TDR Newsletter: Issue 7

January 2013

Dear Fellow,

Welcome to the 7th issue of the TDR website newsletter.

This newsletter features:

- Intro and update
- Fellow's twelve month reports from
    - Michel Mandro
    - Celine Mandara
- Fellow's articles from:
    - Quoc Dat Vu
    - Leo Ayuk
- Courses, Conferences and Meetings
- Call for Applications

Dear Fellow,

Happy New Year and all the best for 2013!

The next round of fellows is to be finalised in the coming months with 19 placements being allocated by the fellowships partner organisation and institutions. We will keep you informed of the progress and I hope that you will use the website to communicate with the new fellows and pass on the experience that you have all gained through the fellowship.

On-line The Global Health Network is constantly expanding with more than 15 research areas and over 46,000 unique visitors to the network. We have also created a Twitter (@info_TGHN) and Facebook account (https://www.facebook.com/TheGlobalHealthNetwork) so please feel free to utilise these outlets as they are a valuable source of information and we are always more than happy to post news and material relating to TDR fellows. If there is something specific you would like to disseminate then we can post across the network and social media. The Network has been specifically designed to share information and I hope that you will utilise these avenues to publicise material.

The global Health Network has also launched a new tool to facilitate research partnerships and enable equity in access to research opportunities. The aim of SiteFinder (http://sitefinder.tghn.org/) is to support research sites in developing their experience and diversity in types of study in which they are involved. Often research sites are involved in externally sponsored trials in one disease area and it is then difficult for them to find further studies which they can take part in and to gain the confidence and skills to run their own independent studies. SiteFinder allows sites to make themselves known within their region and indeed globally so they have access to wider and more diverse research opportunities. This is achieved placing researchers and research sites in contact with hundreds of product development organisations, researchers and funding agencies across the world. Registering is free, easy and could bring potential funding and collaboration opportunities to your home institutions.

I hope you find this newsletter informative and useful. As always this newsletter is designed for you so if there is something you would like to see included then please let me know: liam@globalhealthtrials.org

Best wishes,

Liam
Training & Professional Development Coordinator
The Global Health Network

Fellows' Twelve Month Reports

Report by: Michel Mandro

Home institution: District Sanitaire de Bumia, Université de Bumia, Dem. Rep of Congo

Host institution: Novartis, Switzerland

I. Introduction

This report is produced within the framework of The Clinical Research Career Development Fellowships (CDF) Programme training course, 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).

Within a Clinical Trial Team the trainee will be involved in activities related to:

- Elaboration of the Clinical Development Plan;
- 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, study report;
- Medical safety and regulation: reporting and management of safety, production of safety documents;
- Administration and documentation: filing, tracking, financial agreements;
- Regulatory aspects of medications;
- Project planning and monitoring: human and financial resources management, timing;
- Literature review, attendance at scientific meetings, clinical trial methodology, stringent National Drug Regulatory Authority/ICH requirements, new technologies.

My Goals.

At the beginning of the training I was expected to:

- Acquire further knowledge and skills, that will allow me to resume my position at the University of Bunia and at the Health District
- Pass the acquired knowledge gained to medical and nursing students, share it with the staff at the two new Clinical Research Centres to strengthen their clinical research capacity in my region
- Contribute with my new knowledge and experience to the development and implementation of research activities in my region.

To read the full report please select the link below or visit the TDRfellows website:

Michel Mandro 12-month progress report

Report by: Celine Isaack Mandara

Home institution: National Institute for Medical Research,
Tanga, Tanzania

Host institution: Sigma Tau, Italy

II. Progress report of the training:

1.0 Introduction

This report is a continuation of the previous six month progress report that was submitted to TDR on June 2012. Most of the activities reported are on-going such as preparations for the coming clinical trials in African countries, regular attendance of meetings relevant to these trials, trainings done, ICF & CRF reviews and continuous literature reviews for malaria.

Objectives of the training fellowship

The original objectives of the training were as outlined below:-

- Elaboration or update of Clinical Development Plans including life cycle management activities such as post marketing activities.
- Study preparation: study design, concept and main protocols; case report forms, informed consent and logistics.
- Study implementations: pre-study contacts, study initiation, monitoring.
- CROs and other vendors evaluation for outsourcing activities (Phase I facilities, ECG core lab, Central laboratory for bio analysis and pharmacokinetic analysis).
- 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).

These activities will include:

- 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, knowledge of Sigma Tau I.f.r S.p.A operating standard procedures, ICH and GCP guidelines.

NOTE

The objectives underlined were met during this period of six months and the rest are going to be met during the start-up of the project that is to start early next year 2013.

To read the full report please select the link below or visit the TDRfellows website:

Celine Mandara 12-month progress report

Fellows' Articles

Article by: Vu Quoc Dat
Home institution: National Hospital for Tropical Disease, Hanoi, Vietnam
Host institution: Sanofi Pasteur, France & Singapore

A wonderful opportunity for young researchers in the developing countries

At the time I received the letter from the TDR to inform me that I was selected for the fellowship, I knew that I had a great opportunity to broaden my experience. However, as some other former fellows, my first step to start the fellowship was not easy.

