TDR Newsletter: Issue 4

May 2012

Dear Fellow,

I hope you have had a great start to 2012.

Welcome to the 4th issue of the TDR website newsletter.

This month's newsletter features:

- An introduction
- Fellows' contributions from:
  - Eric Some
  - Julius Atashili
  - Mahmoud Yakub Ma'aruf
  - Oluwagbenga Ogunfowokan
  - Tafireyi Marukutira
- Up and coming Conferences and Meetings
- Conference reporting
- The Professional Membership Scheme.
- The Global Health Trials website's 'Regional Faculties'

Dear Fellows,

I am delighted to write to you as the new Training and Professional Development Coordinator for the Global Health Trials. When I was informed of my new link with the TDR fellows, naturally I did some research and was pleasantly surprised to learn that I would be involved with such a wonderful group of individuals. In time I hope I will get to know each of you and the specific areas you are currently involved in at your placements and in your home institutions.

So a little bit more about myself! I began working for the University of Oxford in 2006 at the Clinical Trials Service Unit (CTSU). CTSU coordinates large international epidemiological studies such as SEARCH, SHARP, THRIVE, REVEAL and provides central analysis for all study samples. I initially worked in the cryogenics team learning about bio banking and the long term storage of samples using Liquid Nitrogen.

As some studies include up to 30,000 participants each providing a range of samples at varying time points I learnt the importance of sample storage within clinical trials. From cryogenics I then worked in the CTSU Wolfson laboratory as a research assistant. Working in the laboratory I received great hands on training in laboratory techniques, sample handling and sample analysis. Woking in a clinical trails laboratory has given me great experience in the role of the laboratory at various trail phases, from randomisation through to final follow up and beyond. As the Wolfson laboratories are accredited I have also been through the rigors of auditing, monitoring and the accreditation process. In 2008 I became involved with laboratory training, assisting the Laboratory Training Officer in their day to day tasks before eventually taking over the role in 2010. As Laboratory Training Officer I organised, designed and ran all training for laboratory staff. I also designed and conducted training sessions for study administrators and study research nurses throughout the UK for several of the clinical trials. I was also involved in writing SOP's and protocols for the laboratory aspects of each trial and maintaining adherence to them. Keeping in contact and dealing with training queries from study clinics in various countries was a necessity but also one of the most enjoyable aspects of the job role.

So that is the last 6 years in a nutshell! I have had the pleasure of working with some brilliant primary investigators, researchers and clinical staff and I hope that this is only the beginning!

From reading all the previous reports and articles posted in the newsletters and on the website I have gained a great understanding of what the fellowship entails and the impact it has on you as individuals and for your respected home institutions. Please continue to submit reports on the progress of your fellowship, problems encountered, papers you have published, presentations you have given, conferences and training attended, posters you presented, etc.

As Mary has mentioned previously, this newsletter is designed for you, so if there is something you would like to see featured, please let me know. I hope to continue the great work Mary has done with the website but please let me know if you ever encounter any problems with the site or any improvements you would like to see.

Best wishes,
Liam
Training & Professional Development Coordinator
Global Health Trials

# Fellows' Contributions

## First six month report

Report by: **Eric N. SOME**
Home institution: **Centre de Recherche International en santé, Ouagadougou, Burkina Faso**

**Synopsis**

The Clinical Research Career Development Fellowships is a training organized by the WHO Special Program for Research and Training in Tropical Diseases (TDR). WHO/TDR is an independent global program of scientific collaboration. The training, supported by the Bill & Melinda Gates Foundation, is a 12-month Career Development Fellowship (CDF) in Clinical Research at selected pharmaceutical companies (host institution). The goal is to provide practical clinical experience to promising developing country researchers to promote high quality clinical research in disease endemic countries (DEC).

I have been notified in February 2011 of my selection in CDF at Pfizer. Then started an intensive e-mail communication between WHO/TDR, the malaria development team and myself. I received the letter of award that stated clearly the objectives I will be pursuing at Pfizer.

**Objectives of Training**

To receive a specialized training programme on clinical research and development, which will involves working as a junior clinician on the Development Team at Pfizer's Global Research and Development (PGRD) facility in New London and participating primarily in all aspects of clinical development of a new product for intermittent preventive treatment of malaria in pregnancy.

Clinical R&D related activities:

• Development/update of the Clinical Development Plan
• Study preparation: study design, concept and main protocols; case report forms, and logistics
• Study implementation: pre-study contacts, study initiation, monitoring
• Study reporting: data validation, study reports
• Administration and documentation: filing, tracking, financial agreement
• Project planning and monitoring, including human and financial resources management
• Knowledge development: literature review, attendance at scientific meetings, clinical trial methodology, ethical and regulatory requirements, new technologies.

**The first days**

We were two fellows selected at Pfizer. We arrived in New London (USA) on 16th of May 2011. We stayed a few days at a hotel, before being kindly hosted by one of the preceding fellows who were still at Pfizer. The plan was that our stay overlapped theirs' so that we could learn from them. On 27th of May, we were able to move to our own two bedrooms apartment rented at 118 Allen Street in Groton, where the malaria team had already moved. We are at one mile from Pfizer office in Groton; we go easily to work on foot or by bike.

**The training**

It started by our introduction to Pfizer system by the two fellows who were finishing. We begin reading the two protocols that are being implemented. In the meantime, we were registering to obtain laptops, ID badges, work e-mail addresses, desk and office phone numbers…

Power to learn or P2L: once we got set up, we have been assigned the initial modules of theoretical training. It consisted in learning the different SOPs that rule Pfizer research system as well as the different software to handle the data and the studies documents. Some of them are validated by a test taken online immediately after having performed the training, online too. After this initial package of SOPs and software, we are routinely scheduled for periodic "maintenance" training performed by the same way; that is to say through the P2L electronic platform.

Learning by doing or involvement in the routine program of the clinical team: There are also training prompted by the need such as how to set up a teleconference, how to implement it using the phone, the laptop with softwares like "netmeeting" or "webex"; how to schedule a meeting and to assign ressources like meeting rooms and the invitation to people to attend.

As part of the training, we have been assigned research sites we have to follow under the supervision of the clinical team lead and the study clinician. Every week we have series of teleconference and meetings:

- with the different sites to follow up the recruitment status as well as the clinical/medical and protocol compliance issues that may raise from the sites.
- With the whole protocol team (two time per week)
- With the operational team at regional level (two time per week).
- Among clinicians (once a week).

Moreover, we have meeting scheduled periodically to address specific issues like safety or lab issues… All these meetings we are allowed to attend help us learn by doing since we are involved in and we are allowed sometime to take actions planned during the meetings.

