

E-VALIDATION PLATFORM

~ A Supporting Tool for Clinical Research

Problem Statement:

Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development. Each phase is considered a separate trial and, after completion of a phase, investigators are required to submit their data for approval from the drug regulators (e.g. FDA) of their country before continuing to the next phase. Each phase is expected to span a couple of years on average.

It is required by clinical firms to compile and manage these data for further exploration and for approval by the authorities. The process is usually time consuming (years of process) and hectic to follow as once a submission is rejected, the process will start all over again.

Our client working in the healthcare space required a platform to store, manage and validate the clinical data records before final submission to the government authorities.

The Solution:

Travancore Analytics team members worked with the customer to understand the requirement in detail and developed an online document/data validation tool to facilitate it.

This web-based system is a helpful tool for clinical research teams and management. The system facilitates storage, management and pre-validation of research data before final submission to the government authorities.

The approving team can toggle enabling or disabling of validation guidelines manually to satisfy certain conditions as required.

This platform is envisaged to be of great help as this will reduce the time between research and validation.

e-Submission and e-Validation

- A web-platform for uploading and managing clinical records.
- Analyze for and suggest standards fit for final submission before government authorities.
- Differential user management.
- Toggle guidelines to accommodate changes under certain conditions.

Benefits:

- The average time spanning research, submission and results is reduced to a great extent.
- The online cloud system enables a large and safe storage space, necessary for such a process.
- Overall efficiency of the process is augmented.

Tech Used:

