

## Key users of Case Report Form:

The Case Report Form is an essential tool in clinical trials used to collect detailed patient information. Accurate and complete data recorded in the Case Report Form ensures the reliability of trial results. Many people involved in the trial depend on the Case Report Form to perform their tasks and maintain the quality and integrity of the study. The following stakeholders mainly use the Case Report Forms for the reason described:

- **Principal Investigators and site staff:** They record the participant's data on the Case Report Form from the source documents during the trial
- **Data entry personnel:** Responsible for entering the collected data into electronic databases
- **Monitors / Clinical Research Associates and auditors:** They review or verify Case Report Forms to ensure data accuracy and compliance with the protocol
- **Sponsors:** Use Case Report Forms to analyze data and evaluate the safety and effectiveness of the treatment
- **Data Managers:** They validate the clinical trial data for accuracy and consistency ensuring the information is complete and reliable for analysis
- **Medical Coders:** Translate clinical terms into standardized codes in the Case Report Form for proper categorization and analysis
- **Statisticians:** Use data from Case Report Form for statistical analysis

## Case Report Form Amendment

A Case Report Form is typically amended when changes are needed after the clinical trial has started

### **This can happen if:**

- The study protocol is updated such as adding new procedures, endpoints or if there is a change in eligibility criteria, assessment schedule or timing
- New safety information becomes available
- Inconsistencies or errors are found in the data collection process. In this case the Case Report Form may be revised to clarify questions or improve formatting
- Any changes recommended by Ethics Committee or Regulatory Authority