Monitoring of the training: The team is working in an open (flex space) area. We have the great luck to work permanently under the direct supervision of the malaria clinical team lead (our supervisor too) who monitors us directly. Weekly, every team member has a face to face meeting with the team head. This is a great opportunity to express personal concerns or challenges that may exceed the daily work need, to encompass career development plan and the after training expectation.

**Challenges and issues to address**

The whole year of fellowship is spent in a team. Fellows come at a specific step of drug development. So they were not there at the beginning of the trip and they leave the team before the end. It is therefore difficult to achieve all the objectives assigned by the programme. Thus I think I will have missed to practice some points entirely or in part like:

- Development/update of the Clinical Development Plan
- Study preparation: study design, concept and main protocols; case report forms, and logistics
- Study implementation: pre-study contacts
- Study reporting: data validation, study reports

Fortunately, thanks to P2L I have been theoretically trained for all these points

**Lessons learn**

Pfizer uses a lot of high technology. In resources limited setting, this technology should be promoted, because it is a great mean to save money. For instance, instead of inviting people who have to travel hundreds of kilometres for some few hours of meeting, a simple teleconference and all is set and people save time, money and even life by avoiding unsafe trip. Also, research institution in developing countries need to learn from pharmaceutical companies and organize a continued training of researchers, using platforms similar to power to learn (P2L). This dream can became reality if research institutions decide to merge totally or partially using together some equipment and technology.

The management of space is also a big challenge in our setting. At Pfizer, I discovered the flex space system and I can see that it allows saving a lot of space, equipment and furniture. It has its own inconveniences. But used cautiously, it can bring a lot of benefits. Moreover, it allows a permanent direct interaction in real time with the whole team and specifically with the supervisors. It may be a great tool to tackle efficiently urgent matters and reinforce the team spirit.

The use of the unique pronoun “you” to talk to somebody you owe formal respect like your supervisor is very helpful also in that point of view, since it reduces gaps among the different members of the team.

The management of human resources: I was able to observe that meeting one on one with one's supervisor is common at Pfizer. Implemented by smart leads, this system is a great way to build team and enhance group energy toward common goal.
To build a team and to achieve objectives, it is crucial to motivate each team member. At Pfizer, I observed that everybody stress on positive aspects of deeds. There is a culture of "thank you" and of recognition of the effort. At each achievement, even very small, the leads never forget to congratulate the team and to say "thank you" for your endeavour. The company does so by issuing posters, adverts on plasma screens… to congratulate those who committed to achieve an objective such as a market authorization for a product or a 25 years anniversary in the company. This is great indeed!

**PLANNED ACTIVITIES FOR THE REMAINING 6 MONTHS OF THE TRAINING**;
These will include;

***Learning about:***

1. Elaboration of a Clinical Development Plan.
2. Administration and documentation (filing, tracking, financial agreements);
3. Regulatory aspects of medications (partly covered); details of the FDA/ICH requirements to be covered in the next 6months.
4. Project planning and monitoring (human and financial resources management, timing);
5. Writing of Clinical Study reports
6. Conduct of Bio-equivalence and Bioavailability studies.

***Perfecting my practical skills in the areas below:***

1. Literature review, clinical trial methodology, FDA/ICH requirements, new technologies.
2. Study preparation (study design, concept and main protocols, case report form and logistics).
3. Study implementation and conduct (pre-study contacts, study initiation and monitoring);
4. Study reporting (data validation, study report)
5. Medical safety and regulation (reporting and management of safety, production of safety documents)

***Conclusion***

Spending one year fellowship at Pfizer USA is an experience that is now and forever part of my career and my life. I strongly believe that it will change my life. I need to work for that.
WHO/TDR, Bill Gate Foundation and all the CDF fellows should commit to leverage this training and all the professional and life skills it grants to enhance autonomous research capacity and research that face challenges in developing country and to provide chance to change or save thousands of millions of lives! This should be the next step challenge after the CDF program.

## The TDR R&D CDF Alumni Network: Exploring the power of diversity

Report by: **Julius Atashili**
Home institution: **Faculty of Health Sciences, University of Buea, Molyko, Buea, Cameroon**

In the January 2012 TDR Research and Development (R&D) Career Development Fellowship (CDF) alumni meeting a laudable plan was advanced by fellows to use the CDF alumni network as a forum for potential research activities. As a reminder, the attending fellows unanimously (or at least near unanimously) agreed to this plan and proposed to pilot it with a study assessing the role of home institutions and the challenges they face in re-integrating and making best use of trained fellows once they return. Beyond this pilot, the network also plans to develop and hopefully implement (after seeking funding) a research proposal addressing a health problem of importance to TDR but also of global importance. One of the principal virtues of such an activity would be the diversity of the people involved. I hereby describe the diversity of the alumni network, indicate the potential strengths and challenges associated with such diversity and explore some other activities that the network may want to engage in.

The CDF alumni network is certainly recognized for its geographical and regional diversity. A review of the alumni and current fellows invited to the recent meeting indicates that fellows are from institutions in 16 countries spanning three continents. Altogether, the countries of origin inhabit an estimated 1.94 billion persons, which represents 34% of the population of less developed countries and 28% of the estimated 6.90 billion world inhabitants in 2010[1,2]. This geographical diversity implies that the network provides a means of access to information regarding these many countries and many people in the world. Imagine there was an outbreak of some emerging disease for which policy makers needed information from diverse sources. Beyond the formal governmental channels, the CDF alumni network could serve as an informal channel for policy makers, serving a parallel source of information to supplement, confirm or negate the findings from official channels. Similar if policy makers wanted to evaluate the effective implementation of some policy guidelines, the network could also serve as an informal channel to quite a diverse number of countries.

CDF fellows also represent substantial diversity in their background qualifications and practice. While a substantial proportion are physicians at least three of the fellows are biomedical scientist and many others are physicians with additional training in fields such as paediatrics, infectious diseases, epidemiology, biostatistics, pharmacology. This diversity in qualifications is further supplemented by the varied characteristics of the trainees' host institutions allowing for a wider view of the pharmaceutical industry and other organizations involved in research on tropical diseases. The virtue of this variety cannot be overemphasized in this era of multidisciplinary research.

Also the linguistic diversity represents a major strength – many fellows speak and write more than one of the six United Nations official languages including English, French, Spanish and Mandarin. Official documents written in any of these languages could thus be exploited by this network. A document in any of these languages could also be directly or indirectly translated to all of the other three languages. The network could thus serve as a resource in transcending language barriers in collecting and or disseminating information on tropical diseases.

Not to be neglected is the gender diversity that should allow for gender sensitive issues to be addressed appropriately.

