

# Implementing Core Clinical Trial Technologies

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In the clinical space today, more technology solutions are being used, and investigational sites often employ multiple solutions within a single study to perform their responsibilities. Solutions include clinical trials management systems (CTMS), electronic data capture (EDC) systems, electronic patient reported outcomes (ePRO) solutions, randomization and trial supply management (RTSM) solutions (typically deployed using IVR/IWR technology), medical imaging technologies, central ECG management and reporting solutions, adverse event and safety systems to name but a few.

Common to every clinical trial are the requirements to project manage and track the study; collect and clean CRF data recorded by the investigator; and manage the logistics of the study including the medication supply chain and the randomization process.

Many biopharmaceutical companies have invested significantly in these technologies and have adapted their processes and procedures to benefit from their use. Most large and mid-sized companies performing a number of clinical trials per year have purchased and licensed a commercial CTMS application. Some smaller organizations manage the same meta data and processes using spreadsheets and databases and while this can be successful for single studies, it is challenging when managing data across a portfolio of trials.

Some biopharmaceutical companies have determined that all phase 2 and 3 trials should employ EDC, and have geared up data management and monitoring resources to adapt to and apply the new electronic processes. In addition to

reducing data management costs, EDC is associated with improving data quality, in particular speeding the data cleaning process, and has been reported to result in lower monitoring costs. Furthermore, the benefits in simplifying logistics and saving medication when using RTSM systems have been realized by many biopharmaceutical companies. Consequently, like EDC adoption, some sponsors choose to employ RTSM by default in all phase 2-3 studies.

Other clinical trial technologies, with the exception of safety systems, are used by individual trials when required and so we might consider the combination of CTMS, EDC and RTSM as foundational and required by every clinical trial, from which additional technologies may be required on a per-study basis.

## Integration of Core Clinical Trial Technology Solutions

The challenge now becomes how CTMS, EDC and RTSM can be used in combination optimally so that users are not faced with duplication of data and activities, and workflows are not burdened with unnecessary keying of data between systems. Additionally, how can other technologies be hooked into these systems when they are needed by a study?

Although each has unique areas of focus and application, there is overlap between the data and functionality contained within CTMS, EDC and RTSM solutions. This overlap can lead to increased burden in their application. For example, one of the key functions of a CTMS is to provide up-to-date information on study progress including patient recruitment, data management and source data verification (SDV). Senior management rely upon these data being

accurately recorded in the CTMS, and as a consequence CRAs are often required to re-key data into the CTMS based upon the information contained within RTSM and EDC reports.

In addition, site users may receive dispensing information from an RTSM system and be required to enter it into the eCRF within the EDC application. Users may make mistakes in entering duplicate information leading to the requirement to reconcile data between databases, or may simply not perform the activity as it appears redundant to them although valuable to another user of the system. Figure 2 depicts the typical touch points between CTMS, EDC and RTSM systems.

Integrating the data between these systems has enormous benefits to the different user types involved in the operation of a clinical trial. Ensuring the CTMS contains accurate study progress data leverages the use of that system as the key management information system within the Sponsor. Key study progress data, if up to date, can also trigger timely site payments.

Providing integration between EDC and RTSM makes working with both technologies more efficient for study site users and monitors in eliminating duplication of activities, data and associated reconciliation, and in ensuring that the optimal value is obtained from each technology investment. Integrating site address and user details contained in a CTMS with the other technology solutions that require that data removes the need for CRAs and study managers to create and maintain accurate duplicate lists of this information.

Simple data integration brings significant benefits to the users of these core technologies and leverages the value of each.