



## Case Study

# Data Validation

# DATA VALIDATION

## Client Situation

A top-5 global pharmaceutical company, like many of its peer companies, had outsourced all of its data management operations to a large BPO (Business Process Outsourcing organization) that delivered these services in a globally cost-optimized model. They had retained the programming responsibility in-house, wherein programmers were mostly in-sourced contractors who were managed by a few senior in-house programmers. The Client's programmers consistently found that data discrepancies and data errors were being flagged while reviewing the draft TLGs (tables, listings, graphs). They realized that the data management team used by the vendor didn't have much experience in global clinical trials and didn't have the depth of understanding of clinical trial data that is required to catch such data errors in the course of the basic discrepancy management activity. However, since the data management function was completely outsourced, they didn't have in-house resources that could train, coach and mentor the DM provider's resources to bring them up to the required level.

## Sciformix Solution

The programming team at Sciformix did a detailed investigation based on a sample of 3 studies. Representative examples of the data issues found while reviewing the TLGs were: (1) number of subjects who discontinued due to AEs (adverse events), as recorded in the Subject Disposition data module did not match the number of subjects who had 'AE action' marked as 'permanently discontinued', (2) abnormal post-baseline lab values were not recorded as AEs. Sciformix programmers wrote specifications for a comprehensive set of cross-module and cross-visit data checks. They also reviewed data derivations defined in the programming rulebooks and specified any additional data checks that were required. Once all specifications were approved by the Client's programming managers, Sciformix programmed these in SAS. Any data checks that are specific to a particular trial, based on the data derivations in the rulebook or any special data modules that exist on the CRF (case report form), are programmed on an ongoing basis.

## Outcome

The additional validation checks are now available to the Client for execution at the same time when the basic edit checks are run by the DM provider. These specifications and the code for these validation checks has been standardized as much as possible (following Client's implementation of data standards), so that only a few new checks need to be defined and written for every new study. The Client is now able to identify most data issues through periodic execution of all data checks and doesn't have to wait for review of TLGs in order to identify them.

Sciformix is a knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.

For more information on how Sciformix Biometrics service can benefit your enterprise contact us at

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