IOSR Journal of Research & Method in Education (IOSR-JRME)
e-ISSN: 2320–7388, p- ISSN: 2320-737x Volume 12, Issue 6 Ser. IV (Nov. – Dec. 2022), 01-08
www.iosrjournals.org

Comparison Of Electronic Data Capture With Standard Data Capture Method In Clinical Trials.

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Abstract:
Pharmaceutical companies, over a period of time, have tried to use innovative and ultramodern technologies for hastily and more effective methods of clinical data capture and analysis. In the present scenario, Electronic Data Capture (EDC) is considered the favored technology that can provide significant benefits over existing manual styles. This article highlights the crunches of the traditional data capture method and discusses the advantages of using EDC for better data quality, enhanced performance and productivity, and demoted expense in clinical trial management. EDC is the future mantra for clinical trials and all stakeholders should face stinks of infrastructure, technology, regulations, and training to frame it a success. Traditionally, clinical research studies depend on collecting data with case report forms, which are later entered into a database to produce electronic records. Although well-established, this system is time-consuming and error-prone. EDC solutions have the capability to produce analogous data delicacy compared to paper-based methods. This study found that if EDC is well designed and implemented with care, and work processes are adjusted to EDC, it will become a more time-efficient, potentially more accurate, and thus cost-effective method than the traditional paper-based data collection method. Overall, the benefits of EDC systems for clinical trials far outweigh the challenges.

Keywords: *Electronic Data Capture (EDC), Data Capture, Traditional Data Capture*

Date of Submission: 02-12-2022 Date of Acceptance: 14-12-2022

I. Introduction:

An electronic data capture (EDC) system is a computerized system designed to collect in an electronic format to be used mainly in clinical trials. EDC is a replacement for the standard data collection method as it streamlines data collection and enhances the turn-around time for medical devices and drugs to flow through the market [5]. Conventional data collection for clinical trials contains paper-based case report forms but in recent days advanced technologies have made this process easier by using this electronic data capture method. In this, we do not need any pen paper or anything and data will be organized. The major advantage of the EDC can check, enter, review, and analysis of data, and by this process, data quality is also maintained. In the USA and Europe EDC is used to protect data and data interchange. Electronic signatures are trustworthy, reliable, easy, and equivalent to paper records. Software and systems involved in the EDC method ensure the authenticity, integrity, and confidentiality of electronic records rather than paper records. This review paper compares the performance between the Standard Paper-based data collection method and EDC (Electronic Data Collection). The cost of the EDC software varies from place to place. It depends on the quality and the advanced features in it. Depending upon the data forms and fields its approximate cost is around $4200. EDC system market in the USA- EDC use increased daily in the USA. In 2016, the global market size was valued at around USD 349.8 million. It is increasing day by day. The standard data capture method is the traditional process of data collection. It includes paper-based data collection. It is a time-consuming and error-prone data-collecting process[5]. Traditionally, clinical research studies calculate on collecting data with case report forms, which are later entered into a database to produce electronic records. Although well-established, this system is time-consuming and error-prone. This study compares four electronic data capture (EDC) styles with the conventional approach with respect to the duration of data capture and delicacy. It was performed in a West African setting, where clinical trials involve data collection from urban, rural, and frequently remote locations [5][8].

Traditionally, clinical research studies rely on collecting data with case report forms, which are subsequently entered into a database to create electronic records using a standard data capture process. Although well-established, this method is time-consuming and error-prone. Electronic Data Capture (EDC) system is software that stores patient data collected in clinical trials. Data is typically first recorded on paper and is then transcribed into the system and saved in an electronic case report form (eCRF).EDC solutions are widely

adopted by pharmaceutical companies and contract research organizations (CROs).[5],[2],[3] The EDC system is considered to be the same as the eCRF. There is no law or regulatory obligations to use EDC in clinical trials. There was a time when EDC was not used in clinical Trials [1]. At that time paper methods were used in Clinical Trials but as time passed new technologies came on track and nowadays EDC solutions are the best option. Firstly EDC minimizes the hassle of paper writing forms and shipping these paper forms. Secondly, EDC software handles the data cleaning process, so that data managers can easily review the data and make changes if there is anything wrong. Thirdly, EDC provides high data security, confidentiality, and accessibility since it has advanced mechanisms to manage and access data traceability. Some of the best EDC software systems widely used are Rave from Medidata, Inform from Oracle, and Trial Master from Anju Software. Today, most clinical trials use electronic data capture software. There are three primary categories of EDC software users: sites, sponsors, and CROs.EDC systems are beneficial for late-phase (phase III-IV) studies, pharmacovigilance, and post-market safety surveillance, thereby becoming a solution to many underlying problems in this industry[1], [4], [5].

