

Clinical Trials Data

EDC Systems

- Electronic Data Capture
- eCRFs (electronic case report forms)
- Real-time data validation
- Audit trails

CDISC Standards

- SDTM (Study Data Tabulation)
- ADaM (Analysis Data Model)
- CDASH (data collection)
- Regulatory submissions

Data Monitoring

- Data Safety Monitoring Boards
- Interim analyses
- Stopping rules
- Adverse event tracking

EHR Integration

- Recruitment from EHR cohorts
- Automated eligibility screening
- Pulling baseline data
- FHIR for trial data exchange