Diversity could however be a double-edged sword. The strengths discussed above could be overridden by certain challenges. The major challenge would be that of resources. Resources are needed to maintain a network. While the network currently benefits from the electronic platform provided the Global Health Trials website, this will need to be sustained. Furthermore the use of this platform requires access to the internet, access which is not a given as many fellows work in institutions that do not provide access to internet. Fellows may thus need to explore means of remaining connected. Beyond the technological challenges, the existence of the network as a volunteer, part-time activity could also mean network activities take a backseat to fellows' primary activities. Additional motivation and commitment will thus be needed from network members. Furthermore, the diverse rules and regulations overseeing research in various countries may sometimes hamper and slow the implementation of proposed activities. Last but certainly not least, and as with any other group of individuals, achieving any results will require committed members and well defined goals, objectives and procedures. Members also need to be acutely aware of the diversity of opinion that accompanies diversity of origins and background. Occasional dissent should thus not be unexpected – dissent should however be cordial, respectful and should not be a barrier to consensus.

Recognizing the above stated strengths and challenges, the network can also engage in other activities aimed at better understanding and controlling tropical diseases, beyond clinical research. Firstly, the network could take on the challenge of conducting systematic reviews and meta-analysis on tropical diseases using standard methods such as those of the Cochrane collaboration. Secondly, the network could also serve a resource for review of policy documents. Thirdly, the network could provide consultancy for external groups seeking development (or review) of proposals for research of addressing tropical diseases. Such a consultancy could be of varied purposes including on language, on relevance, on methodology, on statistical analysis and even on implementation. Nevertheless, it is imperative that the foundations of the network be put in place before it can think of exploring all these other activities. Success in the current pilot project is thus of utmost importance.

The CDF alumni network is thus in a position to, sooner than later, be a force to reckon with in the global world of tropical diseases research. While little nurturing and support from TDR, the Bill and Melinda Gates Foundation and other stakeholders would certainly be more than welcomed, the ball is in our court. Let us not let this opportunity slip by!

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[1]United Nations Population Division. World population prospects: the 2010 revision. Accessed on February 05 2012 at http://data.un.org/.

[2] Population Reference Bureau. 2010 World population datasheet. Accessed on February 05 2012 at http://www.prb.org/pdf10/10wpds_eng.pdf .

**Twelve month report**

Reported by: **Mahmoud Yakub Ma'aruf**
Home institution: **Amino Kano Teaching Hospital, Institute of Human Virology, Kano state, Nigeria**

## REPORT ON CLINICAL RESEARCH AND DEVELOPMENT FELLOWSHIP AT F. HOFFMANN-LA ROCHE LTD, BASEL

### FELLOWSHIP OBJECTIVES

- Elaboration of the Clinical Development Plan (CDP).
- Study Preparation (Study Design, concept and main protocols, case report forms and logistics).
- Study Implementation and Conduct (Pre-study contacts, study initiation and monitoring).
- Study Reporting (Data validation and Study Reports).
- Medical Safety and Regulation (Reporting and management of Safety, Production of safety documents).
- Administration and Documentation (Filing, tracking and financial agreements).
- Project Planning and Management (Human and Financial resources management).
- Knowledge management (Clinical trial methodology, literature review, attendance at scientific meetings, ethical and regulatory requirements, new technologies).

**START DATE-** 8 March 2010.

### SET UP

Within the first few days of my arrival at Roche in Basel, all the essential set up needed for my training such as obtaining access badge, registration with the Learning Management System (LMS) and obtaining the required accesses were set up.

**ACTIVITIES**

My training started with my involvement in a Paediatric (Bevacizumab) clinical trial. I was involved in the clinical science day-to-day running of the study such as:
Medical Data Review, Serious Adverse Event (SAE) reconciliation, writing of clinical narratives, participation in Study Management Team (SMT), Data Safety and Management Board (DSMB) and other meetings related to the study. I was also following the roles that other functions (Statistics, Data management, Biometrics, Operations) were playing in the conduct of the trial. Participation on this trial gave me the opportunity to achieve the following of my fellowship objectives:

- *Understanding of the Clinical development Plan (CDP).*
- *Familiarisation with Clinical trial study protocol.*
- *Appreciation of study design in Oncology clinical trials.*
- *Case Report Form (CRF) and the essential role it plays in the conduct of Clinical Trials.*
- *Study Implementation and conduct.*
- *Medical Safety and Regulation.*
- *Overall understanding of clinical trial methodology.*

After about two months on the paediatric trial, my line management agreed that I could also join another ongoing trial looking at Bevacizumab in Brain tumour (Glioblastoma), so that I could learn from a different study design. I was similarly involved in the clinical science day-to-day running of the trial. The trial had a different study design, higher number of patients and was at a different stage compared to the paediatric trial. My participation on the Brain tumour trial gave me an opportunity to achieve the following of my fellowship objectives:

- *Further understanding of the Clinical Development Plan (CDP).*
- *Understanding of a different study design, concept, protocol, case report form and logistics.*
- *Study Implementation and conduct.*
- *Study Reporting (Data Validation).*
- *Medical Safety and Regulation (Reporting and management of Safety-Serious Adverse Event reconciliations).*

After some reorganisation around my 3rd month into the training, my Line management changed again. My new line manager agreed that I could, in addition, be involved in a third Bevacizumab trial (a lung cancer trial), as it will further exposure me to a different scenario, make me further learn, increase my understanding, knowledge and skills. Therefore, I joined the team managing this trial and I am was involved in the day-to-day running of this trial up to the end of my Fellowship.
The major activities that took place during my participation on this trial were a Database lock in October 2010 and the commencement of writing of the Clinical Study Report for the Lung cancer study, which I was taking part in up to the end of the Fellowship.

