

Electronic Record Validation Process

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ABSTRACT

According to the 21CFR Part 11 guidelines of the FDA, a computer-generated, time-stamped audit trail should be provided for the electronic records of a clinical trial. Within our company the analysis data sets and output files were identified as electronic records and therefore all changes to these files after database lock need to be recorded.

The Electronic Record Validation (ERV) process is a SAS-based solution that is established to track these changes and to create documented evidence about **What** was changed, **Who** made the change and **When** the change took place. In this way regulatory authorities or internal auditors can easily access the required documented evidence for quality assurance.

INTRODUCTION

This paper is mainly intended for statistical programmers but also for anyone who is involved or interested in the creation and validation of clinical analysis data sets and output files. The paper will describe the main principles and functionalities of the ERV process before and after database lock.

1. PREPARATION OF THE ERV PROCESS BEFORE DATABASE LOCK

The ERV process starts prior to database lock by incorporating a number of SAS macro calls into the data set creation program. The main task for the programmer at this point is to specify a set of unique keys for every analysis data set. The ERV macros will check whether the set of keys that is specified can uniquely identify the records of the corresponding analysis data set and will sort the data set accordingly. At this point in the process no audit trail information is kept.

2. THE ERV PROCESS AT DATABASE LOCK

At database lock the ERV process is activated to track the audit trail information by turning an ERV macro input parameter from 'off' to 'on' before the analysis data sets and output files are created. At this time point the analysis data sets are created for the first time and the initial data set structure will be captured in a data set specific TXT-file.

3. THE ERV PROCESS AFTER DATABASE LOCK

Sometimes the analysis data sets and the output files need to be recreated after database lock. For example when there is a re-opening (modification) of the clinical database or when there are updates made to the analysis data set definitions. Whenever the analysis data sets are recreated they will be compared to their previous version and all data set specific TXT-files will be automatically updated with the differences with respect to data set content and structure. Each time the analysis data sets are recreated all output-files need to be recreated as well to keep all the date and timestamps consistent. The ERV process offers a tool to compare the previous version of output-files with the new version and documents the result of that comparison in a difference report. This difference report for output files together with the data set specific TXT files will serve as documented evidence for all changes that occur after database lock.

CONCLUSION

A major benefit of the ERV process for the statistical programmer is that the updates to the analysis data sets and output files are automatically tracked. Through this process, the statistical programmer is also able to provide a list of modified output files to the project statistician and the project medical writer whenever the output files are recreated. This reduces, for instance, the effort of the project statistician to revalidate all updated output files.

PhUSE 2007

ACKNOWLEDGEMENTS

Special thanks to the Arrow System team - Statistical Applications Development group led by C.J. Tian, Ph.D

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