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eBook

IMPROVING PATIENT DATA CAPTURE IN VACCINE STUDIES

How a reusable eCOA platform can benefit sponsors, sites and patients

USING TECHNOLOGY TO SUPPORT DATA COLLECTION IN VACCINE STUDIES

Developing new vaccines often involves different time pressures than traditional clinical trials. Planning for patient data capture is an important aspect of trial preparation. Collecting electronic clinical outcome assessments (eCOA) can help to speed study development and close.

Collecting patient data via questionnaires and symptom diaries across large, often diverse populations generates vast amounts of data in vaccine trials. Additionally, data capture requirements are typically very similar across differing studies, and timely data capture is critical, making them ideally suited to electronic data capture.

The key to efficient eCOA implementation is to develop a platform that enables rapid deployment for multiple studies within a vaccine program. This approach facilitates the reuse of core functionality with simple customizable study-by-study variations in design, patient populations and languages as well as key performance indicators and study metrics. Vaccine studies that collect data electronically are reaping the rewards of rapid analysis, which begs the question: why isn't every vaccine study leveraging eCOA?

REDUCE eDIARY START-UP TIME BY 75% WITH AN eCOA PLATFORM

RESOLVING CHALLENGES IN VACCINE CLINICAL TRIALS

The following pages demonstrate the typical challenges experienced during patient data capture for vaccine clinical trials, along with an explanation of how these can be resolved using electronic data capture platforms.

Challenge

Vaccine study timing is critical. Studies must address unique needs posted by seasonal health concerns, or for fast-track studies during an outbreak, e.g., Zika virus.

Solution

Deploying an eCOA platform can be faster than paper-based studies. Customizing diary cards for each subsequent vaccine study can require expensive and time-consuming validations. However, a platform approach enables rapid study development by utilizing libraries of pre-validated questions that can be selected as required for each study. Thus, the process from study kick-off to first-patient-in (FPI) is streamlined and timelines are significantly reduced.

SIGNIFICANTLY REDUCE TIME TO FPI WITH AN eCOA PLATFORM

Challenge

Vaccine studies often involve large patient populations, which generate enormous amounts of data.

Solution

Although the use of paper diaries is often seen as cheaper than electronic data capture due to initial investments, the back-end costs resulting from the use of paper are huge. In addition to the costs of manually entering and checking the data from paper diaries, data quality can be impacted by the potential to receive incomplete diaries, or the need to validate erroneous data.

The use of eCOA enables customized thresholds to be incorporated to ensure data entry is within acceptable parameters, including specified time windows. More importantly, data are automatically transferred into the study database, removing the need for manual entry, verification and query resolutions, providing real-time access to data for study teams.

ELECTRONIC DATA CAPTURE REMOVES THE NEED FOR TIME-CONSUMING DATA TRANSCRIPTION AND VALIDATION

Data management challenges for paper diaries

Traditional paper data capture solutions generate copious amounts of data that present significant logistical and financial challenges to sponsors and site staff alike. For example, a two-dose vaccine study of 10,000 patients produces a staggering 6.6 million data points from an 11 question, 30 day daily diary. Each single point of data collected will need to be manually reviewed and entered into the trial database by site or sponsor staff.

Electronic data capture platforms enable attributable, time-stamped capture and autonomous transfer of patient data from their electronic diary to the trial database, allowing site staff and sponsors to overcome these challenges while maintaining high clinical standards and data integrity.

PAPER-BASED VACCINE STUDIES GENERATE LARGE AMOUNT OF DATA POINTS THAT MUST BE MANUALLY ENTERED INTO A DATABASE

Challenge

Vaccine studies often require multiple languages/variations of questions for differing patient groups.

Solution

Unlike paper and traditional digital data capture, an eCOA platform approach enables a set of standard vaccine diary cards to be entered, tested and validated upfront. This means each new study can select from a menu of pre-validated questions, patient group variations and languages, as required.

Additionally, diagnostic technology can simplify the diary selection process for sites by automatically assigning the correct diary variant to each patient based on his or her enrollment criteria.

eCOA PLATFORMS SUPPORT PRE-VALIDATED QUESTIONS SUITABLE FOR DIFFERENT PATIENT GROUPS AND LANGUAGES

Challenge

Multi-dose vaccines, such as Dengue Fever and HPV, require a course of treatment over an extended time period. Ensuring that patients complete their vaccination course can be challenging, and affect study compliance.

