

## Guidance on Source Documents

*Source Documents are original documents, data, and records. Source Data is all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.*

The following are commonly used as source documents. They are generally found in the medical chart (also known as medical records, hospital records, clinic charts, and office charts):

### Examples of Source Records:

- Progress Notes, including nurse's notes, patient visit notes, and physician notes.
- Certified transcription of recorded results including dictation.
- Instrumentation printouts: spirometry, ECG, etc.
- Photographic negatives or photographs.
- Radiology reports, Images (usually on CD's): X-rays, CT's, MRI's, PET scans, etc.
- Videos: angiography, endoscopy, etc.
- Laboratory reports
- Diagnostic evaluations or rating scale documents
- Participant diaries, quality of life questionnaires
- Protocol Waiver/Deviation Forms
- Pharmacy records
- Cardiology reports
- Records at medico-technical departments supporting a trial such as past medical history and physician records
- Signed Informed consent form

- Patient-related clinical documentation includes: phone contacts, clinical correspondence with sponsor
- Chemotherapy and medication flow sheets

**Note:** Use of self-stick, removable notes is not recommended as source documents. However, if they are used they must be signed and dated by the originator of the note and affixed to the source page with tape.