

# Data Management Workshop 2011 on SOP's

## Meeting minutes of closing session on Friday 28oct

**Attendants:** Sayouba Ouedraogo, Anish Battarai, Hercule Kalonji, Robert Meester, James Smedley, Sok Sopheak, Mary Thiongo, Arouna Woukeu, Sokleng Sun, Martin Othello, Paritosh Malaviya, Hiwot Debalke, Harry van Loen, Yves Claeys, Raffaella Ravinetto and Lut Lynen

*In the week of 24-28<sup>th</sup> of October, the second Data Management Workshop was held at the Institute of Tropical Medicine in Antwerp with the aim of creating harmonized procedures for Data Management in Clinical Studies. Each participant prepared one predefined SOP and presented this during the Workshop. After lively discussions, each participant is left with the editing of the draft SOP. On Friday 28<sup>th</sup> of October a closing session was held to discuss the future functioning of the group. Raffaella Ravinetto (Head of the Clinical Trials Unit at ITM) and Lut Lynen (Head of the Clinical Sciences Department at ITM) attended this closing session with important contributions on respectively Funding and the formation of a Steering Committee.*

### 1) Poster

The poster which was presented at the 7<sup>th</sup> International Congress for Tropical medicine and International Health (ICTMIH) was distributed to all members of the group on a A2 format.

### 2) Expansion of the group

The question whether the group should expand towards the next Workshop was received as practically difficult both for financial reasons and for practical reasons. The group should however be able to provide tools and information to others through a website, workshops, individual training etc. It will become the responsibility of the steering committee (see 4)) how large the group can be for each specific meeting.

### 3) Funding

The current funding for this network is provided by the Belgian Development Cooperation and will allow us to organize a third Workshop in the beginning of 2013. For the continuation of this groups' activities afterwards, a specific work package on Funding will be created to ensure sufficient funding can be generated for future activities such as workshops, presentations, training, etc..

Raffaella, accepted to chair this Work package.

### 4) Steering committee

Lut proposed to create a smaller but mixed steering committee, that would be responsible for the strategic decision making and coordination of this Data Management group (decide on future activities, representation of the group, budget control, etc). The whole group agreed on this idea and following details resulted from a brainstorm on this concept:

- Paritosh, Harry and Yves will write a draft text in which the structure and responsibilities of this Steering committee will be described, as well as the procedure for democratic election of its members – November
- This text will be reviewed and corrected by the other members of the group, including Raffaella and Lut – End of 2011
- The election of the steering committee is due for January 2012
- The work packages (see 4)) will fall under coordination and control of the steering committee and will be discussed upon ASAP after the formation of this steering committee

## 5) Work packages

Several activities that that could/should be covered were addressed during the Workshop and will become under the strategic coordination of the steering committee:

- Harmonizing SOP's
 

After the SOP's are revised, based on the comments that were noted during the discussions, all SOP's must still be harmonized in order to become a powerful but user friendly instrument. To do:

Lay out, specify semantics and uniform definitions, overall schematic flow which interrelates all SOP's, harmonizing the amount of detail in each SOP, references to other SOP's, input by Physician or statistician (eg SAE reconciliation) , etc

This will too become under the super vision of the steering group but as this was the main topic of this years' workshop, the activities will be started already under coordination by James and Yves
- Website
 

The creation of a website could have several benefits such as:

  - o a platform to share files, abstracts and articles, knowledge and discussions (forum) within the group
  - o a tool to share our products, such as SOP's, with others
  - o enforce our identity and keep the group closer together in between Workshops
- Training
 

Organizing training sessions in the field, in parallel to the Workshops, creating an online eLearning platform, are all activities that could become part of this group in the future, based on our joined experiences and procedures.
- Funding
 

See point 2)
- Dissemination
 

In order to avoid that we stay an isolated group, the dissemination of our activities and how we see the future for Data management in Clinical Research, in particular in our North - South collaboration and academic framework, will become the next important step. In line with the two abstracts already approved at 7<sup>th</sup> ICTMIH and EDTCP form at Addis Abeba in 2011, further investments must be made in terms of writing abstracts, presentations, opinion papers, articles on DM, DM representations on large forums, etc..

## 6) Group name

On the first DM Workshop in December 2010, ATDM (Association of Tropical Data Management) was chosen as name for this group during an improvised voting. This name however is generally not accepted as a good representation because of the unappealing sound and looks. Therefore a call for a new name was raised in this session. Four candidates are proposed:

- tropDAN (**tropical Data management Network**) - Harry
- tropDATA (**tropical DATA**) - Harry
- NTDM (**Network of Tropical Data Managers**) - Paritosh
- CDM (**Clinical Data Management**) – Arouna
- ADMIT (**Association of Data Management In the Tropics**) – Robert

*Post meeting note: According to Jef Van Lint, Project Management at ITM, 'Association' is generic enough in this context, so no problem to use it in our name*

Other proposals are still welcome until the end of the year. The voting of this name will go along with the election of the members of the steering committee.

**The price for the winning proposal will be a box of premium Belgian chocolates!!!**

## 7) Centralized documents

All presentations, draft SOP's and photo's are currently placed on the ftp server. If not accessible please notify Harry or Yves.

Responsible	Activity	Deadline
ALL	Send the revised SOP's, based on the group discussion, back to Yves and James	End of November
James and Yves	Collect, review and start Harmonizing the SOP's	end of November until done
Paritosh, Harry and Yves	Write draft text on Steering committee (functioning, elections, responsibilities)	Mid November
All (incl Raffaella and Lut)	Review draft text on steering committee	Mid December
All (incl Raffaella and Lut)	Submittal of name for the group	end of 2012
All	Elections first steering committee	January
All	Elections on the name of the group	January
Steering Committee	First steering meeting	ASAP after elections