

Transforming data into validity



Key Facts Data Management

- from local survey to complex multinational clinical trial
- paper- or electronic data capture (EDC) based
- validated data management system (postgreSQL data base)
- 21 CFR Part 11 compliance
- full compliance with the study protocol and sponsor's SOPs
- medical data review and coding performed by medical doctors
- tailor-made data validation, listings, reports, eCRF training, helpdesk



Services (1) Data Management

database and documents

- eCRF design (web- and/or app-based)
- CRF design (paper-based)
- ePRO / eDiary
- process documentation:

 data management plan
 structure plan
 data entry guidelines
 data validation plan
 user manuals
- project-specific database:

 installation
 programming
 validation
 maintenance
 audit trail

- tailor-made status reports
- continuous quality assurance
- user account management

data entry

- CRF tracking
- single/double data entry
- reconciliation of data entry
- external data import (e.g. lab, ECG, app)



Services (2) Data Management

data cleaning

- AE / SAE check of (e)CRFs
- reimbursement criteria check
- general and medical data review
- query management
- SAE reconciliation
- database lock

EDC helpdesk

sites / monitors / sponsor

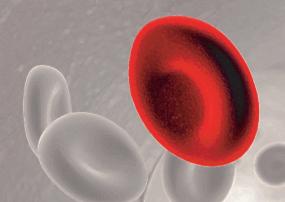
medical coding

- MedDRA
- WHO-DD
- ATC

data transfer

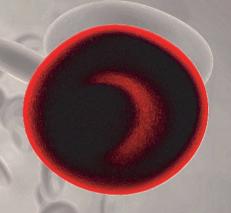
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