TDR Newsletter: Issue 5

July 2012

Dear Fellow

Welcome to the 5th issue of the TDR website newsletter.

This month's newsletter features:

- Fellow's six month reports from:
  - Michel Mandro
  - Celine Isaack
  - Holger Mayta
  - Steven Baveewo
- Fellow's twelve month reports from:
  - Tafireyi Marukutira
  - Quoc Dat Vu
- Conference reports from:
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- Fellow's articles from:
  - Wilfried Mutombo Kalonji
- Up and coming Conferences and Meetings
- Call for Applications
- The Global Health Network Update

Dear Fellow,

I hope this newsletter finds you well. It has been a pivotal time for many of you over the past couple of months with fellows reaching their six and twelve month milestones at their host institutions. All reports (including conference reports) are continually uploaded to the 'notice board' area of the GHT-TDRf website for you to view at your leisure. The reports are a great way to compare each other's experiences whether this is with fellows who are back at their home institutions, currently with their host institution or yet to embark on their journey with the programme. To keep this newsletter informative but streamlined I will include the details of the report's author, an introduction to the report and a link to the remainder of the report on the website. I hope that you will all continue to read the full reports, discuss experiences using the website discussion groups and provide feedback for each other. I have included information of some relevant upcoming conferences which I hope will be useful. If you are attending any of these conferences please let me know as myself and several of the Global Health Network team could be attending and it would be a great opportunity to touch base.

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' Six Month Reports

First six month report

Report by: Michel Mandro
Home institution: District Sanitaire de Bumia, Université de Bumia, Dem. Rep of Congo
Host institution: Novartis, Switzerland

II. Progress report of the training:

II.1.The Fellow appointment in the Clinical Trial Team:

My training started on November 1, 2011 with the "Novartis Welcome Day", a whole day session for all Novartis new associates at Basel & Rhine Valley Sites. At the end of that session, I had a first contact with my Supervisor who presented to me my Office.
For the next two days which involved undergoing the administrative activities: registration to HR service, to the ID service and setting up the Novartis accounts.

My appointment in my new post was published in the communication from EM on 04th November 2011, as following:

WHO Clinical Research Fellow joining the Established Medicine

Michel Mandro, MD joins the EM Franchise as a WHO Clinical Research Fellow from the Democratic Republic of Congo, where he is employed as a lecturer by the University of Kisangani and as a Medical Officer, in charge of the health district of Bunia, by the Ministry of Health. In parallel, he is working as a Clinical Monitor for TDR (a Special Program for Research and Training in Tropical Diseases based at and executed by the WHO). Michel will be involved in the Coartem program. He is based in Basel and reports operationally into Marc Cousin, Program Section Leader (PSL).

During my first month Fellowship in this Global Program Team of Malaria Initiative, I Having had introduction meetings with the members of the GPT and members of Malaria initiatives.
I was also requested to complete a considerable number of on-line courses on: GCP, and new internal processes for conducting clinical research programs, and on the Novartis Code of Conduct.

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

Steven Baveewo 6-month progress report

First six month report

Report by: Celine Isaack Mandara
Home institution: National Institute for Medical Research,
Tanga, Tanzania
Host institution: Sigma Tau, Italy

Introduction

I arrived in Rome, Italy on 5^{1h} Dec 2011 and Dr. Valentini made all things possible for my stay in Pomezia. I had to undergo series of procedures like opening up a bank account, getting fiscal code, processing my residence permit and get the registration at Sigma Tau in order to obtain a special badge to get access to the company.

I arrived while there was a terrible crisis in ST, with lots of strikes within the company that lasted about two months. For this time I had to get oriented to the company and received trainings on safety issues and signing legal documents for maintaining confidentiality and code of ethics.

I started with reading Standard Operating Procedures (SOPs), protocols that were in place and whose studies have started, ICH and EMA guidelines.

Silvia Violetti has made all the effort to show me whatever was necessary for my training, including paying a visit to the Malaria room and seeing how the filling was done for different projects and all necessary documentations. The archiving started in 2007 to date and different inspections has been done, I got acquainted to see the organization of Trial Master File (TMF). This has broaden my understanding in different fields because I have seen a lot that has not been done in my home Institution being done here, that means once I go back I have to implement and bring changes to my Institution. This will improve the quality of the documentation relevant to our clinical trials and will make them ready to be inspected by international Regulatory Authorities.

