

## MUTHI CLINICAL TRIALS WORKSHOP 7-13 February 2013

## Makerere University, Kampala, Uganda

MUTHI (Multidisciplinary University Traditional Health Initiative) is an EU-funded project to strengthen capacity for research on traditional herbal medicines in African Universities: <a href="http://www.mn.uio.no/farmasi/english/research/projects/muthi/">http://www.mn.uio.no/farmasi/english/research/projects/muthi/</a>

This workshop will be run jointly by a team from the University of Oxford, Makerere University, University of the Western Cape, and University of Lausanne.

It is intended for African researchers who are involved in, or planning to become involved in, clinical research and development of traditional herbal medicines. It will cover the basics of setting the research question, designing a protocol, conducting a study, analysis and reporting.

Participants will be required to complete some online e-learning modules, read a few articles, and draft a protocol for their clinical study before the course. After the course, mentors will continue to support participants in the development of their protocols, applications for funding and ethical approval, and throughout the course of their research.

Places are free but participants will have to cover their own travel and accommodation while attending the training. As space will be limited, those interested in participating should complete the online application form at:

 $\frac{https://docs.google.com/spreadsheet/viewform?fromEmail=true\&formkey=dDNjUkppSlZWVEMtSnlHUTBYTG9zVWc6MQ}{}$ 

The deadline for applications is **Sunday 28<sup>th</sup> October 2012**. Successful applicants will be notified by mid-November so that they can start the pre-course preparatory work.

The MUTHI workshop will be followed by a one-day skills-sharing workshop for researchers already involved in any type of clinical research in East Africa, in any disease area. This will be organized by Global Health Trials: <a href="www.globalhealthtrials.org">www.globalhealthtrials.org</a> Registration is also free, but participants will have to cover their travel and accommodation. Participants at the MUTHI workshop will also be invited to attend this.

## DRAFT PROGRAMME

Thursday, 7 <sup>th</sup> Feb 2013			
Introduction and literature reviews			
08h30 - 09h30	Welcome and background on MUTHI	Prof Bernard Kiremire	
09h30 - 10h30	Training needs assessment	Dr Merlin Willcox	
10h30 – 11h00	Tea		
11h00 – 12h00	Participant introductions & expectations of workshop	Dr Patrick Ogwang	
12h00 – 13h00	Pre-course activity feedback	MW	
13h00 – 14h00	Lunch		
14h00 – 15h00	Public keynote lecture: Reverse pharmacology and lessons from clinical trials on <i>Argemone mexicana</i>	MW / BG	
15h00 – 15h30	Discussion and questions on Reverse Pharmacology	MW / BG	
15h30 – 16h00	Tea		
16h00 – 17h00	Presenting PICO questions	MW, PO, BG and all	
17h00 – 17h15	Trouble-shooting, question-banking	MW	

Friday, 8 <sup>th</sup> Feb 2013  Choosing the right question and designing the study		
0830 - 0930	Groupwork: determine the study design	MW, BG
0930 – 1000	Study design questions	MW
1000-1030	Tea and coffee	
1030 - 1300	Statistics: choosing outcome measures and calculating sample size	
13h00 – 14h00	Lunch	
1400-1500	Keynote lecture: Systematic reviews	NS / MW
1500 - 1530	Discussion and questions about systematic reviews	NS / MW
15h30 – 16h00	Tea	
16h00 – 17h00	Randomisation: why and how?	NS/MW
17h00 – 17h15	Trouble-shooting, question-banking	MW

Saturday 9<sup>th</sup> and Sunday, 10<sup>th</sup> Feb 2013: Free days. Optional excursion (e.g. Kibale / Murchison Falls)

Monday, 11 <sup>th</sup> Feb 2013  Writing the protocol and ethical review			
09h00 - 10h30	Presenting PICO questions (part 2)	MW, PO, BG and all	
10h30 - 11h00	Tea and coffee		
11h00 – 12h00	How to write a protocol Trial protocol tool	NS / MW / BG / PO	
12h00 – 13h00	Developing a protocol	all	
13h00 – 14h00	Lunch		
14h00 – 15h00	Public lecture: Good Clinical Practice and Ethics	MW	
15h00 – 15h30	Ethical review of a protocol	MW / BG	
15h30 – 16h00	Tea		
16h00 – 17h30	Ethical review of a protocol	MW / BG	

Tuesday, 12th Feb 2013  Analysing results and publication			
08h30 - 09h00	International Clinical Trial Registration	NS / MW	
09h00 – 10h00	Writing up your study for publication: CONSORT guidelines	MW	
10h00-10h30	Critical appraisal of a trial report	MW	
10h30 - 11h00	Tea and coffee		
11h00 – 13h00	Critical appraisal (continued)	MW	
13h00 – 14h00	Lunch		
14h00 – 17h00	Writing a grant application		

Wednesday, 13th Feb 2013 Site visit		
07h30	Departure	
09h00 – 10h30	Practical questions and logistics for organizing a study site	PO / MW
11h00 – 13h00	Documentation, implementing GCP in practice	PO / MW
13h00 – 14h00	Lunch	
14h00 – 15h30	PROMETRA traditional healers' groups	Dr Yahaya Sekagya
15h30 – 17h00	Data entry, monitoring	PO / MW
17h00	Departure	

## **Facilitators:**

- Dr Bertrand Graz (BG), University of Lausanne
- Dr Patrick Ogwang (PO), Makerere University
- Dr Yahaya Sekagya (YS), PROMETRA
- Dr Nandi Siegfried (NS), University of the Western Cape
- Dr Merlin Willcox (MW), University of Oxford

Thursday, 14th Feb 2013 Global Health Trials skills-sharing workshop		
	Programme yet to be finalised	