The utility of short-term statistics for analyzing the economic cycle and impacting economic and financial policy is highly dependent on their timeliness. Of the steps that may be taken to ensure punctuality, National Statistical Institutes should concentrate on technological invention and on making the tools used by businesses to respond to the statistical checks both user-friendly and effective. It has lately completed a trial run of the yearly checks of enterprises' artificial production using the Teleform program, a fascinating example of a multi-technology approach [6], [7] to data gathering. Teleform 7.0, produced by Cardiff (USA), is devoted to processing forms in both paper and digital formats. It's thus highly suitable for gathering data efficiently in a statistical terrain where various styles of responding are to be made available. Paper questionnaires can be returned by mail or fax, as usual. In the first case, the questionnaire must be scrutinized. In the alternative, if a fax server is available at the place of production, the surveying step is unnecessary. In both cases, the scanner and the fax server can be incorporated into the Teleform network. [6] This makes it possible to make up a single library containing the images of the forms, whether the source is the scanner or the fax server. In a posterior step, OCR/ICR[Optical Character Recognition(OCR)/Intelligent Character Recognition (ICR)] is used to automatically recognize type-written or hand-written characters, mark sense is used for crack boxes, and barcodes are read [6],[7]. Pre-existing paper forms can be reused, or, in an ideal scene, they can be designed from the ground up. Digital forms are delivered to users by e-mail or made accessible on the Web. The data received electronically can be fed into the same data set as data from spontaneous character recognition [6]. Teleform is a modular system that can be expanded according to the conditions assessed by the workload. Three main modules – Designer, Reader, and Verifier – make up its architecture. The developer is the point-and-click interface that makes it possible to produce new forms from scrape or automating existing forms. It allows all the checks and verifications demanded to interpret the documents once they are loaded to be defined beforehand. Once a form has been outlined, it can be produced automatically in various formats, such as traditional paper, fax documents, or PDF or HTML files [6],[7]. The reader is Teleform's core. It handles document importing, capturing images from fax servers, importing images from existing directories, any coupling of output with data in the library, identification of documents from among those stored in the system, and recognition of data. If electronic forms are used, Reader handles mail server management, document capture, form identification, and creating the yield data set [6].

According to a study by Matthew G. Johnson, Jean Williams, Anthony Lee, and Kristy K. Bradley we can state that Acquiring and maintaining certified EHR technology is precious and challenging but will strengthen public health surveillance. In Oklahoma, ELR is formerly outperforming conventional reporting in terms of punctuality; however, changes should be made to improve the completeness of ELR. Time is necessary for laboratories to implement ELR completely; therefore, a transition period is anticipated before ELR is established statewide. In the meantime, taking specific demographic data fields through variations to reportable disease regulations can help to improve the absoluteness of ELR in Oklahoma[5].

An electronic data capture system (EDC) is a collection of clinical data in an electronic format used mainly in clinical trials, EDC is a replacement for the standard data collection method, in the EDC method data is directly entered into the database and it has the advantage/ability to enter, review and analyze the data in real-time and can implement online data validation checks in order to assure data quality more effectively at the point of entry[9],[10],[11],[12].In some studies"it is proved that electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records. It is evidenced by previous literature that, the use of portable handheld computer technology in the field of healthcare and clinical research, is on the rise".[13] [14]

