Protocol Number: GHT SA 01

Improving the capacity for quality clinical research in selected South African public health and/or academic intuitions through an enhanced Global Health Trials Professional Membership Scheme and eLearning for study staff

10th March 2014

Table of Contents

1 Synopsis

In recognition of the lack of resources for clinical researchers in lower income countries, the University of Oxford developed Global Health Trials (GHT)[1]; digital technology brings open access tools, peer-reviewed eLearning, an audited Professional Membership Scheme and discussion areas to all levels of clinical research study staff worldwide. In addition, GHT supports members to hold regional meetings or skills-sharing workshops to address local concerns. Research in other resource-limited settings has suggested that addressing technical competence, trial-related training, knowledge sharing and experience exchange for clinical research investigators, are key factors which would enable an increase in their own confidence and motivation GHT's eLearning courses are knowledge-based resources designed as flexible, accessible, satisfactory and cost-effective, while its Professional Membership Scheme is designed to help staff build a portfolio that will develop with their careers and learning through different jobs and roles. However, it is not known if enhancing GHT's offerings through local facilitation of the material, or otherwise, would improve the learning and development process or the use of the Professional Membership Scheme. This project aims to address this gap by developing, in collaboration with selected support staff such as field workers, research nurse/ coordinators, data managers and/or laboratory staff and their line managers, a flexible, sustainable, blended-learning programme for academic and/or public health clinical research staff by enhancing current GHT online content. Participants will be guided to help design a programme that will be relevant to them but that may also be adapted for use by similar personnel. The programme is likely to include facilitated group eLearning sessions, mentoring/job shadows, guidance in accessing extra resources (SA content on GHT webpages), and an annual GHT skills-sharing workshop/meeting. This formative stage will involve individual semi-structured interviews with line managers and focus group discussions (FGD) with approximately 50 staff from various research groups. We will also quantitatively measure the participants' baseline clinical research competency scores using an existing GHT online assessment tool. The participants will then be supported through a personalised blended-learning programme where we expect a process of knowledge transfer and skills improvement over an approximately 8-month period. The project will qualitatively assess the impact of the programme in terms of access to learning and career development opportunities (including gaps in clinical research knowledge), and acceptability by the participants; reflections on the programme will be elicited through end of project semi-structured interviews for line managers and FGDs with staff. Each staff member will also be given feedback on their post-programme competency assessment and the mean change from baseline of the whole cohort of participants will be measured.

[1] http://tghn.org/

2 Background and rationale

In recognition of the lack of resources for clinical researchers in lower income countries, the University of Oxford developed Global Health Trials (GHT)[2]; digital technology brings open access tools, peer-reviewed eLearning, an audited Professional Membership Scheme and discussion areas to all levels of clinical research study staff worldwide. In addition, GHT supports members to hold regional meetings or skills-sharing workshops to address local concerns. The University of Cape Town (UCT) has been involved with GHT since 2011, hosting an inaugural South African meeting in February 2012. Its theme, "Opportunities and challenges in sustaining experienced teams, and ensuring quality, in non-commercially sponsored clinical research in South Africa", was chosen to complement the South African government's remit to strengthen research and development. As such, the Medium Term Strategic Framework of the National Department of Health set priorities to assist the country in meeting the Millennium Development Goals (Health Systems Trust, 2010). Point 10 of this "10 Point Plan" (“Strengthening Research and Development”) was addressed in 2011 at the Nation Health Summit with priorities subsequently set for clinical research (Bongani M, et al.). These include the development of infrastructure and human resource personnel which was identified as a barrier to clinical research enterprise by the Academy of Science of South Africa (Academy of Science of South Africa, 2009). Barriers such as these potentially impact on research quality and hinder adoption of local research findings into clinical practice (Page, Heller, Kinlay, & Lim, 2003). Since the National Health Summit a National Health Scholars Programme has begun to award PhD bursaries, a positive step towards creating and sustaining human resources for health research (Lansang & Dennis, 2004, p. 767). In addition, though still in the early stages of development, is the plan to develop academic health complexes which will facilitate the delivery of high quality research.

Research in other resource-limited settings has suggested that addressing technical competence, trial-related training, knowledge sharing and experience exchange for clinical research investigators, are key factors which would enable an increase in their own confidence and motivation (Franzen, et al., 2013, p. 6). However, the authors also found that capacity building attached to foreign-led studies typically focuses on training individuals in specific skills or providing one specific service or resource. Efforts should rather be made to integrate the building of short-term and project-oriented skills with a more comprehensive and sustainable human resource development plan that address continuing challenges and health inequities faced in clinical research (Lansang & Dennis, 2004, p. 767). In addition, while often emphasis is placed on supporting senior researchers, it is critical to develop personnel at all levels, particularly those working in lower middle income countries (LMIC) as they may find it more difficult to access up to date information about the required or optimal way to operationalise studies. This is likely to be exacerbated if staff are employed on short-term contracts as they, and their line managers, have limited time to focus on career development for its immediate gains but also for the benefit of future studies. GHT's offerings have

[2] http://tghn.org/

therefore always been aimed at the range of personnel involved in clinical research, including support staff (such as research nurses and coordinators), regardless of their employment status. This is also important should research groups use the skills built within their teams to develop their own studies to address important local health problems or clinical trial methodology questions.

It is important to ensure that the most appropriate resources are available and used to support learning and development of these clinical research support staff. The local and international collaboration inherent in GHT's open access platform is designed to promote training and experience exchange using information technology, the latter which can have a significant impact on the delivery and provision of resources for education (Calverl`ey & Shephard, 2003; Franzen, et al., 2013, p. 6). Indeed, learning in today's society has been transformed by the introduction of web based, mobile and embedded technologies (Sun, Tsai, Finger, & Chen, 2008). This transformation is not unique to higher income countries, and has also become the means by which users in lower and middle income countries access and gain new knowledge. Like all major fields, the health care sector has also been revolutionized by these innovations in techonology and e-learning is rapidly increasing in medical and nursing education (Lahti, Hatonen, & Valimaki, 2014). The usefulness of this approach is reflected by research into web-based learning that has shown that interactivity, practice exercise; repetition and feedback improved learning outcomes while using e-Learning interventions (Cook, Garside, Levinson, Dupras, & Montori, 2010b).

GHT's eLearning courses are knowledge-based resources designed as flexible, accessible, satisfactory and cost-effective, while its Professional Membership Scheme is designed to help staff build a portfolio that will develop with their careers and learning through different jobs and roles. However, it is not known if enhancing GHT's offerings through local facilitation of the material, or otherwise, would improve the learning and development process or the use of the Professional Membership Scheme. Enhancement could, for instance, overcome practical problems, contextualise the content or encourage staff more to actively own their careers. Ideally, learning should be integrated into the work environment but it could be important to support typically busy and financially-constrained line managers to assist staff in their chosen learning path through GHT. The broad aim of this project therefore is to improve the quality of academic and/or public health clinical research through supporting study staff such a research nurses, coordinators, data managers, field or laboratory staff (and their line managers) to access new learning opportunities and manage their career development with GHT. It is proposed that this be achieved through enhancing the current available GHT offerings. As blended-learning (combining online with face-to-face components) has been shown to have high approval amongst students and result in good acquisition of knowledge (Back, et al., 2014) we will invite participants of this project to take an active role in developing a programme of this type. It will be intended to be flexible enough to be tailored to meet their own or others' needs and also likely to be sustainable beyond the development project. The results from this preliminary project will then be used to inform adoption of the programme more widely and/or in other contexts.

3 Conceptual framework: clinical research staff actively involved in developing a clinical research blended-learning programme

Clinical research is at the cutting edge of healthcare discovery. A constant need to innovate, means that those working in this field must keep pace with developments in required or best practices. Those based in LMICs are not exempt. The uptake of knowledge in the clinical research environment is typically Good Clinical Practice courses combined with on-the-job training, where learning is embedded into work processes; work, therefore, has been the largest source of learning. However, clinical research resources available through the internet have increased over the last 10 years. GHT's online offerings are unique in that it has an open access, participatory ethos. It is therefore proposed that this project reflect GHT's ethos through its participatory action research methodology. Meanwhile blended learning has emerged as the "third generation " of the distance education system. It is characterized as maximizing face-to-face with technology-mediated learning, to deliver a highly efficient and effective output (So & Brush, 2008). This model can be used to personalize learning, allow for thoughtful reflection and differentiate instructions from student to student across a diverse group of learners (Kaur, 2013).