My participation on the Lung cancer trial enabled me to achieve the following of my fellowship objectives:

- *Understanding of the Clinical Development Plan (CDP).*
- *Further understanding of study design, concept, protocol, case report form and logistics.*
- *Study Implementation and Conduct.*
- *Medical Safety and Regulation (carrying out Medical Data Review)*

- *Study Reporting: Data validation and Clinical Study Report.*
- *Knowledge management (Clinical Trial Methodology, Literature review, Ethical and Regulatory requirements).*

**OTHER TRAININGS -**

I have done the following SOP trainings:

- History of Roche.
- Roche Competitive Intelligence Sensitization E-Learning Programme (RoCIS).
- ICH GCP Roche Mode.
- Roche LMS for Learners Basics v 1.3.
- GCP eSOP Portal Tutorial.
- Drug Development Fundamentals.
- Investigator's Brochure.
- Study Planning and Conduct.
- Clinical Study Protocols and Case Report Forms.
- Clinical Trail Protocol Registry.
- Study Start-up.
- Managing Subject Eligibility, Screen Failures and Protocol Violations.
- Informed Consent.
- Randomisation List.
- Standards in Data Collection 1.
- Standards in Data Collection 2.
- Data Handling.
- PDM General Safety Procedures.
- PDM Serious Adverse Events.
- Periodic Safety Update Reports (PSURs).
- RO-GNE Independant Data Monitoring Committee and Data Review Board.
- Prerequisite Course Work Graphical Data Review Tool- Module 1 (Basic Foundation).
- Data Review Alignment Modules 1 to 5.
- Review of Clinical Data Display.
- Roche Clinical Repository Policy.
- Trial Master File.
- Statistics: An Overview in Clinical Research.
- Study Close Down.
- Clinical Study Report.
- Clinical Trial Results Database.
- Managing Issues, GCP Breaches and Misconduct in Clinical Trials.
- Interactions with External Healthcare Professionals.
- Grants, Sponsorships and Donations to Healthcare Providers and Patient Organisations.
- Authorship Agreement- Roche.
- Authorship Agreement- Genentech.
- Publication Implementation Form.
- Experiencing Change.
- Roche Good Clinical Practice course.
- ShareWeb Reader's and Editor's training (Virtual).
- Project Library Virtual (Modules 1 & 2).
- Ethical Decision Making For F. Hoffmann-La Roche.
- Ethics Cases.
- Behaviour in Business (Principles and Guidelines- Code of Conduct).

**Other Trainings I have done include:**

- Pharma Development Basel Induction Program 2010.
- Clinical Development at Roche.
- Graphical Data Review Tool Module 1 (Basic Foundation).
- Basic Laboratory Statistics.
- MS Word Module 1 (Daily Business).
- MS Word Module 2 (Professional Usage).
- MS Outlook Module 1 (Daily Business).
- MS Outlook Module 2 (Professional Usage).
- MS Power Point Module 1 (Daily Business).
- MS Power Point Module 2 (Professional Usage).
- Touch Point Owner Module 1 (Basic).
- Roche Automated Production of Integrated Dossiers (RAPID) Author.
- Roche Automated Production of Integrated Dossiers (RAPID) Global Dossier Templates.
- Common Human Resource Information Solution (CHRIS) System Training.
- Mobile Computing Practices.
- Videoconferencing

**Presentations**

I was attending the Oncology and Clinical Science Specialist (CSS) Forum seminars. Some of the topics that were presented at the Oncology Forum were:

- Trials with Adaptive Designs in Oncology.
- BRAF Update.
- The Highlights of European Breast Cancer Conference (EBCC) 2010.
- Design and Analysis of Oncology studies and the use of Progression Free Survival (PFS) in Oncology studies from a Regulatory perspective.
- Highlights from the American Society of Clinical Oncology (ASCO) 2010.
- The SATURN Experience (Tarceva®).
- The MAIN Study.
- Patterns and mechanisms of Cardiovascular toxicity with Oncology treatments.
- The AVAGAST study: a randomised double blind placebo controlled Phase III study of first line capecitabine and cisplatin + bevacizumab or placebo in patients with advanced gastric cancer.
- Clinical Implications of new molecular classifications of early breast cancer.
- Optimal Endpoints in Glioblastoma and Challenges when assesing efficacy.
- Integrated PET in Response criteria for solid tumours.
- An open-label multi centre phase II study of continuous oral dosing of RG7204 (PLX4032) in previously treated patients with BRAF V600E mutation-positive metastatic melanoma.
- Post American Society of Haematology 2010 Updates:
  * Rituximab
  * GA101 (Type II anti-CD20 antibody) and Phase II trial data (NHL and CLL).
- Neoadjuvant pertuzumab and trastuzumab: anti-tumour and safety analysis of randomised Phase II study.
- Results of a randomised open-label phase III study of adjuvant doxorubucin plus cyclophosphamide followed by docetaxel with or without capecitabine in high risk early breast cancer.
- Paediatrics: Obligations and Opportunities.

Similarly, have been attending the company's monthly Lunch Talk where the talks have been on topics like Roche Goals by the Roche Chief Executive Officer (CEO), Cancer in Africa, new Project Governance Model, Great Place to Work initiative.

## CONGRESSES AND MEETING

**AIDS 2010-**

I was sponsored by the WHO-TDR to attend the XVIII International AIDS Conference from the 18- 23rd July 2010 in Vienna, Austria. An earlier detailed report on my attendance to this conference have been submitted to the WHO-TDR.

**ESMO 2010-**

F. Hoffmann-La Roche Ltd sponsored me to attend the European Society of Medical Oncology (ESMO) 2010 congress from the 8- 12th October 2010 in Milan, Italy.
Some of the sessions that I attended in this congress include:

- Young Oncologists Breakfast session
  * How to write an outstanding manuscript).
  * How to conduct effective public speaking and slide presentations).
  * Medical Information: Where to find it, what to trust.
- Educational Session (Prevention and treatment of side effects of systemic treatment).
- Educational Session (Early stage Non-small cell lung cancer: Challenges in staging and adjuvant treatment.
- Educational Session (How much do we know about cancer cells?).
- Multidisciplinary Interactive session (MIS): Localised Prostate Cancer.
- Special symposium (Toxicities of targeted therapies: prevention and management).
- Special session (Towards effective communication in Oncology).
- Special Session (Oncology Mentor forum).
- In addition to the above, attended some poster discussion (symposium) sessions.

**Swiss TPH Autumn Symposium 2010**

I also attended an autumn symposium organised by the Swiss Tropical and Public Health Institute (TPH) titled 'Human African Trypanosomiasis (sleeping sickness)- Towards new chemotherapeutic tools' in Basel, Switzerland. I attended the following sessions in this symposium:

- Where to find and how to diagnose sleeping sickness.
- Human African Trypanosomiasis Drugs: history, status quo, future: A bumpy road.
- From in vitro cultivation to drug screening.
- cAMP-specific phosphodiesterases of *T. brucei*: New drug targets for an old disease.
- Mining African Biodiversity to provide advances in drug discovery and development via low cost medicinal chemistry.
- Preclinical cascade, what is needed to reach the clinical phase.
- The challenges of conducting clinical trials in Human African Trypanosomiasis.
- The discovery of benzoxaborole SCYX-7158 (AN5568) as oral treatment of stage 2 (CNS) Human African Trypanosomiasis.

