



Bayer HealthCare
Bayer Schering Pharma

Clinetics Data Merge Overview

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Clinetics Data Merge - General Project Definition

Global platform for data
exchange between
Bioanalytic Laboratory (BA),
Data Management (DM) and
Clinical Pharmacokinetic (PK)



Clinetics Data Merge - Goal

- Develop interfaces to department specific platforms
- Harmonize exchange file format, variable names, formats, and content
- Take into account the BSP Global Medical Standards
- Prevent unblinding of DM by concentration data
- Document transfer activities
- Automatically notify involved departments about transfer activities



Clinetics Data Merge - Realization

- BA, DM and PK can develop their platform specific tools independent from each other
- They have to deliver their data in the agreed format
- The 'Data Description Document DDD' defines harmonized data formats for data transfers between the departments
- Data are exchanged via a central area on a Unix server
- Data are delivered in a fixed CSV file format
- All transferred files are archived
- Automatic emails generated if transfer was successful or not



Clinetics Data Merge – Data Description Document

- Definition of data exchange file
 - File type
 - File content
 - Variable Names
 - Linked GMS code list
- Definitions are implemented as SAS data sets
(Translation tables)



Clinetics Data Merge - Process Description 1

- Bioanalytics (**BA**) transfers concentration data to the central data exchange area
- System transfers data files to a locked directory in the study repository of **DM**
- After unblinding **DM** gets access to the locked directory
- **DM** takes the analytic data and integrates them into the Clinical Database (match to CRF sampling data)

