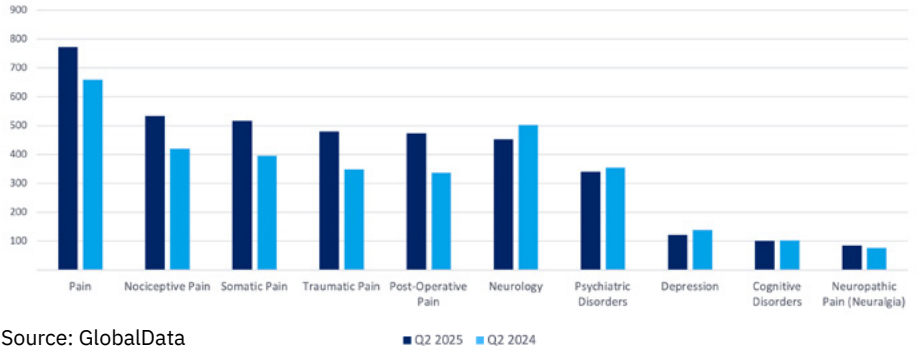
Source: GlobalData

Trials initiated in the 10 most active oncology indications in Q2 2025 versus Q2



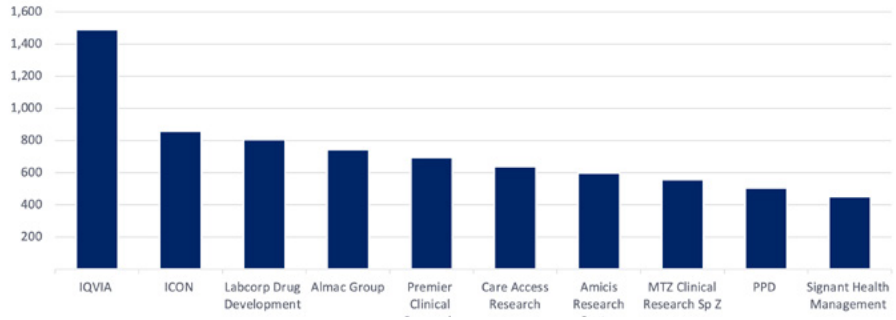
Source: GlobalData

Trials initiated in the 10 most active CNS indications in Q2 2025 versus Q2 2024



Source: GlobalData

Top 10 CROs by number of sites in Q2 2025



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Chapter 6
Medical Devices

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Navigating the Future of Medical Device Trials and Regulation

By **Hatice Bilgic Lim**, Director Clinical Innovation at Philips

Practical Insights for Today's MedTech Professionals

The medical device sector is evolving at remarkable speed. Each year brings new technologies, heightened regulatory expectations, and growing demands from clinicians, patients, and payers. For many organizations, the challenge is not only to innovate but to navigate a landscape where evidence, compliance, and patient outcomes must align seamlessly.

Drawing on over more than a decade of experience in medical device clinical development and regulatory strategy, I aim to share practical insights that can help clinical teams design more strategic trials, plan more efficiently, and position their devices for sustainable success.

1. The Evolving Landscape

Medical device development today operates at the intersection of technology, data, and regulation. Devices are no longer purely mechanical solutions—they are increasingly software-driven, data-enabled, and often connected to digital ecosystems. While these innovations expand possibilities, they also introduce new dimensions of complexity.

Some of the most significant shifts shaping the field include:

Integration of software and AI.
Devices now collect, analyze, and respond to data in real time. Regulators are adapting, issuing guidance for artificial intelligence, machine learning, and cybersecurity validation.

Global harmonization of standards.
Frameworks such as the International Medical Device Regulators Forum (IMDRF) and the EU's MDR/IVDR are aligning expectations, but regional variations remain important to consider.

