Proposal for registration of Good Clinical Practice Courses in South Africa

A. Background:

Several years ago, the Medical Control Council (MCC), mandated that any investigator wishing to participate in a clinical trial would need certification of Good Clinical Practice (GCP) training before the MCC would approve the investigator's participation in a clinical trial. Since then many service providers have been offering GCP courses without any regulation or standardization of the course content, course duration or qualifications of the trainers. A concern about the suitability of the courses has been raised by some ethics committees, and in 2008 the Human Research Ethics Council of the University of the Witwatersrand rejected the participation of several investigators in clinical trials as the HREC was not confident that the investigators had received adequate GCP training.

The meeting began with presentations from three different view points. The chair of the National Health Research Ethics Committee (NHREC), Prof Danie du Toit gave an overview of the role and objectives of the NHREC. Nathanial Ramuthaga, the Director of Clinical Research at Pfizer and the Chair of the NHREC sub-committee on training, gave a presentation summarizing the current challenges with standardizing GCP courses and listed several questions that should be asked when deciding how to proceed. Prof. Keymanthri Moodley gave a presentation on the workings and challenges of Ethics Committees in relation to the unclear guidelines on how to accredit GCP certificates and courses. Savi Chetty-Tulsee gave the last presentation giving a GCP course provider's perspective of what issues should be resolved before we decide how to standardize GCP courses.

The reasons cited by attendees at the meeting for GCP courses being rejected by the HREC were as follows:

- no tests were written following the training to examine the participant's understanding or level of knowledge obtained during the course
- the training provider was not known to the Ethics Committee
- the training was provided electronically and not a face-to-face training
- the course material was compiled in the US and was not tailored to the South African situation or the SA GCP Guidelines.

The main objection from industry was that the policy of rejecting GCP courses was implemented without any formal communication to industry regarding the suitability of GCP courses, and no list of acceptable GCP courses was provided to the applicants. Consequently, many investigators wasted time and money attending courses that were not acceptable to the HREC.

The objective of the forum was to get people with several years of experience in either providing GCP courses, conducting clinical trials or on ethics committees to use their

experience to propose how GCP courses can be evaluated and accredited or endorsed, to enable GCP courses to be regulated.

B. Proposed Guidelines for the way forward:

Based on the group discussions held on the 23 Jan 09, the following proposal on how GCP courses can be regulated is being provided to the NHREC for consideration.

1. The Responsible Authority

It was unanimously agreed that the NHREC should be the responsible body to review, register and accredit GCP course providers.

The NHREC representatives mentioned that they would probably be able to take on the responsibility by allocating the responsibility to the training sub-committee of the NHREC. The training subcommittee would more than likely request input from various stakeholders and appoint a sub-sub committee before implementing the registration process.

Due to the urgent need for courses to be regulated, it was suggested that course providers be requested to submit an initial application to the NHREC which included a course outline, duration of the course, training material, and an example of a course assessment, quality plan and CVs of the trainers to enable the course provider to be registered.

The applications should be reviewed and the course providers should be given a registration number if the application is suitable.

It is recommended that the NHREC works on developing a system to ultimately accredit course providers.

2. Duration of GCP Courses:

Introductory Course:

- The course should include a minimum of 12 hours teaching time.
- Additional time should be given between the course and evaluation for reflection and consolidation before the knowledge gained is evaluated

Refresher:

- The course should include a minimum of 4 teaching hours.
  This is the minimum time required for an experienced investigator who clearly has a thorough understanding of GCP. The course should be extended for candidates who

require further GCP training. The course should include a recap of all training modules included in the Introductory Course.
All refresher courses should include case studies, pertinent past and current audit findings, updates on changes in SA and international GCP guidelines. The roles and responsibilities related to all aspects of a clinical trial should be included in all courses.

- Alternatively, candidates should be allowed to compile a portfolio of training in order to obtain recertification. A list of subject categories stating the minimum number of hours of training per category should be compiled to ensure that the candidates obtain continuing education credits in all required topics before they obtain re-certification.

3. Frequency of Updating GCP Certification

Candidates should obtain recertification at a minimum of every three years, as per the MCC requirements.

