FIRST DATA MANAGEMENT WORKSHOP

'SWITCHING THE POLES' CLINICAL RESEARCH NETWORK

INSTITUTE OF TROPICAL MEDICINE
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Table of Contents

Contents

List of abbreviations

CRF	Case Report Form
CRO	Contract Research Organisation
CTMS	Clinical Trial Management System
CTU	Clinical Trial Unit
DB	Database
DM	Data Management
GCP	Good Clinical Practice
GDP	Good documenting Practice
GOP	General Operating Procedure
GPS	Global Positioning System
ICH	International Conference on Harmonisation
PDA	Personal Digital Assistant
PPT	Powerpoint
QA	Quality Assurance
SAE	Serious Adverse Event
SD	Secure digital
SDV	Source Document Verification
SOP	Standard Operating Procedure
WHO	World Health Organisation
WI	Work Instruction

Summary

The *Switching the Poles* Data Management Workshop 2010

From 6 to 10 December 2010, the ITM Clinical Trials Unit organized, in collaboration with the Network's partners, an international workshop on data management in non-commercial, North-South collaborative clinical research.

Eight data managers from the ***Switching the Poles*** Network, five Northern and Southern guest speakers and some interested ITM collaborators attended the Workshop, with the aims to exchange their knowledge and experience on challenges and problems encountered with clinical data management, and to strengthen international collaboration among data managers (full list of attendees see appendix 1).

The focus was on clinical data management tools and procedures, and their links with monitoring and quality assurance of clinical trials.
Therefore, there were presentations and discussions on data management software (Open Clinica, Microsoft Access, MACRO), hardware (PDA's, digitalising CRF's and source documents by scanning, IT housekeeping), system validation and general data management activities (also in relation with site monitoring). Also, a workshop was given on Open Clinica; the free clinical trial software which sees a rapid growing interest worldwide. In conclusion a steering meeting was held to outline the future perspectives of the data management workshop, which is the first in a series of three meetings. The others will be held at the ITM (2011) and at a partner institution in the South (2013). All the above subjects are discussed in detail in this report.

List of Data Managers

in alphabetic order

	Anish Bhattarai	BP Koirala Institute of Health Sciences	Nepal
	Yves Claeys	Institute of Tropical Medicine	Belgium
	Robert Meester	Amsterdam Medical Center	Netherlands
	Hercule Kalonji	University of Kinshasa	Democratic Republic of Congo
	David Mwakazanga	Tropical Diseases Research Centre	Zambia
	Sayouba Ouedraogo	IRSS/Centre Muraz	Burkina Faso
	James Smedley	Liverpool School of Tropical Medicine	UK
	Sopheak Sok	Sihanouk Hospital Centre of Hope	Cambodia
	Mary Thiongo	International Centre for Reproductive Health	Kenya
	Harry van Loen	Institute of Tropical Medicine	Belgium
	Arouna Woukeu	London School of Hygiene and Tropical Medicine	UK

1. INTRODUCTION

1.1 Objectives of the Workshop

Clinical research requires adequately specialized personnel, which on one side have to understand well the general features of clinical research (medical concepts, as well as methodological and ethical aspects, regulatory and legal issues, etc.) and on the other side have to be skilled in specific technical aspects. In the case of data managers, this encompasses IT issues, database software and hardware and GCP- and regulatory rules applied to data management. In absence of a formal study curriculum, only years of multi-disciplinary on-the-job training will result in the professional figure of the so called 'clinical data manager'.

