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Study conduct in a global integrated SAS environment

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ABSTRACT

Global organizations are usually distributed across many countries all over the world. Trying to establish global harmonized processes is often influenced by locally established systems and tools. Limited global access to local environments, redundancies of tool/macro development and risk of inconsistencies could either increase the effort to keep all loose ends under control or even completely hinder the roll-out of global processes. The presentation will give an example from a Global Data Management perspective, how reduction of systems and processes, application centralization and integration (e.g. EDC-Electronic Data Capture, Coding, JReview, SAS) and central storage areas can contribute to support global process harmonization, resource sharing and consistent company standards cross functions (e.g. data management & biostatistics).

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INTRODUCTION

Many companies become more and more complex organizations with staff and functional reporting lines across the globe. In addition the cross functional interaction is growing and this is often also combined with in-sourced staff and CRO cooperation. Data and information needs to be made available and shared in a faster and more consistent way.This situation makes it very difficult and inefficient to work with distributed environments and applications as it breaks down global process harmonization, data and information access and resource sharing. On top of this, the IT components with data replications, trying to keep tools and standards in sync across the globe and to provide data in a timely manner cross functionally is nearly impossible to be managed. This paper will address some of the options and risks based on a centralized integrated working environment with SAS backend and EDC as data source system and Global Data Management and Global Biostatistics working in the same shared environment.

INITIAL SITUATION

The initial situation was based on a distributed hard and software environment with locations in Europe, America and Asia. Some times different applications were used for same tasks, but even same applications used for business could cause problems with inconsistent use and replication problems. All this lead to a situation, where local standard programs had to be established with high effort to ensure consistent algorithms and functionality. Also different kinds of data bases and interfaces for same and cross functional departments were needed to be maintained in a consistent way for e.g. meta data, code lists and thesauri. On top of this, there was still the down side of no or very limited global access to local environments and limited options to share resources.
Several years ago, Bayer Health Care decided to change this situation completely. Intention was the reduction of complexity of the global IT environment with different hardware, operating systems and applications. Direction was to establish one central server environment in Germany with global access from all locations and to focus on EDC and SAS in the business area of Global Data Management. Expectation from the first step in this approach was a reduction of maintenance, interface and related costs and a major benefit in the area of global process harmonization and global tool development without duplication of development effort and potential risk of replication inconsistencies. In addition a harmonized approach for a global coding environment for Global Data Management and Pharmacovigilance was planned to be established for medical and drug coding (MedDRA and WHO-DD).

ACTUAL SITUATION

Bayer Schering Pharma is actually using a purely EDC and SAS based environment for daily work in Global Data Management. This already reduced the complexity of processes for many departments at BSP as paper and electronic CRF development and processes have not to be lived and maintained in parallel. As eCRF development is not part of this paper, focus will be on the centralized integrated environment, jointly used by Global Data Management and Global Biostatistics. The central SAS server environment located in Leverkusen is Unix based and used by all data management departments in Europe, America and Asia. Access to applications and SAS backend is ensured and controlled by a central Citrix server application farm.

This environment actually controls and support, but is not limited to the following Global Data Management processes:

- Global, Therapeutic Area and Clinical Project Standards
  ➔ actually limited to SAS data base structures, format libraries and SAS edit checks
- Study data base setup and access control
- Global coding environment for MedDRA and WHO-DD
- Integrated serious adverse event report for reconciliation purpose
- Laboratory value conversion
- Creation of derived items (e.g. relative days etc.)
- SAS edit checks and query generation
- Protocol and validity checks
- Report generation (ASCII, PDF, RTF & Excel) and data generation
- CDISC SDTM generation
- Consistency checks between DB setup and according BSP standards
- Interfaces to other global applications as there are to be mentioned EDC, Safety System, Trial Management System, Medical Review Application, "Data Exchange Area between Bioanalytic, Data Management and Pharmacokinetic", Coding application

WORKING ENVIRONMENT

For a global central environment a platform is needed, which controls all SAS related processes and interfaces like programs, logs, outputs etc. As many processes in Global Data Managements are executed and partially even automated on a daily basis, there is still the need of a powerfull SAS interface, but especially also a SAS batch oriented environment. This ensures that processes can be also executed over night or with batch processing also long lasting jobs will not hold back people from further daily tasks they have to do, because of waiting for job results. Working in a regulatory environment requires that the system provides a development and production area as well as audit trail for production area. This should guarantee on one hand that all changes from a certain point in time are controlled, but that there is also the ability to compare data changes between certain dates or even roll back e.g. a database to a certain point of time. As you see this kind of data handling and integration is key, one further core element, in addition to access and object management (with audit trail or version management), should be the maintenance of study related meta data and code lists always linked to the standards, which are established in your company. To support daily data management business with insurance of global harmonized processes, a protected and controlled area for process tools is also one of the key elements of an integrated environment. Building / configuring such a central global environment, you might also be hit with topics like local languages and UTF8 vs. double byte character processing. This you have to evaluate carefully as it will have consequences for daily study work as well as for data integration/pools.

