Day 1

Monday, 11 June 2012

Clinical trials: main scientific and ethical aspects

08.30 Registration of participants

09.00 Welcome Message
Tanzania Governmental Authority (to be confirmed)
Mwele Malecela, Director, NIMR (t.b.c.)
Luca Pani, Director AIFA (t.b.c.)
Jonathan Lucas, Director UNICRI (t.b.c.)
Melba Filimina Gomes, TDR/WHO
Umberto Filibeck, Paediatric Hospital Bambino Gesù

THEORY SESSION (10.00-15.30)

10.00 **First Module - *The international framework regulating research with human participants***

Chairperson: Julius Massaga, NIMR (t.b.c.)

10.00 *The international guidelines and documents on the ethical aspects of clinical trials*
Melba Gomes, WHO/TDR

10.30 *The role of EDCTP in supporting ethics review and regulatory capacity*
Charles Mgone, EDCTP

11.00 – 11.30 Coffee Break

11.30 *General aspects and principles of ICH-GCP*
Umberto Filibeck, UNICRI- OPBG

12.00 *Adapting the international principles to the developing settings*
Maureem Ebigbeyi, NAFDAC, Federal Republic of Nigeria

12.30 *An overview of the institutional capacity for clinical trials evaluation and authorization in Tanzania*
Mwele Malecela, NIMR, United Republic of Tanzania

13.00 *Randomized and controlled studies, blind and double blind studies, non inferiority and superiority studies, BE and BA studies: peculiarities in developing settings*
Carlo Torti, University of Brescia, Italy

13.30 - 14.45 Lunch

15.00 *Overall aim of UNICRI's initiatives in this field and specific objectives of this training course*
Alessandra Liquori O'Neil, UNICRI

15.15 *Structure of the training course*
Umberto Filibeck, UNICRI- OPBG

PRACTICE SESSION (15.30-17.30)

Group A: Investigators, Assessors, Ethics Committee and Regulatory Group

15.30 *Protocol and amendments for randomized clinical trials:3 sub-groups*

1) *Protocol for randomized clinical trials*
Facilitator: Carlo Tomino, AIFA

2) *Protocol amendments*
Facilitator: Carlo Torti, University of Brescia

3) Ethical aspects
Facilitator: Melba Gomes, WHO/TDR

17.00 *Reporting on the results by the three subgroups*

Group B: GCP Compliance Group

15.30 *Protocol and Case Report Form*
Facilitators: Angela Del Vecchio, AIFA; Maria Luisa Paoloni, OPBG Clinical & Research Services; Anna Maria Lepore, OPBG Clinical & Research Services

17.00 *Reporting on the results by the three subgroups*

20.00 Working Dinner

Day 2

Tuesday, 12 June 2012

Guidelines on Good Clinical Practice: application of principles (Part I)

08.30 Registration

THEORY SESSION (9.00-15.00)

09.00 **Second Module - *Clinical trials: main regulatory, methodological and scientific aspects***

Chairperson: Alessandra Liquori O'Neil, UNICRI

09.00 *Guidelines on Good Clinical Practice: protocol and amendments*
Carlo Tomino, AIFA, Italy

09.30 *The respect of ethics and GCP in the clinical trials authorization procedures in the European Union*
Umberto Filibeck, UNICRI- OPBG

10.00 *Scientific evidence and data publication*
Ramadhani Abdallah Noor, Harvard School of Public Health, United Republic of Tanzania

10.30 *The role, duties and responsibilities of clinical trials personnel*
Umberto Filibeck, UNICRI- OPBG/Maria Luisa Paoloni, OPBG, Clinical & Research Services, Italy

11.00 – 11.30 Coffee break

11.30 **Third Module - *Operational aspects of clinical trials with difficult/critical scientific and ethical issues***

Chairperson: Mwele Malecela, NIMR (t.b.c.)

11.30 *Placebo and active comparator: ethical aspects*
Godfrey Tangwa, University of Yaounde, Republic of Cameroon

12.00 *Placebo and active comparator: specific issues in developing settings*
Ramadhani Abdallah Noor, Harvard School of Public Health, United Republic of Tanzania

12.30 *Informed consent procedures and confidentiality aspects in clinical trials: ethical aspects*
Yohana Mashalla, University of Botswana, Botswana

13.00 *Informed consent procedures and confidentiality aspects in clinical trials: specific issues in developing settings*
Aceme Nyika, P.H.P. Africa, Republic of Zimbabwe

13.30 – 14.45 Lunch

PRACTICE SESSION (15.00-17.30)

Group A: Investigators, Assessors, Ethics Committee and Regulatory Group

15.00 *Placebo and active comparator*
Facilitators: Ramadhani Abdallah Noor, Harvard School of Public Health; Godfrey Tangwa, University of Yaounde

16.15 *Informed consent/Confidentiality issues*
Facilitators: Aceme Nyika, P.H.P. Africa; Yohana Mashalla, University of Botswana, Botswana