Beyond this training, there are still a lot of challenges, which may become particularly acute in externally funded, North-South collaborative clinical research:

- New views on medical issues and the rapid developments in IT and communication technology put a constant pressure on data management.
- The academic working environment with its limited budget allows only small data management teams in big contrast to the private sector. But this does not mean we cannot try to work by the same standards.
- The context of resource-poor countries can present additional difficulties (e.g. in what concerns the availability and speed of Internet connections)

1.2 Objectives of this Document

This document summarizes the various presentations and discussions, in particular the highlights, of the 5-day workshop. **All attendees received a DVD with all PPT presentations** (except PPT 'scanning tools for data management'). **A copy of this DVD is available and can be requested to Harry van Loen or Yves Claeys.**

Monday 6/12	Tuesday 7/12	Wednesday 8/12	Thursday 9/12	Friday 10/12
Introduction Presentations by each participants on their activities and organisations	**DM related activities** -Data Management -Monitoring -QA	**IT and hardware** -IT housekeeping -PDA -Scanning tools for data collection	**Software for clinical trials** Experts' presentations on the application of - MS Access - MACRO - Open Clinica	**Steering meeting** -Evaluation of the Workshop -Plans for future

(For detailed agenda see Appendix 2)

2. INTRODUCTION OF THE PARTICIPANTS AND THEIR ORGANIZATIONS

- Each data manager or guest speaker presented his/her professional background, his/her institute; his/her daily/long term DM activities, the challenges and/or problems which are experienced.
- It was striking that a lot of challenges and frustrations were shared within this group. Most participants mentioned the following:
    - No optimal interaction with the study clinicians/project managers:
        - Too late involvement at study protocol and CRF development; study clinicians/project managers should be made aware of the necessity to involve DM at early stages;
        - Delays of study teams in solving queries;
        - Research teams do expect things happen 'overnight';
        - Research teams consider data managers as 'junior level' staff;
    - Lack of human resources;
    - Unrealistic timelines;
    - Workload underestimations;
    - Lack of expertise in validation, programming, GCP, documentation;
    - Technical issues such as low internet connectivity and power instability.
- Furthermore was mentioned:
    - Only few publications on DM tasks in clinical trials are known. Experiences should be shared;
    - Investigators often do not agree with single data entry and prefer double data entry. However, how can we best assure data quality in case of single data entry? Different measures were mentioned, among them use of electronic checks, use of source documents mirroring exactly the CRF, clinicians doing review of recorded data (source document vs. CRF),source data verification by external monitor
    - Inefficient organization of archiving/filing of documents at the study site;
    - The high turnover of researchers;
- Much attention went to the use of some data management software, in particular Epi-Info. Limitations on using the tool 'Data Compare' were discussed.

3. DATA MANAGEMENT, MONITORING & QUALITY

Clinical Data Management – A plunge into the (un)known - A guidance

by Harry van Loen

Highlights/Discussions

- DM of clinical research is more than creating a database!
- DM of clinical research is a variety of processes and activities with expertise needed on diverse issues such as medical concepts, GCP, IT, organization skills….
- Amongst others, the following was emphasized:
  - Multi-disciplinary team building;
  - Regular communication;
  - Planning;
  - Documentation;
  - Efficient DB and CRF design;
  - Adherence to realistic timelines.

Questions/answers

Q1:Why do we need to keep all emails with the research team and study sites? (Robert)
A: Only the important ones, since key information on processes, procedures and decision-making should be stored in formal documents.

Q2: How to check the quality of the lab data e.g. microscopy results? (David)
A: This is the responsibility of the Laboratory staff, rather than the DM. The Lab should rely upon well-established quality control and quality assurance mechanisms of quality (e.g. for microscopy). DM can however put some edit checks in an e-CRF or database which reduces entry errors of lab results. In addition DM can ensure other data entry quality by, for example, ensuring double entry. It is important to make clear that DM is not responsible for the quality of data originally provided by the research team.

Monitoring a Clinical Study

by Maaike De Crop, Study Monitor, CTU, Belgium

Highlights/Discussions:

- Trial monitoring includes verifying the respect of rights and well-being of human subjects, the compliance with the study protocol, GCP and ethical and regulatory requirements, and to check consistency of data recorded in the CRF with the source documents.
- By preference on site monitoring is needed, before, during and after the trial.
- 100% SDV is generally required for:
    - Informed Consent;
    - Demographic data;
    - Compliance with Study protocol inclusion/exclusion criteria;
    - Serious Adverse Events (SAEs) and safety related withdrawals.

