



## **Randomised Controlled Trial Management Workshop hosted by the SUPPORT Collaboration for Southern African Researchers**

The SUPPORT Collaboration in association with the South African Medical Research Council is offering a workshop on Randomised Controlled Trial Management at the *South African Medical Research Council* campus in *Pretoria* from *16 to 17 October 2008*.

### **Background**

The SUPPORT collaboration is a European Funded collaboration of ten partners in nine countries SUPporting Policy relevant Reviews and Trials. Two of the aims of this collaboration are to develop tools and conduct workshops to support the *conduct* of pragmatic trials of interventions when reliable evidence is lacking. The tools will support the day-to-day conduct and management of trials so that it is easier for researchers in lower and middle income countries to address knowledge gaps. This randomised controlled trial management workshop is therefore one of the activities of the SUPPORT collaboration, <http://www.support-collaboration.org/>.

### **Nature of the workshop**

The workshop will be run over two days and will be based on the format of the successful Edinburgh Clinical Trial Management Course (<http://www.dcn.ed.ac.uk/ectmc/>). This concession was negotiated through the Scottish partner in SUPPORT: the Health Services Research Unit at the University of Aberdeen. The course will be adapted and pitched at trials conducted in Southern Africa but the structure and format of the ECTMC will be followed. The SUPPORT collaboration is also developing a Trial Management Tool and hopefully the first version will be available for the practical session of the workshop.

### **Content**

The workshop will be a blend of interactive presentations and group sessions. The proposed topics for the presentations will include:

- Key elements of trial design and management
- Trial governance and regulation
- Managing multi-centre trials
- Community participating in research
- Data management
- Safety reporting in trials
- Audit and inspection

The proposed topics for the group sessions will include:

- Starting a new trial
- Management systems
- Risk assessment and monitoring
- Project management
- Recruitment, retention and follow-up
- Information technology for RCT's
- Publication and dissemination of trial findings

### **Facilitators for the workshop**

**John Norrie:** MSc. Professor of Clinical Trials and Biostatistics, Robertson Centre for Biostatistics, Glasgow University, and formerly (until Sep 2008) Director of the Centre for Healthcare Randomised Trials (CHaRT), in the Health Services Research Unit (HSRU), at Aberdeen University (see [www.abdn.ac.uk/hsru/chart](http://www.abdn.ac.uk/hsru/chart) for further details on CHaRT's remit, staff, and current trials). He is a statistician by training and has extensive experience of both the organisational and technical challenges in conducting long term, large scale, multicentre randomised controlled trials. He considers trial management as of fundamental importance amongst the core competencies that are needed to deliver high quality publicly funded trials. He is particularly interested in (a) the optimal use of often scarce trial management resource to effectively monitor trial quality (for example, by targeting resource at centres with emerging problems), and (b) minimising the burden of bureaucracy on trial managers in the light of recent guidelines and legislation, and (c) the development of relevant, accessible training for trial managers (including continuing professional development), and (d) providing real career structure in academic trials units for all clinical trial professionals (and particularly trial managers).

**Lara Fairall:** MBChB, PhD, Head of the Knowledge Translation Unit in the Lung Health Institute and senior lecturer, Department of Medicine, University of Cape Town. She has been involved as collaborator and principal investigator in a number of large pragmatic health systems trials that have been completed or is ongoing in the Free State and Western Cape: PALSA, PALSA-Plus and STRETCH. These trials relate to the management of lung diseases as well as HIV and ARV treatment.

**Cheryl Nikodem:** DCur MCur Bcur. Associate Professor, Department of Nursing, University of the Western Cape. Synopsis of research interests: Clinical trials, systematic reviews, midwifery, neonatal health, women's health, prevention of mother to child transmission of HIV, obstetrics, health systems evaluation, breastfeeding, alternative and traditional medicine. Co-investigator on the Intrapartum Nevirapine Trial (SAINT) , a multicenter randomized controlled trial of nevirapine versus a combination of zidovudine and 3TC to reduce intrapartum and early postpartum mother-to-child transmission of human immunodeficiency virus type 1 and the PROMISE-PEP trial which will be looking at the efficacy and safety of infant peri-exposure prophylaxis with lamivudine to prevent HIV-1 transmission by breastfeeding.