Initially I had an unexpected delay with my starting date for the fellowship because of French visa processing. The delay immediately impacted on my work at my home institution, partly because I couldn't tell my boss exactly how long the delay was. I contacted TDR and requested a supporting letter to state that the fellowship would start as soon as possible and asked my home institution to let me continue my work until the starting date was re-confirmed. Thanks to TDR's support, I could continue my work until my visa was ready 8 months after than expected.

After a storm comes a calm. I arrived in France; a beautiful country, with a warm welcome from my mentors and new colleagues in Sanofi Pasteur Clinical department. Working with Sanofi Pasteur during my fellowship, I was happy to join with them in their fight against infectious diseases with the vision "a world in which no one suffers or dies from a vaccine preventable disease". One of the most important benefits that I gained from the fellowship is an opportunity to learn from real events during clinical trial implementation. In my opinion, what I call events-based learning is one of best ways to improve my analysis skills and ability of making decisions in trial implementation.

I completed my fellowship with Sanofi Pasteur on April 2012 and returned to Vietnam to continue my work at my home hospital. One of the difficulties I faced when I returned was that there was a question regarding the fellowship's certification. Although I received a letter of completion and a mail of support from TDR, in my country a certificate is often required to prove the attendance of a course and the acquired skills. From my experience, I think that the TDR could open doors to more options for future fellows. In case some fellows have the same interests in a specific skills or knowledge, TDR could help to arrange classroom training for a short-period and provide a certificate. It may be helpful to people who are in the same situation where certification is often required by home institution as me.

For my situation, working in a teaching hospital in my country usually required a PhD degree. I believe that the experience with the TDR fellowship is very useful for me to find PhD opportunities in the future. It is my hope that TDR will support more for the former fellows.

Happy New Year and all best wishes for 2013!

Vu Quoc Dat,

Article by: Leo Njock Ayuk
Home institution: Provincila Hospital, Bamenda, Cameroon
Host institution: GSK Biologicals, Belgium

I am called Dr Leo Njock Ayuk, M.D., with primary research interest in TB, HIV and Malaria. I am working in the Regional Hospital Bamenda, North West Region Cameroon, as a clinician and program Manager for TB control for the North West Region. I did my fellowship attached to GSK Biologicals in Rixensart Belgium starting March 2009. On arrival, my training objectives were defined together with my training mentor, and I was rapidly integrated into the TB clinical team. I had to work 50% as a GSM (Global Study Manager) and 50% as a CDM (Clinical Development Manager).

As a GSM, I had to do central coordination of studies under the TB project. The tasks included preparation of clinical supplies and vaccines to be sent to the clinical trial sites, preparation of documents needed at the central level for the study file both at central and regional level, organization of TC's with the sites to follow-up on a regular basis what is happening on site, and also to inform the higher management of the company on what is going on in the field. I was lucky that in this regard, I had 2 phase II studies going on for which I acted as GSM, and I really found the work exciting when the sites are responsive. In one of the sites, I had the opportunity to go for co-monitoring in Cape Town with the lead monitor for that site. The experience I got from there was quite great. I was so interested in the work of that monitor that she offered to give me a full day of her time at the end of the visit, to teach me more tips and insights about clinical monitoring.

As a CDM, I also had a good experience. My tasks were also well defined by my line manager who was also my training mentor. I had to learn how to do site selection, and in this light I was lucky to travel to India to select a site for a phase II b study and phase III study to come. I had the opportunity to meet with eminent scientists in India, with whom we exchanged a lot.

I also participated in the writing of the protocol for a phase 2 study in India, a phase 1 study in China, and a phase 3 study, all under the TB project. Being part of this team to write these protocols, meant a lot to me as I felt I have been given trust and I had to do my best to merit this trust. And so I worked pretty hard to satisfy my supervisors and they were visibly satisfied.

In terms of conferences attended, I was privileged to travel to Tanzania, to attend the TB/HIV annual conference in Arusha, for one week. Valuable contacts were made with renowned scientists during this conference. I completed my training in Geneva, at the TDR headquarters, where I was drilled for 2 weeks on project management and some aspects of clinical coordination.

I returned to Cameroon in April 2010, full of ideas and hope to contribute significantly to the development of my home institution. My bosses welcomed me warmly as they were being briefed with my progress report on a regular basis by my training mentor. My director called me for a meeting and we discussed some aspects that we can improve in the hospital. We thought of the laboratory of the hospital that needed to be upgraded in terms of quality of service. We thought that if we want, in the long term, to conduct trials, we will need a quality laboratory. And so we embarked on improving the infrastructure of the laboratory and enrolled in an accreditation process with the Centers for Disease control In Atlanta, U.S.A. Very soon, this process will be completed. So far we are doing very well in the improvement of quality. Then we thought of a review board for proposals. We didn't have one, and we created an IRB for the Regional Hospital, and I was honored to be the president of this board of 7 persons. So far we have been reviewing proposals from both locals and international organizations wishing to carry out research in our hospital.