Solution

One way to increase patient engagement is to allow patients to utilize their own smartphone to enter study data. This approach, known as bring-your-own-device (BYOD), can add a benefit over paper or fully-provisioned eCOA by enabling ongoing contact with the patients through their own phone. BYOD helps sustain engagement through diary entry prompts or notification when the next course of treatment is required.

FLEXIBLE PROVISIONING

A common misconception within the pharmaceutical industry is that BYOD means that all patients must use their own device. A flexible provisioning approach to BYOD enables the use of patients' own devices, where suitable, alongside the use of provisioned devices in the same clinical trial.

Challenge

The cost of handheld devices prevents the use of eCOA in vaccine studies.

Solution

A flexible provisioning approach makes electronic data capture extremely affordable. Patients' use of their own device reduces the cost of introducing eCOA to vaccine studies. It also puts the patient at the center of the study, helping to improve patients' experiences by seamlessly integrating study participation into their everyday lives.

However, provisioned eCOA studies can be used as a low-risk stepping stone to launch an eCOA platform, with a view to introduce the use of patients' own devices in the future.

ELECTRONIC DATA CAPTURE IMPROVES EXPERIENCE WHILE PROVIDING AN AFFORDABLE SOLUTION TO SPONSORS

Challenge

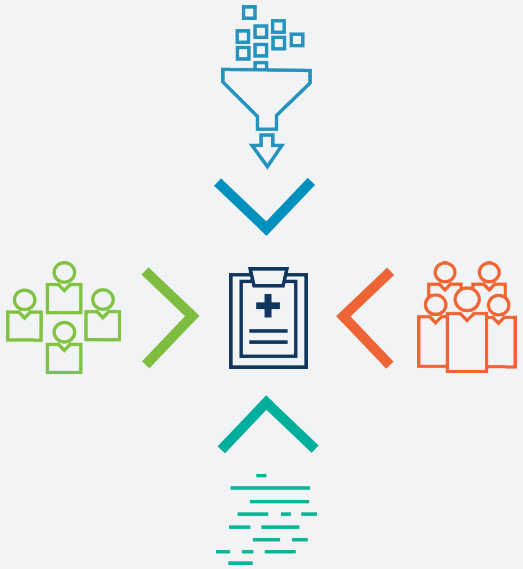
Sponsors are in competition for sites, so to meet recruitment targets they need to make trial participation simple and attractive to site staff.

Solution

Electronic data capture platforms ease the burden on sites by providing a simple and easy-to-use system that removes the need to store large amounts of paper records. A patient management portal simplifies the enrollment process and eliminates the need to rearrange appointments for patients who have forgot their provisioned device. The integration of automated management tools allows the automatic selection of correct diary variants to suit local language and patient groupings. In addition, the reconstructive archive feature of electronic data capture platforms allows studies to be updated to address changing regulatory requirements.

STORAGE CHALLENGES

Paper-based studies require sites to physically store large amounts of paper diaries, which can be extremely cumbersome. This is particularly true for studies that involve multiple population groups and languages, as each requires their own version.



PAPER DIARIES CREATE SIGNIFICANT SITE STORAGE CHALLENGES

THE BENEFITS OF AN eCOA PLATFORM APPROACH

Electronic data capture platforms clearly provide many benefits to sponsors, sites, and patients in vaccine studies. A vaccines platform can generate higher-quality data by limiting the collection of incomplete and erroneous data, sustain patient engagement and provide a cost-effective solution that adapts to individual study requirements.

The development of a vaccines platform enables standard diary card questions to be fully validated upfront, meaning individual questions, patient groupings and languages can easily be selected, saving the study team weeks of development and helping them meet FPI. An intuitive management portal can simplify patient enrollment and help site staff manage patient visits, while removing the need to store paper diaries on site.

The challenges and solutions presented within this eBook are just some of the ways an easy-to-implement electronic data capture platform can resolve perceived challenges and strengthen vaccine study data collection, enabling sponsors to develop a global standard that can be configured to meet the needs of individual studies. A vaccines platform provides a consistent means to means to capture all forms of patient data in a cost and time efficient manner, helping meet FPI and ultimately to database lock.

Learn how ERT improves patient data capture in vaccine studies with our configurable eCOA platform.

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotechs and CROs have relied on ERT solutions in 10,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.

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