**Carl Lombard:** MSc, PhD. Director of the Biostatistics Unit of the Medical Research Council. Co-investigator and statistician in a number of clinical and pragmatic trials conducted in South Africa. He is a member of the African Data and Safety Monitoring Board of the NIAID, NIH for trials sponsored by the NIH in Africa as well as member of the Data and Safety Monitoring Board of the Caprisa 004 microbicide trial sponsored by Family Health International. He was involved in the Practic Collaboration which held workshops on the design of pragmatic trials in Southern Africa.

## **Participants**

Investigators, trial managers and data managers of ongoing or planned (soon-to-start) randomized controlled trials.

If you are interested in attending this workshop you should complete the application form at the bottom and fax or e-mail it to Roseline Cupido at fax: 021-9380310 or e-mail: [roseline.cupido@mrc.ac.za](mailto:roseline.cupido@mrc.ac.za). The closing date for applications will be 29 August 2008. Successful applicants will be notified by 8 September.

## **Cost, travel and accommodation**

There will be no charge for the workshop which will include refreshments and dinner on the Thursday evening. Participants will however have to make their own travel and accommodation arrangements and carry these costs. Since the workshop will start early on the Thursday morning you will be advised to arrive in Pretoria on the Wednesday night. The course will finish at 16h30 on Friday afternoon.

## **Other requirements**

Some of the course material will be made available on CD and therefore having access to a laptop for the course will be necessary. The system should have Windows XP as a minimum since this will be the format required to access the material. The Trial Protocol Tool from <http://www.practic.org/> will be one of the bits of material used for orientation and trial examples.



**APPLICATION FORM:**

**Randomised Controlled Trial Management Workshop  
hosted by the SUPPORT Collaboration for Southern African Researchers**

**South African Medical Research Council Campus, Pretoria**

**16 – 17 October 2008**

Please return your completed registration form to:

Roseline Cupido  
Biostatistics Unit  
SA Medical Research Council  
P O Box 19070, Tygerberg, 7505  
Tel: 021 938 0335 Fax: 021 938 0310  
E-mail: [roseline.cupido@mrc.ac.za](mailto:roseline.cupido@mrc.ac.za)

Title: \_\_\_\_\_ First Name: \_\_\_\_\_

Surname: \_\_\_\_\_

Affiliated Institution: \_\_\_\_\_

Qualification(s)/Degree(s): \_\_\_\_\_

Postal Address: \_\_\_\_\_

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\_\_\_\_\_

\_\_\_\_\_

Tel: (w): \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

Cell: \_\_\_\_\_

Current responsibilities: \_\_\_\_\_

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Please provide some information on your involvement/experience in trials: \_\_\_\_\_

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Please provide your motivation for wanting to attend this management of trials workshop:

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Please indicate whether you have access to a laptop with a CD-rom and Windows XP:

Yes/No: \_\_\_\_\_

Dietary /other special requirements: \_\_\_\_\_

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**Please note:**

Participants are responsible for their **own travel, accommodation and transport arrangements**. Rietondale Lodge ([www.rietondalelodge.co.za](http://www.rietondalelodge.co.za)) and Premier Hotel ([www.premierhotels.co.za](http://www.premierhotels.co.za)) are very close to the MRC Pretoria campus. Shuttle transport services are available from EZ Shuttle (<http://www.ezshuttle.co.za/>), or if a vehicle is preferred for private use please make use of the different car hire services available at (<http://www.car-rental.co.za/>).

**Closing date for applications:**  
**29 August 2008**

**Notification of acceptance:**  
**8 September 2008 via email**