OpenClinica

CRO Playbook

If you're juggling spreadsheets and systems, waiting too long for study configurations, and feeling like every delay threatens your contracts—we know the feeling. You're managing trials with lean teams, tight timelines, and sponsors who expect sponsor-grade performance without enterprise budgets.

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

Understanding Your Flow State

You know the feeling when you're mastering studies, not just managing them. Sponsor requests are handled before they become urgent. Your team launches trials quickly. You have clear visibility across every study, site, and metric. That's your Flow State—when operations run smoothly and systems work with you, not against you.
When you are in a Flow State, you experience:

Proactive Oversight
You spot and fix issues with site performance or data quality early, keeping studies on track and sponsors happy.

Operational Control
You manage multiple studies with unified workflows, making your processes repeatable, scalable, and more profitable.

Effortless Compliance
Your data is clean and audit-ready from the start, which means no last-minute scrambles before a sponsor review or inspection.

Achieving this state allows you to move faster, win more bids, and deliver better results for your clients. It creates an environment where your team can perform at its best, and your business can grow.

Why It Matters Now

Every delay hurts your contracts. Every manual workaround costs time your lean teams don't have. Speed isn't just about efficiency—it's about winning bids, keeping sponsors happy, and managing more studies without burning out your team.
By adopting a Flow State, you ensure:

Quick Builds With Reduced Dependency on Senior Data Managers
Launch studies quickly with intuitive tools and templated workflows.

Timely Oversight
Regular visibility into site performance, data quality, and enrollment across all studies.

Sponsor-Grade Compliance
Built-in audit trails and tools that help teams maintain compliance and prepare for regulatory inspections with significantly reduced manual effort.

Your Study from Start to Finish

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

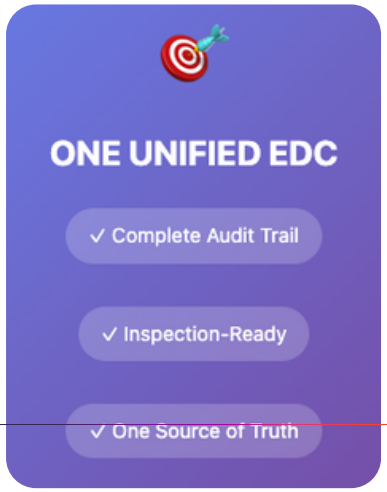
Phase 1: Pre-Launch & Setup
You've signed a new sponsor contract. Instead of waiting weeks for senior data managers to configure complex systems, your team uses drag-and-drop tools to build study forms quickly. You set up eConsent with standardized templates that work across sites, configure eCOA forms for patient-reported outcomes, and establish randomization schemes. If your study requires specialized recruitment support, you can integrate Recruit to build your participant pipeline early. Your study is ready to launch in days—not the typical weeks or months of configuration cycles.

Phase 2: Launch & First Participant In
Your first site activates. Participants review and sign eConsent either at the site or remotely. The moment they sign, their consent data flows automatically into your EDC (Electronic Data Capture) and creates their participant record. Site coordinators complete enrollment visits in the EDC with edit checks catching errors immediately. Eligible participants are randomized directly within the EDC, with treatment assignments automatically updating kit management. Participants receive automated reminders to complete eCOA surveys.
All the data syncs to one platform, giving you visibility from day one.

Phase 3: Mid-Study Operations
A few weeks in, your Analytics dashboard shows you current enrollment progress across all sites, query rates, data completeness, and safety signals. You identify that Site 8 has higher-than-average query rates—your team provides targeted training before it impacts sponsor timelines. 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 using MedDRA, with coded data feeding into safety reports and analytics.

Your project manager needs to prepare a sponsor update. Instead of coordinating data exports from multiple systems and reconciling spreadsheets, they generate a comprehensive dashboard from the unified platform. Site enrollment metrics, data quality indicators, and safety summaries—all in one sponsor-ready view.