4 Aim and objectives

4.1 General aim

To improve the quality of clinical research in selected South African academic and/or public health institutions by offering study teams a supportive environment to access learning opportunities and manage career development.

4.2 Objectives

4.2.1 Primary objectives

- To develop, in collaboration with selected support staff (such as field workers, research nurse/ coordinators, data managers and/or laboratory staff); and their line managers, a flexible, sustainable, blended-learning programme for academic and/or public health clinical research staff by enhancing current GHT online content
- To qualitatively assess the impact of the blended-learning programme in terms of access to learning and career development opportunities (including gaps in clinical research knowledge), and acceptability of the programme by the clinical research staff and their line managers

4.2.2 Secondary objectives

- To quantitatively assess the impact of the blended-learning type programme on clinical research competencies
- To identify individuals who would like to engage in a long term dialogue about improving clinical research professional development in South Africa

5 Design and methods

5.1 Setting

This study will be set within clinical research teams at academic and/or public health institutes in the Western Cape, South Africa.

5.2 Design

This project employs mixed methods (qualitative and quantitative approaches), where the results from one method help develop or inform the other (Polit & Beck, 2012). The primary objectives will be achieved through a qualitative participatory action research method. This is orientated toward the enhancement of direct practice through a process of planning, implementing and evaluating, working with research participants in their natural settings to inform community change (Moore, Crozier, & Kite, 2012). Secondly, we will quantitatively measure staff baseline and post-intervention clinical research competency scores. As depicted in Figure 1, eligible line managers and staff will be invited to pre-study semi-structured interviews or focus group discussions and staff will complete the GHT online clinical research competency assessment. Individual training plans will then be drawn up and implemented using, but not limited to, GHT content. In parallel, South Africa-specific clinical research resources will be uploaded to the GHT website and a second national skills-sharing workshop will be held. After 6-8 months participants will be invited to post-study semi-structured interviews, focus group discussions and/or a competency assessment. Considering all aspects of the program design , the researchers propose that the study will take approximately 18 months.

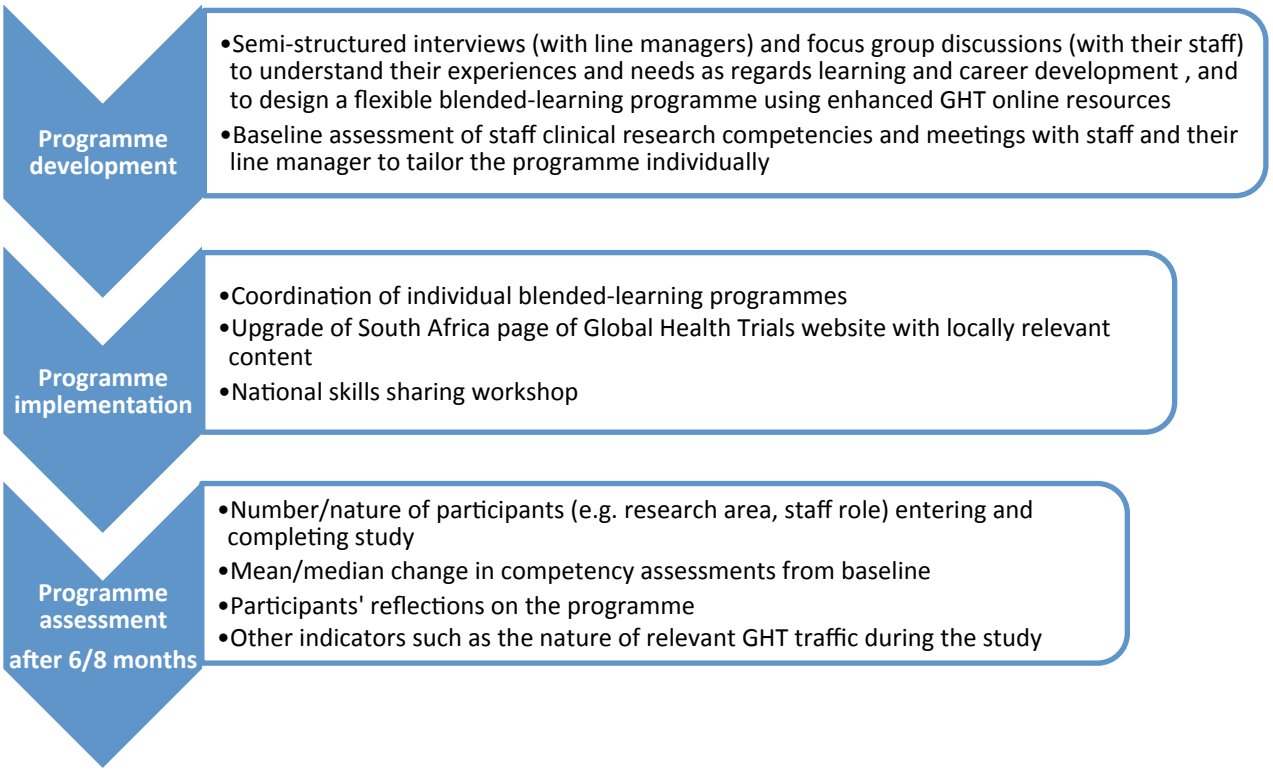


Figure 1: Project design

5.3 Population and sampling

The project's participant population is line managers and their study support staff selected purposively based on eligibility, availability and interest:

Inclusion criteria

Line managers

- More than one year of experience in clinical research
- Currently managing support staff in at least one clinical research study
- Willing and able to commit to working with the GHT project team over an approximately 8 month period, including attendance at 2 semi-structured interviews to develop and implement a blended-learning programme for clinical research staff.
- Willing and able to commit to working with the GHT project team over an approximately 8 month period to support their staff in attending any designated learning/career development sessions

Staff

- Currently working on a clinical research study with the above line managers as support staff (e.g. field workers, research nurse/coordinators, member of data management or laboratory team)
- Interested in improving specific role-related skills/competencies

- Willing and able to commit to working with the GHT project team over an approximately 8 month period, including attendance at 2 focus group discussions to develop and implement a blended-learning programme for clinical research staff
- Willing and able to commit to working with the GHT project team over an approximately 8 month period to take the GHT competency assessments, and attend any designated learning/career development sessions
- Not currently exposed to another knowledge enhancement training or professional development scheme over and above standard work-related schemes

The study is primarily qualitative so that participants can be actively involved in shaping the programme's development. For feasibility we will recruit approximately 50 support staff and their line managers from a minimum of 2 academic/public health institutions in the Western Cape. Approximately 6 focus group discussions will be conducted during the development and assessment phases or until saturation is reached, depending on which occurs first. This limit has been set in order to ensure outcomes are arrived at within a realistic timeframe.

5.4 Methods

5.4.1 Programme development

Clinical research support staff and their line managers will be invited to work with suitably experienced members of the GHT project team, to understand their experiences and needs as regards learning and career development, and to design a flexible blended-learning programme using enhanced GHT online resources. Participants will be guided to help design a programme that will be relevant to them but that may also be adapted for use by similar personnel. The programme is likely to include facilitated group eLearning sessions, mentoring/job shadows, guidance in accessing extra resources (SA content on GHT webpages), and an annual GHT skills-sharing workshop/meeting. This formative stage will involve individual semi-structured interviews with line managers and focus group discussion for their staff with staff from other research groups. Line manager and staff discussions will be separated in order for them to feel more at ease expressing their thoughts and views (Polit & Beck, 2012).

Semi structure interviews for line managers

The study requires input from line managers across different institutions in order to implement a robust and generalizable "blended learning" programme that can be adapted locally for specific staff. Firstly, semi-structured interviews will be held one-to-one with line managers who give consent to allow for them to be involved in development of the programme. The interviews will be held at the line managers' places of work in accordance with a project-specific standard operating procedure to ensure standardisation and quality. A detailed question guide has also been developed to ensure interviews reflect the research questions (Appendix 1). However, the guide will be used in a flexible open-ended manner and may also be refined throughout the data collection process

as data emerge. Topics will include perceptions about their staff's skills, experiences of training and developing their staff, access to relevant resources, and potential attributes of a blended-learning programme using GHT resources to improve staff skills and support career development. An explanation of Global Health Trials and the project's objectives will be used to help the managers understand their role in developing a suitable programme. Interviews will be recorded should line managers give consent; otherwise comprehensive notes will be taken. The recordings will be downloaded and stored on a password protected computer and a copy kept in a revelant access controlled folder on a local UCT server.