We have also been constituting cohorts of patients, a sort of pool of patients with particular characteristics who can be our potential research subjects, especially in HIV and TB. While this ground work is being done, I have been working with research teams from the University of Missouri in the U.S. on new diagnostics and we have together 4 publications in press, and 1 recently published referred at the end of this paper. I am also working with the University of Hamburg on HIV resistance in newly enrolled HIV patients on ARV. The study is ongoing.

At the same time, I do clinical Monitoring for GSK Biologicals and WHO/TDR for studies conducted in Africa. When possible, I still do clinical practice in the field of TB/HIV and malaria in the hospital, as this permits me to have trust from my patients and constitute potential research subjects for future studies.

If I have to give an advice to my fellow colleagues, I will let them know that the time allocated for this fellowship is definitely not enough to meet with your objectives. You have to implicate yourself fully in the activities of your placement company as soon as you arrive. You have to remain humble and adapt fast to your new environment, show your mentors that you are willing to work and you will be given responsibilities. Then while there, always remain in contact with your home institution and start thinking of what you will do for your home institution when you return home.

A recent Publication of Dr Ayuk:

Rapid cell-free CD4 enumeration using whole saliva

Cynthia Bristow, Mariya Babayeva, Rozbeh Modarresi, Carole McArthur, Santosh Kumar, Charles Awasom, **Leo Ayuk**, Annette Njinda, Paul Achu, Ronald Winston

Retrovirology 2012, **9**(Suppl 1):P58 (25 May 2012)

Courses, Conferences & Meetings

Global Health Trials Skills Sharing Workshop
February 1st, 2013
University of Cape Town, South Africa
Contact: mailto:info@globalhealthtrials.org

The 2013 Gordon Conference on Tropical Infectious Diseases: from bench to field
February 10th-15th, 2013
Galveston, Texas, USA
Contact: http://www.grc.org/programs.aspx?year=2013&program=tropical

Global Health Trials Skills Sharing Workshop
February 14th, 2013
Sanctum Hotel, Entebbe, Uganda
Contact: mailto:info@globalhealthtrials.org

2nd West African Regional Workshop on Protozoan Pathogens
March 3rd-16th, 2013
University of Bamako, Bamako, Mali
Contact: mali.workshop@seattlebiomed.org

Course: Immunology in the Tropics

March 4th-15th, 2013

An intensive two week modular course designed for graduates and laboratory researchers

Makerere/UVRI, Kampala, Uganda

Contact: Visit http://www.muii.org.ug or email mak-uvri.rtp@mrcuganda.org

International Malaria Symposium

"New Challenges and Strategies in Malaria Control"

April 16th-17th, 2013

Level 2, Le Lourve Conference Room, Kote Kinabalu, sabah, Malaysia

Contact: www.ums.edu.my/conferences/IMS2013

6th International Congress on Infectious and Parasitic Diseases

June 13th-15th, 2013

Submit abstracts of scientific works and reports of disease control activities by 15th March 2013

Kinshasa, Democratic Republic of Congo

Contact: info_cipip@yahoo.be

Course: Epidemiological evaluation of vaccines: efficacy, safety and policy

July 8th-19th, 2013

London School of Hygiene & Tropical Medicine

Contact: http://www.lshtm.ac.uk/study/cpd/seev.html

The American Society of Tropical Medicine & Hygiene 62nd Annual Meeting

November 13th-17th, 2013

Marriott Wardman Park, Washington, DC

Symposium Proposal Submission Deadline - **March 5th**

Travel Award Applications - Submit by **April 3rd**

Abstract Submissions - Submit by **May 2nd**

Young Investigator Award Applications - Submit by **May 2nd**

American Committee on Arthropod-Borne Viruses (ACAV)

Kelly Labell Student Travel Award - Submit by **May 2nd**

American Committee of Medical Entomology (ACME) Student Travel Award - Submit by **May 2nd**

Elsevier Clinical Research Award - Submit by **June 5th**

Contact: http://www.astmh.org/Home.htm

For more information on all upcoming courses, conferences and meetings please contact info@globalhealthtrials.org

Please continue to write and submit a report on each conference or meeting 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 upload their conference reports to the TDR website or forward to liam@globalhealthtrials.org and I will upload on your behalf. The template for the conference report can be downloaded, in word format, from the 'Conference Report' section of the website: http://tdrfellows.tghn.org/conference-reports/.

Call for Applications

The Public Health Research Data Forum is a group of major international funders of public health research dedicated to increasing the availability of research data generated through their funding in ways that are equitable, ethical and efficient (www.wellcome.ac.uk/publichealthdata).

They have put out a call for an independent consultant to develop an "options paper." This work will involve compiling an inventory of existing training and capacity building activities relevant to management and sharing of public health research data, assessing labor market dynamics for people who possess relevant expertise, and appraising current challenges and gaps. Based on this analysis, the consultant will identify a range of options through which funding agencies could build on their existing activities to develop and retain key skillsets needed to enable data management and sharing in research institutions.

Full information is available in this PDF: Capacity_Skills_RFP.pdf