Phase 4: Database Lock & Delivery
You're ready to lock the database and deliver it to your sponsor. You export clean, submission-ready datasets with comprehensive audit trails. Medical coding is already complete and integrated. You pull comprehensive reports for sponsor review. Every data point is traceable back to source with full compliance documentation. No scrambling to reconcile data from multiple vendors. No last-minute manual checks. You deliver on time, on budget, with sponsor-grade quality.



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 all your studies.

What This Means for Your Program

Speed

- Study launch in days instead of weeks
- Quick builds with reduced dependency on senior data managers
- Meet milestones faster with streamlined workflows

Visibility

- Timely view across all sites and studies
- Identify issues early with proactive alerts
- Comprehensive audit trail from source to delivery

Control

- Oversight and operations in one space
- Standardized and flexible workflows
- Less vendor noise, more focus on execution

Cost Predictability

- Transparent pricing that fits CRO business models
- No extras you don't need
- Modular approach that scales with your portfolio

The Tools Explained

EDC (Electronic Data Capture)

Your foundation. The central hub where all trial data lives. Quick, configurable builds without requiring senior data managers for every study setup. Flexible templates for rapid deployment across multiple sponsors and therapeutic areas. Immediate edit checks, data validation, and comprehensive audit trails ensure sponsor-grade quality. Every module feeds into the EDC, ensuring a single source of truth for efficient oversight and client reporting. 21 CFR Part 11, HIPAA, GDPR compliance-ready.

eConsent

Digital consent with standardized or modular templates across sites. Multimedia support, comprehension checks, and secure eSignatures reduce site administrative burden and accelerate enrollment. 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. Provides consistent oversight and documentation across all sites and sponsors.

eCOA

Mobile-friendly forms with automated reminders for participant-reported outcomes (ePRO) and clinician assessments (eClinRO). Data feeds automatically into your EDC, giving you continuous visibility into patient experiences without manual transcription. Immediate data capture allows you to monitor trends, identify issues early, and deliver high-quality insights to sponsors faster. Reduces site burden and improves data accuracy across global studies.

Randomization

Built into your EDC to manage stratified and block randomization designs. Pulls participant eligibility data directly from EDC to randomize only qualified patients. Updates the EDC automatically with the assigned treatment arm. Integrated kit management (within partner solutions like Sealed Envelope) provides drug supply tracking and automated restocking alerts. Ensures seamless, compliant assignment with automated workflows that reduce manual errors.

Medical Coding

Safety data consistency with standardized coding of adverse events and medical terms using MedDRA. Adverse events and concomitant medications entered in your EDC are automatically coded. Coded data is stored in the EDC and flows into analytics and safety reports. Significant time savings on a typically manual task. Accelerates data cleaning, streamlines medical review, and supports timely sponsor deliverables.

Reporting & Analytics

Up-to-date dashboards for site enrollment, data completion, safety monitoring, and risk-based monitoring (RBM) signals. Pulls structured data from all modules (EDC, eCOA, randomization, coding, etc.). Configurable dashboards display enrollment status, data quality, safety trends, and site performance. Automated alerts to project teams, sites, and sponsors enable proactive management. Transforms raw data into actionable insights and frequent, accessible sponsor updates.

Your Flow State May Look Different

This is one version based on what we've seen work for dozens of CROs managing multi-sponsor, multi-study portfolios. Think of it as your starting point—we'll help you shape the version that fits your specific operational model.

Your unique Flow State depends on your client base, therapeutic areas, study complexity, team structure, and whether you're managing five concurrent studies or 50.

Some CROs start with EDC and Reporting/Analytics for immediate oversight, then add eConsent and eCOA as sponsors request them. Others integrate Medical Coding from the start for studies requiring extensive safety monitoring. The goal is finding the right fit for your operational needs—and for this playbook to show you what's possible.

Next Steps (When You're Ready)

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

Talk to us
Want to activate a pilot study in under 30 days and experience this for yourself? We're here to help. Get In Touch

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