Advocating for Site Readiness:

Ensuring Clinical Sites Are Fully Supported and Recognized for the Time, Effort and Costs Associated with a Successful Clinical Trial Launch.

Study start-up is one of the most resource-intensive phases of a clinical trial, and sites complete dozens of tasks before participant screenings. When these steps are underfunded or overlooked, sites face delays and avoidable enrollment bottlenecks. Sponsors and CROs who understand the full scope of start-up work are better positioned to support timely activation and equitable study performance.

All activities listed below are considered a part of the study start up process.

1. Selection Process

Purpose: Identify and qualify sites capable of conducting the clinical trial.
The selection phase ensures the Sponsor/CRO chooses sites that can safely and effectively deliver the study. Thorough qualification activities reduce downstream delays and minimize protocol deviations by confirming staffing, capability, and operational fit before activation.

Activity	Definition	Comments
Confidentiality Agreement	Legal agreement to protect confidential information shared during trial planning.	Ensures sponsor and site are aligned on confidentiality.
Protocol Review & Database Query	Protocol Review: Site reviews trial objectives, methodology, and responsibilities. Database Query: Submission of feasibility or capability queries.	Supports feasibility assessment.
Feasibility Completion	Site evaluates patient population, staffing, equipment, and timelines.	Determines readiness to conduct the trial.
Site Qualification Visit (SQV/PSV/SEV)	Sponsor/CRO visits to assess site suitability for trial conduct.	Essential step prior to site selection.

2. Paperwork Process

Purpose: Ensure all regulatory, ethical, and contractual documentation is completed.
Without appropriate resources and compensation, these tasks create slowdowns that directly affect study timelines.

Activity	**Definition**	**Comments**
Regulatory & Essential Document Prep, Completion & Submission	Includes 1572s, CVs, licenses, lab certifications, and other required documents.	May include duplicate forms for sponsor submissions and or specific portals to access.

2. Paperwork Process (cont'd)

Activity	Definition	Comments
Ethics Documents Preparation & Submission	Submission to IRB/EC including protocol, informed consent, and recruitment materials.	Critical for study approval. Consider additional work associated with local IRB/EC.
Contract & Budget Review/Negotiation	Negotiation of Clinical Trial Agreement terms and financials.	May include hospital-specific fees, Coverage Analysis.
Rate Card Agreement – Coverage Analysis	Identifies standard-of-care vs research-related procedures and sets pricing.	Ensures billing compliance.
E-Signatures / Wet Ink	Signing documents per sponsor requirements.	Supports timely site activation. Additional system access or validation required.

3. Training Process

Purpose: Equip site staff and investigators with knowledge and readiness to execute the study.
Comprehensive staff and investigator training ensures protocol adherence, consistent execution, and participant safety. Sponsors benefit from reduced variability, fewer errors, and smoother oversight when sites receive adequate time and support for training.

Activity	Definition	Comments
Staff & Investigator Training	Training on protocol, study procedures, safety reporting, GCP.	May include multiple learning formats and portal accesses.
Site Initiation Visit (SIV)	On-site training and readiness assessment by sponsor/CRO.	Consider number of personnel needed for attendance.
Investigator Meeting (IM)	Group meeting for alignment on protocol implementation and expectations.	Travel expectations and/or virtual time to dedicate to IM.
Documentation: DOA & Training Forms	Delegation of Authority logs and staff training records.	Variability in forms of sponsor vs. site documentation.

4. Recruitment Process

Purpose: Identify and enroll qualified participants efficiently.
Pre-screening, chart review, and recruitment planning determine whether a site can identify appropriate participants quickly and equitably. Investing in this phase improves enrollment performance and ensures diverse populations are considered from the outset.

Activity	Definition	Comments
Pre-Screen	Early evaluation against inclusion/exclusion criteria.	Documented in pre-screening logs.
Chart Review	Review of patient medical records to identify potential participants.	Supports recruitment planning.

4. Recruitment Process (cont'd)

Activity	Definition	Comments
Recruitment Plan	Marketing strategy, promotional materials, scripts, AI vendor setup.	Ensures diversity and effective outreach. See Recruitment Initiatives for full scope of work.

5. Equipment & Vendor Management

Purpose: Ensure sites have the required tools, technology, and vendor support for study execution.
Study success depends on seamless integration of technology, labs, equipment, and third-party vendors. When sites have adequate support for system setup, onboarding, and troubleshooting, Sponsors avoid data errors, protocol delays, and rework.

Activity	Definition	Comments
Vendor Management	Selection, oversight, contract management, QA, and issue resolution for third-party providers.	Consider site-owned, sponsor-provided, or study-specific vendors when evaluating.
Site-Owned Technology	CTMS, Participant Payment, eREG, eSOURCE, eCONSENT, Marketing Platforms.	Consider site workflows and professionalism and avoid duplication of effort.
Sponsor-Directed Technology	eCOA, IWRS, Central Lab, Patient Engagement, EDC, eTMF, etc.	Number of systems/portals should be considered in start up fees.
Equipment Procurement & Management	Procurement, setup, validation, calibration, maintenance, and tracking of trial equipment.	Consider site-owned, sponsor-provided, or study-specific equipment when evaluating.
Pharmacy Set-Up	Preparation for investigational product handling, storage, accountability, and training.	Includes comparator medications and device management.
Lab Site Set-Up	Central/local lab readiness for sample handling and testing.	Consider additional costs when local lab set up is required.
HR & IT Support	Onboarding, training, and managing sub-contractors; system access and IT validation.	Consider specific roles/contractors needed as additional set up fee requirements.

A fully supported start-up process enables sites to activate faster, recruit more effectively, and deliver higher-quality data throughout the trial. When Sponsors and CROs recognize and adequately resource each component of start-up, they strengthen operational predictability and reduce barriers that disproportionately affect smaller sites or those serving diverse communities. Investing in start-up is ultimately an investment in trial success, participant safety, and equitable access.