CLINICAL TRIAL DATA INSIGHTS WITH BIZNET-CTM

Big data of Clinical Trial turned into meaningful insights with intelligence

ABSTRACT

Data is the foundation of Clinical Trials. Changing world followed by evolving life style and technology would give rise to the ample of data for every action of the process. Challenges in bringing the entire data at one place with a need to make the biggest impact in real life is the demand using latest technology in eClinical world.

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Background

One of the giant CRO, growing with various domains of services in Clinical Research, Laboratory services and other healthcare services is continuously getting equipped with latest technologies and solutions like; biometric volunteer recruitment using iris recognition as a medium of verification, ability to manage multiple projects simultaneously, ability to compile dossier in clicks for the entire electronically captured data and maintain database in a highly secured environment over servers for several location of their sites.

Key words: Biometrics, Iris recognition, Direct Data Capture (DDC), 21 CFR part 11

Client's Concerns

Upon speaking to the experts from different departments about the process and load management with latest electronic technology, it was cited that growing volunteer numbers and projects exponentially is leading to many problems and challenges in managing subject pool and multiple projects at a time;

1. Mismanagement of the volunteers during enrollment and assignment
2. Excessive paper generation during various operations in premise
3. Challenges of managing resources with rights and roles to specific projects
4. Inward/outward entry management
5. Practice of missing the events and important actions on due date and time
6. Management of several sites with centrally available data
7. Timely dossier generation on sponsor's request
8. Reducing the manpower in Clinical laboratory by automating the release process
9. Interested to adopt the Direct Data Capture (DDC) applications during BA-BE/CT studies

Sarjen's Challenge

Sarjen's key challenge was deploying regulatory complaint solutions followed with integrations with latest technology to cut short time in various operations while eliminating the manual interventions in different processes.

Back-to-back meetings along with sip of hot coffees in a 4-hour session, lead us into brainstorming and conceptualizing logics and methods followed up with a goal to deploy the best and latest technology to streamline the process.

Our approach to give Direct Data Capture (DDC) functionality while adding intelligence in application

At a whole to put this strategy into action, team concluded to have barcode guns in place of manual entries for volunteer IDs, sample IDs etc., to have iris recognition device integrated with our application for verification of the volunteers;

1. Ultimately by clearly demonstrating the functionality of iris recognition, it became the epitome to have it in production as early as possible
2. Bi-directional data transfer between application and laboratory machines was again pioneered a new way of saving time followed up with the auto release of screening reports by the system itself using system intelligence

Role operation matrix simplified with a goal to manage multiple site handling capability followed up with maintaining logs within the system and this eliminated the practice of maintaining the hard records

3. Instead of one size fits all approach, we focused on user needs and thought of deploying solutions where the CROs can design CRF as per their requirement and can have all required reports for further processing

Our long-term goal is to make Project management realistic, address challenges in clinical operations and providing an IWRS based system. This is a step forward to assist CROs of mid and large level operations to accomplish small to large-scale projects in a smooth manner and to add revenue to organizations on a long-term basis.

We are also making various processes go completely paperless.

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