Group B: GCP Compliance Group

15.00 *Theory:* specific aspects of *GCP: setting up the monitoring plan*
Lecturer: Maria Luisa Paoloni, OPBG Clinical & Research Services

15.30 *Practice: preparing the monitoring plan*
Facilitators: Maria Luisa Paoloni, OPBG Clinical & Research Services; Angela Del Vecchio, AIFA

16.15 *Theory: external control/assessment (Quality Assurance and audit)*
Lecturer: Anna Maria Lepore, OPBG Clinical & Research Services

16.45 *Practice: audit simulation*
Facilitators: Anna Maria Lepore, OPBG Clinical & Research Services; Angela Del Vecchio, AIFA

Day 3

Wednesday, 13 June 2012

Guidelines on Good Clinical Practice: application of principles (Part II)

08.30 Registration

THEORY SESSION (9.00-15.00)

09.00 **Fourth Module – *Guidelines on Good Clinical Practice for trials on pharmaceutical products***

Chairperson: Ramadhani Abdallah Noor, Harvard School of Public Health, United Republic of Tanzania (t.b.c.)

09.00 *Minimum requirements for clinical laboratories and Good Clinical Laboratories Practice (GCLP)*
Simon Buhalata, NIMR, United Republic of Tanzania

09.30 *The Trial Master File and the local file*
Angela Del Vecchio, AIFA, Italy

10.00 **Fifth Module – *Operational aspects of clinical trials with difficult/critical scientific and ethical issues***

Chairperson: Umberto Filibeck, UNICRI/OPBG

10.00 *Vulnerable population*
Aceme Nyika, P.H.P. Africa, Republic of Zimbabwe

10.30 *Conclusion or early interruption of the study*
Ramadhani Abdallah Noor, Harvard School of Public Health, United Republic of Tanzania (t.b.c.)

11.00-11.30 Coffee Break

11.30 *Fair Compensation; Reimbursement; Insurance*
Godfrey Tangwa, University of Yaounde, Republic of Cameroon

12.00 *Insurance: the Italian experience*
Carlo Tomino, AIFA, Italy

12.30 *Access to post trial treatment*
Jerome A. Singh, University of Kwala-Zulu Natal, Republic of South Africa

13.00 *Human rights and the law to enhance protection of participants in biomedical research*
Jerome A. Singh, University of Kwala-Zulu Natal, Republic of South Africa

13.30 – 14.45 Lunch

PRACTICE SESSION (15.00-17.30)

Group A: Investigators, Assessors, Ethics Committee and Regulatory Group

15.00 *Vulnerable population*
Facilitators: Aceme Nyika, P.H.P. Africa; Godfrey Tangwa, University of Yaounde

16.15 *Access to post-trial treatment*
Facilitators: Jerome A. Singh, University of Kwala-Zulu Natal, Ramadhani Abdallah Noor, Harvard School of Public Health (t.b.c.)

Group B: GCP Compliance Group

15.00 *Trial Master File and Local File*
Facilitators: Angela Del Vecchio, AIFA; Maria Luisa Paoloni, OPBG Clinical & Research Services

16.15 *Minimum requirements for clinical laboratories and Good Clinical Laboratory Practice (GCLP)*
Facilitators: Simon Buhalata, NIMR; Anna Maria Lepore, OPBG Clinical & Research Services

Day 4

Thursday, 14 June 2012

The Inspection of Clinical Trials

08.30 Registration

THEORY SESSION (9.00-15.00)

09.00 **Sixth Module – *The Inspection capacity and the effective control of clinical trials***

Chairperson: John Changalucha, NIMR, United Republic of Tanzania (t.b.c.)

09.00 *The five Ws of the inspection mechanism: who, what, where, when, why*
Willem Verweij, IGZ, The Netherlands

09.30 *Inspections of Ethics Committees*
Umberto Filibeck, UNICRI- OPBG, Italy

10.00 *Inspections: findings and grading, outcomes, critical issues and decisions*
Willem Verweij, IGZ, Netherlands

10.30 *Pharmaco-vigilance inspections in the EU*
Angela Del Vecchio, AIFA, Italy

11.00 – 11.30 Coffee break

11.30 **Seventh Module for Group A (Assessors and Regulatory Group) – *Presentation of Selected Clinical Trials***

Chairperson: Carlo Tomino, AIFA, Italy

11.30 *The natural history of tumors as a basis for controlled clinical trials: breast and cervical tumors and specific methodological aspects of clinical trials.*
Dino Amadori, Scientific Institute of Romagna for the Study and Treatment of Cancer, Italy

12.00 *Clinical trials related to different stages of the natural history of cancer*
Oriana Nanni, Scientific Institute of Romagna for the Study and Treatment of Cancer, Italy

12.30 *Clinical trials of HIV/STD in developing settings: main aspects, problem issues and perspective**s***
John Changalucha, NIMR, United Republic of Tanzania

11.30 **Seventh Module for Group B (GCP Compliance Group) – *Organizational aspects of the inspection process***

Chairperson: Willem Verweij, IGZ, The Netherlands (t.b.c.)