Questions/answers

Q1: What about the use of PDAs? The data is entered directly in the database, there is no paper source document. Some monitors don't agree with this way of working and the GCP is not clear on this (WHO GCP are dated 1995 and ICH GCP 1996, and they are based on the use of paper CRFs) (Arouna)
A: According to GCP, it should be clearly stated in the protocol which data should be recorded in the source document and which data will be entered directly in the CRF. If the protocol has been approved by the appropriate ethics committees and regulatory authorities (if applicable), and if the procedure was well described in the protocol, then there is no issue.

Q2: Are we working with local monitors? (Robert)
A: Yes, for some studies. Sometimes, working with a local monitor can create a difficult situation, for example: a PhD student may be both PI and monitor (so, "controller" and "controlled" at the same time); high educated people may need to perform administrative tasks; being at the same time a monitor and a previous member of the site staff can put the person in a situation of psychological conflict of interest.

Q3: What is the difference between a monitoring visit and an audit? (David)
A: A monitoring visit is performed by an internal team member, generally appointed by the sponsor, while an audit is performed by an external person. Monitoring visits are mandatory in GCP, audit isn't. Both monitoring visits and audits provide preparation for potential inspections by competent authorities. During an audit the quality of monitoring (not only the site) is also checked.

System Validation

by Tim Vertongen, Validation Consultant, Ordina, Belgium

Highlights/Discussions:

- System validation is
  - a steps wise process;
  - respecting regulations;
  - consistent→ to be certain that the system works always;
  - based on a risk based approach → things we are sure are put aside;
  - establishing documented evidence ;
  - proving that you "are in control", for each change you have to go through the "change control" document.
- You have to invest time in development of system, get the system to high standards, but you gain time afterwards
- You must know what to do, what the requirements are and prove these by testing:
  - Validation Plan(VP), User Requirements document (URS) and Validation Report(VR) are required and are the most important validation documents;
  - Functional Specifications document (FS) might be optional.

Questions/answers

Q1: If you would use Open Clinica, do you have already a list or requirements? (Robert)
A: .- .to be able to store different types of data
- double entry
- audit trail
- offline use

At the moment we don't have specific list yet, but we have an idea about what we want and experience in what we don't want.

Q2: How to handle constantly changing requirements? (Arouna)
A: You can gather requirements during workshops, meetings. Different users have each their own prioritization, they should come together for a discussion.
Best according to Tim, a combination of:
- point of view of key/personal users (own list)
- come together, workshop, list becomes shorter
- compare against the system

You can still change after validation, but it must be documented. The more time invested upfront, the less modifications are needed during the process.
Flexibility can be positive and negative: if you are continuously changing, it is not positive and becomes burdensome.

Q3: Task of an expert in validation in a research institution?
A: - SOPs, validation of IT related systems in the lab

- validation assessments of computerized systems
- validation of some of the studies database (for instance, at ITM this is needed for studies where DM is done with the Macro software; Macro CTMS is global, but for each study an eCRF has to be created, certain checks, configuration and programming are needed).

The effort put in the validation depends on:

- The regulation in place
- The attitude of the institution: if it is “quality minded”, it will be willing to fund-raise or to invest for quality

It is important to remind that short-term investments, even if substantial, will be translated in less problems (and less unplanned costs) afterwards.

