Bioequivalence Study Management

Type of Study	Timelines
Fasting study	Pilot Study: 3 to 4 months
	Pivotal Study: 4 to 5 months
Fed study	Pilot Study: 3 to 4 months
	Pivotal Study: 4 to 5 months
Steady state (Multiple-dose) study	Pilot Study: 4 to 5 months
	Pivotal Study: 5 to 7 months

Key Activities for BE Study:

1. Review and Approval of Study Documents drafted by CRO

- Project contracts, protocol, consent form, case report form, insurance documents, Ethics committee and clinical trial application dossier, statistical analysis plan, clinical study report

2. Conducting Monitoring Visits

- Visits are conducted before, during and after the trial; as per ICH-GCP, it is the responsibility of the sponsor to ensure the trial is adequately monitored.
- Both Clinical and Bioanalytical phases are monitored; for the Bioanalytical phase, it is performed in accordance with the principles of GLP and EMA's Guideline on Validation of Bioanalytical Methods

3. Evaluation of PK/PD results

- Thorough review of PK data generated from the pilot study is crucial as the design of the pivotal study is based on the PK data from pilot study
- Pharmacokinetic data from a pivotal BE study needs to be reviewed diligently as the success of the BE study is dependent on this PK data.

4. Strong Link Between the Sponsor and CRO/Vendor

- To fill in the gaps and ensure high quality of the overall project

5. Oversight of the Study

- Overview of all activities managed by the CRO/vendor to ensure compliance with the study protocol, GCP, and applicable regulatory requirements

6. Final Audit Visit and Managing Regulatory Inspections

- To ensure accuracy of the generated study data and the process applied
- Preparing responses for the pre-study and/or post-study regulatory queries

How ELC can support your project

ELC can offer oversight and project management, thereby accelerating the overall clinical development of the drug. We offer:

- Designing bioequivalence study synopsis
- Managing bioequivalence, therapeutic equivalence PK/PD, Phase I to IV studies
- CTA preparation and regulatory filing
- Drafting and review of study documents
- Site feasibility and site initiation
- Clinical trial monitoring
- Audits
- Managing the role of a Medical and Safety expert; Responsible person (required in Europe)