

Site Preparation Process

- Capacity building at sites.
- Training site staff in ICH GCP and study procedures.
- Training the site staff on protocol specific issues.
- Developing site work processes.
- Equipping sites.
- Developing source document templates (language translations).
- Implementing and training staff in practical site Standard Operating Procedures.
- Refining the site profile specific to the particular project.
- Developing communication plans.
- Developing and implementing quality systems.