Focus group discussions with study staff

At the start of the project study staff will also be invited to participate in one of several recorded focus group discussion (FGD) with staff from other research groups. These will take advantage of group dynamics for accessing rich information in an economic manner and will efficiently aid in providing the research team with information about study staffs' perceptions of their learning experiences in clinical research prior to final development of, and enrolment into, the blended eLearning programme. Approximately 6 FGDs will be held with 8 to 12 participants, with at least two research teams represented in each, selected pragmatically depending on availability. The FGDs will take place in a private area at an accessible location and convenient time to ensure maximum uptake from staff at different institutions. The FGD facilitators will follow a project-specific standard operating procedure to ensure standardisation and quality of data collected. A detailed question guide has been developed to ensure interviews reflect the research questions (Appendix 2). However, they will be used in a flexible open-ended manner and may also be refined throughout the data collection process as data emerge. Topics will include participants' experiences of learning and career development in the clinical research setting, perceptions on career development opportunities, access to relevant resources, and ideas for a feasible staff professional development programme including enhancing GHT online methods through local facilitations. A power-point presentation introducing Global Health Trials and the project's objectives will be integrated into the FGD to help the study staff members understand their role in developing a suitable programme.

Baseline competency assessment and design of individual programmes

After each FGD staff members will be assisted to complete the GHT Professional Membership Scheme competency assessment to ascertain a baseline score of their experience and skills to perform tasks relevant to their clinical research role (Appendix 3). Participants will be guided as to how to access the online site, register as a member of GHT and complete the assessment. The assessment will then be reviewed by core GHT staff as per the current process.

A member of the GHT project team will then make an appointment to meet with each staff member and his/her line manager where feedback will be given on the results of the semi-structured interviews and their own competency assessment. A detailed plan will then be negotiated to be implemented over an approximately 6 month period to help the staff member improve competency in specific areas. This meeting could be incorporated into any institutional professional development programme (e.g. formal appraisal). This plan should complement any existing staff development ventures within the team or institution and include specific facilitated group eLearning sessions, mentoring/job shadows, guidance in accessing extra resources (SA content on GHT webpages, including existing training courses), and an annual GHT skills-sharing workshop/meeting.

5.4.2 Programme implementation

The participants will be supported to undergo a process of knowledge transfer and skills improvement over an approximately 8-month period (Lahti, Hatonen, & Valimaki, 2014). While this is predominantly individual, staff with the same needs may be brought together, e.g. for facilitated group GHT eLearning sessions. Study staff will be encouraged to maintain a journal throughout the process; to make notes about how they experience the eLearning tools etc. as this will help with gaining insight into the needs of support staff in clinical research from subsequent FGDs and ongoing feedback from participants. The GHT project team will be on hand to speak to line managers and staff about the implementation of the programme, facilitate eLearning and guide them in finding appropriate material.

5.4.3 Programme assessment

The program will be assessed based on the number of participants entering and completing the project, and reasons for non-completion will be documented. Each staff member will then be given feedback on their post-programme competency assessment and the mean change from baseline of the whole cohort of participants will be measured. Reflection on the programme will be elicited through end of project semi-structured interviews for line managers and FGDs with staff. Topic guides will be developed for these prior to their conduct so that they can be tailored to the programme's eventual attributes. Other indicators, such as the nature of relevant GHT traffic, and other community effects (self-initiated on-line discussions within or without the cohort of included participants) will also be observed where possible.

6 Data management and analysis

6.1 Qualitative methods:

Data management will be according to a project-specific SOP while analysis will be according to a referenced manual (Chandler). To summarise, audio recordings will be transcribed into Word and a meta-matrix will include a summary of quantitative data to describe the participant's demographic and work-related characteristics (age, gender, qualification(s), study role, length of experience in role and/or previous clinical research role), the location and other key information to situate the interview and/or focus group discussions (Polit & Beck, 2012). Major interruptions by other people or telephones will be recorded to contextualise any breaks in speech or repetitions. However, minor interruptions will not be recorded in order to ensure the flow of the transcript supports interpretation and analysis. Data analysis will be conducted concurrently with data collection. The transcriptions will be proof-read against the audio file by a member of the research team to check for accuracy, identify missed or misheard words and to clarify any areas of confusion or unclear terminology. Queries and changes will be made using MS Word's track changes tool. An agreed "clean" version of the transcription will be created for exporting to NVivo Version 11 (QSR International, Cambridge, MA). Transcripts will be read to gain an overall view (Bruce & Klopper, 2010) and to gage a sense of the underlying meaning. A first level of basic descriptive coding of ideas will be developed by 2 independent members of the research team who will debate any differences such that the remainder are coded by one person (Polit & Beck, 2012, p 736). The data will then be reduced using a coding scheme agreed to by members of the research team (Tesch, 1990, pp. 141-145). The scheme developed will use qualitative content analysis, whereby coded data will be condensed into categories or themes with constant reference to the original transcripts (Weber, 1990). Once coding is complete, an initial brainstorming session by the researchers will identify as many psychological theories and theoretical constructs as possible of relevance to program implementation, and a theoretical narrative developed (Michie et al, 2005, p.27).Electronic documents will be maintained in password-protected computer hard drive and back-up drive. Paper documents will be maintained in a secure location only accessible to the investigational team.

6.2 Quantitative methods:

Quantitative endpoints relating to the numbers and nature (demographics) of participants taking part in the programme will be described by proportions. Items from the Professional Membership Scheme competency assessments will presented in a spreadsheet format for importation into NVivo and mean or median change in competency scores calculated.

7 Ethical considerations

Only after approval from the Research Ethics Committee (or other pertinent department) of the institute where participants work will any study related activities begin.

The researchers will respect the rights of the individuals to decide whether or not to consent to participate in the study, without any risk of penalty or prejudicial treatment (Brink, 2012, p 35). An information sheet will be provided and the researcher will answer any questions of participants to the best of her ability. There will be no remuneration for taking part but transport costs to any training venues other than the participants' normal places of work will be provided. Each participant will be made aware of how interviews will be recorded and who will have access to the data collected. It will be made clear that refusal to participate or withdrawal from the study at any stage is without any disadvantages for his/her employment. Informed consent forms will be available in English and the local language of the study population. Each participant will be provided with a copy of the written informed consent form.

Identifying information will be restricted to the research study team and not published. The data will be kept in a locked cupboard or password protected computer at UCT or (for the Professional Membership Scheme) under secure conditions at GHT (Oxford University). Five years after publication the data will be destroyed.

This project is estimated to be of minimal risk to participants. The researcher will be particularly sensitive to anticipate potential problems associated with the process of in-depth reflection and interviews will be conducted in private spaces. FGDs have some inherent risk as confidentiality cannot be guaranteed and some participants may feel uncomfortable discussing certain topics. The informed consent documents declare this possibility and explain that they do not need to discuss anything if they do not want to. Participants may benefit in terms of being involved in developing their own career and in helping other line managers or staff working in clinical research in South Africa.

8 Bibliography

Health Systems Trust. (2010, July). The 10 Point Plan. *Kwik Skwiz , 2* (1).

Mayosi,B.,Mekwa, N.J., Blackburn, J., Coovadia, H., Friedman, I.B.,Jeenah, Mohammed., et al. (2012). *Strengthening research for health, innovation and development in South Africa: Proceedings and recommendations of the 2011 National Health Research Summit.* Republic of South Africa, Department of Health. Department of Health.

Lansang, M. A., & Dennis, R. (2004). Building capacity in health research in the developing world. *Bulletin of the World Health Organization , 82* (10).

Franzen, S., Chandler, C., Enquselassie, F., Siribaddana, S., Atashili, J., Angus, B., et al. (2013). Understanding the investigators: a qualitative study investigating the barriers and enablers to the implementation of local investigator-initiated clinical trials in Ethiopia. *BMJ Open , 3*.

Calverley, G., & Shephard, K. (2003). Assisting the uptake of on-line resources: why good learning resources are not enough. *Computers & Education , 41*.

Polit, D., & Beck, C. (2012). *Nursing Research: Generating and Assessing Evidence for Nursing Practice* (9th Edition ed.). Wolters Kluwer Health| Lippincoyy Williams & Wilkins.

Lahti, M., Hatonen, H., & Valimaki, M. (2014). Impact of e-Learning on nurses' and student nurses knowledge, skills and satisfaction: A systematic review and Meta-Analysis . *International Journal of Nursing , 51*, 136-149.