**On the path to fulfilling a dream- the turning point and the progress**

Reported by**: Oluwagbenga Ogunfowokan**
Home institution: **National Hospital Abuja, Abuja, Nigeria**
Host Institution: - **Eisai Inc. New Jersey USA**
Fellowship period: - **April 2010 – March 2011**

It is my pleasure and privilege to tell my story on the platform of the TDR CDF Newsletter. My background is in the specialty of family medicine. I work as a consultant family physician in National Hospital Abuja Nigeria. I am grateful to all the stakeholders that are involved in putting me on the path to fulfilling a dream. My dream has been to contribute to global effort to find a lasting solution to the infectious diseases of poverty that ravage the patients I care for daily. I have taken care of children that eventually died of cerebral malaria and have longed for a time when such will no longer happen. So, you can imagine my joy when I was selected by TDR and Eisai Inc as a fellow for clinical research career development in tropical diseases with funding from Bill and Melinda Gates Foundation.

The opportunity became a turning point leading to a career path in clinical research in tropical disease. This was established during the one year I spent in Eisai Inc. under a loving and capable supervisor. The opportunity to learn about product discovery and development, project management, team work, regulatory compliance, protocol writing, safety monitoring, data management, medical monitoring, ICH GCP, collaboration between pharmaceutical industry, academic institutions, contract research organizations and funding agencies etc. laid a solid foundation for my career in clinical research.

It is now eleven months since I returned to my home institution in Nigeria. Despite the challenges, some progress has been made and I am hopeful of greater progress with time.
Since my return to National Hospital Abuja, Nigeria, I have

1) Written and submitted to the management of my institution a proposal on how to strengthen institutional research capacity. It included raising the standard of the ethics committee to international standard, building institutional research team of international standard, strengthening laboratory capacity and training of researchers on ICH GCP among others.
2) I have trained ten young researchers in the department of family medicine of the institution on various aspects of research. These resident doctors are presently doing dissertations for fellowship examinations of either National Postgraduate Medical College of Nigeria or West African College of Physicians.
3) I have built a research team that is currently involved in a global study sponsored by Pfizer in which I am one of the principal investigators.
4) I recently presented a research paper during the 35$^{th}$ General and Scientific meeting of the West African College of Physicians in partnership with the Royal College of Physicians which held from 6$^{th}$ to 11$^{th}$ November 2011 in The Gambia. Below is a picture taken while I was giving the presentation and the abstract of my presentation:

Title: Relationship between Bite-to-hospital time and Morbidity in Victims of Carpet Viper bite in North-central Nigeria

Oluwagbenga Ogunfowokan, Dawam A Jacob, Odor L Livinus

*Department of Family Medicine, National Hospital, Abuja, Nigeria; Department of Family Medicine, Jos University Teaching Hospital, Jos, Plateau State, Nigeria*

ABSTRACT

Introduction: Envenomation resulting in morbidity among victims of snake bites is a public health hazard in tropical countries.
Objectives: 1) Discover the bite-to-hospital time among victims. 2) Describe the morbidity among victims and 3) know the relationship between bite-to-hospital time and morbidity.
Methods: A prospective study was conducted in a rural community in North-central Nigeria. A morbidity score was computed to assess the morbidity in each patient from admission to discharge from hospital. A score of 1 was given to each objective sign. Among others, the morbidity scored were edema, tenderness, prolonged whole blood clotting time on presentation, and length of hospital stay. Each day on admission attracted a unit score. Bite-to-hospital time of 233 subjects with known morbidity outcomes was obtained. Relationship between bite-to-hospital time and morbidity was determined.
Results: The median bite-to-hospital time was 5 hours with range 0.5 – 216 hours. Major morbidity were edema, tenderness and bleeding accounting for 212 (91.0%; 95% CI = 86.6 – 94.3%), 201 (86.3%; 95% CI = 81.2 – 90.4%), and 75 (32.2%; 95% CI = 26.2 – 38.6%) respectively. The mean morbidity score was 8 ± 4. For every unit increase in log bite-to-hospital time, the morbidity score increased by 1.85 in a linear fashion ($p < 0.001$). There was a linear trend in relationship between increasing bite-to-hospital time group and blood incoagulability at presentation (p for linear trend = 0.02)
Conclusion: Morbidity caused by carpet viper bite is high in North-central Nigeria and correlates with increasing bite-to-hospital time.

The recent 2nd Alumni Clinical Research Meeting for Career Development Fellows that took place in Geneva from 25th to 27th January 2012 was quite encouraging. The Fellows agreed to collaborate on a research project that will be supported by TDR. This collaboration of fellows from disease endemic countries will hopefully snowballed into something that will further contribute to the global effort to provide solution to the burden of infectious diseases in disease endemic countries.

Finally, we are planning to hold a global health clinical trial research workshop in National Hospital Abuja Nigeria sometimes in May 2012. The modus operandi has not been fully worked out but the workshop will bring together researchers in Nigeria and no doubt will go a long way to build research capacity in my home institution.

**Six month Progress report**

Report by: **Tafireyi Marukutira**
Home institution: **Botswana-Baylor Children's Clinical Centre of Excellence**

## 1.0 INTRODUCTION

The fellowship training takes place at Astellas Pharma Global Development (APGD) in Deerfield, USA. This is a large pharmaceutical company with headquarters in Japan and also present in Europe and North America. The therapeutic areas of focus at Astellas include Acute Care Cardiovascular Disease, Central Nervous System, Dermatology, Diabetes, Gastrointestinal Disease, Infectious Disease, Inflammation, Immunology, Kidney Disease, Metabolic Disease, Oncology, Pain, and Transplantation & Urology.

The training started 1 April 2011 and is expected to run for a period of 12 months until 30 March 2012. I reported to APGD on Monday April 11, 2011

## 2.0 OBJECTIVESS OF THE TRAINING

The following outlines the general objectives, specific objectives as well as the proposed activities during the training.

### 2.1 GENERAL TDR OBJECTIVES/GOALS

- To improve existing and develop new approaches for preventing, diagnosing, treating and controlling neglected infectious diseases which are applicable, acceptable and affordable by developing countries which can be readily integrated into the health services of sub-Saharan Africa.
- To strengthen the capacity of disease endemic countries to undertake the research required for developing and implementing these new and improved disease control approaches.

My main goal is to improve research capacity at the Botswana-Baylor Children's Clinical Centre of Excellence (BBCCCOE) which is my home institution.

