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A Guide to Source Data Extraction and Verification

Clinical trials are conducted in order to determine if new medical devices or pharmaceuticals prove safe and effective, and to support marketing decisions. Inaccurate data collection can cause trials to miss their study objectives and/or statistical analysis goals, or worse, can provide erroneous data that physicians rely on to treat the public.[1] Ensuring proper data extraction and source data verification is paramount to ensuring data integrity and subject safety in a clinical trial. Understanding that source data may be located in a multitude of areas within a medical chart is one of the first steps to ensuring accurate data collection in a clinical trial. It is crucial to remember that there is no one-size-fits-all approach to extracting and verifying source data.

What Makes Up a Medical Chart?

A medical chart can consist of a variety or sources including case notes, nursing records, anesthesia records, administration records, laboratory records, pharmacy records, registries, and numerous other forms of documentation.[2] As noted in 21 CFR 312.68b and 21 CFR 812.140, progress notes of the physician, hospital charts, and nurses' notes are just a few examples of what record-keeping and retention are required by Investigators. Understanding where to locate these different types of records while reviewing data can be challenging. Frequently, data can be buried within multiple levels of records and if these are not properly reviewed, potential inaccuracies, unreported adverse events, and other discrepancies may occur. As Electronic Medical Records (EMR) continue to develop, it is crucial that those collecting and verifying data understand the types of source that should be available in order to request adequate access within the system(s).

The following table describes the types of source available in medical charts and why each is useful.

TYPES OF SOURCE	USE
Nursing Notes: notes written by a nurse encompassing all aspects of patient care planned, given, or communicated.	These can be used to identify potential adverse events, clarify certain data points (intake/output), and give an overall impression of patient care and safety.
Operative Reports: a report written in a patient's medical record to document the details of a surgery and is usually dictated immediately after surgery and transcribed later.	Illustrate how the operation was conducted and also can enhance transparency into complications, anatomical measurements, and important device accountability and reconciliation. It can also detail the order of an operation in regards to adherence to Instructions for Use (IFU) or protocol requirements.
Intra-operative Reports: also known as perioperative and generally refers to the three phases of surgery: preoperative, intraoperative, and postoperative.	These can be used to gather data points such as ASA (American Society of Anesthesiologists) status, devices used, outcome measures and many other forms of source documentation.
Anesthesia Record: a written or electronic account of drugs administered, procedures undertaken, and physiologic responses noted during the course of surgical or obstetric anesthesia.	Can fall under intra-operative reports and usually the most accurate source regarding vital signs, medications given, blood loss, and other factors maintained during an operation involving anesthesia.
Laboratory Reports: usually consist of ranges and values involving a multitude of different tests associated with blood, urine, and other types of collection.	Used for lab data points and can reveal potential adverse events if out of expected norms and allowing better transparency into certain conditions (renal function, liver function, etc.).
Diagnostic Reports: a report that can show results from diagnostic tests such as an x-ray, MRI, or ultrasound.	Often used to include or exclude participation in a research study as well as adverse event reporting and overall status of condition.
Discharge Summaries: the primary documents communicating a patient's care plan to the post-hospital care team and usually accompanies the subject to the next level of care.	Can help summarize overall patient care and stay and can provide insight into a patient's condition if transferred to a long-term care facility or home-care nursing.

Medical Terminology

Understanding the fundamentals of medical terminology can aid a clinical researcher in review of medical records and source data extraction/verification. Most of the medical terminology is derived from Latin or Greek and can be broken down into three different parts: prefix, root, and suffix.[3] As an example, the word myocarditis can be broken down into its three basic parts: the prefix “myo”, the root “card”, and the suffix “itis”. Further, “myo” meaning muscle, “card” meaning heart, and “itis” meaning inflammation can be combined to form myocarditis which is defined as inflammation of the heart muscle. If a researcher decided to review a dictation and the suffix of this word was changed to “megaly” but the root word stayed the same (forming cardiomegaly), that researcher should be able to deduce that the word relates to a heart condition. Having a firm grasp on medical terminology can provide a more thorough and accurate chart review. A few examples are in the table below.

PREFIX	ROOT	SUFFIX
Myo (Muscle)	Card (Heart)	Itis (Inflammation)
	Card (Heart)	Megaly (Enlarged)
Osteon (Bone)	Myelo (Marrow)	Itis (Inflammation)

Scenario 1 provides an example for why a clinical researcher would have to combine their knowledge of medical terminology with an understanding of what records should be available and reviewed as part of the medical chart in order to adequately report data in accordance with a protocol.

Scenario 1

A research coordinator on an orthopaedic study for a hip replacement device notices that one of the progress notes for a subject includes a diagnosis of myocarditis and osteomyelitis. The protocol dictates that only adverse events related or possibly related to the hip procedure and/or device need to be reported. Considering myocarditis as an inflammation of the heart muscle, the initial reaction might be that this event is unrelated to the device and procedure and therefore is not an adverse event. In regards to osteomyelitis, understanding that the word osteomyelitis with the prefix "osteon" meaning bone, the root "meylo" meaning marrow, and suffix "itis" meaning inflammation; one might conclude this is a potential adverse event and related to the orthopaedic surgery or device.

