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

PhUSE
October 19th, 2009

Céline TENDEREO
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
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.
Sanofi aventis – Céline TENDEREO

20 avenue Raymond Aron
Antony 92165
Work Phone: (33) 1 55 71 44 26
Email: celine.tendero@sanofi-aventis.com