4. Content of the training agenda

- The content of the GCP courses offered by The Foundation for Professional Development, Wits Health Consortium, Pfizer and Ingongo Co-ordinators were reviewed during the discussions. It was generally agreed that the content of the courses is acceptable, but that the NHREC should compile a detailed course outline for course providers to use as a basis for their training courses.
- When compiling the course outline, the outline should consist of a core component required for GCP training courses in all disciplines of health research and additional specialist components specific to clinical trials, or other disciplines such as sociology research.
- Clear objectives for GCP courses should be compiled which can be used as a guide for evaluating candidates comprehension of the course material.
- The core component of the course content should include, but should not be limited to:
    i. Historical overview of the development of GCP
    ii. The regulatory and ethics environment in which clinical trials are conducted
    iii. Basic study design and methodology
    iv. Informed consent
    v. The role of various stakeholders in a research project
    vi. Insurance coverage and obtaining compensation for affected subjects
    vii. Case Report Form (CRF) completion, drug accountability, Adverse Event (AE) and a Seriously Adverse Event (SAE) reporting exercises etc can be added at the trainer's discretion.

5. Course Format

During the discussions it was apparent that there are differing opinions on what the format of the courses should be, so attendees at the meeting were asked to vote on what they thought the format of the courses should be. The votes were as follows:

- Face-to-face only 1
- Preferably face-to-face, 15
- Either face-to-face or electronic 7

The reason supporting face-to-face training was that the format enables the spontaneous interactions between the trainees and between the trainees and the trainer. These interactions provide opportunities for contentious or misunderstood items to be clarified and discussed.

The arguments against the use of electronic courses were based on the difficulty of communicating the intangible aspects of GCP without personal interactions. The practical components of the face-to-face courses are invaluable, such as completing CRFs, drug accountability exercises, and role-playing in an Informed Consent module, and would be difficult to replicate using an electronic format.

The arguments in support of e-based learning are that it is far more convenient for candidates who have busy schedules or who are based in remote locations, and the self paced learning allows the learner to take their time to learn through the modules and therefore a lot of extra study to understand the various research concepts can take place.

The technology currently available enables the courses to be interactive. The software can measure the amount of time spent in training and can control the candidates progress through the course material which enables the system to only allow progress to a subsequent component once the candidate has comprehended the fundamental components of the previous component. The course material can be very practical and can provide interactive opportunities for candidates to file documents and complete e-CRFs which is often not possible in a face-to-face setting.

6. Certificates

Certificates should only be awarded once the candidate has passed the assessment after successfully completing the course. It was recommended that the pass mark should be 80%.

The course provider's registration or accreditation number should be provided on the certificate which would indicate that the course meets the standards set by the NHREC.

The inclusion of a CPD accreditation number would be optional, and would be independent of the NHREC review of the course.

7. Assessment – Standard

It was generally agreed that the objective of GCP courses was to impart knowledge of GCP and not necessarily GCP competence, which can only be learnt through experience. It is the responsibility of experienced principal investigators, monitors, auditors and ethics committees to continually monitor the implementation of GCP during research projects. It is the responsibility of the GCP trainer to impart knowledge about GCP in the most effective way possible.

It was recommended that the objectives of GCP courses should be written to clarify the expected outcomes which will help standardise the endpoints of the candidate assessments.

The content of the assessment does not need to be prescribed by the NHREC, but there should be guidelines of what the assessments should test.

A recommendation was made that candidates should be given time between attending the course and writing a test to reflect on the material covered and to assimilate what they have learnt. However, the gap between training and assessment should not be mandatory as some candidates may need to obtain a certificate in short period of time to meet a regulatory submission date.

8. Trainer Requirements

It is essential for training organizations to have an internal quality control system in place that provides a comprehensive plan of how trainers and training schedules are followed up and assessed. This would include having a system to record data on the trainer/s, trainees, when training was received and the course content. This would mean that at any given time, should an ethics committee need to follow up a particular reference, all data would be readily available. The course providers should include a quality plan in the application to get the courses registered or accredited.

There were strong opinions expressed that it should be mandatory that all trainers should have suitable education, training and experience. That is, all trainers not only need to be suitably qualified but they must have had previous on-the-job experience.

Each course provider should allocate a responsible trainer who will be accountable for the quality of the course, and be responsible for ensuring that the course meets the NHREC requirements. The CVs of the main presenters should be presented to the NHREC to support their application for registration & accreditation. Course providers should be allowed to include non-registered trainers to provide training on specialist components of the course.