Multi-Center Clinical Trial Management – Data Driven and Complete Tracking based approach

Sarjen Systems Pvt. Ltd.
ISO 9001:2008 certified company

Brief Description about BizNET:

Clinical Trial and Bioavailability-Bioequivalence (BA and BE) studies are continuously carried out and are increasing in volume to acquire the best available treatment options in the market. These processes involve various steps for a study/trial to be completed and are under strict vigilance by Country Authorities, so as to ultimately ensure the safety of patients/volunteers and quality of data generated. BizNET-CTM provides a collaborative solution for conducting these trials/studies by exploiting available technology and generate real-time data.

Problem Statement

Clinical trial, Bioavailability and Bioequivalence studies constitute of different phases, ranging from subject enrollment, verification, assignment of the subjects, written instructions, signing off records, checkups, follow ups, compensation to the subjects etc. Managing subjects followed up with enrollment seems to be an endless task for CROs for short and long period studies. Management of subject population at any CRO is a major concern starting from enrollment to dosing to housing and so on. Verification at every level becomes challenging, hectic and cumbersome at CROs.

Major hurdles being faced

1. Verification at the time of enrollment for subjects
2. Manual data entry in multiple forms
3. Storage of the big chunk of file records for each subject to each project
4. Tracking of the project operations at various stages
5. Report generation for various department and activities
6. More time consumption and resources for manual tracking of the process

7. Physical meetings among peers for resolving issues, clearance and signatures
8. Heap of papers on table to review and sign
9. Numerous tests per subject that needs manual intervention

What market demands?

It has become mandatory for any of the center where subjects (i.e. volunteers) need to be managed at large, to show potential and experience for smooth management of flow of activities, enroll subjects, record all required data for sufficient evidence during entry, to keep the record of in and out of the subjects throughout the study and archival years, analysis data, compensation records etc. and many other study related records.

The process has taken a new turn with the help of Information Technology penetrating into core for the management of activities in study set up processes. Updated approach for recruitment and retention of the volunteers has coined a new era by optimizing enrollment process followed up by case report form filling. Verification has become easier by using centralized system integrated with digital technologies.

Highlights of technology being deployed at CRO

1. Quick enrollment of the subjects at facility
2. Subject verification by reliable biometric methods at various levels (attendance, screening, check-in, check-out, dosing, compensation and exit formalities)
3. 24/7 access to data online
4. Authorized access to the peers and other management level person in facility
5. Training of the employees to geographic and regulatory compliance
6. Auto scheduler for project planning and subject visit scheduling
7. Reminder facility for project tracking, missed appointment or medication
8. Access to dashboard to analyze enrollment status, dropouts and adverse events
9. Dashboard to give report at a glance for all projects
10. Audit trail of the overall activity as per the regulatory guidelines
11. Subject records, analysis records maintained online per subject per project
12. Investigational Medicine and Products (IMP-Track) for Pharmacy Management

Based on the recent trend, BizNET has helped CROs to adapt updated technology for managing force and work from scratch to end, followed up with the customized reporting system.

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