

The background of the slide is a microscopic view of blood cells. It features several red blood cells, some appearing as bright red discs and others as greyish, semi-transparent structures. The cells are scattered across the frame, with a higher concentration in the center and bottom right.

# DATA MANAGEMENT

Transforming data into validity



GKM

Gesellschaft für  
Therapieforschung mbH

# 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

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

## EDC helpdesk

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- sites / monitors / sponsor

## medical coding

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- MedDRA
- WHO-DD
- ATC

## data transfer

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- format as requested





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