ELECTRONIC DATA CAPTURE SERVICES

Electronic Data Capture (EDC) is a widely accepted alternative for paper trials, and has numerous advantages such as immediate access to both trial data and trial status reports via the web, improved data quality by auto-queries that are sent by the EDC system as soon as data is entered, and full control over the time point that trial changes are activated allowing adaptive trial design.

DESIGNING eCRF'S FOR INFORM™ AND RAVE®

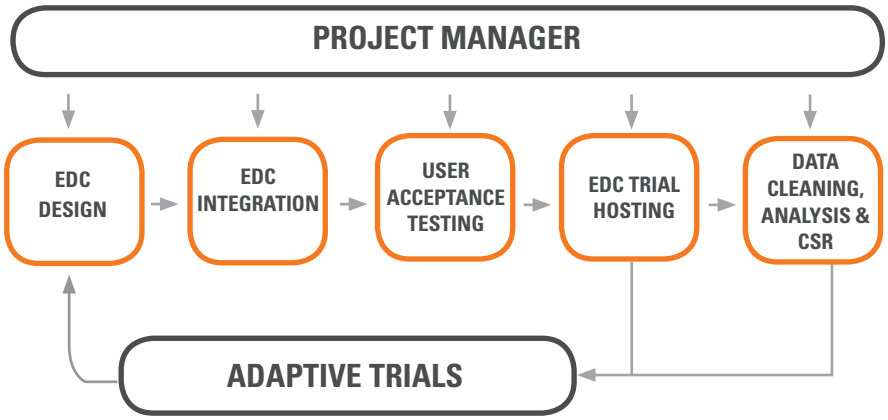
The SGS Biometrics team has extensive experience in setting up your eCRF application in two major EDC systems: InForm™ and Rave®. Our eCRF designers understand how to translate your clinical data requirements into a well designed eCRF because they understand your language and your needs from a clinical perspective.

The SGS EDC experts take your EDC trial to the next level by adding:

- Edit checks
- Automatic e-mail notifications that send alerts to the clinical team for data points that require immediate follow-up
- Dynamic forms and visits that are triggered upon data entry which customizes the eCRF based on subject data
- Custom programmed functionalities

Adaptive trial design is not just a concept but a speciality of the SGS EDC experts who evaluate design changes during the trial and implement them in the most efficient way, guaranteeing both continuous availability of the EDC trial and data consistency.

EDC TRIALS UNDER FULL CONTROL AT EACH STEP



INTEGRATING EDC TRIALS

EDC applications are not stand-alone systems but require one-way or even two-way data integrations with other electronic applications. Our team takes the lead in writing the integration requirements and defines a solution for all technical challenges to allow a successful implementation.

USER ACCEPTANCE TESTING

Before Go-Live of your InForm™, Rave® or other EDC application, a pool of SGS testers can perform full User Acceptance Testing. First, thorough test scripts are created that list all clinical trial requirements and 21 CFR Part 11 regulations. The testing itself results in a complete validation package documenting the entire testing process. The EDC application can be released for Go-Live upon finalization of the validation report.

MANAGING EDC TRIALS

The SGS Project Manager is your dedicated key trial contact that is responsible for all deliverables for each EDC trial. Starting from the trial kick-off, the project manager initiates the EDC design and follows-up on timelines and quality until finalization of the Clinical Study Report (CSR). With extensive experience in designing EDC trials and managing eCRF data, SGS ensures a high quality and efficient eCRF set-up, database cleaning process, data analysis and medical writing.

IN ADDITION

SGS primarily uses Oracle®'s Central Designer™, InForm™ and IRT™ solutions as well as Medidata® Rave®. In addition, SGS processes trials running on other

EDC systems based upon our clients' needs.

The advanced skills of SGS brings an important advantage to your EDC trials, including:

- Single log-on platform
- User friendly entry screen
- 24/7 multilingual helpdesk support
- Real time reporting
- Superior Clinical Trial Management

Additional EDC services offered by SGS include:

- In-house InForm™ hosting for small phase I trials
- InForm™ end-user training

With the efficiency that comes with experience, SGS is able to provide you with competitive price offerings for your trials.

ABOUT SGS

With innovative study designs, optimal facilities and strong regulatory intelligence, SGS can favorably impact client's drug development timelines and decision-making process.

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