Cook, D., Garside, S., Levinson, A., Dupras, D., & Montori, V. (2010b). What do we mean by web-based learning? A systematic review of the variability of interventions . *Medical Education , 44*, 65-774.

Back, D., Haberstroh, N., Sastmann, K., Schmidmater, G., Putsier, M., Perka, C., et al. (2014). High efficacy and student satisfaction after voluntarty use of an e-Learning program in Traumatology and Orthopedics - A follow up study Pro. *Journal of Surgical Education* .

Brink, H., van der Walt, C., & van Rensburg, G. (2012). *Fundamentals of Research Methodology for Healthcare Professionals* (3rd Edition ed.). Juta & Company Ltd.

Bruce, J., & Klopper, H. (2010). A model for incoporating specialist nurse education into a university context. Part 1 Methodological Perspectives. *Health SA Gesondheid , 15* (1).

Moore, J., Crozier, K., & Kite, K. (2012). An action research approach for developing research and innovation in nursing and midwifery practice: Building research capacity in one NHS foundation trust. *Nurse Education Today , 32*.

Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., & Walker, A. (2005). Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and safety in health care*, *14*(1), 26-33.

Page, J., Heller, R. F., Kinlay, S., & Lim, L. e. (2003). Attitudes of developing world physician to where medical research is performed and reported. *BMC Public Health* (3).

So, H.-J., & Brush, T. (2008). Students perception of collaborative learning, social presence and satisfaction in a blended learning environement: Relationships and critical factors. *Computers & Education , 51*, 318-336.

Kaur, M. (2013). Blended Learning - Its challenges and future. *Procedia - Social and Behavioural Sciences , 93*, 612 - 617.

Sun, P., Tsai, R., Finger, G., & Chen, Y. Y. (2008). What drives successful e-Learning? An empirical investigation of the critical factors influencing learner satisfaction. *Computers & Education , 50*, 1183 - 1202.

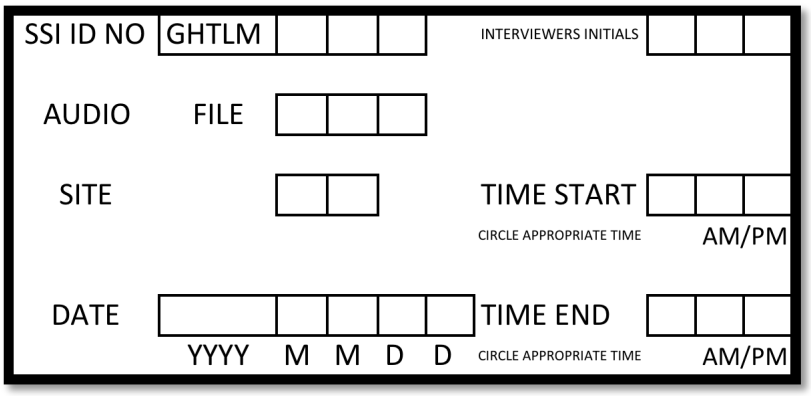
Tesch, R. (1990). *Qualitative Research: Analysis Types and Software Tools.* New York: Falmer.

Weber, R.P. (1990). Basic Content Analysis. Newbury Park, CA: Sage Publications.

Udo-Akang, D. (2012). Theoretical Constructs, Concepts and Applications. American International Journal of Contemporary Research, 2(9), 89-97

Zhang, Y., & Wildemuth, B. M. (2009). Qualitative analysis of content.*Applications of social research methods to questions in information and library science*, 308-319.

Academy of Science of South Africa. (2009). *Consensus Report on Revitalising Clinical Research in South Africa:A Study on Clinical Research and Related Training in South Africa.*



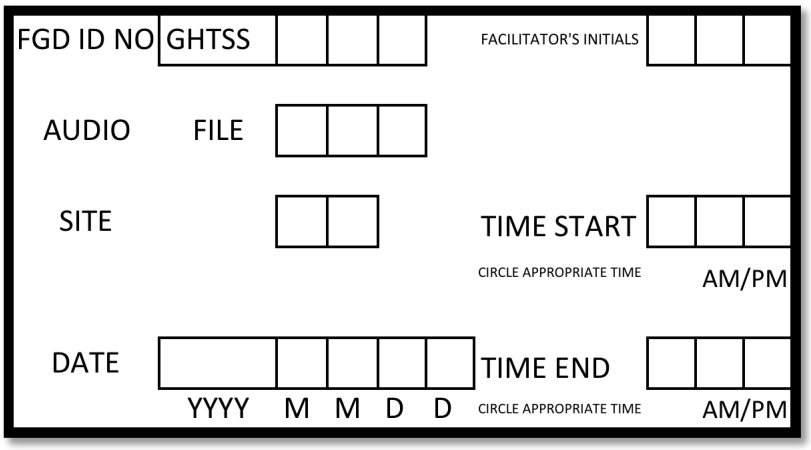
I am _____ from _____

- ✓ Introduce yourself
- ✓ Discuss consent document and obtain demographic details
- ✓ Explain general purpose of the study:
- *For Interview:* Your input is needed to facilitate us in the development of a blended-learning and professional development program for study staff
- *For overall project: To improve the quality of clinical research through offering line managers and their study teams a supportive environment to access learning opportunities and manage career development*
- ✓ Expected duration (1 hour)
- ✓ Why the participants' cooperation is important
- ✓ What will happen with the collected information and how the participant/target group will benefit
- ✓ Any questions?
- ✓ Check position and functioning of tape recorder

Now we will have a discussion that should help us develop a blended-learning and professional development program for study staff

Domain	**Topic and Probes**
Current learning opportunities	In order to perform their study role, do you feel your staff, in general, have the necessary skills and knowledge to "get the job done right"? Probes: Do you feel staff have the opportunity to learn what they need to perform their role? What are the current methods you use to improve your staff's skills and knowledge related to their job? Probes: What works and doesn't work with the current methods? What would make these methods better? What are your challenges with training and developing your staff? Probes: What would help you to overcome these challenges?
Career development	Tell me about career development opportunities or pathways for your study staff. Probe: Can you explain further? What about career development for those doing these jobs in South Africa in

	general? What would their career path look like if anything was possible? Where do you want to see your staff in 5 years' time? Probe: Do you think you will be able to achieve this? Why/why not?
Ideas for a blended-learning program	Have you heard of Global Health Trials? Probes: Have you used the resources provided on Global Health Trials? How would we be able to best use these resources to improve your staff's skills and knowledge? **Present GHT eLearning, other resources, discussion pages etc. and Professional Development Scheme then introduce our ideas for a program (facilitated group eLearning, national skills-sharing workshop, perhaps job-shadows or mentoring)** What do you think of these ideas? Probe: How would face to face interactions enhance understanding of the eLearning resources by your staff How would job shadows or mentoring help you and your staff? What other affordable, flexible, sustainable ideas do you have for improving learning opportunities and career development for your study staff? How would these opportunities be structured? Probe: Do you and your staff have capacity for such a program
Closing Thank you for taking time out of your day to meet with me. Once all interviews have been analyzed we will come and meet with you and your staff to set personal development plans for the next 6 months. In the meantime please log onto the GHT website and have a browse. ✓ Summarise ✓ Provide extra information and contacts to participants	



I am _____ from _____ (Facilitator)
I am _____ from _____ (note-taker)

- ✓ Ask group to introduce themselves using first names
- ✓ Capture demographic details – using first name for discussion
- ✓ Explain general purpose of the study:
- *For FGD:* Your input is needed to facilitate us in the development of a blended-learning and professional development program for study staff
- *For overall project: To improve the quality of clinical research through offering line managers and their study teams a supportive environment to access learning opportunities and manage career development*
- ✓ Aims of the discussion and expected duration (1 hour)
- ✓ Who is involved in the process (other participants)
- ✓ Why the participants' cooperation is important
- ✓ What will happen with the collected information and how the participant/target group will benefit
- ✓ Ask group to define their own ground rules, for example:
  - Only one person talks at a time.
  - It is important for us to hear everyone's ideas and opinions.
  - There are no right or wrong answers to questions –

    (just ideas, experiences and opinions, which are all valuable)
  - It is important for us to hear all sides of an issue – the positive and the negative.
  - "What is shared in the room stays in the room."
- ✓ Any questions?
- ✓ Check position and functioning of tape recorder
- ✓ Check for everyone's consent to participate and be recorded
- ✓ Refreshments will be served after the discussion

Now we will have a discussion that should help us develop a blended-learning and professional development program for study staff