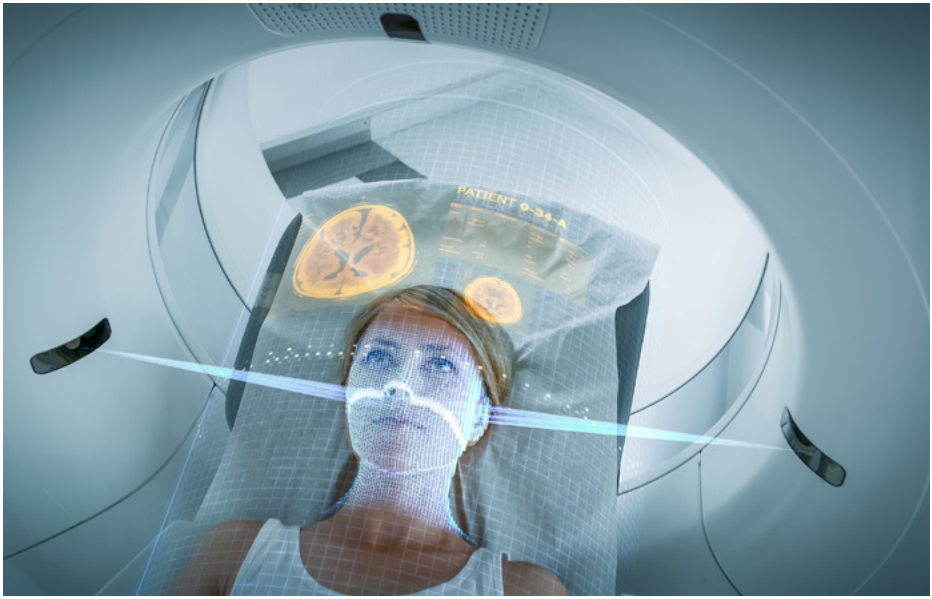
Emphasis on real-world evidence (RWE).
Post-market data and performance monitoring are now central to regulatory and reimbursement strategies, extending the evidence lifecycle beyond initial approval.

Focus on patient-centricity.
Usability, human factors engineering, and patient-reported outcomes are critical to demonstrating device safety and effectiveness in real-world use.

The message is clear: "clinical evidence" now encompasses much more than a single pivotal study. Success depends on the ability to integrate pre-market, post-market, and real-world data into a coherent and credible body of evidence.

2. Designing Trials with Purpose

A clinical trial should serve as more than a regulatory requirement—it should be a strategic asset. The most effective programs integrate scientific rigor, regulatory alignment, and commercial foresight from the outset.



Here are key principles to guide that approach:

1. **Begin with the right questions.** Define the clinical and regulatory objectives early. What must be demonstrated to establish safety, performance, and value?
2. **Engage early and often.** Pre-submission meetings and scientific advice sessions with authorities can confirm assumptions and prevent delays.
3. **Design for adaptability.** Adaptive or staged trials allow for modifications based on emerging data, particularly valuable for devices that evolve iteratively or through software updates.
4. **Integrate usability and human factors.** Human factors studies should not be an afterthought—they are now fundamental to demonstrating real-world safety and performance.
5. **Plan for post-market evidence.** Develop your post-market clinical follow-up and surveillance strategy during the trial planning phase to ensure continuity across the device lifecycle.

This integrated mindset transforms clinical programs from isolated exercises into evolving systems that support regulatory approval, reimbursement, and market adoption.

3. Regulatory Trends Shaping the Future

The regulatory landscape for medical devices continues to mature in response to innovation, data-driven healthcare, and patient safety priorities. Three trends in particular drive close attention:

Lifecycle-based regulation.
Regulators increasingly expect manufacturers to treat devices as dynamic systems, providing ongoing updates, cybersecurity monitoring, and periodic safety reports throughout the lifecycle.

Accelerated pathways.
Initiatives such as the FDA's Breakthrough Devices Program and comparable schemes worldwide are designed to expedite market access for technologies addressing unmet needs—but they require robust early engagement and evidence planning.

Data transparency and interoperability.
As connected health expands, authorities are emphasizing data integrity, privacy protection, and system compatibility, requiring manufacturers to embed data governance into their quality systems.
These shifts reinforce an important reality: regulatory engagement is no longer a single milestone. It is an ongoing dialogue, and successful organizations approach it as a partnership built on transparency and shared purpose.

4. Common Pitfalls and How to Avoid Them

Despite advances in process and technology, several recurring pitfalls continue to hinder medical device development. Anticipating these challenges early can prevent costly delays and improve regulatory outcomes.

1. **Misaligned stakeholder priorities.**
When clinical, regulatory, and commercial functions are not aligned, trial designs may meet compliance requirements but fail to deliver data that supports adoption or reimbursement. Begin every program with cross-functional planning sessions to define shared success criteria.
2. **Underestimating human factors.**
Devices that perform well technically can still fail in practice if usability risks are overlooked. Integrate human factors evaluation throughout development, from concept testing to validation.
3. **Insufficient data infrastructure.**
Connected devices often generate large, complex datasets. Without a clear plan for data capture, validation, and analysis, trial integrity and compliance can be compromised. Invest early in robust, validated systems.
4. **Neglecting post-market responsibilities.**
Regulatory authorities expect continuous performance monitoring, periodic reporting, and proactive surveillance. Build these requirements into your development plan and allocate appropriate resources.
5. **Overlooking regional variations.**
Global launches require careful mapping of regulatory differences in classification, clinical expectations, and labeling. Conduct a regulatory gap analysis early to align trial design and submission strategies across regions.

