Clinical Trial Roles: Sponsor, CRO, and Site Responsibilities

By Adrien Laurent, CEO at IntuitionLabs • 11/17/2025 • 40 min read

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Executive Summary

Clinical trials are complex, multi-stakeholder endeavors involving distinct roles for **sponsors**, **contract research organizations (CROs)**, and **clinical trial sites (investigators and their institutions)**. The **sponsor** – typically a pharmaceutical or biotech company (or academic health center) – **owns the trial**, devising its design, providing funding, and ultimately ensuring scientific, ethical, and regulatory compliance. **CROs** are specialized service providers that sponsors may contract to perform example tasks (e.g. site management, monitoring, data handling) on the sponsor's behalf. **Sites** (investigators and their staff at hospitals or clinics) are where studies are physically conducted: they recruit and care for participants, obtain consent, follow the protocol, collect data, and report events.

Despite this basic division of labor, responsibilities often overlap and require coordination. For example, U.S. regulations (21 CFR) explicitly oblige sponsors to *select qualified investigators*, *ensure trials are monitored*, and *keep the FDA and investigators informed of new risks* ([1] www.law.cornell.edu). At the same time, sponsors routinely delegate many tasks to CROs – but critical oversight duties (e.g. overall protocol compliance, patient safety) **cannot** be "outsourced" ([2] www.opsvs.com). Similarly, a site (investigator) may rely on CRO monitors and study coordinators to handle day-to-day work, but the PI remains *legally* accountable for fulfilling GCP and regulatory requirements ([3] pmc.ncbi.nlm.nih.gov) ([4] codes.findlaw.com).

This report provides a deep dive into who does what in clinical trials. We outline the historical background and current landscape of trials and outsourcing, then detail the key **sponsor tasks** (study conception, funding, protocol/regulatory submissions, overall oversight, data management, etc.), the core **CRO functions** (trial management, site selection, monitoring, data services, etc.), and the on-the-ground **site/investigator duties** (participant recruitment, informed consent, protocol execution, data entry, safety reporting). We discuss how responsibilities are allocated (or can be delegated) by law and good practice, using actual regulations and guideline language (e.g. FDA and ICH GCP) ([1] www.law.cornell.edu) ([5] ichgcp.net). We include quantitative data on outsourcing trends (e.g. market size, usage statistics) and note real-world examples and case studies illustrating effective sponsor–CRO–site collaboration. Finally, we examine emerging trends (e.g. decentralized trials, digital tools) and their implications for future role distribution.

Throughout, we emphasize that **clear role definitions and strong communication** are vital. Redundancy or confusion (e.g. duplicate monitoring visits by sponsor and CRO, or conflicting instructions to sites) can waste resources and risk trial quality. Conversely, when each party understands its duties and works in concert, trials run more efficiently—ultimately advancing therapies for patients.

Introduction and Background

The **clinical trial** ecosystem involves many moving parts and personnel. At the top level, a **sponsor** initiates and funds a trial to test a new drug, biologic, device, or intervention. Sponsors can be:

- **Industry (pharma/biotech) sponsors** developing commercially-backed products ([6] pmc.ncbi.nlm.nih.gov) ([7] pmc.ncbi.nlm.nih.gov);
- **Government or academic sponsors** in investigator-initiated (non-industry) research ([6] pmc.ncbi.nlm.nih.gov);
- **Sponsor-investigators** (rarely, an investigator who is also the sponsor under regulations).

Historically, sponsors performed most roles in-house. They designed the protocol, supplied the investigational product (IP), and oversaw trials at each site. Over time, however, the complexity and volume of trials grew

dramatically. As of 2019, over **300,000** trials were registered on ClinicalTrials.gov (79% of which were interventional) ([6] pmc.ncbi.nlm.nih.gov). To manage this scale, sponsors increasingly use **CROs** – specialized service organizations that offer everything from full-study management to discrete functions (e.g. monitoring, data analysis) ([8] pmc.ncbi.nlm.nih.gov) ([9] www.appliedclinicaltrialsonline.com). One analysis (2017–2021) found the top 10 CROs grew revenues by 17% from 2020 to 2021, reflecting heavy sponsor reliance ([9] www.appliedclinicaltrialsonline.com), and the global CRO market is forecast to reach ~$127 billion by 2028 ([9] www.appliedclinicaltrialsonline.com).

The **site** is the hospital, clinic, or research center where the trial is conducted. The **principal investigator (PI)** – an investigator qualified by training and experience – runs the trial at the site. The PI and site staff (sub-investigators, coordinators, nurses, lab personnel, etc.) enrol and manage participants according to the protocol. In practice, the site interacts with both sponsor and CRO: for example, sponsor or CRO monitors make on-site visits, while the sponsor may send medical representatives or engage investigators through conferences.

The global nature of trials further blurs lines. A trial for a new oncology drug, for instance, might involve an American sponsor, a European CRO, and sites in North America, Europe, and Asia. Each region has local ethics boards, regulations (FDA, EMA, etc.) and cultural practices. Coordination is therefore essential.

Regulatory frameworks mandate clear sponsor and investigator (site) responsibilities. In the U.S., Title 21 CFR Part 312 (for drugs) and Part 812 (for devices) spell out sponsors' and investigators' duties. ([1] www.law.cornell.edu) ([10] codes.findlaw.com). The voluntary ICH GCP guideline (adopted by 90+ countries) likewise defines these roles, emphasizing subject safety and data integrity ([11] ichgcp.net) ([5] ichgcp.net). For example, 21 CFR §312.50 mandates that *"Sponsors are responsible for selecting qualified investigators… ensuring proper monitoring… [and] ensuring that the investigation is conducted in accordance with the… protocol"* ([1] www.law.cornell.edu). Similarly, ICH E6 (R2) reminds sponsors to implement quality management systems and to oversee critical trial processes (5.0 Quality Management) ([12] ichgcp.net).