"Title 21 CFR Part 11 of the "Code of Federal Regulations" under which the agency considers electronic records state that electronic signatures and handwritten signatures that are executed to electronic records are trustworthy, reliable, and equivalent to paper records and handwritten signatures executed on paper. And for records that are required to be maintained but not submitted to the agency persons may use electronic

records and electronic signatures instead of paper records and traditional signatures. And in e-records there are controls for closed systems and open systems, persons who use closed systems for electronic recording shall employ procedures and controls designed to ensure authenticity and integrity, when appropriate confidentiality by Limiting access to authorized individuals and they must be accountable for falsifications and other actions and in controls for open systems procedures and controls designed to ensure e-recording from point of their recording to point of their receipt. Signed e-records contain the printed name of the signer with the date and time when it was executed, and are linked to their respective e-records.[15]

ELECTRONIC DATA CAPTURE SOFTWARE OVERVIEW:

Electronic Data Capture Software (EDC) is a software system that stores patient-related data collected in clinical trials. It simplifies and expands the abilities of remote data entry (RDE) software. Upon inspection the software allows researchers or surveyors to collect data immediately in order to increase data validity. EDC Software can be utilized by sponsors, CROs, and sites for simple and complex trials in each phase of research. EDC software allows the collection and submits data via a mobile, handheld device by field teams, surveyors, researchers, and others, It may also refer to mobile applications used by financial institutions to collect signatures digitally. And may also refer to applications used by clinicians and researchers to collect observed or subject data during a clinical trial. EDC Software can be used with data integration software since both focus on the collection of large quantities of data, Data integration tools can be used to expand the existing services provided by EDC software.

FEATURES OF ELECTRONIC DATA CAPTURE SOFTWARE:

EDC software provides capabilities like an integrated camera for the collection of image data, an integrated form builder for collecting entered data, and the collected data can be used for conjunction and integrated with medical reports and other trials, data can also be customized into various form and report templates, it can checklist, data validation workflow, and can collect data by mobile or handheld device through the mobile application, due to regulatory compliances data is protected and backed up by the vendor.[16]

ECRF IN CLINICAL TRIALS:

An ECRF clinical study control chart is a written or electronic questionnaire designed specifically for use in clinical trials. During the trial, it is used by both the investigator and the trial's regulatory agency to collect information from each trial subject. This data assists investigators in determining whether the study's primary endpoint has been met. This data is required by investigators and regulatory agencies to calculate the success rate, the percentage of trial subjects who meet the primary endpoint, and the overall success of the trial. A typical ECRF clinical trials control chart includes detailed information about the trial's patient characteristics, data collected in the control chart includes the patient's demographic details, disease severity, vital signs, laboratory values, and general health status, which may help investigators determine which groups are at risk for any given condition questionnaire should also inquire about the subject's smoking habits and types of alcohol he or she consumes, and any pre-existing diseases that may increase the risk of developing the disease. It also contains important information such as the investigator's contact information, case number, time of the study, registration number, treatment period, patient designation, treatment plan, consent form, consent instructions and treatment protocol, clinical study protocol, study name, and number, the catalog description, pharmacy facility code, telephone numbers, and address may also be included in the data. The micellar of clinical trials' inclusion and exclusion criteria are designed by healthcare experts by good clinical practice guidelines.

CLINICAL TRIAL ACCURACY AND EFFECTIVENESS:

Subjects participate in ECRF clinical trials through data entry personnel who are recruited by the investigators based on the information provided by the subject. These data entry technicians are trained to enter information into desktop computers. After the information has been entered, the results are sent back to the investigators. This entire process is carried out in an automated manner, saving both time and effort.ECRF clinical trials employ a large number of support personnel. These support personnel assists data entry personnel with any questions they may have and they are about protocols and treatment arm management. They are also in charge of ensuring that the trial went perfectly and within the scheduled time. It is obvious that without the use of electronic case report forms in clinical trials, it would be extremely difficult to conduct these trials effectively. Furthermore, running clinical trials would take longer to complete and would most likely cost more in the long run. These electronic case report forms must be utilized in clinical trials for many years to come.