Tasks continuously requested from the validation expert within a research institution:

- interaction with DM (and indirectly, via DM, with study team and monitors)
- interaction with the IT helpdesk in relation to DM
- to check if DM systems are installed correctly and that they work properly

Good Documentation Practice

by Tim Vertongen, Validation Consultant, Ordina, Belgium

Highlights/Discussions:

- Good Documenting Practice (GDP) is aimed:
  - To create complete, legible, accurate, traceable records;
  - To guarantee quality of the Lab, Research, Production activities, credibility of the Data/Results;
  - To comply with GCP, GMP, GCLP…requirements.
  - Ideally, it should be set up in an integrated document system which starts from a 'Mission statement' and is structured over 'Manuals', 'GOPs', 'SOPs', 'Methods', 'Forms' to 'Records' (raw date).
- Raw data is noted or recorded when acquired or when a task is performed (signed & dated at that moment)
- Software on its own is NOT 21 CFR part 11[1] compliant. It is the set up/validation/ use of the system ….that defines compliancy to part11.

Questions/answers

Q1: Is there really need for a structured system GOP/SOP/WI '? (Harry)
A: SOPs and work instructions are needed on short term for QA, GOP, while a vision manual should be set on long term.

Q2: Tracking changes in an electronic system; who, what, when capturing is evident, but should an electronic audit trail also view the reason why a change is done? (contrary to corrections on paper)? (Harry)
A: Not necessary. Any change or correction to a CRF should be dated, initialled, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail shouldn't be maintained); this applies to both written and electronic changes and corrections (mailed by Tim after the workshop)

Q3: When a mandatory person is absent to sign an official document, can it be signed by someone else? (Is signing 'in order of' allowed?) (Harry)
A: depending on organization (can be marked in a responsibility matrix) often; depending on 'ranking'

person signing > in ranking than you; final signature
person signing =< in ranking than you; you should countersign

[1] Title 21 CFR Part 11 of the Code of Federal Regulations deals with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. This by implementing controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data

4. IT AND HARDWARE

Introduction to IT housekeeping practice

by Joseph Assayag, IT collaborator, ITM, Belgium

Highlights/Discussions:

- Avoid unsecure internet use which may lead to virus, spam, spyware and phishing (=attempts to acquire sensitive information such as usernames, passwords and credit card details by masquerading as a trustworthy entity in an electronic communication).
- Hard drive and CD rom drive are the first hardware to break. Therefore foresee always a BackUp of your data and information if you go 'in the field' for a long period!
- During a guided visit to the ITM Server room, emphasis was made on the organization of the servers and the security measurements such as the authorization via badge control, the constant low room temperature and the possible use of Argon gas (in case of fire).

Questions/answers

Q1: What do you recommend for sharing data? (Harry)
A: I recommend "drop box", to be found at http://www.dropbox.com/

Q2: Which are the websites, which consider good information on IT issues?
A: I use a lot Slashdot.org and Tweaters.net.

Using PDA's and GPS for enumeration & field-based surveys

by James Smedley

Highlights/Discussions:

- Although various hardware (PDA, GPS unit, SD card, Otterbox, Tall GPS Pod, Extended battery, Tethered stylus) and special software (Visual CE) is needed, and even if the field work is intensive, the users in the field picked it up easily and quality results were presented 72 hours after a survey in the field!
- You can check with GPS if the survey was done correctly, for example: if you need to go to the household but you notice with the GPS that everything was entered in the PDA under a tree.
- Additional instructions are needed. On a paper CRF you can read all possible answers, whereas you use a dropdown list on a PDA, so you could add an instruction to read all the responses in the list before choosing one.

Questions/answers

Q1: Is it possible to charge an extra battery in the office while you are in the field with PDA? (Mary)
A: It is, but then you need an extra device, and this is an extra cost!

Scanning as a data collection tool in scientific and clinical research

by Arouna Woukeu

Highlights/Discussions:

- 'Teleform', the scan-fax based data capture can be considered similar to double data entry.
- A merge with an already existing data base from the site is possible, for example, date of birth is entered automatically, you only need to complete the missing fields.
- There are some challenges:
  - You should minimise the open questions in order to minimise the handwritten information, while you should maximize the use of constraint boxes;
  - At the top of each page there is an identifier (code): if some changes are made to a form, the code will change and a new form is created.

Questions/answers

Q1: How minimizing text errors ?