In shared arrangements, sponsors often delegate certain activities to CROs or CROs delegate some tasks to sites, but the **accountability cannot be fully transferred**. By law, a sponsor may transfer (delegate) trial obligations to a CRO in writing ([10] codes.findlaw.com) – but any non-transferred obligations stay with the sponsor. The CRO then becomes subject to the same FDA regulations for the tasks it assumes ([4] codes.findlaw.com).In short: *delegation is allowed, but ultimate responsibility remains with the sponsor (and with the PI at the site)* ([2] www.opsvs.com) ([10] codes.findlaw.com).

Figure 1 below summarizes in broad strokes the key distinctions. The sponsor "owns" the trial and ensures its scientific validity and compliance. A CRO executes many operational details under contract to the sponsor. The site **implements** the protocol with patients. (Each category overlaps at points – e.g. sponsor/CRO both engage with sites, and CROs often coordinate site activities – so clear contracts and communication are essential.)

Figure 1. *Overview of Sponsor, CRO, and Site Roles in a Clinical Trial.*[Figure: concept diagram (Sponsor–CRO–Site interactions)]

Sponsor Responsibilities

The **sponsor** of a clinical trial bears the ultimate responsibility for the study's integrity, safety, and compliance. Core sponsor duties include: protocol development, funding, regulatory submissions, investigator selection, monitoring oversight, safety reporting, data handling, and final analysis. (Sponsors may hire CROs or consultants to carry out many of these, but regulatory accountability remains with the sponsor.) Below are the main sponsor functions, with regulatory citations:

- **Scientific Rationale and Protocol (Study Design).** The sponsor must ensure the trial is scientifically sound. They **design or commission** the protocol, defining objectives, inclusion/exclusion criteria, interventions, and endpoints ([13] blog.cloudbyz.com). The protocol should be detailed, clear, and justifiable: per ICH E6, the sponsor should identify critical processes and design efficient protocols to protect subjects and data quality ([12] ichgcp.net). The investigator (site) *signs* the protocol or a contract to confirm agreement ([5] ichgcp.net). Sponsors often ask CROs to review feasibility or suggest practical adjustments, but the sponsor ultimately approves the final protocol.

- **Regulatory Approvals and Compliance.** The sponsor submits applications for regulatory authorization (e.g. IND in the U.S., Clinical Trial Application in EU) and obtains ethics committee (IRB/IEC) approvals. They provide investigators with necessary documentation (e.g. Investigator's Brochure, product label). In many regions (e.g. FDA 21 CFR 312.50), the sponsor must *"maintain an effective IND or IDE"* and *"ensure that the FDA and all investigators are promptly informed of significant new adverse effects or risks"* ([1] www.law.cornell.edu). Crucially, the sponsor is required to *select qualified investigators* ([1] www.law.cornell.edu). Federal regulations also obligate sponsors to ensure informed consent requirements are met (though the site obtains consent, the sponsor provides approved forms). Sponsors are responsible for compliance with all applicable GCP and local regulations ([14] blog.cloudbyz.com).

- **Funding and Contracts.** Sponsors **fund the trial**, providing the investigational product (IP), supplies, and financial support. They negotiate budgets and contracts with CROs and sites. In practice, sponsors set the overall funding (grant or study budget) and often negotiate agreements (clinical trial agreements, confidentiality/legal agreements) with sites – although CROs may handle much of this on the sponsor's behalf. For example, one analysis noted that sites depend entirely on sponsor/CRO payments (often milestone or per-patient) and thus require robust, fair budgets at the outset ([15] pmc.ncbi.nlm.nih.gov). Sponsors typically reimburse trial costs only as milestones are met; if a site under-enrolls, revenue may not cover its upfront expenses ([15] pmc.ncbi.nlm.nih.gov). Thus sponsors must negotiate clearly defined payment schedules. Contracts (including indemnity) are ultimately between the sponsor and each site (though CROs often draft them).

- **Investigator and Site Selection.** As noted, regulators require sponsors to choose qualified investigators. Sponsors (sometimes with CRO input) issue site feasibility questionnaires and analyze site performance data (e.g. disease prevalence, past recruitment) before selecting sites. Sponsors confirm investigators meet qualifications (e.g. through CV review, references). Once chosen, the sponsor (or CRO) provides the site with study materials and training to initiate the trial there.

- **Study Monitoring and Oversight.** By regulation, sponsors *must ensure proper monitoring* of the trial ([1] www.law.cornell.edu) ([16] www.clinicalleader.com). Whether done by sponsor-employed monitors or outsourced to a CRO's monitors (CRAs), frequent oversight is required. The sponsor defines the monitoring plan and may conduct audits or visits to sites to verify compliance. In practice, CROs often perform the on-site source data verification (SDV) visits. But the sponsor must supervise the CRO's performance. (As one consultancy notes, from the FDA's standpoint the sponsor is "still in charge of the ship's ultimate destination" even if a CRO performs the work ([2] www.opsvs.com).) For this reason, sponsors typically have an internal quality control team that audits vendors and reviews monitoring reports. FDA guidance reminds sponsors that even when *delegating* tasks to a CRO (by written agreement), they retain responsibility for ensuring the trial stays on track ([10] codes.findlaw.com) ([2] www.opsvs.com). Thus sponsors review site monitoring logs, address any compliance issues, and document oversight activities.

- **Data Management and Analysis.** The sponsor defines what data will be collected and how it will be analyzed (e.g. statistical analysis plan). They ensure an appropriate *database lock and analysis* at study end. Often a CRO handles the operational aspects of data management (see below), but the sponsor specifies requirements (case report forms, eCRF structure, endpoints, metadata) and ultimately owns the dataset. At trial close, the sponsor reviews cleaned data and generates the final study report.

- **Safety Reporting and Pharmacovigilance.** Sponsors are responsible for evaluating IP safety and reporting serious adverse events (SAEs) to regulators. They must have a pharmacovigilance system to collect, review, and submit safety data. For example, FDA regulations require sponsors to report unexpected fatal or life-threatening events within 7 days and all others within 15 days ([17] www.clinicalnet.com). CROs may handle routine safety data collection, but the sponsor's safety team adjudicates and reports events to health authorities. The sponsor also provides investigators with updated safety information (e.g. protocol amendments, IB updates) as needed, and may arrange compensation/indemnity policies.

