

Clinical Trials Data Management

profile

Client:

Radiological Research and Accreditation organization.

Industry Sector:

Life Sciences

Technology Platform:

- Java
- Power Builder

Our client is a reputed radiological research and accreditation organization. They serve patients and the society by advancing the science of radiology, improving the quality of patient care, positively influencing the socio-economics of the practice of radiology, providing continuing education for radiology and allied health professions, and conducting research for the future of radiology.

The Need

Our client regularly conducts clinical studies as part of investigations into radiological therapy. Practitioners submit proposals for alternative/ improved therapy. These proposals are reviewed by a panel of doctors before submission to the FDA for approval. Studies are executed only after approval by the FDA.

Results of the clinical study were tracked manually. Our client required a faster, more accurate solution to reduce the cost and time for designing and executing trials.

Marlabs Solution

Marlabs designed and developed a solution to store and track progress of FDA approvals as well as protocols for approved studies. Using a custom forms designer and standard templates, the application makes it easy to create schemas to collect study data. It includes stratification schemas to determine patient eligibility.

The application uses patient calendars to schedule events for each treatment arm of the study. Sophisticated algorithms such as permuted block randomization are used to assign patients to study groups in order to ensure that patient sampling is truly random. The application includes Question and Response Banks to enable quick set up of questions. Marlabs successfully migrated 1.5 million legacy data points to the new application. Key functionality of the application includes:

- Study setup
- Patient accruals
- Protocol setup and management
- Automation of patient calendars for multi-step studies
- Management of facilities and provider databases
- Creation of SAS data sets for further analysis
- Enhanced reporting

Benefits

Marlabs' application provided an efficient data management system to manage clinical trial data. It provided standardization, improved flexibility, increased real-time access to clinical data, automated tracking of changes, enhanced clinical research data quality, and streamlined data entry.

The automated application has helped our client eliminate manual procedures for data capture and compilation, and has significantly reduced the time taken for report preparation.