

Advancing Clinical Data Capture: Embracing Electronic Data Capture (EDC) for Enhanced Efficiency and Quality

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Abstract: *Pharmaceutical companies have continuously pursued innovative and cutting - edge technologies to improve the speed and effectiveness of clinical data capture and analysis. Among the various options available, Electronic Data Capture (EDC) has emerged as the preferred technology, offering significant advantages over traditional manual approaches. This article aims to shed light on the limitations of conventional data capture methods while emphasizing the numerous benefits of adopting EDC, including improved data quality, enhanced performance, increased productivity, and reduced expenses in clinical trial management. In the traditional data capture method, clinical research studies rely on collecting data with physical case report forms, which are then manually entered into a database to create electronic records. While well - established, this approach is known to be time - consuming and prone to errors. On the other hand, EDC solutions have the potential to deliver comparable data accuracy to paper - based methods but with a more streamlined process. This study reveals that with careful design and implementation of EDC, along with appropriate adjustments in work processes, it can become a time - efficient, potentially more accurate, and cost - effective alternative to traditional paper - based data collection.*

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1. Introduction

Electronic Data Capture (EDC) systems are computerized tools designed to collect data in electronic format, primarily used in clinical trials. EDC serves as a replacement for traditional data collection methods, streamlining the process and accelerating the flow of medical devices and drugs to the market [5]. While conventional clinical trial data collection relied on paper - based case report forms, recent advancements in technology have made the transition to electronic data capture more accessible and efficient. With EDC, there is no need for physical documentation, as all data is organized and stored electronically. One of the primary advantages of EDC is its ability to facilitate data checking, entry, review, and analysis, which ultimately ensures data quality. [1]

In both the USA and Europe, EDC is employed to safeguard data and facilitate secure data interchange. The utilization of electronic signatures provides a trustworthy, reliable, and equivalent alternative to paper records. EDC software and systems guarantee the authenticity, integrity, and confidentiality of electronic records, surpassing the capabilities of traditional paper - based records. This review paper aims to compare the performance of the Standard Paper - based data collection method with Electronic Data Collection (EDC). The cost of EDC software may vary based on its quality and advanced features, with an average price of approximately \$4200, depending on the data forms and fields involved. [2]

In the USA, the adoption of EDC has been steadily increasing. The global market size for EDC reached around USD 349.8 million in 2016, and it continues to grow daily.

As EDC becomes more prevalent, the traditional data capture method, with its paper - based approach, is increasingly viewed as a time - consuming and error - prone process [5]. In this study, we compare four electronic data capture (EDC) styles with the conventional approach in terms of data capture duration and accuracy. The research was conducted in a West African setting, where clinical trials involve data collection from urban, rural, and often remote locations. By analyzing the efficiency and reliability of EDC in this diverse context, we can better understand its potential benefits and applications in clinical research across different regions. [3]

Electronic Data Capture Software (EDC): A Comprehensive Overview

Electronic Data Capture Software (EDC) is a sophisticated system that stores patient - related data gathered during clinical trials. It significantly streamlines and expands the capabilities of remote data entry (RDE) software, enabling researchers or surveyors to collect data promptly and enhance data validity. EDC Software finds extensive applications across various phases of research, benefiting sponsors, Contract Research Organizations (CROs), and research sites alike. Utilizing EDC software, field teams, surveyors, and researchers can conveniently collect and submit data through mobile or handheld devices. Additionally, it may refer to mobile applications used by financial institutions to collect digital signatures. In the context of clinical trials, EDC software serves as a vital tool for clinicians and researchers to collect observed or subject data efficiently. [4]

Key Features of Electronic Data Capture Software:

EDC software offers a range of essential features, including:

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- Integrated camera for image data collection
- Integrated form builder for easy data entry
- Customizable form and report templates
- Checklists and data validation workflows
- Mobile application support for data collection
- Data integration with medical reports and other trials
- Data protection and backup to comply with regulatory requirements [16]
- Understanding ECRF in Clinical Trials:

An Electronic Case Report Form (ECRF) is a specialized questionnaire, either written or electronic, designed explicitly for use in clinical trials. It serves as a crucial tool for both investigators and regulatory agencies to collect essential information from each trial subject. The data gathered through ECRFs helps investigators determine whether the study's primary endpoint has been met, which is essential for calculating the trial's success rate. Typically, an ECRF in clinical trials includes detailed patient information, such as demographic details, disease severity, vital signs, laboratory values, and general health status. It helps investigators identify groups at risk for specific conditions and inquire about subjects' smoking habits, alcohol consumption, and any pre-existing conditions that may impact the disease's development. [5]

The ECRF also contains vital information, including the investigator's contact details, case number, study registration number, treatment period, patient designation, consent form, treatment protocol, clinical study protocol, and study name and number. It plays a crucial role in adhering to good clinical practice guidelines, as healthcare experts carefully design the inclusion and exclusion criteria for clinical trials.

Enhancing Precision and Efficiency in Clinical Trials: The Role of Electronic Case Report Forms (eCRFs)

In clinical trials, subjects participate through the assistance of data entry personnel recruited by investigators based on subject-provided information. These data entry technicians are trained to efficiently input data into desktop computers. Once the data is entered, the results are transmitted back to the investigators, streamlining the process in an automated manner and saving valuable time and effort. eCRF clinical trials rely on a dedicated team of support personnel to assist data entry technicians with any inquiries they may have regarding protocols and treatment arm management. These supportive individuals play a vital role in ensuring the smooth execution of the trial within the scheduled timeframe. The integration of electronic case report forms has proven indispensable in conducting clinical trials effectively. [6]

Without the implementation of eCRFs in clinical trials, the process would be significantly more challenging and time-consuming. The absence of such technology would likely lead to prolonged trial durations and increased costs, hindering the progress of medical research. By leveraging electronic case report forms, researchers can optimize data management, enhance accuracy, and ensure efficient trial progress. The use of eCRFs empowers clinical trials to achieve precise results swiftly and cost-effectively, thereby accelerating the development of medical interventions and ultimately benefiting patients worldwide.

Staying Updated with Technological Advancements in Clinical Trials:

To remain innovative and achieve meaningful and positive outcomes in Electronic Case Report Form (eCRF) clinical trials, clinical trial organizations must keep abreast of technological changes. Embracing the latest technological advances ensures that future trials can access the best available treatments and cutting-edge technology. Failing to adopt technological advancements may lead to insufficient support for the development of new and improved treatments for various medical conditions. In the realm of eCRF systems, several well-known platforms are prevalent in the industry, such as "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" by Target Health, "Veeva vault EDC" from Veeva, "case link" from DSG, "Medrio EDC" from Medrio, "Captive EDC" from clinCapture, "REDCap EDC" from REDCap Cloud, "Nukleus EDC" from TCD eClinical, "Bioclinica EDC" by Bioclinica, "iMedNet EDC" from MedNet, and "Caster EDC" from Caster. While many of these EDC systems offer the aforementioned benefits, their market acceptance varies significantly [18]. As clinical trial organizations explore these diverse EDC options, they must carefully assess each platform's suitability for their specific research needs and objectives. By staying updated and choosing the right EDC technology, clinical trial organizations can optimize their research processes, enhance data accuracy, and ultimately contribute to the development of improved medical treatments for patients worldwide. [7]

Utilizing Electronic Data Capture (EDC) Systems in Clinical Trials:

A critical aspect of any clinical trial lies in the data it generates. Multi-center clinical trials often encounter challenges in data management due to data collection occurring across a wide geographic area. Traditional paper-based case report forms (CRFs) can lead to delays in collecting data from all sites. However, the introduction of EDC has revolutionized the data collection process through web-based data entry, medical monitoring, data review, and data clarification processes, offering a cost-effective and efficient approach to conducting clinical trials. By integrating with statistical software, EDC expedites report generation by providing error-free (clean) data. [7]

For a successful implementation of EDC in clinical trials, it is crucial to properly integrate clinical research, data management, and biostatistics into the trial design. This ensures that the data entry process is user-friendly for clinical sites and that the exported database structure aligns with the planned statistical analysis. Consequently, planning and implementing EDC should occur before enrolling the first patient. [6]

The front end of EDC encompasses data entry screens with various data fields for input. It is essential to validate all data fields before the first data entry, ensuring the system performs as intended and will continue to do so in the future.