- **Quality Management and Compliance.** Modern GCP emphasizes a risk-based quality management approach. Sponsors must set up quality assurance (QA) systems to oversee all stages. This includes vendor qualification (auditing CROs), SOPs, and ensuring personnel are trained. ICH E6(R2) advises sponsors to identify critical processes/data early and tailor QA activities to risk ([12] ichgcp.net). Regulators expect sponsors to keep full trial records (e.g. TFLD – trial master file, regulatory binder) and to cooperate in inspections.

Table 1 (below) summarizes these key functions and which party typically handles each. In brief, sponsors drive the *why* and *what* of the trial (rationale, funding, compliance), CROs handle much of the *how* (operational execution), and sites handle the *who* (participants) and on-site *when/where* activities.

Table 1. Key Clinical Trial Functions and Responsible Parties (Sponsor vs. CRO vs. Site). Entries note typical responsibilities; actual arrangements may vary by contract. (Sources, examples cited in text.)

Function / Activity	Sponsor Role	CRO Role	Site Role
Protocol and Study Design	Develops and finalizes protocol (objectives, endpoints, methodology) ([13] blog.cloudbyz.com); ensures scientific rationale.	May advise on feasibility; assist in drafting or refining protocol ([18] blog.cloudbyz.com).	Provides input on feasibility; PI/institution signs protocol to confirm agreement ([5] ichgcp.net); later ensures all procedures are followed at site.
Regulatory Submissions	Submits IND/CTA to regulators; obtains central IRB/ethics approval ([14] blog.cloudbyz.com); provides investigators with required docs (e.g. IB, DSUR).	Prepares documentation (e.g. regulatory filings, site packages) under sponsor oversight.	Completes and submits local IRB/IEC applications and informed consent forms; responds to IRB queries.
Investigator/Site Selection	Initiates site feasibility surveys; selects qualified investigators ([1] www.law.cornell.edu); verifies site has needed capabilities.	Conducts feasibility assessments; identifies, pre-screens, and recommends potential sites ([19] premier-research.com).	Expresses interest via feasibility questionnaire; demonstrates PI qualifications; prepares site for activation.
Contracts & Funding	Provides trial funding; negotiates global budget and payment milestones ([15] pmc.ncbi.nlm.nih.gov); finalizes agreements (CTAs, indemnity) with sites (often via CRO).	Negotiates detailed site budgets and contracts on sponsor's behalf; manages payment process.	Engages negotiator to discuss local budget and contract terms; invoices milestone payments.
Site Training and Initiation	Organizes investigator meetings; ensures sites are trained on protocol and IP.	Conducts site initiation visits and training sessions; provides study materials and systems training ([19] premier-research.com).	Attends training; ensures site staff are qualified (GCP, protocol, equipment); sets up study infrastructure.
Patient Recruitment	Sets enrollment targets; may support central advertising or provide materials.	Drives feasibility and recruitment strategy (e.g. patient outreach) ([20] premier-research.com); monitors enrollment metrics.	Identifies and enrolls eligible patients from clinic ({ ([13] blog.cloudbyz.com)}shows primary recruitment by site); performs screening per criteria; manages patient outreach.
Informed Consent & Ethics	Provides IRB-approved consent forms and updates; ensures GCP-compliant processes at sites.	Ensures sites have the latest IRB-approved consent; verifies consent documentation.	Obtains and documents informed consent from each participant ([14] blog.cloudbyz.com); protects patient rights and welfare throughout trial.

Function / Activity	Sponsor Role	CRO Role	Site Role
Monitoring & Oversight	Ensures monitoring is conducted (FDA: "proper monitoring") ([1] www.law.cornell.edu) ([16] www.clinicalleader.com); reviews monitoring reports.	Performs routine monitoring visits (on-site and/or remote); verifies data and compliance; escalates issues.	Cooperates with monitors; corrects deficiencies; answers queries; ensures protocol adherence during everyday conduct.
Data Management	Defines data to be collected; ensures data integrity; plans final analysis.	Implements EDC/database; processes CRFs; cleans and summarizes data ([21] blog.cloudbyz.com).	Collects source data (medical records); enters data into CRFs/eCRFs accurately; resolves queries generated by CRO/data team.
Safety (Adverse Event Reporting)	Collects overall safety data; submits SAE reports to regulators; analyzes risk–benefit.	Facilitates AE data flow (collects from sites, maintains pharmacovigilance systems) ([22] blog.cloudbyz.com).	Records and reports any adverse events or exposures to the sponsor/CRO immediately; follows up on outcomes.

Each row in Table 1 illustrates a function of the trial and which party typically handles it. Of course, real-world practice may vary (e.g. a large sponsor might staff in-house monitors rather than hire a CRO), but the table highlights common role divisions. In particular, sponsors lead at the conceptual and oversight level, CROs at the operational level, and sites at the execution level.

CRO Responsibilities

Contract Research Organizations (CROs) are commercial entities that partners with sponsors to conduct clinical trials or pieces of trials. Their involvement can range from *functional outsourcing* (handling one or two tasks) to *full-service* (managing end-to-end operations) ([23] www.appliedclinicaltrialsonline.com) ([24] blog.cloudbyz.com). In 2023, about half of trials used a **functional service provider (FSP)** model, outsourcing specific tasks like monitoring or data management, while the sponsor retained core functions ([25] www.appliedclinicaltrialsonline.com). (By contrast, purely full-service models are more common in highly complex programs such as oncology) ([26] www.appliedclinicaltrialsonline.com).

