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Bayer Schering Pharma

Study conduct in a global integrated SAS Environment

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- Initial situation
- Build, implement and maintain global DM processes, tools and standards
- Interfaces
- Working more effectively on one central server environment
- Conclusion

Initial Situation



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Initial Situation



Distributed environment

- Different locations in several countries in Europe, America and Asia
- Different hardware systems
- Different operating systems
 - Windows, MVS, Open VMS, ...
- Different version of common programming language
- Different applications for same tasks

- Local “standard” programs
- Local maintenance of clinical data base standards
 - Data base structure
 - Code lists
 - Thesauri
- Limited global access to local environments
- ...

Decision for change and build

Decision for change



Decision for change

- Reduce complexity for global IT and application environment
- Central server environment in Germany
- Application and server access via Citrix Terminal Server
- Central maintenance of clinical data base standards
- Focus only on EDC and SAS based processes
- Establish global harmonized processes
- Establish central coding environment (for clinical and safety)
- Interfaces to other global systems
- Development of global used standard programs

Implementation & Maintenance



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- Central Server environment in Germany (SAS based)
 - Unix environment
 - Production, Test and Development server
 - Fail over concept established
- Application access via Citrix Server Farm
- Global access from US, Europe and Asia

- **Development and central maintenance of clinical data base standards for SAS server environment**
 - Concept of Global, Therapeutic Area and Project Standards
 - Central Maintenance of DB structure
 - Central Maintenance of code lists
 - Established consistency checks between clinical studies and Project standards
 - Central Maintenance of SAS edit checks

- **Central coding environment**

- One environment to code clinical and safety data base
- Interface to Drug Safety System
- SAS interface to handle all internal & external studies and data pools
- Central Thesaurus maintenance incl.
 - Synonyms
 - SMQs
 - Medical Entities (ME)
 - Coding Algorithms

- **Interfaces to other global systems**
 - Electronic Data Capture (EDC)
 - Medical Review Application (JReview)
 - Drug Safety System
 - Coding System
 - Trial Management System
 - Data Exchange Area between Bioanalytic, Data Management and Pharmacokinetic
 - Study- and Patient Tracking System
 - Random Application

- **Development of global used standard programs**
 - SAE reconciliation – Interface & Reports
 - SAS based edit checks
(incl. library for several layer of standards)
 - Consistency checks between clinical study data and BSP standards
 - EDC data download
 - Standard programs for derived items (e.g. study day)
 - Lab conversion into standard units
 - CDISC SDTM generation
 - Etc.

- **Integrated SAS programming and working environment**
 - Study setup and user access control
 - Platform to control all SAS related processes and interfaces
 - Program, log and output handling etc.
 - Interactive and batch queue environment
 - Program development and production area separated
 - Audit trail and file history
 - Meta data and code list handling on several standard hierarchies
 - Clinical data handling and integration
 - Single and double-byte (for Kanji) data extraction from EDC
 - Protected tool and standards area with version management

- **Example of Data Management tasked executed in central server environment**
 - Data export and mapping from EDC to BSP standard DB structure
 - SAS Coding interface setup for all internal and external studies
 - SAS based edit checks
 - Programming of validity and protocol deviation criteria
 - Consistency check of internal and external studies
 - Integrated SAE reconciliation report



Working within central environment-2

(used by Global Data Management and Global Biostatistic)



- Study status tracking (EDC, external data and internal processes)
- Creation of listings (incl. data review listings), reports and graphs
 - Setup in JReview or SAS environment
- Case summary / narrative report setup
- Data transfers (incl. external data like LAB, ECG, etc.)
- Annual IND report generation for all BSP studies
- Creation of key risk indicator reports
- ...

Benefits of ONE central environment

- Global access to all data and programs stored at central place (incl. audit trail and version history for production area)
- Share of resources globally on study related tasks as well as for standard tool development
- More efficiency for clinical studies in overall process e.g.
 - Daily EDC data download as basis for all further DM processes
 - Direct data access for statistical programmer
- Standards are maintained once without inconsistencies of local copies
- Reduction of development effort for global standard programs (incl. central update and version control)

Conditions/Limitations for a central environment

- Powerful hardware environment needed (especially I/O)
- Fail-over environment required
- Performance (bandwidth) and stable local and global network needed
- 24/7 SLAs for central hotlines of global environment (servers & net)
- Standardization as efficiency driver for central environment, but in particular for DM process in clinical studies
- Well planned hardware maintenance and software installations needed (ideally over weekend)
- Local contact persons within function for global tools and processes

Conditions/Limitations for central environment

- **Training, training, training,**
 - Central environment and tools will not automatically guarantee unique global processes
 - Different processes for different study types needed
 - Phase I to IV and non interventional studies (NIS)
 - Integration of Bioanalytics and Pharmacokinetic processes
 - Unique data exchange format
 - Careful handling of PK values during study conduct

Possible next steps

- **Extend scope and usage of central server concepts to**
 - ... Implement central standards maintenance tool
 - ... Give access to data and standard reports to further BSP functions
 - ... Establish joint central platform with strategic external partners
 - ... Streamline global processes along all systems
 - ... Enhance source to target traceability for data and output
 - ... Streamline interfaces
 - ... Etc.

Conclusion



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A well defined central integrated environment will help a lot to work real time globally, share resources and avoid duplication of work and inconsistencies within standards. Even more beneficial a central environment can be used, if standards are well established for tools, clinical studies and processes across the company and they are one of the key driver. IT and global network should be not underestimated in the whole context as well, because bad network performance or server capacity will have a much higher impact in an integrated environment than in a local environment. For development of standard programs also specific factors like local language (e.g. KANJI for Japan) support should be taken into account. Ongoing training and knowledge exchange needed to ensure unique global processes.

Thank you for your attention



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