Awareness and early coordination across disciplines can prevent these issues and ensure that innovation progresses smoothly from concept to market.

5. Practical Steps for Strengthening Your Strategy

To navigate the evolving regulatory and clinical environment, medical device companies can take several practical actions:

1. **Establish a regulatory intelligence** process. Track new guidance on digital health, AI, and RWE. Regularly update your teams to maintain awareness of emerging expectations.
2. **Design multipurpose studies.** Build protocols that generate evidence relevant to regulators, payers, and clinicians simultaneously.
3. **Embed usability milestones.** Make human factors engineering a formal part of your project timeline rather than a late-stage requirement.
4. **Ensure data readiness.** Validate your systems and workflows for data collection, cybersecurity, and compliance before the trial begins.
5. **Adopt a lifecycle perspective.** View regulatory approval as the midpoint of a continuous process that includes post-market evidence generation and device evolution.

These actions create a foundation of preparedness and resilience that not only supports compliance but strengthens organizational credibility.

6. Looking Ahead

The future of medical device development will be defined by integration—of data, disciplines, and decisions. Regulatory frameworks will continue to evolve, but their direction is clear: greater transparency, continuous evidence generation, and closer collaboration between regulators and industry.

For medical device companies, this presents both challenge and opportunity. Those that invest in robust evidence strategies, strong cross-functional alignment, and proactive regulatory engagement will be best positioned to lead in this new era of innovation.

“The future of medical device development will be defined by integration—of data, disciplines, and decisions.”

As you plan your next clinical program or submission, consider three guiding questions:

- Does our trial design reflect real-world use and patient needs?
- Are we building evidence that meets regulatory and commercial expectations simultaneously?
- Do we have a sustainable plan for lifecycle monitoring and continuous improvement?

The answers to these questions will shape not only your project outcomes but your organization’s reputation for quality and integrity.

Closing Thoughts

Innovation in medical devices is as much about evidence and trust as it is about technology. The most successful organizations are those that treat clinical and regulatory excellence as central pillars of innovation—not as procedural hurdles.

By aligning scientific rigor with patient focus and transparent communication, we can ensure that groundbreaking devices reach those who need them most—safely, efficiently, and with lasting impact.

Clinical Evaluation Strategy for AI Medical Device Software: A Startup's Journey in the Regulatory Relay Race - Demonstrating Clinical Benefit for CE Mark and Commercialization

By **Autumn Lang,** PhD, RAC, Director Clinical Affairs, deepeye Medical

For startups venturing into the realm of AI-based medical device software, navigating the regulatory landscape isn't just traversing a minefield; it's akin to running a high-stakes relay race. Clinical affairs is a vital runner, needing to be fast and efficient in gathering clinical evidence to **demonstrate clinical benefit to secure CE Mark approval and have this clinical benefit used for commercialization.** This article shares a startup's journey, focusing on how we strategically approached clinical evaluation using retrospective data, streamlined the path to market, and built a strong foundation for commercial access, viewing clinical affairs as a key "relay runner" ensuring this clinical benefit is translated into real-world adoption.

Important Clarification: We're discussing **AI medical device software**, a clinical decision support tool. We're **not** building a medical device that replaces clinical judgment. Our **AI medical device software** *supports* healthcare professionals; our flagship product has a prediction model for a specific area of medicine (Ophthalmology) . The output report serves as a second opinion tool to supplement, not replace, the clinician's professional judgment in treatment planning decisions.

The Relay Challenge: Speed, Efficiency, and Seamless Handoffs from Regulatory to Commercial

Traditional market approval pathways often involve extensive, prospective clinical trials – time-consuming and resource-intensive for startups. However, the EU MDR acknowledges clinical data from clinical investigations, literature reviews, or both. The key is a fast, strategic approach, leveraging data and resources to prove safety, performance, and clinical benefit, ensuring a smooth "handoff" to commercialization, where this clinical benefit translates to market acceptance and initial adoption.

Our Approach: Retrospective Data Demonstrating Clinical Benefit – A Quick Start, Focused on Real-World Impact

Facing startup constraints, we used a retrospective clinical data strategy. This efficiently gathered insights into our **AI-based medical device software** (MDSW) , a clinical decision support system (CDSS) for a specific therapeutic area (Ophthalmology).