CROs have "pivotal roles" throughout drug development: they act as the sponsor's hands-on representative and often bring expertise in specialized areas (biostatistics, regulatory, labs, etc.) ([8] pmc.ncbi.nlm.nih.gov). Key CRO responsibilities include:

- **Operational Management.** CROs translate the sponsor's plan into action. They coordinate study start-up activities (e.g. site contracts, regulatory submissions), maintain study timelines, and manage vendors (labs, imaging, logistics). As one description notes, CROs provide **"operational oversight tied directly to the conduct of the study"**, often leading study setup and tracking (timelines, query resolution, compliance) ([27] premier-research.com). For example, CRO clinical ops teams typically drive site activation and recruitment support, ensuring training and inspection readiness ([19] premier-research.com) ([27] premier-research.com).

- **Site Selection and Management.** CROs often **identify and qualify sites**. They issue feasibility questionnaires, assess site infrastructure, and invite sites to participate. Once sites are selected (by sponsor approval), the CRO manages contracts (via master service agreements or CTAs) and organizes site initiation. During the trial, CRO staff (including CRA monitors) oversee site performance. They conduct regular monitoring visits, address site queries, and ensure documentation is up-to-date. The CRO provides sites with tools and sometimes local training. In essence, if the sponsor is building the team, the CRO is its project manager.

- **Monitoring.** The CRO is commonly *contractually delegated* to perform monitoring visits (often under an agreement as per 21 CFR 312.52 ([10] codes.findlaw.com)). CRAs verify that the trial is conducted per protocol and GCP at each site. They check informed consents, source data, drug accountability, and record-keeping. The CRO also implements central monitoring activities (reviewing data trends) and ensures all deviations and issues are reported. (Recall that even when CROs monitor, FDA considers the sponsor ultimately accountable ([4] codes.findlaw.com) ([2] www.opsvs.com).)

- **Data Management and Biostatistics.** Many sponsors outsource data handling to CROs. CRO data management teams set up the electronic capture system, manage databases, and clean incoming data ([21] blog.cloudbyz.com). They run edit checks, generate queries, lock the database, and transfer clean data to statisticians. CRO biostatisticians may perform interim and final analyses under guidance of the sponsor's statistical plan.

- **Regulatory Support.** CROs may prepare regulatory documents on behalf of the sponsor. For example, they compile common technical documents (CTDs), submit IND amendments, and coordinate with health authorities. In multi-country trials, CROs navigate local regulatory submissions, translating documents and managing country-specific applications. They also assist with IRB submissions by providing essential documents and copies of sponsor communications.

- **Pharmacovigilance and Safety Support.** While the sponsor retains safety oversight, CROs often handle the logistics. This includes building safety databases, triaging investigator-reported events, and preparing reports or line listings for the sponsor's review. The CRO might also manage medical monitoring tasks, such as responding to investigator inquiries about AEs or determining if an event is related to the study drug (under the sponsor's guidance).

- **Quality Assurance.** Large CROs have internal QA units that perform vendor audits (even of other CROs or labs), and ensure all processes (monitoring, data mgmt, etc.) follow SOPs and applicable regulations. In practice, sponsors audit CROs at baseline and periodically to verify their compliance. (Regulations explicitly state that CROs assuming sponsor obligations *"shall comply with the specific regulations…"* ([4] codes.findlaw.com) and are subject to inspection just as sponsors are.)

CRO involvement has grown because of the high cost and labor intensity of trials. For example, monitoring alone can represent 35–45% of trial costs; many sponsors report that outsourcing monitoring (via FSP) **reduces costs and improves efficiencies** ([28] www.appliedclinicaltrialsonline.com). As a result, **FSP vs. Full-service** dynamics have shifted: only a few years ago, the majority of outsourced spending went to full-service CROs, but recently large companies are embracing functional models ([28] www.appliedclinicaltrialsonline.com). This trend reflects more granular outsourcing: instead of handing a study to one CRO, sponsors now fragment it across multiple specialized providers or in-house teams.

Table 2 (below) illustrates some of these outsourcing trends and trial performance metrics (from Lamberti et al., 2023). It shows how predominant FSP usage is and that sponsors themselves remain responsible for study delivery in the vast majority of cases.

Table 2. Outsourcing Models and Trial Performance (Lamberti et al., 2023) ([www.appliedclinicaltrialsonline.com](https://www.appliedclinicaltrialsonline.com/view/outsourcing-model-usage-and-its-relationship-to-clinical-trial-performance#:~:text=Table%202%20lists%20the%20frequency,respectively)) ([www.appliedclinicaltrialsonline.com](https://www.appliedclinicaltrialsonline.com/view/outsourcing-model-usage-and-its-relationship-to-clinical-trial-performance#:~:text=total%20revenue%20spent%20on%20contract,2)) ([www.appliedclinicaltrialsonline.com](https://www.appliedclinicaltrialsonline.com/view/outsourcing-model-usage-and-its-relationship-to-clinical-trial-performance#:~:text=The%20frequencies%20of%20responses%20to,3)). The table highlights that *functional service provider (FSP)* models now dominate (especially for monitoring/data tasks) and that sponsors drive nearly all studies to completion. Half of trials finished on time, and \~75% were on budget (see bottom rows from Applied Clinical Trials, 2023 ([www.appliedclinicaltrialsonline.com](https://www.appliedclinicaltrialsonline.com/view/outsourcing-model-usage-and-its-relationship-to-clinical-trial-performance#:~:text=The%20frequencies%20of%20responses%20to,3))). (See text for details.)

Metric / Model	Key Value or Role
Functional Service Provider (FSP) model	Used in \~50% of trials; most common approach for monitoring and data management ([25] www.appliedclinicaltrialsonline.com).
Full-Service CRO model	Dominant in complex programs (e.g. large oncology trials \~30%); overall used less often than specialized models ([26] www.appliedclinicaltrialsonline.com).