## 2.2 SPECIFIC OBJECTIVES

At APGD, the programme is meant to give me specialized training on drug development/life cycle management *for* the Micafungin paediatric program. Working with the clinical R&D team I am expected to fulfil my objectives by being involved in activities related to:

- Elaboration or update of the Clinical Development Plan including life cycle management and review of investigator initiated study proposals
- Study preparation: study design, concept and main protocols; case report forms, informed consent and logistics
- Study implementation: pre-study contacts, study initiation, monitoring
- Study reporting: data validation, study reports, scientific communication
- Administration and documentation: filing, tracking, financial agreement
- Project planning and monitoring, including human and financial resources management
- Clinical contribution to regulatory activities (registration dossier, license renewal dossier, PSURs, labelling).
- Pharmacovigilance
- Role of clinical pharmacology in drug development
- Role of Bioanalytics and Toxicology in drug development
- Interactions with drug safety and epidemiology, drug metabolism and pharmacokinetics, and research department as well as external experts in the field
- Review of the scientific literature, attendance of scientific meetings, clinical trial methodology, knowledge of *APGD's standard* operating procedures, stringent national drug regulatory authorities, ICH requirements (plus FDA) and GCP guidelines.

## 3.0 PROGRESS REPORT

Astellas prepared the following fellowship programme based on the objectives of the training and progress will be reported based on the actual activities and status will be assessed against the objectives of the training.

The training at Astellas is based on pediatric development for fungal infections under infectious diseases. The core activities are based on the Mycafungin pediatric protocol which is now in phase III development. The company is planning on a pediatric protocol in order to have the drug licensed for use in the pediatric population and also to fulfill the PIP. Beside following this team there is also another antifungal in development which will be followed. Rotations will also occur in the various other divisions under Astellas.

| Time Period | Functional Area | Areas of Focus | STATUS<br>- **Based on main objective**<br>- **Including specific knowledge acquired**<br>- **Integration/contribution in the team** |
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| **April 2011 and On-going** | **Overall Astellas and Overall APGD** | • Overview of Astellas, APGD and the pharmaceutical industry<br>• Introduction to mentor network<br>• Attend "meet and greet" welcome sessions<br>• Attend Astellas Orientation Program<br>• Take e-courses for Outlook, Excel, PowerPoint, Word, Astellas SOPs and other systems | • **Introduction**<br>- Took e-courses for Outlook, Excel<br>- Completed the following SOPs for Astellas.<br>• APUS Recall, Market Withdrawal, and Stock Recovery Procedure<br>• Research and Development Training and Documentation<br>• Product Safety Information Reporting Policy<br>• APUS Recall, Market Withdrawal, and Stock Recovery Procedure<br>• General Practices for Regulatory Authority Inspections<br>• Transfer of Obligations to a CRO and FDA Notification<br>• Debarment Certification<br>- Reviewed ICH, CIOMS, GCP guidelines plus various FDA guidelines for the pharmaceutical industry. |
| **April/May 2011** | **Medical Affairs** | Clinical Drug Development and the role of the Medical Director | • **Elaboration of the clinical development plan**<br>- Roles of a Medical Director in clinical drug development include<br>  • Medical extended team and related deliverables<br>  • Clinical strategy to demonstrate efficacy, tolerability and safety<br>  • Ensuring (with regulatory and/or commercial input) that the clinical development program supports the target product profile, satisfies global regulatory requirements, and differentiates the compound from other treatment options<br>  • Design and execution of protocols and monitoring of safety<br>  • Medical input to early development program<br>  • Plans to monitor safety and assess risks in partnership with other project team members, including those in Pharmacovigilance.<br>- Joined the Mycafungin Local Project team<br>- Update of the clinical development plan including life cycle management.<br>- Mycamine data and mycamine protocol review |
| | | Attend meetings for ongoing studies, regulatory document reviews, IITs and publications | • **Review of investigator initiated trials (IITs)**<br>- Involved in reviewing protocols for IITs which are mainly phase IV studies. |

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| | | | - Reviewed Mycafungin IITs and attend the monthly meetings<br>- FDA type C meeting for Mycafungin attended. Participated in the drafting of the briefing document (BD). Actively participated on the literature review.<br>- Attended an Experts meeting with KOL during the preparation of the BD<br>- Briefing document included proposal to amend an existing PIP for Mycafungin.<br>- Preparation for submission of a sNDA<br>- Planning to submit own research project as an IIT: Epidemiology of fungal Infections at Princes Marina Hospital, Botswana. |
| **May/June 2011** | **Development Operations** | **Clinical trial conduct and study management (include site selection process and monitoring plan)** | • **Study implementation: pre-study contacts, study initiation, monitoring**<br>- This is through the ongoing pediatric development for Mycafungin. |
| | | **Attend site initiation or monitoring visit (if possible)** | • **Study implementation: pre-study contacts, study initiation, monitoring**<br>- Attended site initiation visits including for a Phase 1 unit as well as a University Research Centre conducting a Phase III study.<br>- Attended monitoring visits at 2 sites. Reviewed SOPs and regulatory documents such as:<br>• Form FDA 1572<br>• CV of PI<br>• CV of Sub-Investigators<br>• Medical licenses of all investigators<br>• Signed protocol/amendment page<br>• IRB approval of protocol/amendment/ICAF<br>• Sample IRB- Approved ICAF<br>• IRB Membership list<br>• IORG number or Assurance Number<br>• Laboratory Certifications/Normal<br>• Financial disclosure forms<br>• Other regulatory forms |
| | | **Gain understanding of how there are differences to address for global trials between US and EU** | • **Regulatory activities (registration dossier, license renewal, dossier, PSURs, labeling).**<br>- Understand regulatory procedures for the US and some differences with EU. To cement this with a visit to the EU office.<br>- Example: PIP is mandatory for EU marketing authorization and developed after phase 1. PREA was introduced in 2003 and the US has 5 year authorization cycle. PREA after Phase III for NDA submission |
| **May/June 2011** | **GDS (Statistics)** | **Role of statistics in study design and data analysis including statistical analysis plan** | • **Study design and reporting: data validation, study reports, scientific communication** |