KEEPING UP WITH TECHNOLOGICAL CHANGES:

Clinical trial organizations need to keep up with technological changes to continue to innovate and produce meaningful and positive results for ECRF clinical trials. Keeping up with technological advances helps to ensure that the best treatments and technology are available to assist in future trials. Without technological advancements, there may not be enough technology to support new and improved treatments for various conditions.[17] Some well-known EDC systems are "Rave from Medidata, Inform and Oracle RDC by Oracle, nowEDC from data trial, Data labs EDC from perceptive (a Parexel subsidiary), Macro from Elsevier, QDS EDC from QDS, Data Trak EDC from Data Trak, Trial Master from Omnicomm, Escapism from Cmed, IBM EDC from IBM, Target Health EDC is a product of Target Health, Veeva vault EDC from Veeva, case link is of DSG, Medrio EDC from Medrio, Captivate EDC is of clinCapture, REDCap EDC from REDCap Cloud, Nukleus EDC is of TCD eClinical, Bioclinica EDC is a product of Bioclinica, iMedNet EDC from MedNet, Caster EDC from Caster."While most of these EDC systems provide the benefits mentioned earlier, their market acceptance varies significantly.[18]

CLINICAL TRIALS USING ELECTRONIC DATA CAPTURE (EDC) SYSTEMS:

The most important aspect of any clinical trial is, the data generated Data from multi-center clinical trials will be generated across a wide geographic area, making data management difficult, In the case of clinical trials using paper-based CRFs, collecting data from all sites takes time.The initiation of EDC has advanced the data collection process through web-based data entry, medical monitoring, data review, and data clarification processes, and cost-effective approach to clinical trials. Integrating with statistical software, it also speeds up the report generation process by providing error-free (clean) data. As a result, proper integration of clinical research, data management, and biostatistics into the trial design is required to ensure that the data entry process is user-friendly for clinical sites and that the exported database structure is compatible with the planned statistical analysis. As a result, before enrolling the first patient, EDC must be planned and implemented. The front end of EDC includes data entry screens with a set of data fields into which data is entered. Before the first data entry, all data fields should be validated, Validation is defined as the accumulation of evidence that a system does what it claims to do and will do so in the future. All necessary programming for creating forms, validation (edit check specifications), and CRF annotation is completed in the back end of EDC. In addition, programming is done to integrate the EDC system with data management and statistical analysis for report generation.Once the forms are created, all the forms specific to a therapeutic area are nested together to form a complete CRF that can be assigned to a patient once the trial is initiated. The created forms can be saved in the EDC system's library, copied from the library, and used in future trials. To initiate a study, use the system's copy function and add roles, users, and sites to obtain access to the EDC system. With the introduction of EDC systems, query management has accelerated dramatically, previously query management was a time-consuming process. However, with EDC systems, queries can be resolved in minutes rather than weeks, assuming that the site is responsive to the query. Data manager serves as a bridge between the field and biostatistics, Statistics require error-free data from data management. The EDC system makes it easier to generate error-free data from a clinical trial. Standard Operating Procedures (SOPs) should be established and followed for the below processes, but not limited to them are System configuration and installation, Data collection and management, Maintenance of the system, Backup, recovery, and disaster recovery plans, Security, Change control. EDC has already been adopted as a new data management tool for clinical trials though the goal will remain the same; to ensure "clean" data at the end of the study.[19]

Table 1 PROS AND CONS OF EDC (Electronic Data Capture Method):

Pros	Cons
➔ EDC promises to make accurate data for the research program available as soon as possible.	➔ Significant risks associated with achieving this goal. Pens may be misplaced, and devices may be defective, broken, or stolen. Devices are exposed to dust and humidity, especially in a setting like the Gambia
➔ If EDC is well designed and implemented with care, and work processes are adjusted to EDC, it will become more time efficient, and potentially more accurate.	➔ A malfunction or loss of the device may imply that data will not be collected on time, or the data that is collected may be lost or must be collected again.This will significantly increase the time spent gathering such information, and error rates are likely to rise as a result.
➔ It is a more cost-effective method than the traditional paper-based data collection method.	➔ Longer study duration and device replacement are associated with higher costs. [13]