Metric / Model	Key Value or Role
Key functions kept in-house	Sponsors often retain core tasks such as study start-up, project management, statistics, and medical writing (in-house or via staff augmentation) ([25] www.appliedclinicaltrialsonline.com).
Sponsor responsible for study delivery	Identified as lead party in 96.4% of trials (per sponsor reports) ([30] www.appliedclinicaltrialsonline.com).
Trials on time	\~50.0% of trials finished by original timeline ([30] www.appliedclinicaltrialsonline.com).
Trials on budget	\~74.7% of trials met the planned budget (24.1% went over budget) ([30] www.appliedclinicaltrialsonline.com).

As Table 2 shows, sponsors see themselves as responsible for almost all study outcomes, even when much work is outsourced ([30] www.appliedclinicaltrialsonline.com). This underscores a crucial point: **outsourcing does not absolve the sponsor of accountability**. Sponsors selecting CROs and other vendors must vet them thoroughly (as one expert notes, choosing the right "teammate" is critical ([2] www.opsvs.com)) and maintain strong oversight throughout the trial.

Site and Investigator Responsibilities

A **clinical trial site** is the facility (e.g. a hospital or research clinic) where participants are enrolled and treated. At each site, the Principal Investigator (PI) – a physician or qualified researcher – **controls** the trial. Commonly, the PI is supported by a team of study coordinators, sub-investigators, nurses, and other staff. The site's constituents are the ones with direct patient contact, so their role is central to both participant safety and data quality.

Under regulations and GCP, the site (investigator/institution) has several binding obligations. Key site responsibilities include:

- **Qualifications and Resources.** Each PI must be qualified by training and experience to conduct the trial. ICH GCP §4.1 states the investigator should provide evidence of qualifications (CVs) to the sponsor and regulators ([11] ichgcp.net). The investigator (and institution) must have adequate time, staff, and facilities to conduct the trial and recruit the required subjects ([31] ichgcp.net). For example, ICH 4.2.4 requires that the investigator ensure all trial assistants are trained on the protocol and investigational product ([32] ichgcp.net). Sites should have proper storage (e.g. temperature-controlled, access-controlled refrigerators/freezers) and record-keeping systems for investigational products and samples ([33] pmc.ncbi.nlm.nih.gov) ([34] pmc.ncbi.nlm.nih.gov).

- **Ethics and Oversight.** The site must obtain **IRB/IEC approval** before enrolling any participants. Amendments to the protocol or consent form must also be approved by the IRB before implementation ([35] ichgcp.net), except in emergencies for subject safety. The site is subject to monitoring and auditing by the sponsor/CRO ([11] ichgcp.net) and to regulatory inspection. In many countries (e.g. USA), the site must maintain FDA forms (Form 1572 or IDE agreements) and update them as needed ([36] pmc.ncbi.nlm.nih.gov). PI responsibilities are legally substantial; an Ochsner Journal review reminds us that *even if tasks are delegated, the PI is responsible* and can face warning letters or worse for noncompliance ([37] pmc.ncbi.nlm.nih.gov) ([38] pmc.ncbi.nlm.nih.gov).

- **Informed Consent and Participant Safety.** Sites have the front-line duty of protecting participants. They take consent using the approved forms and process ([14] blog.cloudbyz.com). The PI must verify inclusion/exclusion criteria, explain procedures/risks, and ensure consent is documented correctly. During the trial, sites must report any adverse events immediately to the sponsor, IRB, and (if required) health authorities ([39] pmc.ncbi.nlm.nih.gov). The PI must maintain logs of delegation (who did what task) and financial disclosures ([40] pmc.ncbi.nlm.nih.gov). The PI's paramount obligation is to the subjects – above even the needs of the protocol.

- **Protocol Conduct and Data Collection.** The site is **expected to conduct the trial exactly as written** in the approved protocol. Per ICH 4.5.1, *"The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor…"* ([5] ichgcp.net). Deviations are only allowed with sponsor and IRB approval (except to remove an immediate hazard ([35] ichgcp.net)). Investigators must meticulously record all trial activities. This includes administering the investigational product according to schedule, doing required tests and assessments, and thoroughly documenting everything in source documents. Investigational product accountability is explicitly the site's duty: the investigator/institution must maintain delivery and usage records (dates, lot numbers, subject codes) ([5] ichgcp.net) and reconcile inventory with the sponsor. In short, what the site does "drives" the trial feed – it is where data are generated.

- **Participant Recruitment and Retention.** Sites recruit participants (often the biggest bottleneck). They advertise to patients (within IRB rules), prescreen candidates, and enroll eligible subjects ([13] blog.cloudbyz.com). In practice, a few high-performing sites often yield most enrollments. One analysis cited that ~80% of trial recruitment is achieved by just ~20% of sites ([41] pmc.ncbi.nlm.nih.gov). This makes effective site selection crucial for sponsors. (Many sponsors and CROs increasingly involve sites or patient advocacy groups early to boost enrollment.) The site also manages patient follow-up, addressing drop-outs or lost-to-follow-up per protocol.

- **Reporting and Records.** Each site must maintain trial records: Case Report Forms (CRFs), source documents, and logs (drug shipments, consent forms, deviations, CVs). Sites answer queries from the sponsor's data management team. They also cooperate with remote or on-site monitoring – for example, uploading relevant records, clarifying data, and implementing corrective actions after an audit.

Financially, sites rely on sponsor/CRO funding. The sponsor usually reimburses approved expenses (e.g. lab tests, procedures, coordinator time) via the invoicing schedule. Sites typically invoice per enrolled patient or completed milestones; earmarks like "screening costs" or extra visits must be negotiated. Because startup costs come upfront (e.g. lab kit, staff training) and payment may lag, many sites negotiate **per-patient pricing** to ensure they do not lose money ([15] pmc.ncbi.nlm.nih.gov). Repeat business – winning future trials – depends on past performance and trust with the sponsor/CRO ([33] pmc.ncbi.nlm.nih.gov).

In summary, the site's core mission is to carry out the sponsor's study at the local level. The site must faithfully apply the protocol to human subjects and remain the guardian of those subjects' welfare. Regulatory statements underscore this: *"The investigator… [must] protect the rights, safety, and welfare of subjects"* ([42] pmc.ncbi.nlm.nih.gov), and the investigator/institution has final duty for IP accountability and documentation ([5] ichgcp.net).

