eCOA Improving Patient Recruitment and Data Quality in DCTs, Says Geeky News

The Role of Electronic Clinical Outcomes Assessments in Shaping the Future of Clinical Research

Surrey, United Kingdom Nov 8, 2023 (Issuewire.com**)** - The landscape of clinical trials and healthcare is undergoing a transformative shift, driven by technological advancements. Decentralised clinical trials (DCTs) and hybrid study models are taking centre stage in clinical research, and the pivotal role played by technologies cannot be overstated. The latest article published on Geeky News delves into how electronic clinical outcomes assessment (eCOA) is revolutionising patient recruitment and retention, driving the rapid adoption of DCTs in the clinical research sector.

The adoption of eCOA gained momentum during the COVID-19 pandemic, as trial sponsors and contract research organisations (CROs) turned to remote patient data capture for more accurate results.

The healthcare industry is racing to bring life-improving treatments to market more swiftly. A key component of this mission is understanding patient health status and treatment outcomes. However, traditional paper-based patient-reported outcome (PRO) assessments present significant challenges. The challenges include poor data quality and data integrity issues that hinder regulatory approval.

Healthcare professionals require a comprehensive understanding of a patient's overall health and

quality of life to deliver patient-centred care. Unfortunately, the use of paper-based patient-reported outcome measures (PROMs) often results in data quality challenges.

Incomplete or ambiguous data, contradictory information, and the inclusion of superfluous data pose challenges for healthcare professionals involved in clinical trials. Querying and validating such data can be tedious and impractical.

Moreover, data quality and accuracy problems persist even when data is collected under expert supervision during site visits. Research indicates that approximately 44% of participants in a study using traditional paper-based PRO assessments reported incomplete and ambiguous responses when using the SF-36 quality-of-life questionnaire.

Maintaining the fidelity of patient-reported data according to the study protocol is essential for data integrity. However, traditional paper diaries lack automated reminders, notifications, and time/date stamps. That makes it challenging for patients to document symptoms and health status punctually. This significantly affects the reliability of PROMs, resulting in missing data and non-compliance.

Additionally, paper-based clinical outcome assessments increase the burden on patients and impede data compilation and analysis for trial sponsors. In 2009, the FDA stressed the importance of upholding PROM fidelity for data integrity and recommended that CROs ensure patients document their health status at intervals specified in the study protocol.

The answer to the challenges associated with paper-based patient assessments is eCOA, states Geeky News. It’s a critical tool in the clinical trial sector that prioritises patient-centricity and data quality to support regulatory assessments and consent.

eCOA technology encompasses a suite of software and hardware components that streamline the capture and management of patient-reported outcomes (PROs). The software component is the eCOA app installed on electronic devices used for data collection, while the hardware component includes the devices themselves, such as smartphones, sensors, wearables, and tablets.

eCOA offers a more efficient alternative to traditional paper-based data collection methods, enabling clinical trial sponsors to improve data collection, enhance data quality, and boost patient recruitment and engagement rates.

As clinical trial sponsors strive for patient-centred research, eCOA technologies, including "bring your own device" (BYOD), have emerged as vital tools for efficient and time-saving patient assessments. Allowing patients to complete PROs using their own devices provides the flexibility to participate in trials from the comfort of their homes.

Leading virtual trial organisation ObvioHealth, citing FDA recommendations, underscores the importance of electronic patient outcomes data capture. The FDA supports the use of digital health technologies (DHTs), including mobile apps, for administering eCOAs in clinical trials.

Moreover, electronic devices like sensors, fitness trackers, geolocation apps, and more automatically capture data on a patient's health status. This automated process enhances data context, reinforcing trial outcomes without imposing additional burdens on patients.

Implementing eCOA in DCT models empowers trial sponsors to capture precise patient-specific data, ensuring the safety and effectiveness of the therapies being developed.

Read the full article on Geeky News to discover how eCOA is reshaping the future of clinical research: https://www.geekynews.co.uk/ecoa-transforming-dcts/

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