Switching the poles clinical research network

Proceedings of the third meeting of ADMIT

Association for Data Management In the Tropics

Varanasi, 4th-8th March 2013

The *Switching the Poles Clinical Research Strategic Network*[1] was created in 2008 under the Framework Agreement between the Institute of Tropical Medicine in Antwerp (ITM) and the Belgian Directorate-General for Development Cooperation (DGD). In this framework, a group of clinical data managers and database developers, all engaged in North-South collaborative medical research, met at the ITM in December 2010, for setting up a network for knowledge-sharing and reciprocal support on data management (DM) activities.

The 2010 meeting showed that problems commonly met by clinical data managers include underestimation of the workload by study coordinators and donors; short timelines, which have negative impact on the quality of deliverables; late involvement in projects, making streamlining of DM with project purposes difficult; and low position in hierarchy of research groups, causing communication problems during projects. In addition, in the absence of colleagues and broader networks, a data manager is often left alone to choose appropriate technical solutions (e.g., software or validation methods adapted to the research constraints), without consulting fellow colleagues.

A second workshop, which took place at ITM in October 2011, focused on drafting common standard operating procedures (SOP) for clinical data management.

The final SOPs, as well as an internet-based platform dedicated to clinical data management in North-South and South-South collaborative research, were presented at the third workshop of the network, which took place in Varanasi, in India, on 4th-8th March 2013. This workshop, which is the object of these proceedings, was funded by the DGD and jointly organized by the Banaras Hindu University (BHU) and the ITM.

[1] http://www.itg.be/itg/GeneralSite/Default.aspx?WPID=705&MIID=670&L=E).

Day 1 - Monday 4/3/13

Welcome and presentation

Prof. Shyam Sundar (Banaras Hindu University, Varanasi) and Raffaella Ravinetto (Institute Tropical Medicine, Antwerp) welcomed the participants on behalf of the hosting institution. They reminded the key-role played by data managers for the accurate documentation of the findings of medical research, and underlined that ADMIT may help to overcome their current situation of "neglect" in non-commercial research, by bringing them together in an active network, where experience is shared and appropriate and context-adapted tools are jointly developed.

Noteworthy, this is the first ADMIT workshop which takes place outside Belgium, which proves the willingness to "switch the Poles" and set in the South the responsibility for research in the South.

This first day was dedicated to the presentation of activities of the host organization (BHU) and of the newcomer organizations.

Clinical DM in Banaras Hindu University, Varanasi, by Paritosh Malaviya (please sent *presentation)*

http://www.bhu.ac.in/

The main research lines at Banaras Hindu university (BHU) concern visceral leishmaniasis and filarial disease. Routine collection of data from field surveys, interviews, observations and laboratory is carried out in Muzaffarpur district and transferred to the DM Center of the BHU Medicine Faculty (located at some 350 km) via secured e-mail line. The data collection system at Muzaffarpur District Surveillance System (DSS), the data flow between the field and the hospital, and the quality system of the Data Management Center were presented and discussed by Paritosh, as well as every step of DM. It was noted that a mobile phone system is being piloted for data collection and filing, and there was a suggestion from the audience to consider the possibility to scan and digitalize the data from the DSS.

Clinical DM in MRC, The Gambia, by David Parker

http://www.mrc.gm/

The Medical Research Council Unit in the Gambia has about 900 employees and three DSS. David described its structure, and the activities of the DM group, which currently belongs to "IT and DM", but will next either join Statistics or be a separate entity. Different DM software are used, depending on the typology of each research, including OpenClinica (with data moved directly into SAS) and the use of bar codes for samples and e-CRF. Difficulties and challenges were briefly discussed, such as staff retention, funding of posts, retention on projects and standardization among the DSS.

Clinical DM in College of Medicine, University of Malawi, by Alfred Malili

http://www.medcol.mw/

Alfred Malili presented the two research projects where he's currently in charge of DM. The DM approaches are different in the two studies (respectively data scanning and the commercial software MACRO), which may represent a challenge for the team. Other difficulties and challenges include the great deal of manual work required by data scanning and the lack of resources (e.g. for user licenses,

poor internet connection, frequent electricity power cuts). It was noted that a national forum for DM (Data Management Peer Group) is being created in Malawi.

Clinical DM for the PREGACT clinical site in Ghana, by Godfred Owusu-Ansah

http://www.knust.edu.gh/pages/

Godfred described the structure and mandate of the Center for Global Health Research at the Juaben Municipal Hospital, and then gave a detailed description of the projects supported (mainly in the field of malaria research) since 2003 to date, with focus on the database used in such projects. Currently, he works with the commercial software MACRO. The pros (user friendliness) and cons (poor room for long term capacity building) of MACRO were broadly discussed in this session.