Delegation, Oversight, and Regulatory Context

A critical theme in modern trials is the *division of labor*, especially when sponsors use CROs or delegate tasks. Both FDA regulations and ICH GCP clarify how delegation is handled:

- **Delegation by Sponsor.** U.S. FDA allows sponsors to transfer (delegate) trial obligations to CROs by written contract ([10] codes.findlaw.com). For example, a sponsor can contract a CRO to perform monitoring, data management, or even drafting of regulatory submissions. Per 21 CFR §312.52(a), such delegation *"shall be described in writing"*, indicating which responsibilities the CRO assumes. If **all** sponsor obligations are transferred, a generic statement suffices; otherwise the contract must enumerate each delegated task ([10] codes.findlaw.com). Importantly, any obligations *not* explicitly transferred remain with the sponsor.

Once transferred, the CRO steps into the sponsor's regulatory shoes for those tasks. Under §312.52(b), the CRO *"shall comply with the specific regulations in this chapter applicable to this obligation"* and is *"subject to the same regulatory action as a sponsor for failure to comply"* ([4] codes.findlaw.com). In effect, FDA treats the CRO as a sponsor with respect to delegated duties.

- **Sponsor Accountability.** Even with CRO involvement, sponsors retain **ultimate accountability** for the trial. ICH GCP and FDA emphasize that sponsorship carries responsibility for the trial's quality. As one industry commentary colorfully puts it, the sponsor is the "captain" and the CRO the "crew" – you choose your crew carefully, but *you're still steering the ship* ([2] www.opsvs.com). Sponsors must monitor their CROs: reviewing progress reports, auditing data, and ensuring tasks are executed. U.S. FDA expects sponsors to verify that the CRO's work meets all requirements ([4] codes.findlaw.com) ([16] www.clinicalleader.com). For instance, 21 CFR forbids sponsors from abdicating monitoring – even if a CRO has on-site monitors, the sponsor must still ensure *"proper monitoring"* ([1] www.law.cornell.edu) ([16] www.clinicalleader.com). If a CRO error occurs, regulators will still hold the sponsor responsible if the error involves a non-delegated duty. In short, delegation can shift the *implementation* of tasks but not the *liability*, unless fully and perfectly assigned in contract.

- **Investigator Responsibility.** Similarly, even if a PI delegates many duties to study coordinators or CRO personnel, the PI remains responsible to the FDA (or other agencies) for the trial conduct. This is why sponsor/CRCs insist on a PI of record: signing the FDA Form 1572 (for IND trials) pledges that the investigator agrees to follow regulations. The Ochsner J. article reminds us that *"a clinical principal investigator who has signed FDA Form 1572 is held responsible for noncompliance and misconduct by anyone working on the study."* ([3] pmc.ncbi.nlm.nih.gov). In practical terms, this means the PI must maintain delegation logs and supervise staff and vendors.

- **Regulatory Inspections.** Both sponsors and sites can be inspected by authorities. FDA or EMA may audit a sponsor's records to ensure adequate oversight (21 CFR 312.58, 812.60), and can similarly inspect sites during trials. Significantly, FDA will also inspect CRO sites if violations are suspected – since the CRO is accountable for delegated sponsor duties. For example, an FDA Form 483 might be issued to a CRO or sponsor if issues arise. Sponsors should thus not only qualify CROs carefully but also include audit rights in contracts to verify compliance.

- **Contracts and Insurance.** Good practice dictates that all delegation is spelled out in formal contracts (CRO agreement, CTA, etc.). These cover indemnification, insurance (often sponsor provides liability coverage for site), and publication rights. CRO contracts specify which SOPs and standards the CRO will follow (e.g. that monitors are qualified, as 21 CFR requires ([16] www.clinicalleader.com)). Site CTAs (or a master agreement) delineate the site's obligations (informed consent, data confidentiality) and authorize suppliers (CROs) to access site records under GCP.

- **Quality Systems:** Modern trials emphasize risk-based quality oversight. Sponsors typically maintain a Quality Management System (QMS) that covers outsourced partners. This includes periodic audit of CRO processes and random checks of site compliance. In turn, sites often have internal quality controls (e.g. sponsor or IRB audits of consent, data verification). These overlapping checks help ensure that Sponsor→CRO→Site is a closed loop where each party understands its duties.

In summary, the regulatory environment imposes a **tiered accountability**: the sponsor is top-level accountable, the CRO inherits sponsor duties per contract, and the investigator/site is independently accountable for local trial conduct. All parties must communicate transparently. Table 1 and the text above illustrate that while many tasks can be delegated, *nothing is fully off the sponsor's books unless formally transferred*. This is essential to prevent gaps: for example, if a CRO's contract forgot to mention data archiving, the sponsor must still fulfill that duty or FDA would hold the sponsor responsible.

Site Management and Sponsor/CRO Coordination

Because each party relies on the others, effective collaboration is key. Sites in particular must juggle multiple lines: patients, data collection, and communications with both the sponsor and CRO. These interactions play out through meetings and documents:

- **Site Initiation and Activation:** Before enrolling subjects, a site goes through a start-up process. At initiation visits (often run by a CRO), staff are trained on the protocol, CRFs, and safety reporting procedures. The sponsor or CRO confirms that the site has IRB approval, drug storage, and qualified staff. (As Table 1 notes, training is often done by the CRO, though sponsors attend investigator meetings to contextualize the study.) Once initiated, the site can begin screening patients.

- **Ongoing Communication:** During the trial, sites submit data (CRFs) to the sponsor/CRO. They report adverse events, protocol deviations, and enrollment numbers. Monitors (CRO CRAs or sponsor staff) regularly visit or contact the site to review documents. Monitors address problems in real time, ensure query resolution, and document any changes needed. Sponsors may also conduct their own visits: regulators expect sponsors to verify high-level aspects (e.g. data integrity, informed consent) periodically.

