CASE STUDY

EPAM'S REAL-TIME CLINICAL DATA PULLING SOLUTION HELPS ELIMINATE DRUG FAILURES IN R&D

THE BACKGROUND: DRUG FAILURES RESULT IN HUGE R&D COSTS

Drug failures account for a substantial proportion of research and development costs and result from a variety of risk factors, most of which relate to concerns about drug safety and drug efficacy. When drugs fail because of these safety concerns, time costs become another factor as a tremendous amount of resource expenditures are lost forever. To remedy costs associated with drug failure, pharmaceutical companies have long explored ways to reduce phase lengths through more efficient approaches to R&D. One approach is the development and implementation of innovative analytical technology solutions that enable scientists to appropriately interrogate trial data and make data-driven, scientific decisions earlier in the process.

CASE STUDY:

EPAM'S REAL-TIME CLINICAL DATA PULLING SOLUTION HELPS SNUFF OUT DRUG FAILURES IN R&D

The client is a multinational pharmaceutical and biologics company with operations in over 100 countries. Its portfolio of products spans major disease areas such as cancer, inflammation, cardiovascular, infection, gastrointestinal, neuroscience, and respiratory.

THE CHALLENGE: ENABLE REAL-TIME CLINICAL DATA INVESTIGATION IN PHARMA R&D

Before the engagement, EPAM's client had already established a robust approach to clinical trial safety management, putting into place multiple standard procedures to review data and mandate the reporting of serious adverse events. While this data was being continuously gathered and analyzed for safety, the standard clinical results from ongoing trials were limited to static reports that lacked the necessary flexibility to easily answer specific data queries.

As a result of this situation, scientists had to perform manual analyses by taking paper-based static reports and reproducing data values in tools like Microsoft Excel and Microsoft PowerPoint. Not only were researchers losing valuable time with this process, but the workflow was also preventing the availability of reports upon request, inhibiting decision-making processes.

The client approached EPAM to develop a system that reduces manual effort in R&D, provides effective analysis of ongoing clinical trial information, and introduces best practices in defining the format and content of clinical trial reports. To meet these specifications, EPAM began work on an Extract, Transform, Load (ETL) platform that makes up-to-date clinical trials data in the preferred SAS format available for analysis via Spotfire.

EPAM built the Clinical Data Pulling Solution through a collaborative, multi-disciplinary effort that included several functions from the client's R&D Information, Biomedical Informatics, Statistics, Patient Safety, and Oncology Innovative Medicines departments. Over the course of the engagement, EPAM developed an Open-Source Parso library to read SAS7BDAT files for use in future technologies.

TECHNOLOGIES

- Oracle
- Java
- Spring MVC
- Highcharts
- AngularJS
- D3
- Spotfire Visualizations
- Spotfire SDK
- Spotfire Automation Services
- SAS

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THE SOLUTION: A FLEXIBLE ETL SOLUTION WITH ACCURATE, ACTIONABLE VISUALIZATIONS

The EPAM team designed and implemented an adaptable, flexible ETL solution that delivers the core functionality requested by the client, working to Extract, Transform, and Load data from source files every 24 hours. The solution works by extracting the data from the source SAS files and then transforming it into objects within an Oracle database. From there, the data is loaded and analyzed via Spotfire, a data visualization and analytics software. As a platform, the Clinical Data Pulling Solution offers other innovative features such as:

- Ability to monitor drug safety, tolerability, efficacy, and clinical study protocol deviations in Spotfire analyses via developed templates each with a set of visualizations tailored to provide insight into one of four areas
- Up-to-date clinical trials information available for analysis via Spotfire
- Template-based approach for Spotfire views, management of Spotfire views, and propagation across multiple studies with the help of custom Spotfire Automation services created using Spotfire SDK
- Consistent look and feel of pages regardless of visualization type across each of the following elements:
  - Summary page with information on last data updates and amount of data present in the analysis
  - Explanation of a page and links to further help
  - Set of user functions for customizing the visualization
  - Data filters
  - Hierarchical pattern of visualization layout from top to bottom
- Ability to create customized visualizations (e.g. JavaScript-based) via the additional abstraction layer in the database that bears the visualization logic
- Automated data processing allowing the study team to focus on data analysis
- Configuration to support new sources of data, new formats of input data, and new types of visualizations (Spotfire and JavaScript-based)

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THE RESULT: IMPROVED ANALYSIS OF CLINICAL DATA & DECREASED DRUG FAILURE COSTS

EPAM's Clinical Data Pulling Solution constitutes a step forward in the real-time investigation of clinical trials data and represents a measured improvement on the previous system, which consisted in large part of examining data that had been validated through manual processes. Upon implementation, EPAM's solution enabled the client to achieve the following objectives in clinical trials:

- Improve safety monitoring and support operational decision-making
- Provide an intuitive, powerful, and flexible tool for study teams to interrogate clinical study data from ongoing clinical trials within phases I and II
- Gain insight into areas of drug safety, drug tolerability, and treatment efficacy, as well as into the capture of clinical data
- Introduce best-practice reporting procedures that ensure the integrity of clinical trial data as well as the privacy of trial subjects
- Automate and standardize workflow to achieve cost-effective resourcing and decrease the costs of drug failure
- Increase drug safety and ethicality for patients by ruling out drugs that are not effective and/or have significant adverse effects

As a result of its positive impact on process effectiveness and data availability for the client, the solution won the client's internal CIO Excellence Award and Innovative Medicine Award as well as the external BioIT World 2014 Award. To learn more about this project and how EPAM's award-winning innovations in Life Sciences can benefit your organization, contact us today!

QUESTIONS?

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