Clinical DM in Centre de Recherches Entomologiques de Cotonou (RCEC), Benin, by Alain Nahum

http://www.ird.fr/les-partenariats/nos-principaux-partenaires/crec2

Alain gave an overview of the mandate and activities of the CREC in the field of malaria research. As far as clinical trials are concerned, the CREC is currently mainly engaged in commercial clinical trials, but there is a strong aspiration to acquire and develop the resources needed for autonomously conducting non-commercial, public health oriented trials too. During this session, there was an interesting debate on data ownership and data-sharing.

Clinical DM at DNDi India, by Abhijit Sharma/Vishal Goyal

www.dndi.org

The general mandate and activities of the 10-year old Drugs for Neglected Diseases Initiative were presented, with some extra focus on the Indian branch. The DNDi has a strong African DM group, which unfortunately could not be represented at this meeting despite the willingness to do so. For the Indian projects, DM is outsourced to CROs, and the modalities and implications of working with CROs were further discussed. It was noted that the need to use paper CRF at some sites may bring logistic problems and delays.

Clinical DM at EGPAF and Rinda Ubuzima, by Gilles Ndayisaba

http://projet-rinda-ubuzima.org/

http://www.pedaids.org/What-We-re-Doing/Where-We-Are-Working/Rwanda.aspx

Gilles gave an overview of the mandate and activities of the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) and of the project Rinda Ubuzima, both engaged in HIV/AIDS research and clinical studies, which was followed by a review of databases used in the studies where Gilles has collaborated. These include Epi info, MySql, MS Access and CsPro. It was noted that the option of having an *ad hoc* database designed locally is often limited by the lack of expertise for the design and/or the maintenance of the database itself. Other challenges are due to the fact that the role of data managers is often misunderstood; poor Internet connectivity; lack of harmonization in multi-site studies; and the poor or late involvement of data managers in all steps of the research.

Conclusions of Day 1

Despite the large variety of presentations and contributions, at the end of Day 1 it was possible to identify some common challenges and problems, which had been mentioned in several presentations. In this non-exhaustive list, we find:

- The poor Internet connectivity, which in some places hampers or even prevents the electronic data transmission.
- The lack of appropriate open-access software with offline remote data entry further complicates this issue, while commercial (user-friendly!) software are generally expensive and do not allow capacity building
- The frequent appearance of new versions of existing software, which often cannot be installed on older hardware
- The financial resource constraints, e.g. the difficulty to secure sustainable funding for structural investments and structural positions in-between the specific projects, and the lack of funds for the design and/or the maintenance of an *ad hoc* database
- The human resource problems, e.g. the difficulty to retain skilled personnel, or the impossibility to keep on site skilled staff at the end of a project due to end of funding, or the lack of expertise for the design and/or the maintenance of an *ad hoc* database
- The poor understanding of the role of data managers, and their poor or late involvement in all stages of a research
- The difficulty to harmonize procedures, e.g. in multi-site studies or in remote sites/DSS

Day 2 - Tuesday 5/3/13

ADMIT e-platform: demo and proposals for management, by Yves Claeys and Harry van Loen

http://admit.tghn.org/

Harry and Yves presented the ADMIT e-platform, just released on the platform of Global Health Network. The e-platform will give an opportunity to ADMIT members to actively share knowledge and information, as well as to broaden the ADMIT network to other individuals and networks (e.g., the network in Malawi). All the ADMIT partners are warmly encouraged:

- to send comments and suggestions to Yves and Harry
- to post documents and other relevant information
- to launch and animate the discussions.

ADMIT SOPs: presentation and discussion, by Yves Claeys and James Smedley

http://admit.tghn.org/articles/sops/

James and Yves presented the ADMIT SOPs for Data Management, which they have finalized in the last months, based on the draft versions developed during the second workshop held in October 2011. This activity has the main objectives of (a) providing a set of model procedures for partners that are starting a quality system in data management and (b) harmonizing and standardizing practices among partners.