- **Site Engagement:** Historically, sponsor-site relationships were transactional. Sites only heard from sponsors when collecting data. However, recent trends emphasize **sponsor engagement to strengthen site performance**. Industry surveys (e.g. CenterWatch) report that investigators now demand more from sponsors – responsiveness, reasonable budgets, and transparent communication ([43] www.clinicalleader.com). In response, many sponsors have created site liaison roles or sponsor medical liaisons who "walk the halls" of hospitals, attend conferences, and even visit sites outside of individual study demands. One clinical leader notes sponsors now invest more time in site visits *after* the initial kickoff meeting – listening to coordinators' challenges, not just asking for more enrollment ([44] www.clinicalleader.com). Such efforts build trust and can improve retention of sites across multiple trials.

- **CRO–Site Dynamics:** CROs and sites interact mainly through monitoring and coordination. In fact, one industry article highlights that strained Site–CRO relationships (due to high turnover of monitors or poor communication) can jeopardize trials ([45] www.clinicalleader.com). Best practices suggest assigning a consistent CRA to a site portfolio and keeping an open feedback loop. For example, some CROs provide site-facing dashboards so investigators can see enrollment progress, or hold webinars on site-centric topics (as recommended by site-focused guidelines) ([20] premier-research.com). A well-chosen CRO will act as an advocate for the site to the sponsor, smoothing logistics and turning site concerns into solutions.

- **Lines of Responsibility:** It must always be clear: if a question arises, who does the site contact? Usually, sites have a study coordinator or department contact. For protocol clarifications or serious adverse events, sites often communicate with the sponsor's medical monitor or drug safety team. For everyday paperwork and query resolution, they work with CRO CRAs or data managers. Sponsor oversight adds another layer – for example, sponsors may ensure compliance with global strategies (e.g. standardized training, uniform documentation across sites).

To summarize, **effective site management** is a two-way process. Sites must diligently fulfill their duties (e.g. consenting subjects, reporting events) and reliably communicate with the sponsor/CRO. In turn, sponsors and CROs must support sites: providing clear guidance, adequate training, and recognizing site contributions. Table 1 and the preceding text outline the formal division of tasks – but informal aspects (communication quality, responsiveness) are just as critical for trial success.

Data, Evidence, and Case Examples

The above discussion is supported by both regulatory text and industry analyses. Empirical studies and reports shed light on real-world patterns:

- **Market Trends:** The CRO services market is booming. As shown in Table 2, one industry analysis (Lamberti et al., 2023) reports that the top 10 CROs grew to ~$34 billion in 2022 (69% of global CRO spending) ([9] www.appliedclinicaltrialsonline.com). Forecasts project roughly **10.7% annual growth** to $127 billion by 2028 ([9] www.appliedclinicaltrialsonline.com). This reflects sponsors' ever-greater use of outsourced services. Analytics showed a **shift from full-service to functional models**: in the early 2010s, most sponsors used single CROs for full-service trials, but recently ~50% of sponsors use FSP (e.g. separate vendors for monitoring, data, etc.) ([25] www.appliedclinicaltrialsonline.com) ([28] www.appliedclinicaltrialsonline.com).

- **Study Performance:** The pilot Tufts study (Table 2) found sponsors reported **96.4% of trials** as "sponsor-responsible" for delivery ([30] www.appliedclinicaltrialsonline.com). That is, in almost all cases, the sponsor (not the CRO) is ultimately held accountable for the trial outcome. About 50% of trials finished on schedule, 42.5% were late ([30] www.appliedclinicaltrialsonline.com). Budget adherence was better: ~74.7% on budget (24.1% went over) ([30] www.appliedclinicaltrialsonline.com). This suggests that while oversight is challenging, sponsors generally succeed in keeping trials viable. Notably, full-service outsourced trials (often larger oncology studies) tended to be longer and more complex ([46] www.appliedclinicaltrialsonline.com), emphasizing the need for robust project management in high-stakes programs.

- **Sponsor–Site Relations:** Surveys and commentaries emphasise the human element. For example, a 2018 Column by Audry Rossow notes that **investigators increasingly rate sponsors on site-support quality** ([43] www.clinicalleader.com). Sponsors have responded by dedicating staff to site engagement – beyond just troubleshooting queries. One large sponsor implemented quarterly investigator conferences and direct PI liaisons; they reported higher survey scores for communication and timely payments. Such initiatives align with the idea that hard data (enrollment rates, etc.) improve when sponsors "listen to the site" ([44] www.clinicalleader.com).

- **CRO–Sponsor Partnerships:** Both sides publish best practices. Applied Clinical Trials (Nov 2023) outlines common pitfalls ("warning signs") in CRO–Sponsor relationships ([47] www.appliedclinicaltrialsonline.com) ([48] www.appliedclinicaltrialsonline.com). For instance, unrealistic timelines or underfunded projects can strain a partnership. CROs value sponsors who are responsive and fair; sponsors vet CROs via **requests for proposal (RFPs)** and performance history ([49] www.appliedclinicaltrialsonline.com). ClinicalTrialsArena articles stress that a healthy balance of oversight and trust is essential ([45] www.clinicalleader.com).

- **Case Study – Patient Recruitment:** A concrete example of sponsor–CRO–site collaboration comes from a Phase 3 inflammatory bowel disease trial. The sponsor enlisted PSI CRO to manage global recruitment. PSI leveraged its own patient recruitment teams and digital campaigns (web ads, patient advocacy group outreach) across 40 countries. As a result, the trial **met its target of 600 patients fully 3 months early** ([50] psi-cro.com). This success was attributed to CRO's in-house expertise and close site cooperation: for example, PSI trained site coordinators on engaging local clinics and worked with patient organizations on educational materials ([50] psi-cro.com) ([51] psi-cro.com). Here, the sponsor set the goal and provided the investigational drug, the CRO provided recruitment strategy and execution, and sites delivered patient candidates.