Adapted from Chandler, C.I.R., and Reynolds, J. (2013) ACT Consortium Guidance: Qualitative Methods Protocol Template with example Tools and SOPs. Available at www.actconsortium.org/qualitativemethodsguidance

Domain	**Topic and Probes**
Current learning opportunities	In order to perform your study role, do you feel you have the necessary skills and knowledge to "get the job done right"? Probes: Is there a particular area in which you feel that you have less knowledge or understanding? Do you feel you have the opportunity to learn these things? Can you be more specific? What are the current methods you use to improve your skills and knowledge related to your job? Probes: What works and doesn't work with the current methods? What would make these methods better?
Career development	Tell us about career development opportunities or pathways for you within your research team/department. Probe: Can you explain further? What about career development for those doing your job in South Africa in general? What would your career path look like if anything was possible? Where do you want to see yourself in 5 years' time? Probe: Do you think you will be able to achieve this? Why/why not?
Ideas for a blended-learning program	Have you heard of Global Health Trials? Probes: Have you used the resources provided on Global Health Trials? How would we be able to best use these resources to improve your skills and knowledge? **Present GHT eLearning, other resources, discussion pages etc. and Professional Development Scheme then introduce our ideas for a program (facilitated group eLearning, national skills-sharing workshop, perhaps job-shadows or mentoring)** What do you think of these ideas? Probe: How would face to face interactions enhance understanding of the eLearning resources How would job shadows or mentoring help you? What other affordable, flexible, sustainable ideas do you have for improving learning opportunities and career development for your study role?

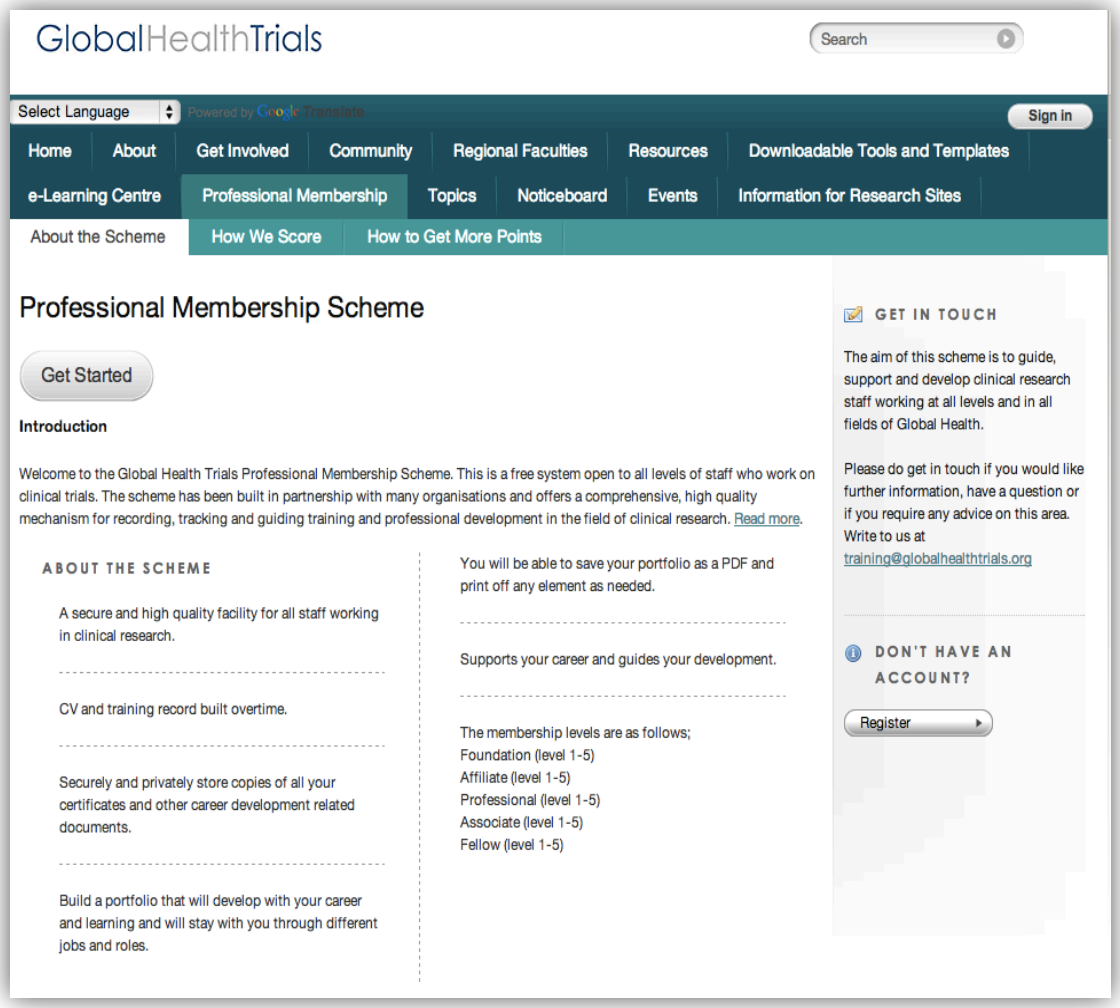
Closing

Thank you for taking time out of your day to meet with me. Once all FGDs have been analyzed we will come and meet with you and your line manager to set a personal development plan for the next 6 months. In the meantime please log onto the GHT website and have a browse.

- ✓ Summarise
- ✓ Provide extra information and contacts to participants

The Professional Membership Scheme is a dynamic, established online tool (https://globalhealthtrials.tghn.org/cpd/about/) that will be used during the GHT SA study, as a competency assessment tool. Baseline scores of participants' level of experience will be assessed prior to implementation of the blended eLearning program and after a 6-8 month (implementation phase) period. For conceptual understanding of the tool we have included screen shots from the webpage.

About GHT section



Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468

Overview of Scoring System

How We Score

The Global Health Trials Professional Membership Scheme is a free, online, system for maintaining an audited professional record and for accruing points to build on your professional skills and experience.

There are five tiers of membership which are determined by scores based on your prior experience and training, and on the accumulation of points for any on-going training and development activities which you may undertake.

The professional membership scheme levels are scored as shown in Table 1.

Table 1

Professional Membership Scheme Levels and Scoring

Tier	Level	Points
Foundation	1	0-736
	2	737-1472
(0-3680)	3	1473-2208
	4	2209-2944
	5	2945-3679
Affiliate	1	3680-4416
	2	4417-5152
(3681-7360)	3	5153-5888
	4	5889-6624
	5	6625-7360
Professional	1	7361-8096
	2	8097-8832
(7361-11040)	3	8833-9568
	4	9569-10304
	5	10305-11040
Associate	1	11041-11776
	2	11777-12512
(11041-14720)	3	12513-13248
	4	13249-13984
	5	13985-14720
Fellow	1	14721-15456
	2	15457-16192
(14721-18400)	3	16193-16928
	4	16929-17664
	5	17665-18400

You can earn points from the following:

1. Academic qualifications
2. Professional courses and qualifications
3. Professional registration
4. Relevant Publications
5. Other professional development activities
6. Core competencies

Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468

Description of Points

How to Get More Points

After you complete and submit your Professional Membership Scheme application for moderation, you will be awarded a score and the appropriate membership level (see Table 1) which will be displayed on your profile.

Table 2

CALCULATING POINTS

Activity	Points
Doctorate	2000
Masters	1400
Bachelors	1000
Diploma	700
Supervision: > 6 students/staff	400
Supervision: 1 – 5 students/staff	300
Professional courses & qualifications	200
Professional registration/membership	200
Conference: Oral presentation	200
Conference: Poster presentation	100
Conference: Attended	50
Publications: 1st author	200
Publications: Last author	200
Publications: Author	100
Attending Training:	
Short course - (0 - 2 wks)	50
Long course - (> 2 wks)	100
Delivering Training:	
Presentation	200
Planning or coordinating	150
Seminar/CMES/Journal Club: Presented	50
Seminar/CMES/Journal Club: Attended	10
Global Health Trials: Submit training material	100
Global Health Trials: Submit an article	100
Global Health Trials: Reviewer	50
Global Health Trials: Taking an e-learning course	25
Global Health Trials: Blog	15
Global Health Trials: Discussion	10
Other relevant professional activities	TBD

Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468

Description of Core Competencies

Table 3

Core Competency Categories

Category	Definition
No experience	I have neither experience nor training in this task or activity.
Trained	I have received training (this can include formal/documented observing of others) but have no personal experience in this task or activity.
Some experience	I have performed this task or activity but not regularly or recently (less than one years' experience, or occasional or past experience).
Capable	I am capable in this task or activity, it is a part of my job and I am competent (1-2 years' experience may be an appropriate guide depending on how often it is conducted and how complex the task).
Experienced	I am consistently competent at this task or activity. It is a normal part of my job and I can conduct it confidently with no supervision (over 2 years could be a guide, depending on regularity of the task and complexity).
Highly experienced	I have been performing this task or activity for many years and I train others. I take a lead role in this task and would be involved in the design or operational aspect.