At the end of this session, it was agreed that:

- All the ADMIT partners are requested to send comments and suggestions to Yves and James **at the latest by the end of April**, **by e-mail**, so that an updated version of SOPs can be issued when needed tentatively **by end of June 2013**
- The "history" of each document including the names of those who wrote/contributed to writing the initial draft versions, will be moved on the top of the SOPs
- In addition to the single SOPs, also the whole binder will be posted in the website, including an introductory page explaining that/why not all procedures are yet covered

Software harmonization, by Paritosh Malaviya and James Smedley (please sent presentation)

This session aimed at compiling the "ideal profile" of a software for clinical DM to be used in the Tropics. James and Paritosh introduced it with a general overview of the possible available options (MOBILE-TELE-MACRO-CLINICA-DMS) and a list of the elements to be taken into account: data capture/entry, data management, data storage and hosting platform. After the introduction, the participants split in three groups of six people each, for detailed discussion.

GROUP 1 – Rapporteur David- please sent PDF

This group developed a detailed list of specifications for each of the proposed elements (data capture/entry, data management, data storage and hosting platform). Noteworthy, it is proposed that DM should be encouraged to be done at the site, for integrating capacity building in most/all projects.

GROUP 2– Rapporteur Harry

This group linked the ideal software specifications to the ADMIT SOPs, to make the “ideal software” user-friendly and compliant with our quality system. They also reminded that a user-friendly price is wished, beside user-friendly and quality-friendly specifications!

GROUP 3 – Rapporteur Mary– please sent word summary

This group listed the specifications of an “ideal software” taking into account quality criteria and user-friendliness at both level (field and central). Special attention was paid to security issues, and on how to achieve a “fit-for-all” product.

Overall, some recommendations were common to all groups, e.g. giving preference to electronic data capture, need of offline mode, and with standardized design of database, need of bar code or equivalent system, possibility to work with multiple sites and need to reduce the dependency on outside (commercial) partners.

Day 3 - Wednesday 6/3/13

How to build a South-South Network and keep it alive , by Raffaella Ravinetto

Two networking models were presented: Global Health Network (http://globalhealthtrials.tghn.org/) and Quamed (www.quamed.org). The former focuses on information and knowledge-sharing, while the latter goes broader, by fund-raising and pooling resources for building new knowledge and tools together. Also within ADMIT, the partners should indicate which model is preferred and more feasible for the future. If going for a more ambitious scenario, including fund-raising for specific activities, the priority activities should also be identified.

Discussion on ADMIT perspectives in 2014-2016, chaired by Paritosh Malaviya and James Smedley

The set of SOPs for DM represents the first output of ADMIT. In this session, members discussed on potential future activities and outputs, based on concrete needs and challenges they experience at their respective sites . Among others, the following ideas were brought forward and discussed:

- A "fits-it-all" software, which may work offline preferred with the following features
    - A drag and drop application for creating and inserting questions variables which may induce a single table storage. A single table would be less flexible but the gain in a low threshold easy to use system is believed to be more important
    - Simple validation layer to allow to write edit checks on and between question variables with limited programming skills. A view to the program language can be interesting for experienced programmers
    - Languages: to investigate how question variables can be defined in different languages for easy switch during studies (eg between English and local language).
- A standardized DM training package
- A standardized DM organogram, including standard job descriptions for the different functions. [In fact, a major challenge faced by data managers is that the other members in research team often do not know what DM/data managers is/are, leading to confusion on respective tasks and roles and also to budgetary shortcomings[2]]
- A standardized DM glossary of definitions and principles
- A format template for data and DM standardization
- A work package on "public relations (PR) and visibility", including but not limited to publications.

At the end of the session, James summarized the potential future activities in the following table:

Software	Comparison of our data management systems (paper)
DM system	System user requirements specification(URS)
	Data standardization - adoption of data management standards (CDISC…)

[2] During the questions & answers session, it was also noted that that the Principal Investigator and Sponsor of each study should have a good general awareness of the data management features and challenges, in order to allow the data managers enough resources and time to perform their tasks according to standards

	Data sharing framework / platform
Training	Training packages
Management	Organogram (harmonization of data management roles)
	Budgeting for data management - WHO style costing per country
Resources	Access to website / resources
	PR Visibility of ADMIT - specific plan for publications
	Funding

Day 4 - Thursday 7/3/13

Training session on Clinical Data management, by Sayouba Ouedraogo *(please sent presentations)*

Sayouba, who's a member of the Steering Committee of ADMIT, transferred to the network the contents of the training on a Data Management Plan (DMP).

The DMP is an auditable document which is essential to ensure high quality of data collected in each specific study. Sayouba firstly gave an overview of the DMP's standard sections, including the cover page, amendments & changes procedure, definitions and acronyms, case report form (CRF), database design, creation & maintenance, data entry and processing, data validation & user acceptance testing, coding[3], SAE reconciliation[4], quality assurance/control process, database lock strategy, and additional sections such as list of team members, communication plan, interim analysis plan, archiving plan etc.

