PhUSE 2015

Paper ####

Implementation of an In-House Developed Data Quality Control Tool to Streamline SDTM Production Release

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INTRODUCTION

In the past decade, while CDISC was expanding and still stabilizing the SDTM standards, it was customary to perform the Quality Control (QC) of databases using a paper process to make sure that all source data was correctly converted to the SDTM format.
Clinical Data Managers (CDM) would print out the converted clinical database and manually crosscheck all items in the database with the source data received form (e)CRF, and external providers.
This process was very time consuming, prone to human error and not cost-efficient primarily because of the repetitive actions. Furthermore, general parameters, such as studyid, domain variables, and visit numbers, were validated over and over within different SDTM domains.

Today, however the CDISC standards have become very extensive and stable, and, because of this, it was possible to develop a standardized electronic way to perform QC on CDISC SDTM datasets before their release for production usage.

HOW TO GET STARTED

As a CRO you have to deal with multiple source systems, together with a variety of different interpretations of the CDISC SDTM standards. The challenge here is mostly to setup a system that can handle this variety of systems and interpretations, so that in the end you have one and the same end product for all.

With 'end product' in this case is meant: a database which is converted to the requested CDISC SDTM structure.
For SGS a conversion is setup using the automated SDTM creation as was explained by Joris De Bondt last year (Automated SDTM creation and discrepancy detection jobs: the numbers tell the tale).
In Figure 1 you see in red which steps are considered to be part of the 'conversion' at SGS.

Figure 1

IN THE EARLY DAYS

The logical next after setup of a SDTM database, is off course checking that all data is converted correctly and that no data got lost somewhere in the process.
At SGS this was, until a year ago, a complete paper driven process.

Consequences for this working with this method were:

- All steps had to be performed in a consecutive order, as indicated in Figure 2
- A CDM first had to complete a review round before a programmer could perform updates, which resulted in waiting periods for both CDM and programmer
- A process prone to errors

- Long process of checkmarks for all reviewed items
- In a new round, the person performing the QC always had to check exactly what was changed in the programming.
- Extensive process to get SUPP and CO datasets checked, every variable used for linking has to be checked in both the base dataset and the SUPP and CO dataset
- Heavy filing, because of all the paper used for QC

Figure 2

Overall this whole process was too time consuming and not cost efficient.

WHY DEVELOP A TOOL

CONTINUOUS WORKFLOW

By taking a snapshot of the data, on which the CDM works, it will be made possible for the programmer to work simultaneously with the CDM on the database for solving issues. The CDM can decide when to make a new snapshot for a next QC round.
By using this method, there is no longer a time delay in the work between the CDM and the programmer.

STREAMLINED WORKFLOW

Streamline the QC workflow for all users and guarantee the feedback to the programmers is given in a unified way. Since all actions are tracked electronically, it is possible to create a full report with all encountered issues and there solutions.

CHECK IT ONLY 1 TIME

The concept of this tool is that all data should only be checked once. To reach this goal, the review is performed in distinct steps. The first step covers top level data points, e.g.: the studyid value and domain value. In the next step data is validated in detail per domain. The detailed validation is performed in multiple rounds. Each record will first be checked using a primary test patient, limiting the amount of data that can be checked.

Figure 3

LESS RESOURCES NEEDED

All data and actions are logged electronically, removing the need for paper printouts, administration and physical storage.

NO TIME DELAY

When the QC is started, a snapshot of the database is taken in the QC tool. This enables the reviewers and the programmers to work on the data at the same time: the programmers on the database, the reviewers on the snapshot.

CONCLUSION

By developing a tool in house, which perfectly matches our needs, we were able to

- Take away a lot of frustrations among the employees, for the waiting and the double work

- Shorten our timelines for setup of a SDTM database
- Lower the cost of the QC

CONTACT INFORMATION

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