These definitions are provided in the right-hand menu of the Core Competencies Section.

Once you have completed and submitted your profile, it will take about four weeks for the moderation process and the awarding of your membership level to be completed. You will be awarded a score, together with the appropriate membership level (see Table 1). You will be able to print off a certificate and both your score and membership level will appear on your profile.

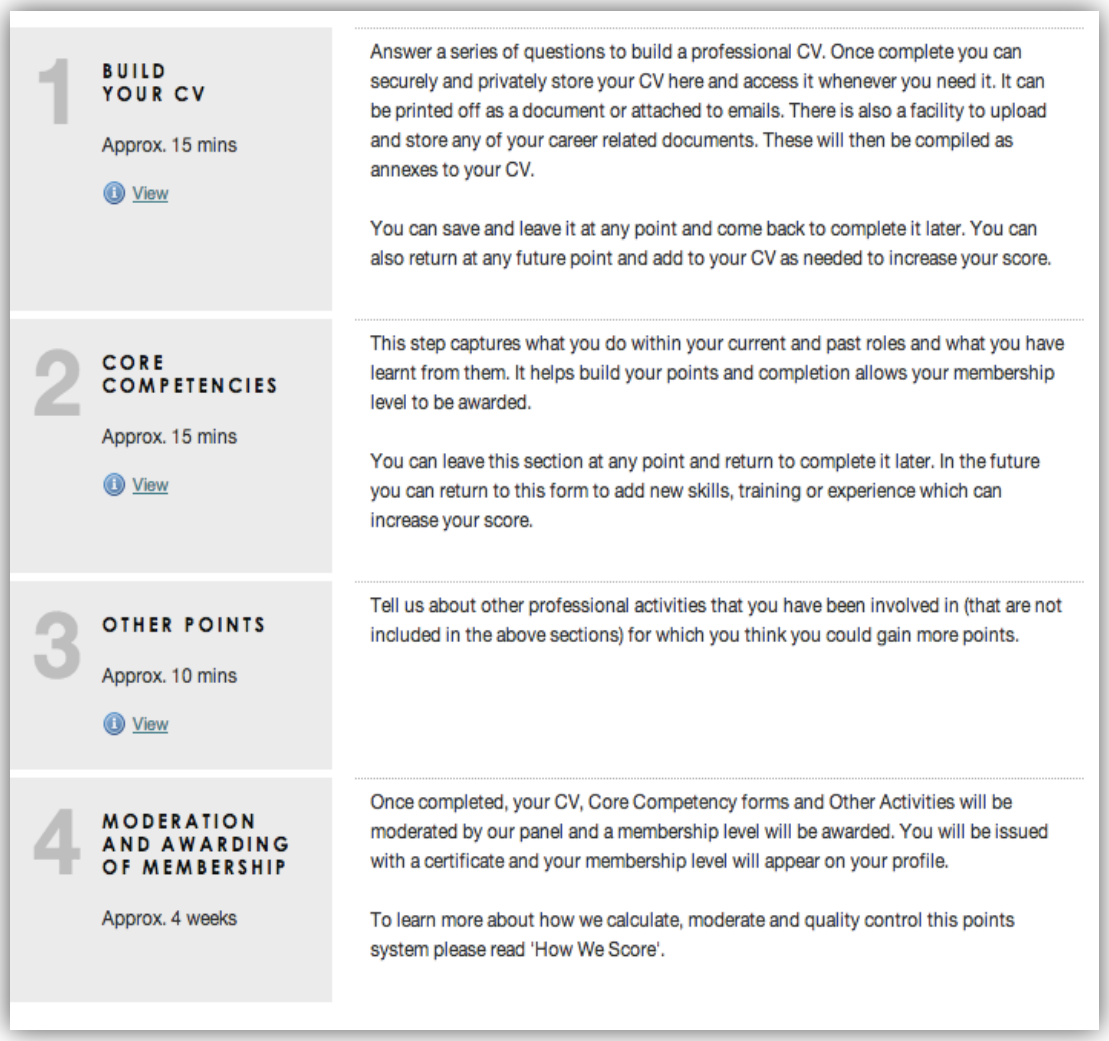
Remember, when completing your Professional Membership Scheme profile you can save and exit at any point and come back to complete later. You can return at any future point and add new skills, training or experience to increase your score. To learn how you can do this see the 'How To Get More Points' section.

Once you have been accepted into the Professional Membership Scheme there are many ways to raise your score so that you can work your way up the different tiers. As you gain new skills, attend meetings, take part in training (these are just a few examples) you can add to your points and enhance your progression through the membership levels.

To add new skills, training, activities, etc., go to your profile and click 'edit' on the section you would like to change. Once you have updated the relevant section(s), save the changes and then re-submit your profile for moderation. Once the panel review your re-submitted profile, you will be awarded your new score and, if appropriate, your new membership tier and/or level.

Table 2 shows you how many points you can earn for different training and activities.

Delineation of Personal Profile



1 BUILD YOUR CV

Approx. 15 mins

View

Answer a series of questions to build a professional CV. Once complete you can securely and privately store your CV here and access it whenever you need it. It can be printed off as a document or attached to emails. There is also a facility to upload and store any of your career related documents. These will then be compiled as annexes to your CV.

You can save and leave it at any point and come back to complete it later. You can also return at any future point and add to your CV as needed to increase your score.

2 CORE COMPETENCIES

Approx. 15 mins

View

This step captures what you do within your current and past roles and what you have learnt from them. It helps build your points and completion allows your membership level to be awarded.

You can leave this section at any point and return to complete it later. In the future you can return to this form to add new skills, training or experience which can increase your score.

3 OTHER POINTS

Approx. 10 mins

View

Tell us about other professional activities that you have been involved in (that are not included in the above sections) for which you think you could gain more points.