After the introduction, specific sessions with practical exercises were given, concerning respectively:

- the CRF
- database design & system validation
- organizing data review.

Noteworthy, David gave on the following day un unplanned and very interesting presentation on a concrete model of DMP. It includes in-depth details of the description, types, format and scale of data to be collected in the specific research project; the data collection/generation (methodologies, quality, standards); the data management, documentation and curation; the data preservation strategy and standards; the metadata standards and data documentation; the data security and confidentiality of potentially disclosive personal information; and the data sharing & access, formulated according to the MRC comprehensive policy for data-sharing.

Gilles send on the following day the document " How to develop a data management and sharing plan".

Training session on Clinical Data management, by Arouna Woukeu *(please sent presentations)*

Arouna, who's a member of the Steering Committee of ADMIT, transferred to the network the contents of the training on Project Management. The presentation and the related debate moved from the general definition of "project management", to the reasons and modalities to implement it in data management of medical research –and in particular in large multicenter studies.

[3] MeDRA is free for academic institutions

[4] SAEs reconciliation is not linked to the timelines of the initial fast-track reporting to ethics committees and regulatory authorities, but it is crucial for verifying the accuracy of data reported in the SAE forms and related correspondence/documentation, as well as its coherence with the study database, before data are sent to the Data Safety Monitoring Board when applicable, or at the latest before the database lock

Day 5 - Friday 8/3/13

Summary from rapporteur and from the Steering Committee – planned milestones & deliverables

Raffaella gave an overall summary of the sessions of the previous days, while Arouna gave a feedback from the Steering Committee (SC) of ADMIT, which met earlier at the beginning of the day.

The following activities are planned:

- Work Package 1: James, Yves and Raffaella will work at the ADMIT Action Plan, based on the conclusions of the Wednesday debate. They are expected (a) to finalize a general description of the action plan and (b) to finalize a reasonably detailed description of each work package. The final draft must be submitted for review to the SC by the end-of-May 2013, and for approval to the ITM by end-of-June. The respect of these deadlines is mandatory, otherwise Raffaella cannot take the SC input into account in the next proposal to the Belgian Development Cooperation. The final version of the Action Plan may be posted in the ADMIT website, in a restricted-access working group.

- Work Package 2: the ADMIT SC is in charge of formulating recommendations to the project management at the ITM, which has the legal responsibility for ADMIT. The SC Constitution, which has been pending since the previous workshop, will be finalized by Arouna and Paritosh by end-of-May 2013. It will be reviewed and approved by the SC on behalf of ADMIT members, and by the ITM project management.
  The constitution will include the description of the roles of SC chair (coordinator and animator) and secretary (link with project management at ITM), as well as the ADMIT membership criteria (Raffaella suggested that the Quamed criteria may be taken as a model).
  It was reminded that the SC is in charge of compiling and updating the list of core active members, who have voting rights for SC elections and ADMIT consultations on specific subjects. This list must be updated by the end of 2013, in view of the next SC election.

- Work Package 3: Yves and Harry are the focal points for the newborn ADMIT website, which requires a lot of work, on a daily basis. However, it is a joint responsibility of all the ADMIT active members to promote it, follow it and keep it alive. Yves and Harry will distribute by end-of-April a one-page guidance for active members, who can also be solicited by the focal points to contribute on specific topics/discussions.

- Work Package 4: Raffaella, with the inputs of David, will centralize information on funding opportunities and will promote initiatives based on opportunities (in the second half of 2013 and onward). External funding should be, in priority, seek to support activities as ranked below:
  - System user requirements specification (URS) for a ”fit-it-all” software
  - Data sharing framework / platform
  - Standardized training package

- Work Package 5: no individual responsibilities have been identified yet, however abstracts and publications should be used more and more frequently, for bringing ADMIT vision of clinical DM as a core research activity to a broader public. For instance, opinion papers could be written on:
    - Comparison of our data management systems
    - Harmonization of data management roles (standard organogram)
    - A standardized DM model for independent research centers.

Last not least, new subjects for the net workshop could include “data sharing” and “privacy and confidentiality of personal data”.

Sub-meetings on specific projects

The last part of the day was dedicated to sub-group meetings about ongoing specific projects, like the PREGACT (Yves, Sayouba, Godfred, Alfred) and the Nidiag (Harry, Paritosh, Sopheak, Anish), and about general subjects like funding and publications (Raffaella, David, Arouna, James).

Final acknowledgement

A special thanks to professor Sundar and to Paritosh for successfully hosting this meeting!