- **Case Study – Site Engagement:** In another example, a sponsor of an IBD study collaborated with PSI on early site outreach. They sent personalized "Dear Investigator" letters, held one-on-one calls with key opinion leaders, and hosted webinars to spark interest ([52] psi-cro.com) ([53] psi-cro.com). Within four weeks, they received 170 confidentiality agreements and 150 completed feasibility surveys from 20 countries. Enrollment proceeded at 90% higher than industry average, finishing **2 months ahead of schedule** ([54] psi-cro.com). This demonstrates how proactive sponsor/CRO efforts can significantly improve site activation and recruitment timelines.

These examples underscore the complementary strengths of each party. The sponsor provided strategic direction and funding, the CRO brought specialized operational firepower, and the sites contributed local patient access and execution. When aligned, the result was timely enrollment that might not have been achieved by any party alone.

Challenges, Implications, and Future Directions

The sponsor – CRO – site model has greatly increased trial capacity, but not without challenges. Key issues include:

- **Overlapping Demands.** Sites often face multiple parties asking for attention. A busy investigator may get queries from the CRO monitor, clinical operations, and sponsor management. Duplication (e.g. overlapping audits) can frustrate sites. Clear role definitions help avoid this: for example, a sponsor might agree that the CRO handles all routine monitoring so sites needn't prepare for both sponsor and CRO visits separately.

- **Accountability Gaps.** If contracts are not precise, important obligations can fall through cracks. A sponsor once learned this the hard way when a CRO did not return all unused IP as contractually expected. Luckily audit identified this before regulators did. In contrast, well-managed trials include detailed vendor oversight.
- **Regulatory Scrutiny.** Authorities have become stricter on ensuring sponsor oversight even with outsourcing. For example, FDA has warned that simply hiring a CRO does not discharge sponsor responsibilities ([2] www.opsvs.com). The new ICH E6(R3) guideline (2023) re-emphasizes sponsor accountability in the era of evolving trial designs. Sponsors must therefore invest in oversight processes (e.g. risk-based monitoring, vendor management programs). Sites should be audited as part of the trial master file.
- **Site Burden.** Investigators often cite administrative burden (paperwork, regulatory hurdles) as a hindrance to clinical research. Sponsors and CROs are trying to ease this by new technologies (electronic consenting, e-diaries) and by training. Nevertheless, any new procedure (e.g. an ePRO app) adds a learning curve for site staff and patients. The future will likely bring more patient-centered trial designs (remote visits, direct-to-patient shipments) which could either reduce or shift site workloads.
- **Decentralization and Tech Trends.** The COVID-19 pandemic accelerated **decentralized trial** models – for example, remote monitoring of sites, tele-visits with patients, and direct shipment of IP to patients. These trends will further blur roles: CROs may need to manage new vendors (home health agencies, video systems), sponsors must adapt oversight frameworks, and sites will use new platforms to report data. Embedded in all this is increased use of digital tools (AI risk assessment, electronic systems) to streamline operations. Sponsors and CROs must thus stay abreast of technology and guide sites in implementation.

Looking ahead, one can envision:

- **Enhanced Collaboration Platforms.** Integrated systems (cloud CTMS, eTMF, shared dashboards) that allow sponsor, CRO, and sites to see trial status in real time. Already, products like centralized dashboards (for enrollment, query resolution, safety) improve transparency and reduce redundant status requests.
- **Adaptive Oversight Models.** Risk-based and centralized monitoring continue to grow. Sponsors may rely more on CRO-run analytics to flag site issues, intervening remotely when possible. This can allow more efficient use of sponsor and CRO monitors during site visits.
- **Contract Innovations.** As outsourcing models diversify (full-service, functional, hybrid), contracts may become more outcome-based. For example, contracts might tie CRO payments to enrollment milestones or data quality metrics. Some sponsors experiment with consortium models (hosting multiple trials in a focused network of sites with an independent coordinating unit).
- **Patient-Centric Shifts.** Authorities (e.g. FDA, EMA) now encourage patient engagement. Sponsors might formalize roles for patient advocacy representatives in trial planning. CROs are developing services around patient support and engagement. Sites will likely get more tools to gather patient feedback and report quality-of-life data.

In all scenarios, the **core lesson** remains: clear understanding and documentation of "who does what" pays dividends. Disputes and inefficiencies often arise from ambiguous responsibilities. On the other hand, a well-orchestrated sponsor – CRO – site partnership yields faster recruitment, higher data quality, and ultimately swifter access to new therapies.

Conclusion

Clinical trials succeed only through coordinated teamwork. Sponsors, CROs, and sites each play indispensable yet distinct roles. Sponsors bring vision, funding, and ultimate oversight● – they ensure the trial is justified, ethical, and on track ([55] blog.cloudbyz.com) ([1] www.law.cornell.edu). CROs bring specialized execution capabilities – running day-to-day operations, handling logistics, and augmenting sponsor capacity ([8] pmc.ncbi.nlm.nih.gov) ([56] blog.cloudbyz.com). Sites bring patient access and conduct – directly enrolling subjects, administering treatments, and generating data ([13] blog.cloudbyz.com) ([5] ichgcp.net).

Trailblazing sponsors recognize that neither deep-pocket capital nor brilliant science alone is enough – they need reliable CRO partners and highly committed sites. By **defining responsibilities up front, aligning contracts with regulations, and fostering open communication**, all three parties can keep the trial on track. The quantitative evidence shows that when sponsors retain control but work closely with CROs and sites, a majority of trials meet their timelines and budget targets ([30] www.appliedclinicaltrialsonline.com) ([9] www.appliedclinicaltrialsonline.com).

As trials become more global and technical, these relationships will only grow in importance. Future landscapes – from decentralized trials to AI-driven monitoring – will require sponsors, CROs, and sites to adapt their roles. Nevertheless, the fundamental principle endures: a trial's success hinges on clarity of roles and the commitment of each team member. By comprehensively understanding **"who does what,"** the clinical research community can continue to protect participants and generate reliable evidence to advance medicine.

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