4 MODERATION AND AWARDING OF MEMBERSHIP

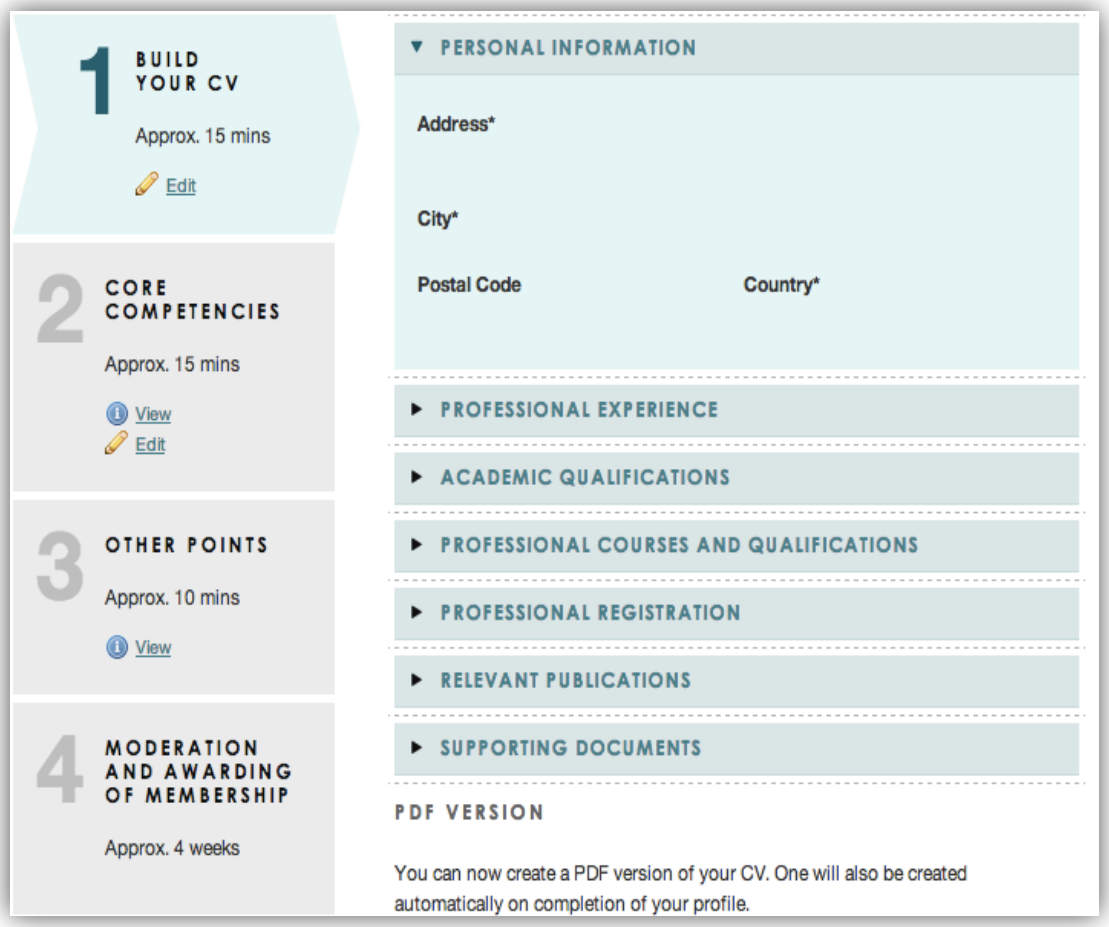
Approx. 4 weeks

Once completed, your CV, Core Competency forms and Other Activities will be moderated by our panel and a membership level will be awarded. You will be issued with a certificate and your membership level will appear on your profile.

To learn more about how we calculate, moderate and quality control this points system please read 'How We Score'.

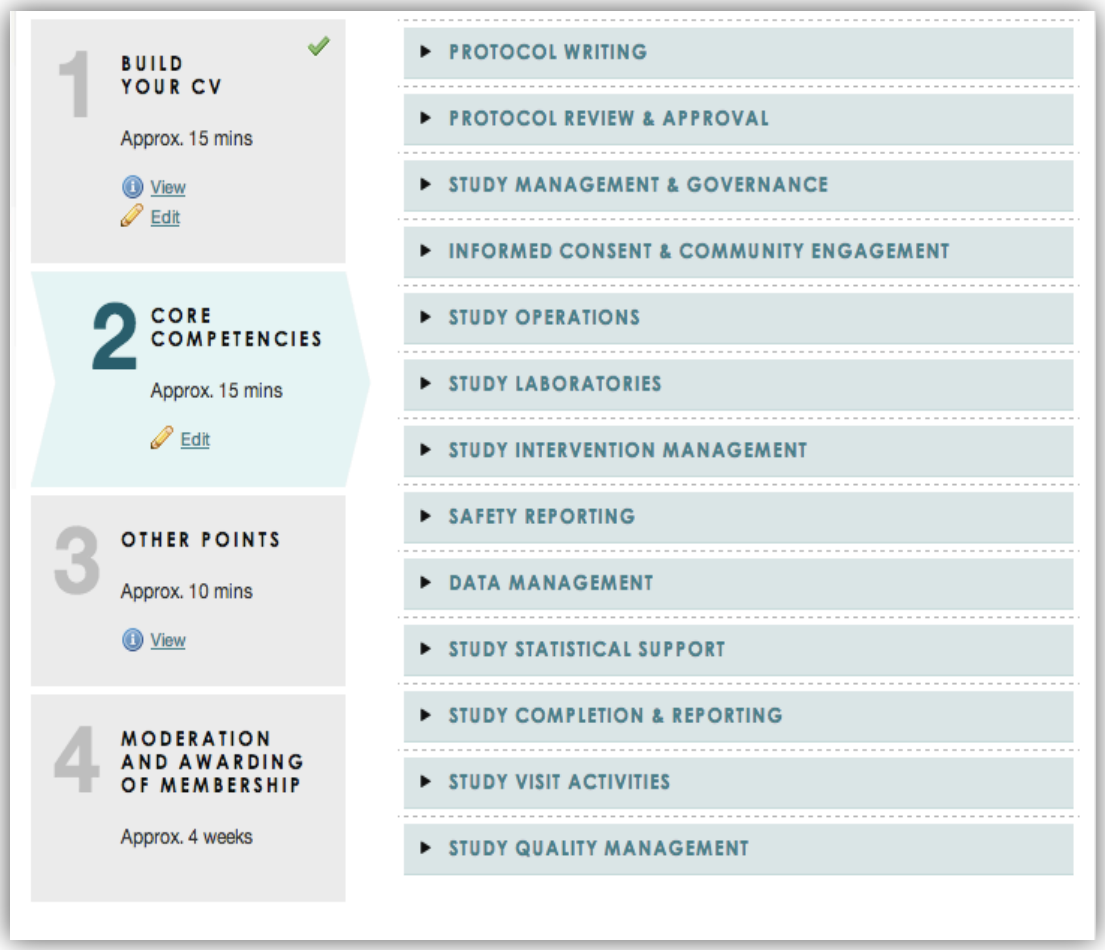
Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468

Build a CV Section

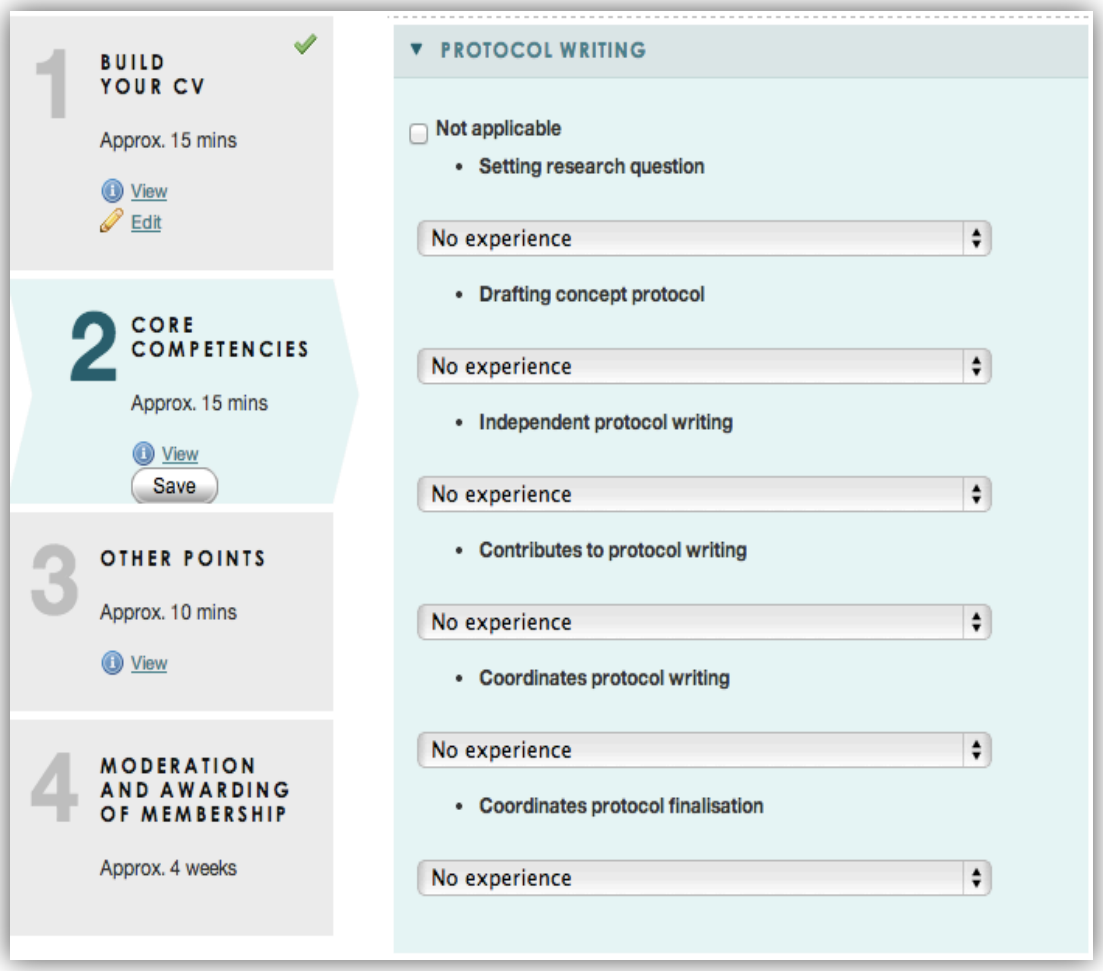


The CV which is build can be printed as a pdf and used within the everyday work situation