A: The use of capital letters reduces errors, you can also select the appropriate language. All boxes can be fine-tuned, for example: alphanumeric (letters and numbers) of alphabetic (only letters).

5. SOFTWARE FOR CLINICAL STUDIES

An Access Database programmed for double data entry and with electronic audit trail

Characterization Novel Microbicide Safety Biomarkers in East and South Africa -

by Mary Thiongo

Highlights/Discussions:

- A system has been designed in Access, mirroring a paper CRF, featuring security issues, implementing controls for ensuring data quality (e.g. edit checks, skip patterns…), having double data entry possibilities, and an electronic audit trail; overall, it is easy to use.
- Each time there is a discrepancy between first entry and second entry, the user will be prompted to accept the correct value.
- Reports, exports and the audit trail are all related to the data of second data entry.
- The user reflected in the audit trail is actually the user of the computer LogOn, not the user of the database LogOn.

Questions/answers

NA

Data management in Clinical Trails using MACRO

by Yves Claeys

Highlights/Discussions:

- MACRO is a commercial clinical data management software for professional use, available with various modules and, contrary to most available software, with online AND offline use (up to version 3.0). Its offline use offered the advantage that MACRO could be used at sites with no or bad internet connectivity. Data transfer is done on a secured line to the ITM server.
- The easy to handle 'Study definition' and 'System Management' modules offer the possibilities that, provided of a minimum 3 days training, a study can be designed within a reasonable short time when based on a final source document (+/--a week to design questions, forms, visits). Edit check programming and its implementing takes proportional more time especially when including validations (several months).
- Live studies have a userfriendly interface allowing quick navigation, data entry, review and follow up of study data.
- The MACRO version 4.0, to be available shortly, will not have offline possibilities anymore. The use of MACRO in the future is therefore under debate at ITM.

Questions/answers

NA

Introduction to OpenClinica

by Robert Meester

Highlights/Discussions:

- OpenClinica is an open source (free) clinical data management software for professional use, available with various modules and fit for online use only.
- The number of user roles are restricted to data manager, study director, data specialist, monitor, data entry person only. No additional roles can be created!
- Programming of 'edit checks' and in particular the 'rules' demand programming skills!

Practical OpenClinica session: Introduction to OpenClinica

by Robert Meester

Highlights/Discussions

- During the rest of the day, a practical session was organized, inviting all attendees to design a study, pre-prepared by Robert.
- Robert instructed, gave tips and supported the attendees during the design.
- The next morning, the study design was continued and in absence of Robert coordinated by Sayouba.

Questions/answers
Questions were answered and support was given by Robert and Sayouba to each of the attendees where applicable.

Discussion on the choice of software for clinical trials

The three presentations in this session showed a different approach toward the use of software for clinical trials. Although the Access database was used for a biomarker study (not clinical trial) it showed what can be done to build an Access database answering to GCP requirements. Audit trail, password security and double data entry are implemented and show great efforts to control data during the process of a study. However, the lack of an in build query system (to raise, answer and follow up on automatic or manual queries), the fact that the audit trail is linked to the PC login and not the DB login and the incapability of locking data after review show that Access, as open source, fails to fulfill all DM challenges for a large clinical trial because of its' 'all round' character. Therefore, to use it for a clinical trial it was thought not to be recommended, in extremis if combined with paper CRF.
In contrast, MACRO (Infermed) shows the advantages of a clinical trial-specialized software. All the 21CFR Part11 requirements are met to use MACRO as CTMS and eCRF. On top of the general requirements (password, audit trail, electronic signature), both the user and programming interface, such as the review module (raise, answer, follow up queries + locking data/forms/visits) or the visit schedule for example, prove to be very effective to manage large clinical trials. The biggest disadvantages are the price and the need for strong and constant internet connectivity starting from MACRO version 4.0.
A good compromise would therefore be OpenClinica as best choice on long term. The software is entirely freeware (although time investment in learning and programming is thought to be considerable higher than for MACRO - in those terms freeware is never entirely 'free' compared to an easy to use commercial equivalent) and shows the biggest reason why OpenClinica would be the best suitable (clinical trial!) software as uniform choice by this DM group. Especially if independent DM of clinical trials is put as future perspective. The disadvantages are the less user-friendliness for the programming, demanding more time from the programmer and the support for which you depend on the OpenClinica 'community' to help each other on a forum(although according to Robert this works well and is satisfactory).
Therefore this DM group would use OpenClinica for the next trial or study to be started up if suitable. Ideally this would be for a reasonable sized study so there is room for first time trial and error. Re-evaluation is still to be done in future after application by some people of this group.
The table below shows a comparative overview of the software features based on three different users (and is therefore subjective) but illustrates the differences in general

