



14 NOVEMBER 2025
Hybrid Event

Strategic Role of Study Coordinator Early Phase Trials





Phase I/II – PK/PD, confinement, complex procedures, strict, timed and monitored closely

Start up:

- Maintain communication with Sponsor/CRO and ensure SQV is timely scheduled.
- Customization/collection of signature on local documents for submission.
- Identification/contracting of local vendors, i.e., lab, imaging facilities, other procedures: Echo, endoscopy/colonoscopy, ophthalmology.
- Ensure site facilities, equipment and supplies (i.e. lab kits, ancillary supplies (lab tubes, ePRO, etc.), medication (rescue/comparator) are available.
- Ensure maintenance of devices calibration documentation.
- Support medical team obtaining access to trial systems (i.e. CRF, IXRS, central lab etc) and have corresponding training performed before SIV.
- Organize recruitment KOM (PI, SI, recruitment team), shortly after the trial is submitted.
- Organize internal kick-off meeting before SIV.
- Assist CRA to organize SIV.



Trial conduct:

- Creation of source data templates, logs (lab, pharmacy).
- Creation of time schedule: intensive PK, vitals signs, ECG with strict timing related to dosing.
- Ensure enough supplies available, i.e. lab kits, ePRO, IMP.
- Organize logistics re subjects' visits, transportation to/from vendors, (i.e., labs (hsCRP) → X-ray → MRI).
- Maintain ISF, logs (enrollment, screening, delegation), ensuring inspection readiness.
- Assist medical team with safety reporting according to Sponsor guidelines and internal SOPs.
- Quality check (QC) of signed ICFs, completed source docs, eligibility.
- Track PDs.
- Timely eCRF/central vendor platforms completion and query resolution.
- Recruitment updates on internal tracking systems.
- Support monitoring visits, provide access to subjects' files, address queries and perform corrections.
- Hosts sponsor audits.



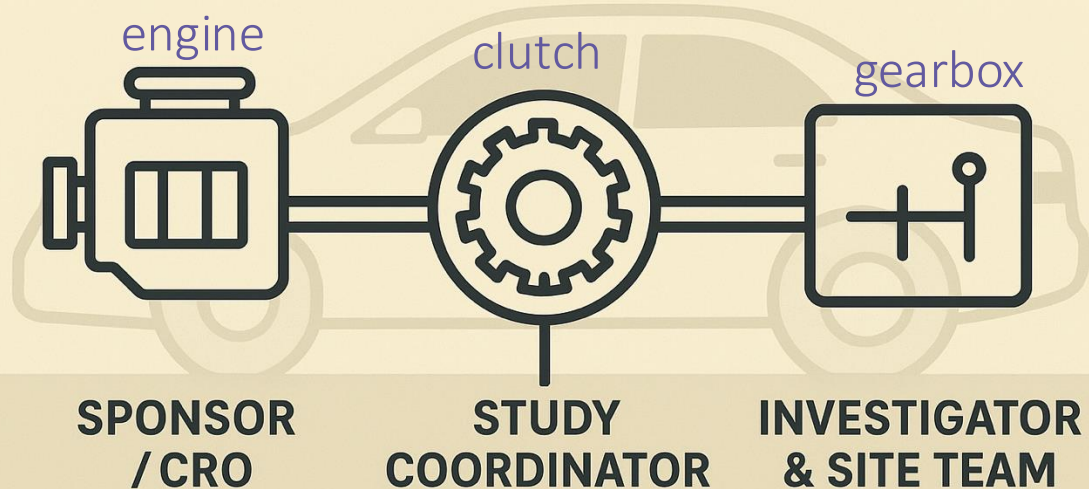
Close out:

- Ensure all CRFs and source documents are complete, accurate and signed off.
- Ensure ISF is complete and ready for archiving.
- Support close-out visits by Sponsor/CRO, coordinate final logistics (return/destruction of IMP, sample shipment).
- Archive all study documents per regulatory requirements.



Conclusion: The study coordinator plays a pivotal role in the success of a clinical trial

CLINICAL TRIAL



Clutch (study coordinator):

👍 trial runs efficiently, data flows, timelines are met

👎 engine revs but car does not move – i.e. sponsor pushes resources, site doesn't deliver results