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| | | **development** | - Mycafungin protocol development (amendment) included the following statistical issues:<br>• Sample size calculation<br>• Non-inferiority margin (NIM) justification<br>• Study design<br>• Endpoints (primary and secondary)<br>• Statistical analysis plan<br>- Reviewed other SAPs |
| **May/June 2011** | **GDS (Data Management)** | **Data collection, re-positing, and development of algorithms for analysis** | • **Study design and reporting: data validation, study reports, scientific communication**<br>- Reviewed CRF development and RAVE software used for data entry at sites<br>- Database build up |
| **July/August 2011** | **Medical Sciences** | **Development of protocols for compound prior to approval** | • **Elaboration of the clinical development plan including life cycle management.**<br>- Involved in work on Isavuconazole Phase III studies. |
| | | **Interact with investigators and monitor safety data from on-going study (Isavuconazole)** | • **Pharmacovigilance**<br>- Attended meetings to review adverse events reports |
| **August /September 2011** | **Clinical Pharmacology** | Importance of Clinical Pharmacology in drug development | • **Role of clinical pharmacology in drug development**<br>- Modeling and Simulation (M&S). Reviewed and discussed different approaches: POP PK modeling and PB PK M&S. |
| | | Identify key issues and data analysis through case study | • Role of clinical pharmacology in drug development<br>- Participating in drug-drug interaction (DDI) studies including review of reports |
| | | Review Population PK modeling approach used for the Mycamine pediatric data | • Role of clinical pharmacology in drug development<br>- Ongoing |
| | | Include a trip to a Phase 1 unit | • Role of clinical pharmacology in drug development<br>- Visited a Phase 1 unit and reviewed their SOPs. Watched preparations for first dose |
| **First Half September 2011** | **Bioanalytics Laboratory and ARIA** | Visit Bioanalytics Lab and observe how samples are analyzed | • Role of Bioanalytics and Toxicology in drug development<br>- Support clinical trials in PK, PD and other diagnostics<br>- PK support for clinical trials mainly phase 1/IIa and they use mainly LC-MS/MS which is mass spectrometry.<br>- The use of PCR in identifying PK outliers with a mutant of CYP450 as slow acetylators |
| | | Visit ARIA and learn about drug discovery process | • Early drug discovery research |
| **Second Half September/ Octobe** | **Bioanalytics/ Toxicology (in EU)** | Arrive at Leidordorp Office in mid September | • Role of Bioanalytics and Toxicology in drug development |
| | | Overview of EU Bioanalytics Lab | • **Role of Bioanalytics and Toxicology in drug development** |
| | | Overview of Toxicology | • Role of Bioanalytics and Toxicology in |

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| **r 2011** | | | drug development<br>- Reviewed a toxicology report under Mycafungin metabolites. NOAEL= No Observed Adverse Event Level. An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control |
| | | Visit PDD Lab | • Role of Bioanalytics and Toxicology in drug development |
| | | Visit Meppel Plant | • Manufacturing of drugs |
| **First Half November 2011** | **Regulatory (in EU)** | Preparation for FDA meeting to discuss Pediatric Plan; work with Pediatric Expert Group | • Clinical contribution of regulatory activities |
| | | Overview of EU Regulatory Requirement | • Clinical contribution of regulatory activities |
| **Second Half November/ December 2011** | **Various TBD** | Work with core teams to learn about various other projects as the calendar year comes to a close<br>• Other activities to be determined | - Attended a CMV Advisory Board meeting: This board has experts to advise Astellas on early development of CMV antibody, small molecules or vaccine.. |
| | | Learn more about specific activities within the Mycamine team | • Elaboration of the clinical development plan including life cycle.<br>- Ongoing |
| **January 2012** | **Commercial** | Attend on-going Advisory Boards | Pending |
| **February 2012** | **GPM** | Overview of global development plans and reviews committee | Pending |
| **March 2012** | **PSP** | Post marketing safety signal monitoring, detection and analysis | • Pharmacovigilance |
| | | International guidelines and Astellas SOP | • Pharmacovigilance |
| | | MRC, CCDS and labeling changes | • Pharmacovigilance |
| **April 2012** | **Medical Sciences** | Development of protocols for compound prior to approval | |
| | | Interact with investigators and monitor safety data from on-going study (Isavuconazole) | |

Key: ----: on schedule
----: ongoing
: pending

## 4.0 TRAININGS ATTENDED ( INCLUDING WEB BASED TRAININGS)

- **None**

## 5.0 ATTENDANCE TO INTERNATIONAL MEETINGS

### 5.1 Drug Information Association (DIA)
### 47th ANNUAL MEETING
**Dates: June 19-23, 2011**
**Venue: McCormick Place in Chicago, Illinois, USA (Reported in TDR/GHT Newsletter: Issue 1, September 2011)**

* **Theme**: "Convergence": The convergence of science, medicine, and health; of scientific and operating functions and technology solutions; of internal and contract personnel; of research professionals, health care providers, patients and public.

The DIA conference is a multidisciplinary event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related health care products

This was an international conference with speakers, attendees and exhibitors from different countries. There were 18 tracks which were offered over the 5 day conference with many sessions running in parallel. The tracks included: Clinical Operations, Development Planning, Outsourcing Strategies and Innovative Partnering Models, Nonclinical and Early Clinical Translational Development, Product Advertising and Communications, IT Methods and Technologies, Research Data and Content Management, Regulatory Affairs and Science, Quality and GXP Compliance, Public Policy/Health Care Compliance, Clinical Safety and Pharmacovigilance, Statistics, Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA), Medical Devices, Professional Development, Global Agency, SIAC Showcase and there were some Late-breaking Topics as well.

### *5.2 51st Inter-science Conference on Antimicrobial Agents and Chemotherapy (ICAAC)*
***Date: 17-20 September 2011***
**Venue: McCormick Place in Chicago, Illinois, USA (See attached conference report)**

This was a scientific conferences which is under the scope of infectious diseases and covered antimicrobial agents. This conference covered physicians, clinical microbiologists, researchers and pharmacists specializing in infectious diseases.

The conference had the following objectives:

- Investigate the pathogenesis and epidemiology of old and new microbes
- Utilize new data from the research of basic microbiological sciences related to human disease to improve their clinical practice and patient outcomes.
- Evaluate the spread of infectious diseases throughout the world
- Review state-of-the-art developments in the field, including timely reviews of recent advances in clinical care and research and original reports of clinical, translational, and basic research
- Identify the most recent trends in health care management
- Incorporate the knowledge gained to assist with bridging any gaps among the fields of infectious diseases clinical practice, clinical research, epidemiological and health services research, translational research, and basic research
- Recognize and better understand recent new antimicrobial agents
- Understand and discuss updates on clinical diagnoses, preventative modalities and therapeutics
- Analyze the developing resistance of pathogens to diverse therapeutics
- Engage in networking and collaboration among clinicians and investigators to facilitate advances in the prevention, diagnosis, and treatment of infectious diseases.

## 6.0 NETWORKING OPPORTUNITIES

- Registered with the DIA website and receive daily communications with an update of regulatory issues as well as any drug developments.

## 7.0 ATTENDANCE OF INTERNATIONAL MEETINGS (NAME, DATE, LOCATION, SUMMARY)

**-** None other than conferences

## 8.0 PLANNED ACTIVITIES FOR THE REMAINDER OF THE FELLOWSHIP

- See fellowship plan above, the areas marked in red.