The setup is simple: ➔ It is very simple to set up a clinical study in an EDC system.	➔ Setup is heavily dependent on the system you select. This is why conducting prior research and looking for the best EDC systems for clinical trials is essential.
Secure Access: ➔ Since a clinical trial requires you to coordinate and collaborate with researchers from all over the world, an EDC system makes communication easier and, more importantly, safer. Data can be reported in real time, reducing the possibility of errors. Data can be reviewed immediately, which is especially advantageous in high-risk trials. Furthermore, EDC software systems have authorized data entry, lowering the likelihood of a breach of privacy. Only specific links can be accessed by specific users, ensuring both access and security.	➔ You must ensure that you select the appropriate EDC system for your needs.
Cost Control: ➔ EDC systems have a faster turnaround time, reducing the time required for data preparation. Queries can be sent more quickly, reducing delays and, as a result, administrative costs. It also reduces the need for storage space, which contributes to lower costs. EDC-based data collection is more cost-effective than other methods because it reduces the risk of human error, which would require time, effort, and money to correct later.	➔ You will have to deal with staff who are unfamiliar with technology. Time and money must be spent on staff training in order for the system to be easily integrated into your institution.

Overall, the benefits of EDC systems for clinical trials far outweigh the challenges. Choose the right EDC software to simplify data management.[20]

STANDARD DATA CAPTURE:

Standard data capture is the process of converting information from any kind of structured or unstructured paper document into a digital format that can be read by computers. [21] To ensure a seamless flow of information in inventory management, data capture technology is utilized to gather data for medications or medical equipment billed in sales and to automatically computer stock left for those pertinent products. These tools streamline, expedite, accelerate, transparently, and effectively the gathering process. [21] A case record form (CRF) is a specialized record in medical studies. It should be study protocol-driven, robust in content, and have material to collect the study-specific data.[22] Though paper CRFs are nevertheless used largely, the use of digital CRFs (eCRFS) is gaining a reputation because of the benefits they provide along with advanced information pleasantness, online discrepancy control, quicker database lock, etc.[22] The main goals in the back of CRF improvement are retaining and keeping pleasant and integrity of information. Data to be prepared in a layout that helps and simplifies information analysis. Collection of big quantities of information will bring about wasted sources in amassing and processing it and in lots of circumstances, will now no longer be applied for analysis.[22]These measures will bring about decreased question generations and advanced information integrity. It is usually recommended to set up and keep a library of templates of well-known CRF modules as they are time-saving and cost-effective. This article is a try and describe the techniques of CRF designing in medical studies and discusses the demanding situations encountered in this process.[22] There are two types of CRFs used in clinical research: traditional paper CRFs and improved electronic CRFs (eCRF). Paper CRFs seem to be the traditional method of data capture and are preferable when studies are small or have varying designs, whereas eCRFs are preferred when studies are large and have similar designs. [23]

PAPER CRF

Paper CRFs are made for manually entering data. They are inexpensive to create and allow for the faxing and carbonless copying of direct copies. Computers can read data produced by staff and automatically enter it into a database using modern technologies such as optical character recognition (OCR). The traditional method of data collection, paper CRF, is preferable if studies are small or have a variety of designs.[24] Designing a paper CRF is a time-consuming task that can lead to data errors and incorrect conclusions, involving cautious attention to reduce duplicate CRF pages. Errors frequently occur while transferring data from the source document to the printed CRF.[24] Clinical trial Case Report Forms (CRFs) are still often collected on paper by biopharmaceutical and medical device companies. In the current global scenario, eCRFs are preferred over paper CRFs because they are less time-consuming and encourage the sponsor/pharmaceutical company to conduct large multicentric studies at the same time due to the ease of administration.[24] Furthermore, if the traditional technique of data collection via paper CRFs are chosen for studies with a large sample size, manual data cleaning may be a serious concern. [24] However, unlike EDC systems, where these things are necessary

before implementation, this method might not demand user training and system validation. Despite all of their benefits, eCRFs are not commonly used.

STANDARD CASE REPORT FORM DESIGN:

The art of creating a CRF should be based on scientific principles, and the person using the CRF (the one who enters data into it) should be kept in mind as you implement the design. All important sections of the CRF should be carefully designed; keep in mind that insufficient/inaccurate data collection will be costly during analysis.[25] As a result, it is advised to have a standard operating procedure for CRF preparation and to adhere to CRF designing best practices. [25] The primary purpose of CRF design is to collect complete and accurate data by avoiding duplication and facilitating data transcription from source documents onto the CRF. CRF should be designed with primary safety and efficacy endpoints as the primary goal of data collection. It should ideally be well-structured, simple to complete without much help, and designed to gather only the highest-quality data.[25] Duplicating data on the CRF should also be avoided. The CRF includes an informative header and footer that can be customized. [26] The header typically contains the protocol ID, site code, subject ID, and patient initials. The footer, on the other hand, includes the investigator's signature, the date of signature, the version number, and the page number. The design of case report forms should be standardized to meet the needs of all data handlers, including investigators, data managers, biostatisticians, clinical research monitors and organizers, database developers and programmers, and personnel who enter data, among others. Furthermore, it should capture legible, consistent, and valid data, reducing the number of queries generated. [26] To improve the quality of data collected, design standards should be followed when creating CRFs. As a result, data should be organized in a format that facilitates and simplifies data analysis.