STANDARDIZATION

Standardization is key for success from several perspectives. Hardware and application is only one of them, but the most beneficial is standardization of objects and processes. Let's assume that also for global departments with one application one process is followed. Still, then there are all the activities on object standardization from source to target deliveries. Ideally this starts already with the protocol design, includes different kind of database structures (operation, SDTM, analyses…), code lists (controlled terminology), edit checks and listings/reports up to standard elements for tables and graphs for the final clinical study report. Some companies establish parts of the full information stream and other try to get the whole picture from start to the end. Also the process, how standards are maintained can be different like one general database standard elements without additional layer or a hierarchical model with e.g. global, therapeutic and clinical project standards(CPS), where CPS is also a good basis for data integration/pooling. The multi layer approach is used at BSP. Most of the standard elements have a direct influence on data management and improves processes, tool harmonization and process automation, but needs some effort to agree upon cross functional and it also needs to be ensured that ongoing maintenance on standards is ensured. BSP has established parts of the topics listed above and maintains actually in the central SAS environment standard meta data for data bases, code lists, SAS edit checks, thesauri and tools and will broaden the scope in near future.

PROCESSES

Once a certain level of standardization is achieved you have the major benefit in a central integrated environment to steamline and harmonize cross regional and cross functional processes, based on the same set of meta data, data, code lists, reports and standard tools. In addition to these internal and external resources in data management they can share their daily work and make use of SAS standard macros and tools in combination with flexible study related interaction. This is important as even with a high level of standardization you need the flexibility to react on special data situations, reporting, checks or also data management workload peaks. BSP uses the actual central SAS environment for all non EDC related tasks like coding, data mapping, calculations, reporting, data exchange, lab conversion, SAS edit checks, SAE reconciliation etc. As even an integrated environment has still to allow for data and process exchange with other global applications, BSP has established core SAS based interfaces for e.g. daily

data exchange with EDC, centralized global coding process with a central coding application for Global Data Management, Global Biostatistics (for data pooling) and Pharmacovigilance. Especially the coding interface ensures consistent usage of thesauri, coding algorithms, synonyms and SMQs across trials and applications.

DATABASES AND ARCHIVING

Databases are another key element and a central integrated environment allows to work with one source for standards and studies for data management and biostatistics. It ensures consistent data and code list usage, common algorithm share and data checking capabilities for consistent data integration. Once this central environment has been established it will easily generate benefits for other departments as well. . Central data environments are growing and once in a while need also version updates and also long-term data archiving. Therefore for each central data environment rules and formats should be defined for external data archiving. This could avoid time consuming long-term data migration of very old data and studies, which does not conform to newer standards or applications.

CONDITIONS/LIMITATIONS

A central integrated global SAS environment shared by data management and biostatistics and maybe other functions has definitely major benefits, but also some conditions or limitations. For the beauty of having all staff working on one central server you need to ensure that it has the right size and is secured by a fail-over concept, once the main production server might have problems. Batch processes seems to be sometimes old fashioned, but definitely helps for daily work on one hand for process automation, but also not to limit a user to execution of just one process, which can be execute at the same time. Independent from internal or external hosting model you need a solid 24/7 service license agreement with IT provider for network and server. A central Citrix environment is one of the options to enable global usage of applications, but in addition you have to ensure a certain network bandwidth as otherwise global access is given, but performance might be to slow for day to day work. What ever you do, implement and standardize, dedicated persons as reference partners are needed and a topic which is often underestimated is training, training, training… as this is needed and basis for consistency and success.

CONCLUSION

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, objects and processes across the company and they are one of the key drivers of success. 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 a central integrated environment than in a local environment. For development of standard programs also specific factors like local language support should be taken into account. Ongoing training and knowledge exchange needed to ensure unique global processes.

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