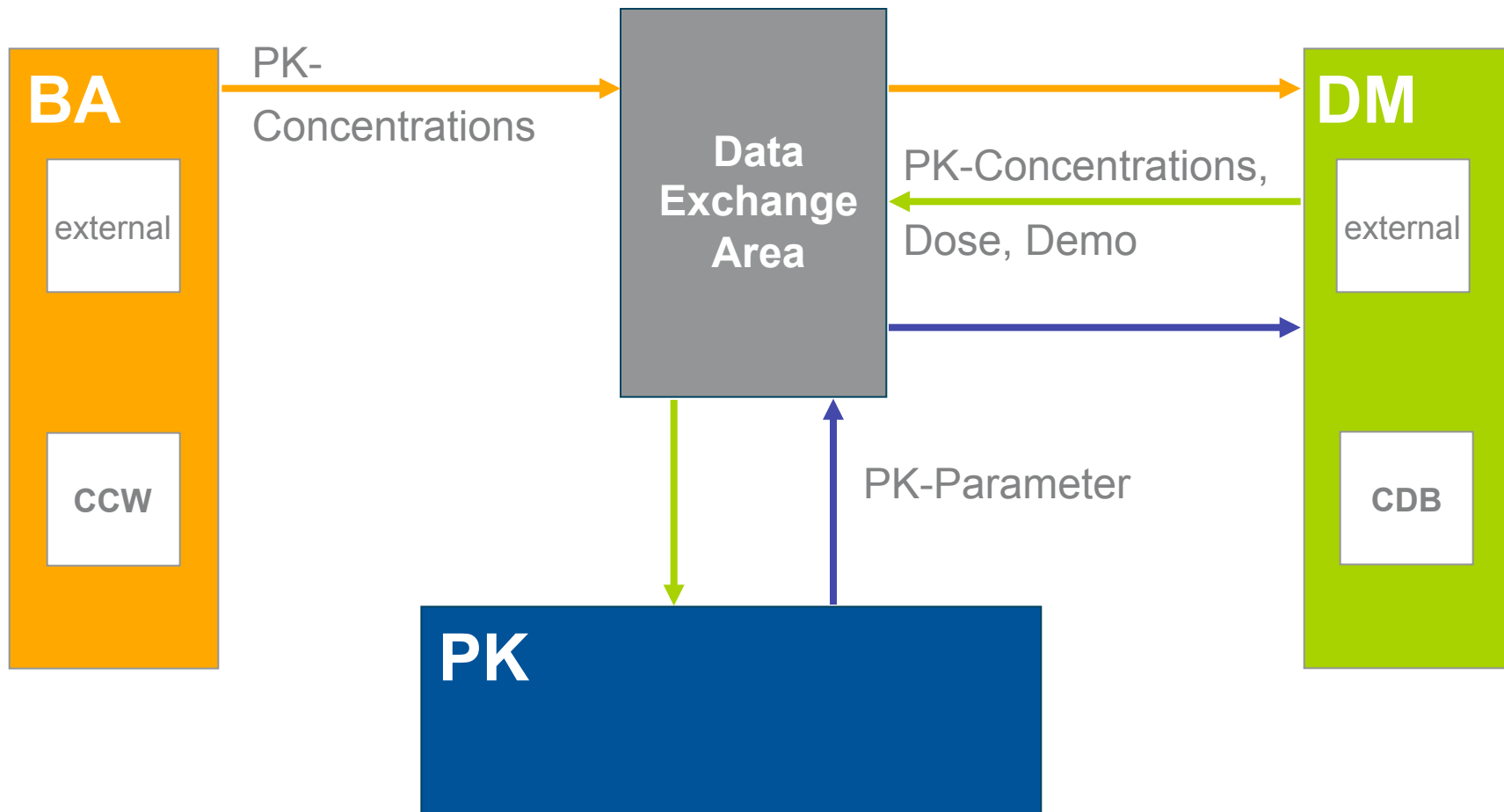


Clinetics Data Merge - Process Description 2

- **DM** creates transfer file to Clinical Pharmacokinetics (**PK**) and transfers the file to the central exchange area
- **PK** picks up the transfer file from the exchange area and performs the PK evaluation
- **PK** transfers the results (PK parameter) back to the exchange area
- **DM** picks up the PK results and integrates them into the Clinical Database



Clinetics Data Merge - Data Flow

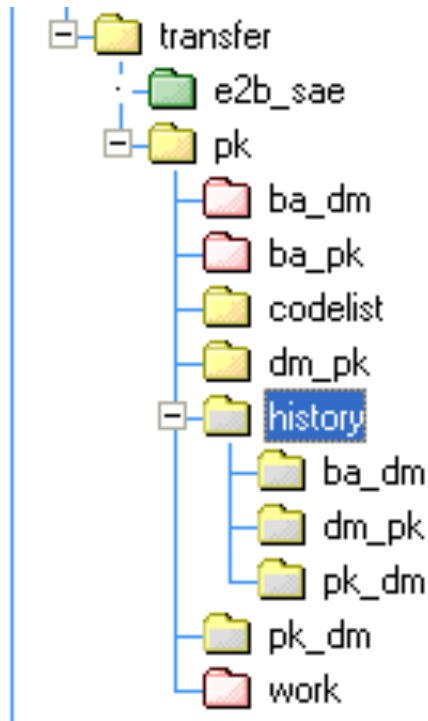


Clinetics Data Merge – Data Exchange Area 1

- Static directory tree on a UNIX server
.../transfer/pk
- Subdirectories per transfer direction for
 - Transfer files
 - Archiving
- Processed files are archived in a history directory branch
- Files are accessible by any department through Samba based network file system



Clinetics Data Merge – Data Exchange Area 2

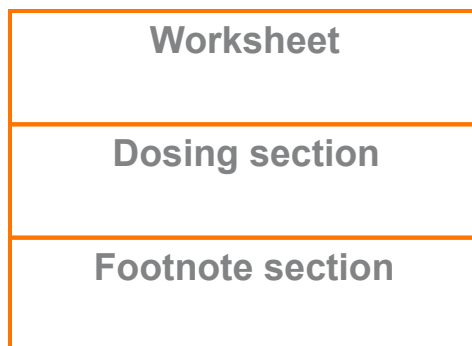


Clinetics Data Merge - File Structure

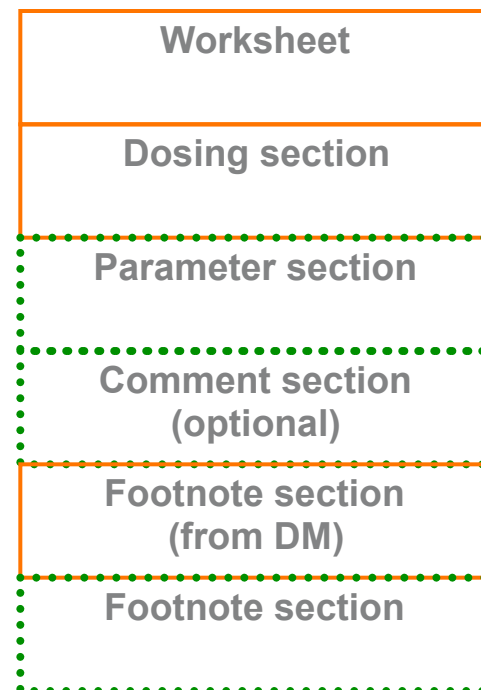
Bioanalytic
*.ba



Data Management
*.dm



Clinical PK
*.cpk



Clinetics Data Merge – Features 1

- Unix based Cronjob checks in predefined time intervals for new delivered files in the transfer area. In case of any findings a transfer process is initiated
- Data integrity of files is assured by use of ZIP archives
- Consistency of data and file structure among departments is checked during transfer by SAS programs called by System after start of transfer



Clinetics Data Merge – Features 2

- Read and Write access is limited to associated departments – premature unblinding based on concentration data is prohibited
- Automatic email notification is done in case of successful transfer as well as in case of any errors





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Questions?

