

FAQ: How are Source documents, study worksheets, and case report forms (CRFs) similar and different? A comparison of purpose, creation, and use.

To clearly understand the data generated during a clinical research study, it's important to differentiate between source documents, study worksheets, and case report forms (CRFs), as well as their purpose, creation, and use.

Source documents serve as the original record and are considered the source of truth for observations, clinical findings, or data generated about an individual during their participation in a clinical study. These can include medical records, laboratory reports, memoranda, subject diaries, study questionnaires/surveys, pharmacy records, recorded data from automated/diagnostic instruments (x-rays), signed consent forms, eligibility checklists (inclusion/exclusion), photographic negatives, microfilm. Source documents contain the data that gets transcribed into a CRF. The purpose of source documents is to:

- Confirm complete and accurate data collection
- Provide an audit trail to permit investigation if and when required
- Provide evidence and support of protocol adherence, and subject oversight
- Verify that data reported on the CRFs is accurate

Study worksheets (either paper or electronic) can be created to facilitate original recording of study data. A study worksheet can be tailored specifically to the study. Study worksheets that contain information and data constitute a source document.

Case report forms (CRFs) are forms, either paper or electronic, designed to capture all protocol-required information to be reported to the sponsor on each clinical trial participant. CRFs facilitate complete and standardized data collection that promotes efficient processing, analysis, and reporting of study results. Data reported on the CRFs is derived from source documents, and should be consistent with source documents. However, direct entry of data onto the CRFs is also permissible per the September 2013 FDA Guidance on Electronic Source Data in Clinical Investigations. Direct data entry into CRFs should only occur with sponsor approval and when it has been pre-specified in the study protocol, the study manual of operations or other study procedural document. When entering data directly into CRFs, extra care must be taken to ensure data is entered accurately.

In summary, source documents, study worksheets, and CRFs are all important components of clinical research studies. Source documents provide the original record of observations or data generated during a study, study worksheets facilitate original recording of study data, and CRFs provide a standardized way to collect and record protocol-required information. By utilizing these documents correctly, researchers can ensure accuracy, completeness, and efficiency in the data collection and analysis process.