



WHY IT MATTERS

Multi-site studies can accelerate recruitment and improve participant diversity, but success depends on strong coordination, oversight, and communication across sites.



SCENARIO

A grant is awarded to run an observational oncology study across three hospitals. The Principal Investigator plans to observe how patients respond to a locally registered cancer drug, prescribed as part of routine clinical care.



BEST PRACTICES TO ENSURE SUCCESS

1 APPROVALS, CONTRACTS & SITE READINESS



KEY ACTIONS

- ✓ Start contract discussions early for legal review to avoid delays.
- ✓ Align site budgets with recruitment targets (where applicable).
- ✓ Confirm each site can perform all protocol-required assessments to ensure complete data collection.
- ✓ Prepare site-specific ICFs and obtain all required IRB/regulatory approvals before study activities. This applies to subsequent protocol amendments.
- ✓ Conduct a Site Initiation Visit (SIV) only after contracts, approvals, logistics, and staffing are in place.
- ✓ Each site should maintain their own investigator files and study logs.

COMMON MISTAKE

Underestimating legal review timelines, preparing only a single informed consent form (ICF) for all sites.

2 OVERSIGHT, ACCOUNTABILITY & DATA MANAGEMENT



KEY ACTIONS

- ✓ Appoint a Site PI at every participating site.
- ✓ Define PI oversight and site accountability before study starts.
- ✓ Document roles and responsibilities using study delegation/responsibility logs.
- ✓ Finalize data requirements before database build.
- ✓ Establish data access controls and ensure research collaborative agreement (RCA) is in place.
- ✓ Establish clear logistic workflow and documentation for shipping of biological specimens or study supplies (where applicable) to and/or from main site.

COMMON MISTAKE

Unclear responsibilities and inconsistent data management across sites.

3 MONITORING, DEVIATIONS & SAFETY REPORTING



KEY ACTIONS

- ✓ Agree on the monitoring approach and plan (where applicable) with each site before study initiation. (Frequency, scope, model)
- ✓ Maintain complete, accurate, and audit/inspection-ready documentation.
- ✓ Report protocol deviations and non-compliance promptly.
- ✓ Ensure SAEs are reported according to institutional and IRB requirements. Respective Site-PIs can submit SAE on ECOS.

COMMON MISTAKE

No agreed monitoring strategy or reporting pathway.

4 MONITORING, DEVIATIONS & SAFETY REPORTING



KEY ACTIONS

- ✓ Facilitate good communication across sites to foster shared learning (e.g., enrolment strategies, navigating common pitfalls).
- ✓ Submit continuing review IRB study status reports on time.
- ✓ Archive study records according to institutional retention requirements.

COMMON MISTAKE

Poor communication during study conduct and incomplete close-out activities.



QUICK REMINDERS

- ✓ Follow your institution's policies and SOPs.
- ✓ Confirm whether additional regulatory approvals are required for your study.

Reference: [NHG Health PCR Standard Operating Procedures 501-A02 Responsibilities of the Research Team, 501-A03 Training and Education, 501-B03 Study Initiation, 501-B07 Study Conduct – Monitoring, 501-B08 Data Collection and Handling, 501-C05 UPIRTSO and Expected SAE](#)
[NHG Health Investigator's Manual Chapter 3: The Study Team](#)

Additional Readings: [ICH E6 \(R3\) Good Clinical Practice \(GCP\) Guideline Regulation of human biomedical research](#)

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental.
Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.