Core Competency Section

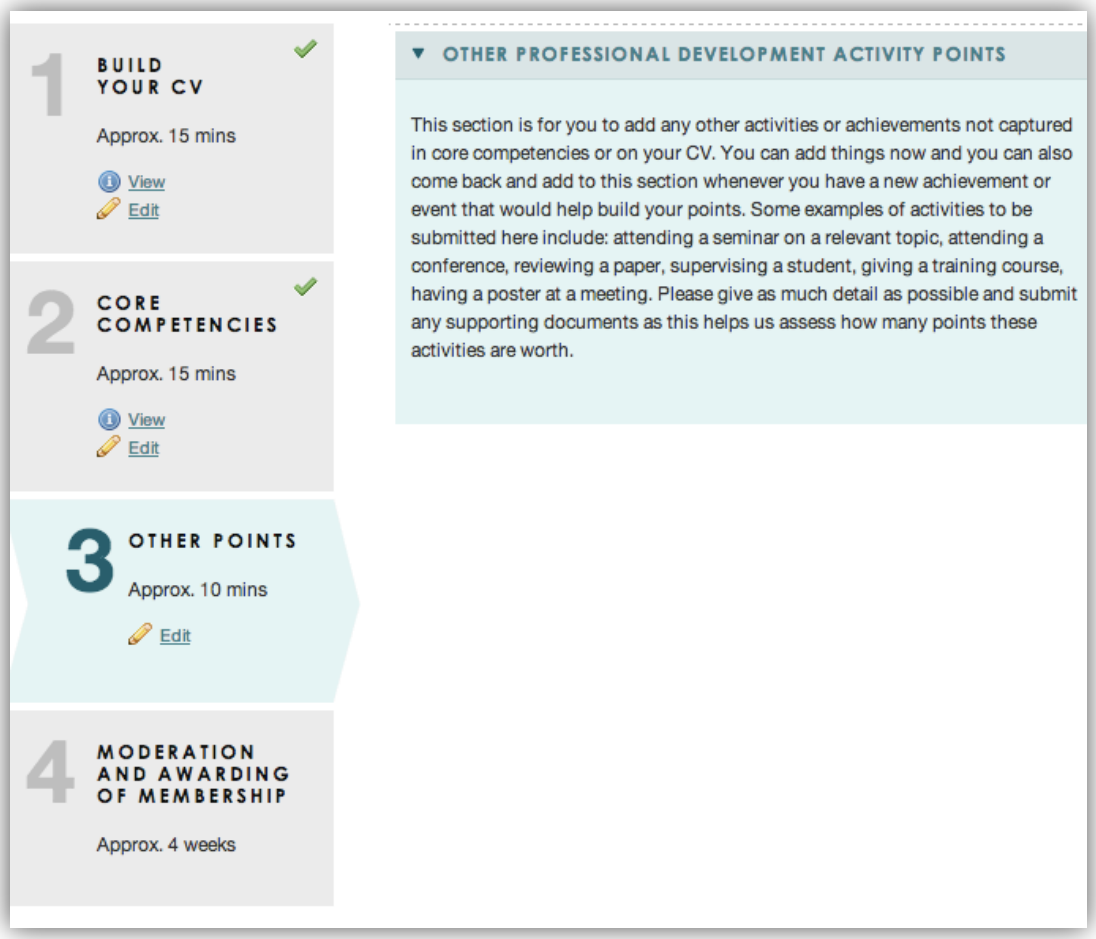


Look and Feel of Core Competency Section

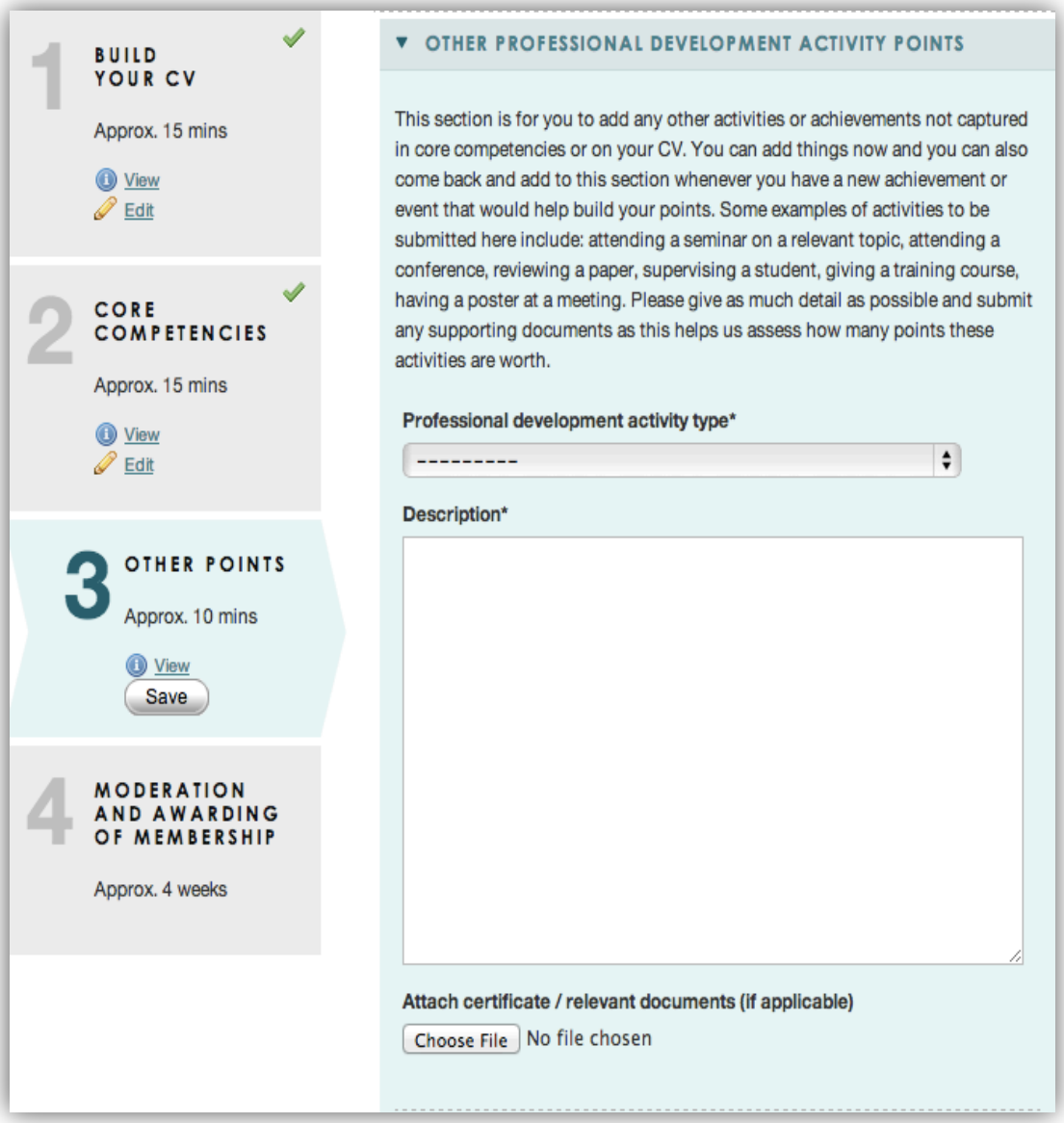


Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468

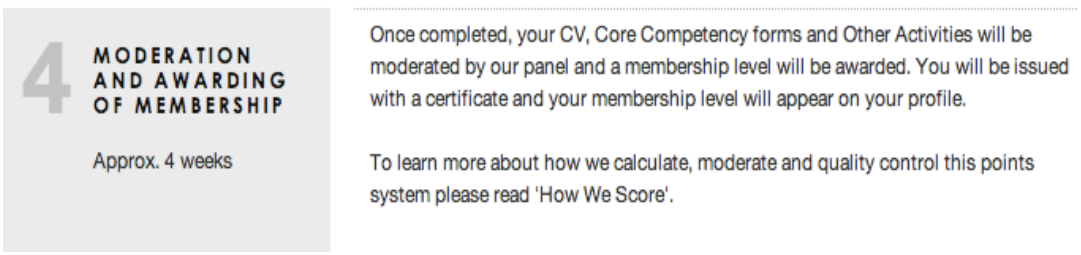
Other Points Section



Look & Feel of Other Points Section



Moderation



Centre for Tropical Medicine, NDM Research Building , University of Oxford, Old Road Campus, Roosevelt Drive, OXFORD, OX3 7FZ, Tel: 0044 1865 857468