

What kind of data is collected

In Clinical Data Management (CDM), the goal is to collect accurate, complete, and reliable data that reflects everything happening to and around a clinical trial participant. Here's a breakdown of the key types of data collected:

DATA COLLECTED IN CLINICAL DATA MANAGEMENT



Demographic Data
Age, gender, Race/ethnicity



Informed Consent



Baseline Data



Efficacy Data



Safety Data
Adverse Events, Lab results



Treatment & Medication Data



Visit and Procedure Data



Coding & Classification Data



Outcome Data

1. Demographic Data

- Age, gender, race/ethnicity
- Weight, height, BMI
- Relevant medical history

2. Informed Consent

- Confirmation that the participant voluntarily agreed to join the trial
- Date of consent, version of the consent form

3. Baseline Data

- Initial clinical and laboratory values before treatment begins
- Used to compare against post-treatment outcomes

4. Efficacy Data

- Data related to how well the treatment is working
- Examples:
 - Symptom scores
 - Tumor size changes
 - Blood pressure or glucose level changes

5. Safety Data

- Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Lab test results (e.g., liver function, blood count)
- Vital signs, ECGs

6. Treatment & Medication Data

- Dose, frequency, route of administration
- Concomitant medications (other drugs taken)
- Compliance (did the patient follow the regimen?)

7. Visit and Procedure Data

- Scheduled vs. actual visit dates
- Procedures done (e.g., imaging, biopsies)
- Missed or delayed visits

8. Outcome Data

- Final trial results (e.g., improvement, no change, withdrawal)
- Survival data or time-to-event data

9. Coding & Classification Data

- Coded terms for medical conditions and drugs (e.g., using **MedDRA**, **WHO-DD**)

10. Case Report Forms (CRFs)

- All of the above are entered via CRFs (paper or electronic)
- CRFs are structured tools used to capture trial data