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Exchange of Information for the Statistical Analysis and Reporting of PK Parameter Data

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ABSTRACT

For a pharmaceutical company the streamlined collaboration between the different departments is extremely important. Therefore a process was rolled out between our BCI and CP department describing the exchange of information for the statistical analysis and reporting of Pharmacokinetic (PK) parameter data. Data and analysis results are exchanged between the different departments to get high quality output as soon as possible into the Clinical Study Report (CSR). The process was set-up by gathering information on how the work was done in the field, in practice. This made the process easy to accept for the employees involved. The main advantages of this process are that subject matter experts do the job, that a lot of work can be done pro-actively and that valuable time is saved.

INTRODUCTION

This paper is mainly intended for Biometrics and Pharmacokinetics personnel of Pharmaceutical companies but also for anyone involved or interested in the analysis of PK parameter data to generate statistical PK parameter output. The paper will describe the main principles and functionalities of the pharmacokinetic parameter data transition and analysis between two departments; BCI and CP.

PROCESS

In the BCI Statistical Analysis Plan (SAP) a PK parameter analysis section is foreseen. This section indicates which tables, listings and graphs are to be generated from the statistical analysis of the PK parameter data .

After the PK analyst creates the PK parameter input file for the statistical analysis based on a standard template, he stores this file on an exchange server.

The BCI statistician saves this input file on the BCI server and converts the file from an excel file to a SAS dataset file. This SAS dataset contains the log-transformed PK parameter values, and may contain some additional derived variables, which are necessary for the statistical analysis.
The statistician also writes a statistical program, executes the statistical analysis of the PK parameters as per the protocol and ensures the statistical analysis of the PK parameters is accurate.

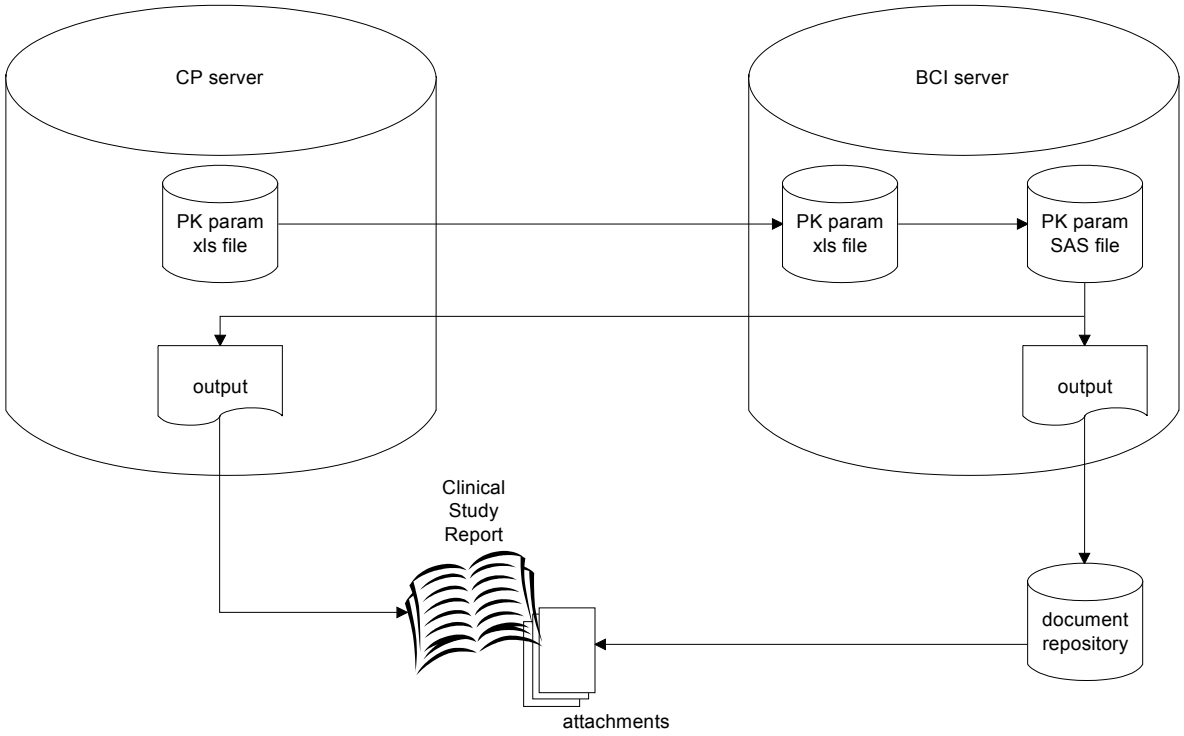
The BCI statistical programmer copies the BCI statistician's program(s) and fine-tunes the program(s) to be in-house analysis system compliant, wherever possible using validated macros. He regenerates the PK parameter dataset by using the in-house analysis system and generates the final outputs as per the SAP.

The BCI statistician reviews the PK parameter dataset, programs and outputs generated by the BCI statistical programmer and drops the final files for the body of the Clinical Study Report (CSR) on the exchange server.

The PK scientist/leader ensures that these final files and tables are incorporated into the CSR as appropriate.

The BCI statistical programmer ensures that the other final files and graphs are uploaded into a document repository. These files and graphs are then incorporated into the attachments or appendices of the CSR.

OVERVIEW



CONCLUSION

A major benefit of the exchange of information for the statistical analysis and reporting of PK parameter data for the company is that the proper systems/resources are used to perform a specific task. By having a streamlined process over departments time and resources are saved. Through this process tasks can be done in parallel and pro-actively rather than being done sequentially on the critical path. The process also reduces the effort of validation and provides the opportunity to work more streamlined together over different departments towards submission. And not to forget it sheds a broader light on the big picture of what a clinical trial is about for each individual whether it's an employee, an auditor or someone working at the authorities we submit our data to.

ACKNOWLEDGMENTS

Special thanks go to the different departmental heads for granting the time and resources to work out this streamlined process.
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CONTACT INFORMATION

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