11.30 *Conduct and follow up of GCP and pharmaco-vigilance inspections at the investigation's site*
Angela Del Vecchio, AIFA, Italy

12.15 *Organization of GCP inspections: an experience in developing settings*
Umberto Filibeck, UNICRI- OPBG, Italy

13.00 *The activities and future development of the GCP inspections in Tanzania*
Godwin Ndossi, Tanzania Food and Nutrition Center, United Republic of Tanzania

13.30 - 14.45 Lunch

PRACTICE SESSION (15.00-17.00)

Group A: Assessors and Regulatory: 2 Sub-Groups

15.00 *GCP scientific and methodological review, analysis and evaluation of protocols; discussion of relevant ethical clinical trials problems*

1) *Oncological protocols*
Facilitators: Dino Amadori, IRST; Oriana Nanni, IRST; Patrizia Serra, IRST

2) *HIV/STD protocols*
Facilitator: John Changalucha, NIMR

16.30 *Reporting on the results of the subgroups*

Group B: GCP Compliance Group

15.00 *Evaluation of GCP compliance:3 sub-groups*

1) *Trial site Inspections: findings, evaluation and grading*
Facilitators: Willem Verweij, IGZ; Angela Del Vecchio, AIFA

2) *Monitoring; evaluation and grading of findings*
Facilitator: Maria Luisa Paoloni, OPBG Clinical & Research Services

3) *Auditing; evaluation and grading of findings*
Facilitator: Anna Maria Lepore, OPBG Clinical & Research Services

16.30 *Reporting on the results by the three subgroups*

17.00 Closing remarks
NIMR Representative (t.b.c.)
Carlo Tomino, AIFA, Italy

17.15 Distribution of Certificate of Attendance and collection of Training Course Evaluation Forms.

Lecturers:

Dino Amadori, Scientific Director, Scientific Institute of Romagna for the Study and Treatment of Cancer, Italy
Simon Buhalata, Lab. Manager, NIMR, United Republic of Tanzania
John Changalucha, Director, NIMR Mwanza Centre, United Republic of Tanzania
Angela Del Vecchio, Head of Pharmaco-vigilance Inspectorate, AIFA, Italy
Maureem Ebigbeyi, Deputy Director, NAFDAC, Federal Republic of Nigeria
Umberto Filibeck, Consultant, UNICRI-OPBG, Italy
Melba F. Gomes, Manager: Steering Committee on Proof of Principle, WHO/TDR, Switzerland
Anna Maria Lepore, Quality Assurance Manager, OPBG Clinical & Research Services, Italy
Mwele Malecela, Director General, NIMR, United Republic of Tanzania
Yohana JS Mashalla, Professor of Medical Physiology, University of Botswana, Botswana
Julius Massaga, Director of Research Coordination, NIMR, United Republic of Tanzania
Charles S. Mgone, Executive Director, European and Developing Countries Clinical Trials Partnership
Oriana Nanni, Director of the Biostatistics and Clinical Trials Unit, Scientific Institute of Romagna for the Study and Treatment of Cancer, Italy
Godwin D. Ndossi, Consultant Nutritionist, Tanzania Food and Nutrition Center, United Republic of Tanzania
Ramadhani Abdallah Noor, Research Associate, Harvard School of Public Health, United Republic of Tanzania
Aceme Nyika, Ethics Coordinator, P.H.P. Africa, Republic of Zimbabwe
Maria Luisa Paoloni, Monitor & CRAs Coordinator, OPBG Clinical & Research Services, Italy
Patrizia Serra, Data Manager Coordinator at the U. O. of Biostatistics and Clinical Trials, Scientific Institute of Romagna for the Study and Treatment of Cancer
Jerome A. Singh, Head of Ethics, Health and Law, CAPRISA, Nelson R. Mandela School of Medicine, Durban, Republic of South Africa
Godfrey B. Tangwa, Professor of Philosophy, University of Yaounde, Republic of Cameroon
Carlo Tomino, Head of Research and Clinical Trial, AIFA, Italy
Carlo Torti, Assistant Professor of Infectious Diseases, University of Brescia, Italy
Willem R. Verweij, Senior Inspector, Health Care Inspectorate, IGZ, The Netherlands

Acronyms:

AIFA: Italian Medicine Agency
EDCTP: European & Developing Countries Clinical Trials Partnership
IGZ: Dutch Health Care Inspectorate
IRST: Scientific Institute of Romagna for the Study and Treatment of Cancer
NAFDAC: National Agency for Food and Drug Administration and Control
NIMR: National Institute for Medical Research
OPBG: Ospedale Pediatrico Bambino Gesù
WHO/TDR: World Health Organization - Special Programme for Research and Training in Tropical Diseases
UNICRI: United Nations Interregional Crime and Justice Research Institute
WHO: World Health Organization

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