

Case report form [CRF]

A case report form is a paper or electronic data entry form used in clinical trials. It is used by sites taking part in clinical trials (such as hospitals) to collect data about each trial participant. All the data on each individual taking part in a clinical trial, including information on adverse events, are held in the case report form.

A case report form is developed specifically for each clinical trial so that all the data needed to answer the research question is captured. The organisation running the trial is responsible for designing a case report form in line with the protocol of the trial. They must also monitor and audit the data that is collected to ensure it is complete and accurate.

Personal data such as, the patients' names, medical record numbers, and any other identifying information are usually not disclosed in the CRF's. Each patient is instead given a unique identifier.