- **Leveraging Existing Datasets:** We used existing clinical study datasets for performance testing , assessing the AI model's ability to classify a condition and predict treatment needs.
- **Retrospective Analysis:** We conducted a retrospective analysis on a patient cohort to investigate the AI "second opinion's" clinical benefit, comparing treatment decisions with and without AI support . This analysis aimed to quantify how the AI could improve treatment decisions and patient outcomes.
- **Focus on Key Performance Indicators:** We concentrated on relevant parameters, including patient outcomes and measurement accuracy. These KPIs were

selected not only for regulatory compliance but also for their direct relevance to clinicians and their daily practice.

- **Key Considerations:** Agility and Precision, with an Eye on Commercial Value
- **Data Quality:** High-quality data is essential. Datasets must be well-documented, representative , and collected using standardized procedures.
- **Addressing Bias:** Acknowledge and mitigate potential biases in retrospective data, selecting investigator sites carefully.
- **Alignment with Intended Use:** Clearly define the software's purpose and ensure retrospective data aligns with it. The device's role is an optional expert second opinion tool, used by qualified specialists within established treatment protocols.

Demonstrating Clinical Benefit: A Strong Finish, A Clear Value Proposition

While retrospective data demonstrate clinical benefit offers insights, supplement it to build a strong commercial case:

- **Literature Review:** Thoroughly review scientific literature to identify similar devices, establish benchmarks, and understand the clinical area.
- **Usability Testing:** Evaluate software usability with healthcare professionals to ensure easy integration into workflows and enhanced decision-making. Emphasize the AI medical device software as a support tool, offering a "second opinion" , not replacing clinician judgment.
- **Highlighting AI's Added Value:** The AI prediction model leverages insights from extensive patient data to create personalized, evidence-based treatment plans.

- **Clinical Performance:** Validate the MDSW's CLINICAL PERFORMANCE by demonstrating testing for intended use(s), target population(s), use condition(s), operating- and use environment(s) and with all intended user group(s).

Navigating the Regulatory Pathway: The Final Leg, Preparing for Market Access

- **Classification:** Determine the correct risk classification per EU MDR Annex VIII . Software intended to provide information which is used to make decisions with diagnosis or therapeutic purposes is classified as class IIa.
- **Essential Safety and Performance Requirements (GSPRs):** Meet all applicable GSPRs in MDR Annex I.
- **Technical Documentation:** Compile comprehensive technical documentation, including a device description, intended purpose, design specifications, risk assessment, and clinical evaluation.
- **Conformity Assessment:** Select the appropriate conformity assessment procedure as outlined in the MDR.

Post-Market Clinical Follow-up (PMCF): The Ongoing Monitor, Fueling Continuous Improvement and Commercial Growth

- **Plan for Ongoing Data Collection:** Develop a robust PMCF plan to collect real-world data on software performance, safety, and clinical benefit after market release. This includes collecting data on visual acuity, therapy burden, therapy adherence and effectiveness.
- **Address Open Questions:** Use the PMCF study to address pre-market uncertainties and gather data to support expanded claims and market positioning.

From Market Approval to Commercial Success: The Final Handoff, Where Clinical Benefit Drives Adoption

- **Focus on User Needs:** Continuously gather user feedback and adapt the software.
- **Demonstrate Economic Value:** Collect data on economic benefits, such as improved efficiency or better patient outcomes.

"A clinical affairs team that acts as a fast, efficient relay runner is essential, contributing to improved patient care by providing valuable support to clinicians through responsible AI development and prediction models."

- **Build Trust and Transparency:** Communicate openly about the AI-based device software's capabilities and limitations.

Conclusion: A Winning Relay Strategy – Clinical Benefit as the Baton

By strategically using retrospective data, conducting literature reviews, focusing on usability, planning for PMCF, and **demonstrating tangible clinical benefit**, startups can efficiently navigate the regulatory pathway, achieve CE Mark approval, and move towards commercial success. A clinical affairs team that acts as a fast, efficient relay runner is essential, contributing to improved patient care by providing valuable support to clinicians through responsible AI development and **prediction models**. The key is to ensure that the clinical benefit demonstrated for regulatory approval is the same benefit that resonates with clinicians and drives commercial adoption.

Suppliers' directory

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Clincierge
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Clinical Services International (CSI)
clinicalresearch.io

Clario
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Clario is a leading provider of endpoint data solutions to the clinical trials industry, generating high-quality clinical evidence for life sciences companies. We offer comprehensive evidence-generation solutions that combine medical imaging, eCOA, precision motion, cardiac and respiratory endpoints. Our global team of science, technology, and operational experts have supported over 70% of all FDA drug approvals since 2012.

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