OpenClinica

Sponsor Playbook

If you're managing vendor sprawl, waiting for visibility into multi-site performance, and facing unpredictable costs that can balloon without warning—we know the feeling. You're leading trials, but it often feels like you're reacting to problems instead of driving progress.

We're here to help. This playbook shows you what it could look like when your study operations, well, flow.

Understanding Your Flow State

BPicture this: you're in complete control of your study, and everything just works. Timelines are met without chaos. Data flows seamlessly from sites around the world. Teams collaborate effortlessly—no silos, no bottlenecks, no friction.

That's your Flow State. It's clarity, ease, and confidence that you're fully in control.

When you're in a Flow State, you experience:

Momentum, not friction

Study launch feels less like a drawn-out negotiation with vendors and more like pressing a button.

Clarity, not complexity

You have a single source of truth for enrollment, data quality, and site performance across every region.

Predictability, not surprises

Your timelines hold steady, and your budget stays intact, free from the hidden costs of disconnected systems.

Achieving this state isn't just about managing trials, it's about mastering them. It's creating an environment where your systems, teams, and sites are so connected, progress feels natural, effortless, and completely within your control.

Why It Matters Now

Speed isn't just about competitive advantage; it's about getting therapies to patients faster. Every week spent coordinating between disconnected systems or chasing down data quality issues is a week your trial timeline slips.
By adopting a Flow State, you ensure:

Faster First Patient In

Launch studies in days, not weeks, with push-button publishing and self-service setup.

Predictable Timelines

Visibility into enrollment, data quality, and site performance keeps studies on track.

Budget Confidence

Transparent pricing and consolidated vendors eliminate surprise costs.

Your Study from Start to Finish

Imagine running your next multi-site trial with everything connected. **Here's what that journey could look like:**

Phase 1: Pre-Launch & Setup

You're finalizing your protocol and preparing for regulatory submission. Instead of waiting months for vendor setup, your team is already building study forms in your EDC (Electronic Data Capture) using drag-and-drop tools. You generate blank CRFs and annotated case books directly from the system for regulatory documentation. You configure eConsent with your IRB-approved language and set up eCOA forms for patient-reported outcomes. You establish randomization schemes and medical coding workflows. If your study requires specialized recruitment support, you can integrate Recruit to build your participant pipeline early. Overall, your study is ready to launch in weeks—not the typical 3-6 month vendor onboarding process.

Phase 2: Launch & First Participant In

Your first site activates. Participants review and sign eConsent on tablets at the site or remotely from home. The moment they sign, their consent data flows automatically into your EDC and creates their participant record. Site coordinators complete enrollment visits in your EDC with edit checks catching errors immediately. Eligible participants are randomized directly within the EDC, with treatment assignments automatically updating kit management and triggering supply alerts. Participants receive automated reminders to complete eCOA surveys. All the data syncs to one platform, giving you complete visibility from day one.

Phase 3: Mid-Study Operations

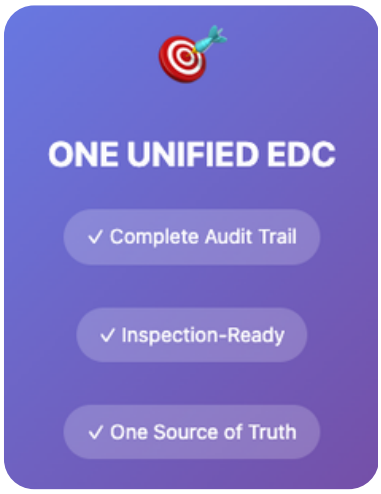
A few weeks in, your Analytics dashboard shows you enrollment progress across all sites, query rates, data completeness, and safety signals. You identify that Site 12 has higher-than-average screen failures—your team investigates and provides targeted support before it impacts the timeline. Participants complete eCOA surveys on their phones. The data flows directly into your EDC with timestamps and audit trails. Medical coding happens automatically for adverse events and concomitant medications, with coded data feeding into safety reports.

If you're using EHR-to-EDC, lab values and medication histories flow directly from site EHRs into your EDC across multiple health systems. No manual entry. No transcription errors. Scalable across dozens or hundreds of sites.

Your data manager needs to pull a safety report for the DSMB. Instead of coordinating with multiple vendors, they generate it themselves quickly from the unified platform.

