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Short Communication

Good Documentation Practice in Clinical Research

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One of the most common inspection findings in investigator site inspections is lack of reliable, accurate and adequate source documentation. This also happens to be the most common pitfall identified during sponsor audits. The importance of good documentation practice needs to be emphasized to investigator sites to ensure that the study results are built on the foundation of credible and valid data. This article focuses on the key principles of good documentation practice and offers suggestions for improvement [1].

Inadequate/misguided case histories shape the second maximum normally cited deficiency in US-FDA inspections of medical investigator sites.

To recognize the importance of appropriate supply documentation we need to first evaluate the motive of supply documentation. The maximum crucial motive of source documentation in a scientific trial is to reconstruct the trial because it occurred. It has to permit an unbiased observer to reconfirm the statistics. Documentation ought to be such that it could offer audit path to allow investigation if and while required. Source documentation is the scientific document of the problem earlier than, in the course of and after the trial. It's far the device which confirms the eligibility standards of the difficulty inside the given trial.

It documents the progress of the difficulty from consenting until the problem completes the examine. It records the duty of the investigational product allotted, ate up and back by using the problem. It serves because the whole clinical report of the difficulty as the reference to the treating health practitioner at any point of time.

In the end it paperwork a strong foundation for the statistics that receives transcribed into a CRF which in the end receives translated right into a medical observe document. Regardless of medical trial, correct documentation helps the fundamental principle of shielding difficulty's rights, safety and nicely-being. There cannot be two thoughts to emphasize the need for reliable and high-quality documentation [2].

Roots of appropriate documentation standards are in the ICH-GCP wherein source records and source document is first defined. All information in unique statistics and certified copies of authentic facts of scientific findings, observations, or other sports in a medical trial essential for the reconstruction and evaluation of

The trial supply information is contained in supply documents (original data or licensed copies).

unique documents, information and facts (e.g., health center statistics, scientific and office charts, laboratory notes, memoranda, subjects' diaries or assessment checklists, pharmacy meting out statistics, recorded facts from computerized contraptions, copies or transcriptions licensed after verification as being correct copies, microfiches, photographic negatives, microfilm or magnetic media, X-rays, concern documents, and information kept at the pharmacy, at the laboratories and at medico-technical departments involved inside the medical trial). Key attributes for correct documentation were first described by US-FDA within the shape of ALCOA -attributable, legible, contemporaneous, unique and accurate. these also are adapted by way of international health enterprise (WHO). These criteria advanced with time. EMA has introduced some greater 'letters' to explain qualities of excellent source documentation particularly for digital documentation [3].

The attributes defined by way of special authorities together are:

It ought to be clean who has documented the facts.

Readable and signatures identifiable

The records have to be documented in an appropriate time frame along with the float of events. If a medical observation cannot be entered whilst made, chronology needs to be recorded. Suited amount of postpone should be described and justified.

Authentic, if now not original ought to be genuine replica; the primary file made through the correct man or woman. The investigator should have the original supply file.

Easily available for evaluation of treating physicians and for the duration of audits/inspections. The documents need to be retrievable in reasonable time.

The data have to be sponsored up with the aid of proof.

Interestingly, it must be referred to that the Drug Controller preferred India (DCGI) could emphasize on the condition in addition to the completeness, legibility and accessibility of investigator source information document as mentioned in DCGI's guidance document for inspections [4].

'Failure to preserve good enough and correct case histories that file all observations and different data pertinent to the investigation on every individual administered the investigational drug or employed as a manipulate within the investigation [5].

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Supply documentation should exhibit the ALCOA and different attributes as defined by way of regulatory authorities and GCP. Source documentation associated findings are the most commonly mentioned during inspections and audits. PI's commitment and involvement inside the trial makes a huge difference. Efforts to educate the websites, understand the web sites practices right from the pre-examine visit and non-stop monitoring and training could certainly help in improving and maintaining the first-rate of site supply documentation practices. In the end the source document ought to speak for itself. It need to narrate the clinical journey of the patient as it took place to an independent observer-an auditor or inspector and accordingly shape a sturdy basis for an awesome medical studies.

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