



Standardization of Data Base : Interaction between Biostatistics and Clinical Data Management

PhUSE

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L'essentiel c'est la santé.



Introduction

- **Methodology for standardization and communication between 2 departments for a same objective :**
 - obtain a clean data base compliant with request of authorities
- **My function : Statistical Programmer in oncology**



Agenda

 Context

 Methods

 Issues/Solutions

 Evolution

 Conclusion



Context (1/2)

- **Organization in Sanofi-Aventis :**
 - Department of Clinical Data Management
 - Department of Biostatistics
- **Regarding Submission data sets : Programmer in Biostatistics are in charge of creating them**
- **New tool in Data Management : Oracle Clinical**
- **Update of CDISCS Documentations**



Context (2/2)

- **First step with collaboration of 1 represent of each department => not sufficient for evaluation of all impacts**
- **After first implementation of standard data base => creation of a new working group**
- **3 objectives :**
 - **1 / Create a standard global library compliant with CDISC's recommendations**
 - **2 / Define conventions (example : if upper or lower limit missing in LAB data)**
 - **3 / Communication/Information with users**



Methods (1/3)

Methodology : New working group

■ Bi-Monthly meeting

■ Actors :

■ Biostatistics department :

- Statistical programmer – User
- Support Function – Evaluate impact and change for applications
- Standard – Update of CDISC's documents

■ Clinical Data Management :

- Clinical Data Manager
- Standard
- Data Base Designer in Oracle Clinical

■ and if necessary input of 'experts'

- Example : tools/macros developed

■ Minutes

- Review
- Approval
- Communications



Methods (2/3)

(1st objective : Creation of standard global library)

■ Comparison of existing OC data base with SDTM/ADaM

- SAS : proc compare between current OC data base and SDTM/ADaM
- Excel sheet with correspondence : sas variable versus OC question
- Review of each variable :
 - Naming
 - Labelling
 - Contents (List of expecting values if needed)
 - Length



Methods (3/3)

■ For the 2nd objective : conventions

■ Training by presentation for technical aspects

- Example : laboratory data with the process of 'Reclab' : Reclab is a tool in Data Management for merging information in CRF and information in central lab
 - Conventions for missing value
 - Methods of calculations for Age ...

■ Discussion/meetings with user's : work with therapeutic area concerned

■ For the 3rd objective : communication

- Therapeutic area meeting
- Staff meeting



Issues/Solutions

■ Languages

- **Wording for methodology :**
 - Timelines : when is it 'finished'? Defined ? Programmed? Put in production?
- => **Define each step of the "project" with a detailed calendar**

■ Technical

- **Oracle Clinical / SAS / CDISCS**
 - Example : question OC=Variable SAS
- => **Training**
- => **Table of correspondence/equivalent**
- => **'experts' presentation/presence at meeting**

■ Understanding therapeutic area's specificities

- => **Contact area represent**

■ Constraints of each department



Evolutions

- **Global Library alive = > a sub-group works for fast implementation**
- **This working group still ongoing**
 - **adaptation of CDISC's evolution**
 - **Work on area specification**
 - **Evolution/Review of conventions**



Conclusion

- Even if time consuming, this kind of working group is a real “bridge” between 2 departments
- Interesting to try to understand each constraints in order to have the good approach regarding authority’s requirement
- Keep reactive with evolution/update of CDISC’S changes



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