	ACCESS	MACRO	OPENCLINICA
Audit trail	OK (PC login)	OK	OK
Password security	OK	OK	OK
2x data Entry	OK	/	OK
Data review	LISTINGS	IN BUILD	IN BUILD
Locking data	/	OK	OK
Development time	+	++	+
Price	FREE for all clients the database will be used on: http://www.microsoft.com/downloads/details.aspx?familyid=d9ae78d9-9dc6-4b38-9fa6-2c745a175aed&displaylang=en	HIGH (depending on licenses)	FREE
Userfriendly for clinical trials	+-	+++	++
SETUP	ONLINE (Intranet)	ONLINE + OFFLINE	ONLINE

6. STEERING MEETING

6.1 Highlights/Discussions

- As some of the attendees were not available on the last day, some brainstorming on networking began already on some of the free moments of the former days.
- Brainstorming resulted in participant evaluations, recommendations and next steps.
- Prof. Dr. Umberto D'Alessandro, invited as a representative of the steering committee of the Switching the Poles network, stressed the importance of data management and data managers and the key-role they play in a research team. "Without the support of the data managers, we would not be able to realize a good conduct of our clinical trials; and when we started to implicate them since the early phases of a research, we noticed a significant improvement of the efficiency of data collection and of quality of data".

6.2 Participant Evaluations

- The attendees rated the workshop and its programme as very interesting.
- Exchanging experiences and networking during a specialised workshop were cited as main points of the workshop.

6.3 Participant Recommendations

- More visibility of this group through:
  - Suggested name - ATDM : Association of Tropical Data Managers
  - Webpage or Intranet communication space (pending for next Workshop)
- Preparation of Standard DM documentation (pending for next Workshop)
- Although open Clinica Training was interesting, more or longer training in OpenClinica will be needed for applying this software
- More training in database design, audit trail, double data entry
- More training in GCP applied to DM
- Mary gives information on online GCP course (DONE)
- More training in basic Clinical Research concepts
- Focus on how database works after the interface
- Focus on differences in study types in relation with DM (clinical trial, surveillance, operational)
- Support and training within the network
- Improving cooperation between Study Clinicians/Project Managers <–> DM
- Possible growth towards a larger interested public, including new attendees

6.4 Future steps

- Preparation of next DM workshops, in particular of the workshop at ITM in 2011: programme, date, possible attendees. Introducing the ATDM network and its current findings to the Clinicians of the Clinical Research 'Switching The Poles' Network or even to a broader public.
- Realization of the listed recommendations. For 2011Workshop the focus will lie on GOP, SOP's and document templates, to start with a uniform base within the group. In addition one or two recommended topics will be scheduled and will be chosen on demand and feasibility.