Phase 4: Database Lock & Submission

You're ready to lock the database. You export clean, SDTM-ready datasets with comprehensive audit trails. Medical coding is already complete and integrated. You pull comprehensive reports for regulatory submission. Every data point is traceable back to source with full compliance documentation. No scrambling to reconcile data from multiple systems and no last-minute vendor coordination.



How The Tools Flow Together

Everything flows into your EDC. One source of truth. One audit trail. One place to see what's happening across your entire study.

What This Means for Your Program

Speed

- First patient in faster with streamlined site activation
- Shortened timeline from database lock to submission
- Study launch in days instead of weeks

Visibility

- Timely view across all sites from executive to site level
- Comprehensive audit trail from source to submission
- Identify issues early with proactive alerts

Control

- One platform instead of multiple vendor relationships
- Standardized workflows with regional flexibility
- Predictable costs with transparent pricing

The Tools Explained

EDC (Electronic Data Capture)

Your foundation. The central hub where all trial data lives. Fast self-service setup with push-button study publishing. Flexible configuration for global programs with edit checks, data validation, and comprehensive audit trails. Build once, deploy across multiple sites and regions. Every module feeds into the EDC, ensuring a single source of truth. 21 CFR Part 11, HIPAA, GDPR compliance-ready.

eConsent

Digital consent with multimedia support, comprehension checks, and secure eSignatures. Standard consent processes with site-level flexibility. Participant data flows directly into your EDC once consent is complete, with time-stamped digital consent records stored for regulatory compliance. Can link with Randomization so only consented participants can be randomized. Consistent oversight across all sites.

eCOA

Mobile-friendly forms with automated reminders for participant-reported outcomes (ePRO) and clinician assessments (eClinRO). Data feeds automatically into your EDC using study schedules to trigger reminders and diary completion prompts. Instantly available for analytics and monitoring dashboards. Improves data quality and ensures timely visibility of patient experiences across your entire study.

Randomization

Built into your EDC to manage randomization, kit assignments, and drug supply tracking in one integrated workflow. Pulls participant eligibility data directly from your EDC to randomize only qualified patients. Updates the EDC automatically with the assigned treatment arm. Integrated kit management provides automated restocking alerts to sites and distributors. Ensures seamless, compliant assignment with automatic workflows.

Medical Coding

Safety data consistency with standardized coding of adverse events and medical terms using MedDRA. Adverse events, medical history, and concomitant medications entered in your EDC are automatically coded. Coded data is stored in your EDC and flows into analytics and safety reports. Accelerates medical review and regulatory submissions.

Reporting & Analytics

Executive and study dashboards with safety alerts and notifications to study teams. Pulls structured data from all modules (EDC, eCOA, randomization, coding, etc.). Configurable dashboards display enrollment, data quality, safety trends, and site performance. Automated alerts to stakeholders (sponsors, CROs, sites). Safety alerts assist with compliance regarding timing of adverse event reporting. Transforms raw data into timely insights for proactive decision-making.

The Tools Explained (cont.)

EHR-to-EDC

Site integration for scale. Pulls verified patient data (labs, vitals, demographics) directly from site Electronic Health Records. Populates your EDC fields automatically, reducing transcription and source data verification costs. Especially helpful for studies with large participant numbers or large datasets—uses data already collected in the EHR to prevent duplicate effort. Less manual data entry and redacting at site level. Faster, more accurate data collection at scale.

Recruit

Patient recruitment services with precision targeting and pre-screening. Recruitment data flows directly into your EDC, giving you visibility from first contact to enrollment across all sites. Reach hard-to-recruit or diverse populations systematically. Reduce screen failures with smart pre-screening. Track recruitment ROI and adjust strategy in real time.

Your Flow State May Look Different

This is one version based on what we've seen work for dozens of sponsors running multi-site, global trials. Think of it as your starting point—we'll help you shape the version that fits your specific needs.

Your unique Flow State depends on your therapeutic area, study complexity, geographic scope, regulatory requirements, and whether you're running one pivotal trial or managing an entire portfolio.

Some sponsors start with EDC and eConsent, then add eCOA and Randomization as they scale. Others integrate EHR-to-EDC from the start for studies requiring large datasets. The goal is finding the right fit for your situation—and for this playbook to show you what's possible.

Next Steps (When You're Ready)

Explore on your own
Check out our Sponsor page for more resources.

Talk to us
Want to explore what this could look like for your study or portfolio?
We're here to help. Get In Touch

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