It is important to note, however, that understanding medical terminology, a great resource to have, can only help direct the researcher down a quicker path to discover potential adverse events. Caution should be exercised though because further investigation is usually warranted. The physician would ultimately need to make the decision on the reportability of these potential adverse events. For this example, the physician determined that myocarditis was possibly related to the procedure as this subject was exposed to staphylococcus during surgery. The diagnosis of myocarditis was the primary diagnosis and interestingly, osteomyelitis, the secondary diagnosis, was caused by the primary diagnosis of myocarditis. The physician determined that osteomyelitis was a symptom of myocarditis and that the infection spread from the heart into the bones. This scenario illustrates why the full medical chart must be reviewed prior to drawing conclusions.

Source Documents

According to 21 CFR 312.62(b) and 21 CFR 812.140, "source data includes all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation."[4] Another definition of source data taken from ISO 14155:2011 describes that a source document is a printed, optical, or electronic document and examples include: hospital records, laboratory notes, device accountability records, photographic negatives, and several others. When reviewing clinical trial data, the source can be found in many different areas such as Case Report Form worksheets, site-created worksheets, and medical records (as described previously). Many times, the same data point can be found in several different areas of the trial records with either the same result or conflicting results. It is critical to remember that source data is where data was first recorded, written, or captured. This data could be captured on a napkin, a sticker, on an operative report, directly into an EDC system, and numerous other locations. Additionally, source should be attributable, legible, contemporaneous, original, and accurate (ALCOA). As an example, Scenario 2 describes a clinical research coordinator looking to find how many units of heparin were given during a surgical procedure. Data can be recorded in more than one location in the medical record and this example illustrates how it may be difficult to determine which data point is the source (the first place written down) and which data point is accurate.

Scenario 2

The research coordinator reviews the operative report revealing 8,000 Units were given, the anesthesia record showing 10,000 Units were given, followed by the intake and output report indicating 8,000 Units of heparin were given. Typically the anesthesia record is the most accurate record to obtain heparin dosage, but with the information available, the research coordinator will need to investigate further.

OPERATIVE REPORT	ANESTHESIA REPORT	INTAKE/OUTPUT REPORT
8,000 Units	10,000 Units	8,000 Units

If the research coordinator only reviewed the operative report would the data for the clinical trial be correct?

Source data verification is much more than locating a data point on a Case Report Form and then trying to match this to a data point to the medical record. Actually, this process could validate very little in regards to accurate source data. Reviewing the medical records first as the researcher did in scenario 2 and then reviewing Case Report Forms and data points creates a better avenue for the researcher to conduct source data verification. The next scenario illustrates how reviewing source data before Case Report Form is the better process for source data verification.

Scenario 3

The monitor is reviewing the Case Report Form that requires a data point for a device lot number. The Case Report Form lists the lot number as 1256 and the operative report matches the Case Report Form. The monitor sees that they match and decides to move onto another data point. Is this a thorough enough review of the data to determine the lot number is accurate?

Actually, reviewing further, the intra-operative report listed a lot number of 1265 and the paper study chart contained a hand-written nursing note with the device sticker attached, also documenting a lot number of 1265. The nursing note, specifically the device sticker, is the true source document in this case. Therefore, the data point should be queried and changed to match the true source.

CRF	OPERATIVE REPORT	INTRA-OPERATIVE REPORT	NURSING NOTE/STICKER
Lot Number: 1256	Lot Number: 1256	Lot Number: 1256	Lot Number: 1256

Operative reports and any other dictated reports should be used with caution. Although usually correct, operative reports begin as dictations and can be inaccurate due to transcription errors and poor memory, especially with numbering.

Best Practice

While reviewing Case Report Forms and what is listed in an EDC system is necessary for data review, looking at these data points prior to review of source data may hinder accuracy. Best practice strategies should include review of the EMR and all recorded source first. If the aforementioned research coordinator looked through the medical chart first in Scenario 3, that research coordinator may have noticed those lot number discrepancies and the Case Report Form may have been completed accurately. In doing so, the monitor may have then verified accurately. This scenario shows an example of how both the research coordinator and the monitor were insufficient in their data review and how applying best practice techniques rather than data point pursuit could have prevented error. Reviewing all medical records and not just a few various progress notes is not enough for good data extraction and verification.

Conclusion

Reviewing a medical chart can be a daunting task for anyone on the research team. Finding and understanding ways to help facilitate accuracy of data extraction such as having a sound understanding of medical terminology can be a way to reduce errors. Thorough review of all reports, records, notes, and other subject information is another way to protect the subject. Realizing that a data point can be found in more than one location is a fundamental skill for a research professional to illicit. Utilizing critical-thinking skills to review data in the EMR first prior to EDC review can allow the researcher to find and correct errors before knowing there was one.

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