APPENDIX 1

Clinical Trials Unit
Data Management Workshop
6-10 December 2010

Participant's list

1. Invited participants

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APPENDIX 2
FIRST DATA MANAGEMENT WORKSHOP
Institute of Tropical Medicine, Antwerp 6-10 DECEMBER 2010

FINAL AGENDA

6 DECEMBER (Theme: Introduction)

10.00-11.00	Welcome (by Raffaella Ravinetto, Head of CTU; Yves Claeys CTU Data Manager, Harry van Loen CTU Data Manager)
11.00-11.30	DM activities at the ITM-CTU (by Harry van Loen, Belgium)
11.30-12.00	DM activities at Centre Muraz (by Sayouba Quedrago, Burkina Faso)
12.00-12.30	DM activities at Sihanouk Hospital Centre of Hope (by Sopheak Sok, Cambodia)
12.30-13.00	DM activities at Institute National de Recherche Biomédicale (by Hercules Kalonji, Democratic Republic of Congo)

13.00-14.00 Lunch

14.00-14.30	DM activities at BP Koirala Institute of Health Sciences (by Anish Bhattarai, Nepal)
14.30-15.00	DM activities at Liverpool School of Tropical Medicine (by James Smedley, UK)
15.00-15.15	Coffee Break
15.15-15.45	DM activities at London School of Hygiene and Tropical Medicine (by Arouna Woukeu, UK)
15.45-16.15	DM activities at the Tropical Diseases Research Centre (by David Mwakazanga , Zambia)
16.15-16.45	DM activities at the International Centre for Reproductive Health (by Mary Thiongo, Kenya)

7 DECEMBER (Theme : Data Management, Monitoring and Quality)

09.00-10.00	Clinical Data Management – A quidance (by Harry van Loen, Data Manager, CTU, Belgium)
10.00-11.00	Monitoring a Clinical Study (by Maaike De Crop, Study Monitor, CTU, Belgium)
11.00-11.15	Coffee Break
11.15-13.00	System Validation (by Tim Vertongen, Validation Consultant, Ordina, Belgium)

13.00-14.00 Lunch

14.00-15.00	Visit to the Institute
15.00-15.15	Coffee Break
15.15-16.15	Minimal Quality Assurance System Requirements (by Björn Van den Sande, Head of QA, ITM, Belgium)
16.15-17.00	Open discussion

8 DECEMBER (Theme: IT and Hardware)

09.00-11.00 Introduction to IT housekeeping practice
(by Joseph Assayag, IT collaborator, ITM, Belgium) – Visit to the IT server room
11.00-11.15 Coffee Break
11.15-13.00 More about Personal Digital Assistants (PDA's)
(by James Smedley, Database Manager, Liverpool School for Tropical Medicine, UK)

13.00-14.00 Lunch

14.00-15.30 Scanning as a data collection tool in scientific and clinical research
(by Arouna Woukeu, Data Management Coordinator, London School of Hygiene and Tropical Medicine, UK)
15.30-15.45 Coffee Break
15.45-17.00 Open discussion

9 DECEMBER (Theme: Software for clinical studies)

09.00-10.00 An Access Database programmed for double data entry and with electronic audit trail
(by Mary Thiongo, Data Manager, ICRH, Kenya)
10.00-11.00 Introduction to MACRO
(by Yves Claeys, Data Manager, CTU, Belgium)
11.00-11.15 Coffee Break
11.15-12.15 Introduction to OpenClinica
(by Robert Meester, AMS, The Netherlands)
12.15-13.00 Open discussion : Pro's/Contra's of the different softwares

13.00-14.00 Lunch

14.00-17.00 Workshop OpenClinica
(by Robert Meester, AMS, The Netherlands)- Practical session with live demonstration - Installing and Getting started with OpenClinica
17.00-22.00 With all attendees : Visit to the old town - Institutional Dinner - An Antwerp night cap

10 DECEMBER (Theme: Strenghtening our Data Management network)

09.00-10.45	Which problems do we (still) face, what are possible solutions, how can we improve? Other topics on demand of the participants? An open discussion - part 1
10.45-11.00	Coffee Break
11.00-12.00	Which problems do we (still) face, what are possible solutions, how can we improve? Other topics on demand of the participants? An open discussion - part 2

12.00-13.00 Lunch

13.00-15.00	Conclusions of the workshop – Steering committee - Future actions 2nd DM workshop 2011

END