

Data management tasks

Draft and maintain data management plan

Case report form (CRF) development

CRF design, review and approval

CRF printing and distribution (paper studies)

Develop, assemble and distribute CRF completion instructions

Electronic data capture (EDC) (including electronic diaries and other eRPO devices)

Develop design specifications

Site assessment, provisioning and training

Design and validate EDC system

Deploy system and support end-users

License fees (if applicable)

EDC help desk support

Database development

Design, test and implement database

Annotate CRFs

Set-up and maintain medical coding dictionaries (e.g., AEs, concomitant medications, medical history, etc.)

Documentation of database design and edit checks (range checks and cross form logic checks)