

Proactive coordination and collaboration across functions expedite the development of a robust clinical trial data collection platform, enhancing efficiency and effectiveness.

Electronic data capture (EDC) systems stand as pivotal technologies for gathering, managing, and scrutinizing patient data throughout clinical trials. Crafting an EDC system constitutes a collaborative endeavor among various stakeholders, encompassing sponsors, CROs, software vendors, project managers, clinical and scientific teams, medical monitors, safety personnel, and biostatisticians. Achieving a prompt go-live requires collective teamwork.

Determinants Influencing EDC Timelines



EDC builds follow a disciplined process that begins with the execution of a sponsor work order and ends with EDC go-live. A critical consideration in the EDC timeline is the status of the protocol.

Aligning on database configuration specs

Establishing core database elements upfront can significantly impact the entire process positively. Components like subject numbering conventions, site numbering, and medical coding dictionary versions serve as vital structural foundations. Modifying these configurations during late-stage development can result in costly downstream consequences and potential go-live delays.

Programming the eCRF

After stakeholders approve the eCRF design specifications, screen programming initiates. The quality of the specifications directly impacts the programming quality. While stable forms allow for parallel programming, working non-linearly carries inherent risks. Rushing timelines by cutting corners or skipping programming steps is a common pitfall to avoid.

Establishing edit check specifications

Edit checks are automated processes verifying data field content against expected properties, minimizing data entry errors. Specifying edit check criteria should commence only when eCRFs are stable and fully programmed.

Programming edit-checks

After edit check specifications are finalized, programming begins, driven by approved specifications for EDC development. While some changes are expected and planned for, significant alterations can impact the go-live date.

Performing user acceptance testing (UAT)

The duration of this EDC phase relies on the sponsor's UAT depth. Given platform variations and unique builds, understanding sponsor and team platform familiarity is vital for efficient UAT. Mandating EDC eLearning beforehand ensures team proficiency in system navigation and data entry pre-UAT.

Key Takeaway for and Effective EDC Go Live



Effective Oversight provides a safety net to ensure due diligence before making key decisions, identification, monitoring and mitigation of potential risks and to ensure business processes and systems were working well.



Effective Planning ensures strategic thinking and action from every contributor to achieve the joint goals.

Effective Resource Management is crucial to ensure quick action in a competitive environment and this increased efficiency helped to gain a competitive advantage.

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