## 9.0 APPRAISAL FROM THE FELLOW

This training has been enlightening this far and wouldn't have come at an opportune time than this.

**Expected long term outcomes**:

- Boosted research capacity in sub-Saharan Africa, Botswana.
- Research capacity specifically in tropical diseases research in sub-Saharan Africa, Botswana.
- Drug discovery and vaccine development in sub-Saharan Africa, Botswana.
- Development of scientific evidence for policy changes in management of infectious diseases in Africa.

## 10.0 COMMENTS

## 11.0 SUPERVISOR COMMENTS

## 12.0 ACKNOWLEDGEMENTS

I would like to thank the sponsors for my scholarship, United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank, the World Health Organization (WHO) and Bill & Melinda Gates Foundation. I would like to thank my institution for allowing me to be part of this training. My host institution, Astellas Pharma Global Development has been superb. Specific mention goes to my supervisor, Bernhart Zeiher who has supported me throughout my rotations, Azie Nkechi and the Mycafungin team, Neddie Zadekis and the Isavuconazole team as well as the various departments that I have been attached to so far, thank you. And the support I get from Nancy Sacco, Amy McLean and Adel Domingo, Thank you.

# Up and Coming Conferences & Meetings

### *ASTMH 61st Annual Meeting*

November 11th-15th, 2012
Atlanta Marriott Marquis, Atlanta, Georgia USA
Contact: www.astmh.org

### *RSTMH 2012 biennial meeting*

September 19th – 21st, 2012
University of Warwick
Coventry, UK
Contact: www.rstmh.org

- Abstract submission for oral and poster presentations is now open and we the deadline for abstract submission is **31st May 2012.**
- Delegate registration is also open, preferential early bird delegate rates available until **31st May 2012.**
- Student hall accommodation is bookable directly via Warwick conference office.

### *Global Health Trials One Day Skills Sharing Workshop*

12th July 2012
Dar es Salaam
Tanzania

- For more information please contact info@globalhealthtrials.org

# Conference Reporting

Please continue to write and submit a report on each conference you attend (and a photo if possible). This allows colleagues to learn from your experience and perhaps help them decide whether any future conferences by that organisation/on that topic would be of use to them.

I would also like to request that all current fellows send me their conference reports which will be put up on the TDR website. The template for the conference report can be downloaded, in word format, from the 'Conference Report' section of the site: http://tdrfellows.tghn.org/conference-reports/ .

*Eric Some, Mary Logan & Abdullahi Ahmad ASTMH, Philadelphia, Dec 2011*

# Professional Membership Scheme

We strongly encourage every Fellow to become a member of Global Health Trials' 'Professional Membership Scheme'. The scheme is designed for individuals to advance their careers through flexible, straightforward, steps which can be followed in your own time, to career goals of your own making.

It takes 30-40 minutes to sign up and complete the four steps that make up your 'profile'. The information requested covers basic career history, core competencies, professional qualifications, registrations and publications. There are five membership tiers each with five levels. The system automatically creates a GCP-standard CV, which can be used for job applications, is stored in your profile and can be updated regularly.

On completion of the relevant sections, you submit your profile for moderation. Once submitted, the profile is locked and cannot be amended until approved. An email will be sent to you to acknowledge receipt of your application and to let you know that you will be contacted if further information is required. Approval takes approximately four weeks. Once the profile is approved, a score is given and a membership tier and level is award. There are five tiers: Foundation; Affiliate; Professional; Associate; and Fellow. Each tier is graded from levels 1 to 5. You will receive an email to let you know that your profile is approved and what your score and tier are. You are also issued with a certificate which is stored your profile and can be printed out at any time.

Once approved, there are many ways to update your membership and raise your score. As you gain new skills, attend meetings, take part in training, etc., you can add to your points and enhance your progression through the membership levels. When you add to/amend your profile you must re-submit it. The moderators will review and award the appropriate new points.

A condition of membership is that every user has a review meeting once a year with either their line manager or a senior peer, the report from this review is submitted to the scheme. The purpose is to gain the employer's support in the individual's career advancement. The review will also help set realistic short, medium and long term, training and career goals with the employer. Additionally, the review is validation and confirmation of the skills that the user has reported in their profile. This gives the system another checking process on the award of appropriate points and membership level.

The CPD scheme has been developed in conjunction with the TDR Fellowship Scheme so we are very keen to have your feedback on your experiences of using this system. For further information, please go to http://ght.globalhealthehub.org/login/?next=/cpd/.

# Global Health Trials' Website

## Link to GHT Website

TDR fellow Vu Quoc Dat has suggested that each fellow could place a link to the GHT website onto each of the home institution websites. This would be most helpful in promoting use and support of the GHT platform. The aim of GHT is to provide all those working on trials in resource limited settings a platform where they can work together to share guidance, tools and resources. Therefore placing a link on your home institution websites would go a long way to spreading the message to those who may not be aware of the benefits the platform can offer. For further information on using the GHT link on home institution websites please contact info@globalhealthtrials.org

## Regional Faculties

The Regional Faculties provide a regional presence for the Global Health Clinical Trials Programme. The aim is to facilitate the sharing of skills and knowledge at a local level between members working in different disease areas and research centres.

The regional faculties will be coordinated by volunteer members who are willing to offer a small amount of their time to support this programme alongside their normal jobs. Each regional faculty will have its own area on the website where users will be able to:

- Find local courses running that are offering free places to GHT members
- Identify expert and colleagues locally for collaboration, mentoring and staff exchanges
- Get involved in reciprocal monitoring schemes
- Learn about local events, conferences and workshops.

*Our first faculties:*

- West Africa, coordinated from Ghana. This group have a discussion area that is already up and running so join the debate.
- East Africa. To reach the discussion and introduce yourself to the group.
- Central Africa, coordinated from Cameroon. Please join the discussion to join the group.

We will shortly be launching a South African regional faculty, with many more areas to follow. If you're interested in working with Global Health Trials to start a regional faculty in your area, please don't hesitate to email us on info@globalhealthtrials.org.

*Get involved*

We invite people interested in establishing a regional faculty to get in touch. Regional faculty members contribute by:

- Establishing links with all the different groups engaged with trials locally
- Encouraging these groups to invite small numbers of GHT members to any courses or activities being run in their centres or locally by their trial sponsors
- Working with local researchers to identify good practices and to submit these as articles
- Organise local events or workshops - we may be able to organise these being recorded and placed online for the benefit of all members.

We are looking for keen members to get involved with this rewarding and beneficial activity. It does not take that much of your time so please get in touch to find out more.

The web link to the Regional Faculties section of the Global Health Trials' Website is as follows: http://globalhealthtrials.tghn.org/regional-faculties/