The back end of EDC involves programming for creating forms, validation (edit check specifications), CRF annotation, and integration with data management and statistical analysis for report generation. The created forms can be saved in the EDC system's library, copied, and utilized in future trials, streamlining the process for subsequent studies. With the introduction of EDC systems, query management has significantly accelerated, reducing what was previously a time - consuming process. Queries can now be resolved in minutes, assuming sites respond promptly to the queries. Data managers play a crucial role as intermediaries between the field and biostatistics, ensuring error - free data for statistical analysis. To ensure consistency and adherence to best practices, Standard Operating Procedures (SOPs) should be established and followed for various processes, including system configuration and installation, data collection and management, system maintenance, backup, recovery, disaster recovery plans, security, and change control. EDC has already been widely adopted as a new data management tool for clinical trials, maintaining the goal of producing "clean" data at the study's conclusion. The continued utilization of EDC systems will further contribute to streamlining clinical trial processes and ensuring the accuracy and reliability of collected data. [8]

Streamlining Standard Data Capture: Transitioning from Paper CRFs to eCRFs

Standard data capture involves transforming structured or unstructured information from paper documents into a digital format that computers can interpret. In inventory management, data capture technology plays a vital role in gathering data on medications or medical equipment sales and computing the remaining stock for these relevant products. These tools streamline, expedite, and enhance the data gathering process, ensuring efficiency and transparency. [6]

A Case Report Form (CRF) is a specialized record used in medical studies. For optimum effectiveness, CRFs should be study protocol - driven, robust in content, and capable of collecting study - specific data. While traditional paper CRFs are still commonly used, electronic CRFs (eCRFs) are gaining popularity due to their numerous advantages, including enhanced data quality, online discrepancy control, and faster database locking. The primary goals behind CRF development are to maintain data quality and integrity and to ensure that the data is structured for easy analysis. Collecting large amounts of data without proper organization can lead to wasted resources and hinder data analysis. Implementing measures to reduce data errors and enhance data integrity will lead to decreased query generation and improved data reliability. Creating and maintaining a library of templates for standard CRF modules is recommended for time - saving and cost - effective CRF design. [5]

In clinical research, there are two main types of CRFs: traditional paper CRFs and modern electronic CRFs (eCRFs). Paper CRFs involve manual data entry and are cost - effective, allowing for faxing and carbonless copying of direct copies. Modern technologies like optical character recognition (OCR) enable computers to read data entered by staff and automatically input it into a database. Paper CRFs are ideal for small studies or those with varying designs.

However, designing paper CRFs can be time - consuming and may lead to data errors if not done carefully to minimize duplicate pages. As the global landscape evolves, eCRFs are increasingly preferred over paper CRFs. eCRFs offer time - saving advantages and enable the execution of large multicentric studies simultaneously due to their ease of administration. For studies with a large sample size, manual data cleaning becomes a significant concern if the traditional paper - based data collection method is chosen. In contrast, eCRF systems are equipped with tools that facilitate data cleaning and validation, ensuring data accuracy and reliability. [9]

Overcoming Challenges in Case Report Form Designing:

The process of data collection in case report form (CRF) design can present several common challenges, including ensuring design consistency, precise data collection, and user - friendliness. However, these challenges can be effectively addressed through proper planning by a team of data management professionals, biostatisticians, clinicians, and medical writers [8]. Another significant issue is the absence of standard templates for case report forms, which can be resolved by creating standardized templates. To optimize the data collection process and maintain accuracy and quality, it is essential to avoid collecting extraneous data. Processing irrelevant data can become tedious, leading to potential data errors. Moreover, preventing the duplication of data is crucial to maintain data integrity and cost - effectiveness in data collection. [10]

2. Conclusion

Designing case report forms is a critical initial step in translating a clinical trial protocol into structured questionnaires. The success of a clinical trial largely depends on the proper design of the standard CRF, ensuring the consistent and valid collection of data, ultimately leading to accurate data submissions to regulatory authorities and acceptance. To achieve this, it is essential to carefully plan and develop a valid Statistical Analysis Plan (SAP) to assess the suitability of the CRF and determine the necessary data points that must be collected. By adhering to well - thought - out design principles during the CRF development process, future modifications can be minimized, resulting in a well - designed CRF optimized for efficient and meaningful data collection.

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