When creating a CRF, the following considerations must be made:

- Throughout the CRF booklet, use consistent formats, font styles, and font sizes.
- choose between portrait, landscape, and combination layouts [26]
- Questions, prompts, and directions should be used clearly and concisely.
- Check boxes are preferable to the "circling of replies," which should be avoided because it's difficult to interpret.
- At appropriate locations, clear guidance about skip patterns, such as what to skip and what not to skip, should be provided.
- The responses should be placed in boxes or separate lines. This helps to visually distinguish it from the entry fields for other questions and indirectly instructs the data recorder where to write or enter the response.
- Make thick lines to separate the columns.
- If necessary, page numbering should be consistent throughout.
- To avoid making assumptions about the clinical data, do not use the phrase "check all that apply." [26]
- Indicate the unit of measurement.
- Indicate how many decimal places should be recorded.
- Throughout the CRF, use standard data format (e.g., dd/mm/yyyy).
- When possible, precoded answer sets such as yes/no, male/female, medication administration route, and adverse event (AE) intensity (mild/moderate/severe) should be used.
- When possible, use precoded answer sets such as yes/no, male/female, medication administration route, and AE intensity (mild/moderate/severe).
- To ensure an identical copy of the CRF, use "no carbon required (NCR)" copies.
- Use instructions that include the page numbers where data must be input (for example, during a follow-up visit, the investigator is required to record if any adverse events (AEs) have happened and, if so, details of the AE in the AE module, therefore the field related to this question on the module for the specific visit would have the options "yes" or "no").

Table 2 PROS AND CONS OF SDC (Standard Data Capture method):

PROS OF SDC	CONS OF SDC
➔ Paper Based studies are less expensive.	➔ It is time-consuming and prone to errors.
➔ Clinical data stored in the paper is secure and locked in a vault.	➔ When dealing with large volumes of data, it can be challenging to keep track of everything.

➔ Easy to correct the problem during the study. Accessed at any time without a computer.	➔ It is difficult to organize and analyze large volumes of data.

CHALLENGES IN CASE REPORT FORM DESIGNING:

- Common problems that can occur during data collection include design consistency, precise data collection, and user-friendliness. [26]
- These challenges can be overcome by proper planning by a team of data management professionals, biostatisticians, clinicians, and medical writers. [26]
- Another issue is the lack of standard templates for case report forms. This can be resolved by creating templates.
- The collection of extraneous data, should be avoided because processing it becomes tedious. In such cases maintaining accuracy and quality becomes a major challenge.
- Duplication of data should be avoided. Creating the goal of avoiding referential and data collection should be cost-effective. [26]

II. Conclusion:

Designing case report forms is the first stage in transferring the protocol into typical questionnaires, and it is essential to a clinical trial's success. The standard CRF should be structured in such a way that it improves the collection of consistent and valid data, culminating in data submission to regulatory authorities and acceptance. The right data points (answer to a CRF question/data is input) must be collected regardless of the time and effort made into performing the trial; otherwise, a meaningful analysis may not be possible. As a result, a valid SAP should be developed as a way to create and assess the suitability of the CRF, and it should be available to answer questions on the data points that must be included in the CRF. It is crucial to have design principles in mind well in advance of beginning the CRF development process to prevent future modifications. These suggestions will help in creating a CRF that is well-designed for data collection.

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Amrita Mahanti, et. al. "Comparison Of Electronic Data Capture With Standard Data Capture Method In Clinical Trials." *IOSR Journal of Research & Method in Education (IOSR-JRME)*, 12(06), (2022): pp. 01-08.