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eSource in Clinical Research

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ABSTRACT

This topic of eSource came to my mind from my experience in Clinical Research/ Pharmaceutical Research while conducting clinical trials at different sites. Whenever a site conducting trials then this site will be in need for a data documentation system to document and store the data that is being created and establishing from the clinical trials that are being conducted. This data documentation system is called Source. However, the Source could be electronic Source as in eSource or not electronic as in Paper Source. I have used both the eSource and the Paper Source. This Symposium presentation will show the advantages of the eSource in the Clinical Research.

Keywords: eSource; Clinical Research

eSource in Clinical Research

INTRODUCTION:

Within the rapid and fast pace in the recent years in businesses in general and for the purpose of clean environment then electronic approach and electronic administration is being more dependable and more useful in safe time, store data, reminding tasks, and analyze.

In clinical research, using eSource to replace paper source would save time, store data, use data in multiple purposes, and search or looking for data easily. The eSource would support the purpose of the clean environment by applying paperless perspective. The eSource would make any site that is conducting trials to use less actual physical spaces so fewer physical spaces will be needed.

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IMPLEMENTATION AND APPLICATION

Per OneStudyTeam, eSource is easy-to-use and secure, and is recommended method for the purpose of capturing data in one, central place (OneStudyTeam, no date).

According to Andrea Bastek, Ph.D., Senior Director of Innovation at Florence, FDA is supporting eSource by stating that "in an effort to streamline and modernize clinical investigations this guidance promotes capturing source data in electronic form". So, FDA is advocating the usage of eSource because by doing so then clinical trials can be run faster than the paper source clinical trials (Andrea Bastek, no date).

According to Advarra "Processing paper forms can create many obstacles for your clinical trial team, including added labor hours and increased risk of errors. Gathering data digitally with eSource decreases operational costs, improves the participant experience, reduces study delays, and elevates the quality of the information your staff collects. Staff can easily collect data using a PC or a tablet, which can also result in more time to spend with participants" (Advarra, no date).

Implementing eSource in a site that never used Paper Source as it is new established site can be smoother and easier than old already established sites. Implementing the eSource in sites that already have been using Paper Source could be challenging and many obstacles can be faced so such implementation of the eSource in old sites has to be gradually and strategically especially when it comes to transferring data from Paper Source to eSource in which Data Migration might be needed. Data Migration has to be done carefully and responsibly because losing data while processing Data Migration is very common.

ADVANTAGES

Advantages of using eSource would be reducing the time of the Data Capture, increasing source Data Quality, reducing payment cycle time, minimizing onsite monitoring visits, availability of the remote access, organizing documents and enhancing financial performance.

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