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Detailing key considerations and challenges of EDC in terms of implementation and statistical aspects

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Worldwide, in the past few decades the emerging incorporation of electronic systems has accelerated rapidly. We witness many official services; like banking or government services, and others like shopping or even gambling that have moved on-line, yielding huge efficiency gains for suppliers along with improved customer experience. The question that we should ask is "Where does the clinical trials industry incorporate in that sense?" or being more specific, "How does the implementation of an EDC system affect the clinical trial working procedures?" We will start by reviewing the FDA prospective on eSource as a means of clinical data collection followed by examples of electronic data originators. Then continue by giving an overview of the modified data collection and handling procedures and presenting the existence of data element identifiers driven by EDC deployment. When considering EDC implementation there are still barriers to be overcome, all of which can be categorized into the following: high upfront cost, lack of technical knowledge and resistance to change. On a personal note, in my lecture I will try to address these issues by presenting the available types of EDC systems in the market today. Trying to address the economic considerations via a case study describing a full EDC implementation in addition the two last sections will be dedicated to the importance of statistical knowledge when designing an eCRF. Finally, I will conclude by intriguing future availabilities in terms of statistical process control. Incorporating such controls into the EDC system could detect real time unusual data variations and deprive the loss of statistical power.

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