Furthermore, I managed to attend various meeting within the company and outside Italy, discussing on-going trials but also future projects relevant to pharmacokinetic studies, drug-drug interaction studies, safety and efficacy studies in Europe but also in endemic countries. I was also involved in monitoring activities and attended a monitoring visit in France to practice a little bit on scientific monitoring activities.

I participated in the revision of a multicenter study protocol on Malaria and I Joined the first investigators' meeting in Ghana for such a future clinical trial.

I drafted a new protocol and informed consent on a pharmacokinetic study with a new formulation of an antimalarial drug and participated at the design process of a relative bioavailability study comparing two different formulations of such a drug.

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

Celine Isaack Mandara 6 month progress report

First six month report

Report by: Holger Mayta
Home institution: Universidad Peruana Cayetano Herdia, Lima, Peru
Host institution: Merck, USA

Introduction

The career development fellowship on Clinical Research & Development is a Special Programme for Research and Training in Tropical Diseases (TDR). It is a 12 months career training at selected pharmaceutical companies and related institutions globally. The main goal is to develop human resources to promote high quality research and development in the disease endemic countries. The training is focus in drug development in the areas of project management, regulatory compliance and good practices. It is expected that after training completion fellows should return to their home institutions to assume leading roll on research and development in neglected diseases. TDR clinical research and development fellowship is being supported by the Bill and Melinda Gates foundation.

My training is taking place at the Merck Research Laboratories at Kenilworth, New Jersey, USA; this part of Merck was the former Schering and Plough Research Institute.

The process of starting at this institution was a little bit challenging due to administrative issues mainly from TDR; that hopefully will be overcome in the future. The selection process was smooth and according to schedule but once selected; there was a lapse of time where I was not sure even if I was coming to the training. According to the company, the training was expected to start on February or at the most on March; but nothing was done until August 2011. The reasons not known and not well understood TDR have already place trainees in USA (although not at Merck), so it cannot be a lack of experience. By August, at Merck, the project that was assigned for the training, was cancelled and was assigned to a different project.

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

Holger Mayta 6 month progress report

First six month report

Report by: Steven Baveewo
Home institution: Makerere University College of Health Sciences, Department of Medicine, Kampala, Uganda
Host institution: Pfizer, USA

Summary activities covered in the last 6 months

- Administration and documentation (filing, tracking of safety data, protocol deviations, protocol amendments, monitoring enrollment and retention progress at multiple sites was covered).
- *Regulatory aspects of medications (partly covered in the first 6 months)*
- Online I accessed and read the previous clinical study report that was prepared for the A0661157 study.
- Conduct of Bio-equivalence and Bioavailability studies. (John Obourn-The Development Team Head, Emerging Markets at Pfizer spared his valuable time, discussed with me and shared with me the Drafted FDA Guidelines on how to conduct Bioequivalence and Bioavailability studies)
- Study implementation and conduct (pre-study contacts, study initiation and monitoring); Rojo Ricardo shared with me his skills he acquired while working as a monitor and a Quality assurance manager for Pfizer Mexico for 2 years.
- Practiced Study reporting (data validation, study report) in terms of review of the data listings, blinded data reviews; the clinicians on the malaria program were helpful in honing my skills.
- Medical safety and regulation (reporting and management of safety, production of safety documents) (I worked closely with Rojo Ricardo, the Lead Clinician on the Malaria program who was able to show me how to do conduct safety reviews using Oracle clinical safety database; he also reviewed my presentation slides, gave constructive comments that formed a great learning experience for me on safety reviews.
- Provided weekly updates on the progress of Tanzania study site that I was allocated by the Supervisor (Dr Richa Chandra)
- **Development of at least one Research proposal to address a specific Uganda health challenge or gap for** implementation back in Uganda; this will provide me with an opportunity to contribute to solving health challenges and obtain data for a scientific presentation at any of the next international conferences. (This is in progress)

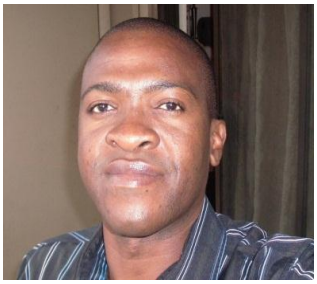
To read the full report please select the link below or visit the TDRfellows website:

Steven Baveewo 6-month progress report

Fellows' Twelve Month Reports

Six month Progress report

Report by: Tafireyi Marukutira
Home institution: Botswana-Baylor Children's Clinical Centre of Excellence
Host institution: Astellas, USA



2.0 SPECIFIC OBJECTIVES

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

At APGD, the programme was meant to give me specialized training on drug development/life cycle management *for* the Micafungin paediatric program and other products focusing on paediatric drug development. Working with the clinical R&D team the following specific objectives were specified:

- 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

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

Tafireyi Marukutira 12 month progress report

Six month Progress report

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

II. Progress report of the training:

My one-year training course in Clinical department, Sanofi Pasteur include following objectives:

- Development and update the clinical development plan
- Study preparation: study design, concept and main protocol, case report forms, and logistics
- Study implementation: pre-study contract, 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, training on GCP and on Sanofi pasteur SOPs

This fellowship consists of 2 periods of each 6 months in France and in Singapore. The first part lasted from 15/04/2011 to 17/11/2011 in Clinical department, Sanofi pasteur, Lyon, France. This report included activities in the training course from 18/11/2011 to 13/04/2012 in Singapore. All activities has been planned to accomplish the training objectives without changes from the original.

1) Introduction

The main activities of training course that were reported in the 6 month progress report continued during the last 6 months of the fellowship, including involvement in on-going clinical trials and regular meetings, training attendance and reviewing the literature. Additionally, the second part of the fellowship is focused more on Standard Operating Procedures (SOPs) training, clinical site monitoring and field visits.

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

Quoc Dat Vu 12 month progress report

Fellows' Conference Reports

ASTMH 60th Annual Meeting 3-8th December 2011

Report by: Holger Mayta
Home institution: Universidad Peruana Cayetano Herdia, Lima, Peru
Host institution: Merck, USA

1) Objectives for attending this conference (1 page max)

To gain knowledge on the control and prevention of tropical infectious diseases based on immunological approaches.
To learn about the most recent studies on tropical diseases directly from researches, through conferences, oral and posters presentations.
To meet researchers and to build and strength research networks

2) Agenda of the conference

December 3, 2011
Basic Science Pre-Meeting Course: New Approaches for Immunologic Intervention in Tropical Infectious Diseases.
December 5, 2011 Symposium: Cestodes
Symposium: Protective Immune Mechanisms in Helminth Infection
Symposium: Kinetoplastida: Epidemiology, Diagnosis and Treatment

December 7, 2011
Symposium: CYP51 As a Target for Chagas Disease Drugs
Symposium: Induction and Maintenance of Immunologic Memory to Infectious Antigens and Vaccines
Symposium: Antimicrobial Resistance and Diarrhea in South America Symposium: Leishmania Knockouts: Candidates for Live Vaccines? Plenary Session V: ASTMH President's Address and Annual Business Meeting

December 8, 2011
Scientific session: Malaria: Epidemiology - The Changing Map - vivax and falciparum
Symposium: Parasitology Molecular Diagnostics

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

American-society-tropical-medicine-and-hygiene-60th-annual-meeting-Holer-Mayta

Fellows' Articles

Article

Report by: Wilfried Mutombo Kalonji
Home institution: Programme National de la Lutte contre la Trypanosomiase Humaine Africaine (PNLTHA), Kinshasa, DRC
Host institution: Sanofi Aventis, Paris (6m), DNDi (6m)

CHALLENGE OF CLINICAL TRIAL ON SLEEPING SEECKNESS

Human African Trypanosomiasis (HAT) is a pasitological disease caused by a parasite called trypanosome. HAT is an endemo epidemic in intertropical Africa. It run into two stages, the first one called hemolymphatic caractérised by generals symptoms like fever,headhache,priritus…and the second one called neurologic or the stage of cerebral polarisation. Not treated HAT kills.
Treatment depends on stage. **Pentamidine** is used for the first stage, **melarsoprol** and **eflornithine** are the mains drugs for the stage two. **Nifurtimox** is use as compassionnel treatment. Since may of 2009 WHO recommends the association of Eflornithine – Nifurtimox (NECT) for the treatment of the stage two .
Most ot those drugs are toxic (i.e melarsoprol) or need complex manipulation for using them (eflornithine).
More and more initiatives are taken to look for new drugs or new therapeutic combination for the treatment of HAT. There is a need of clinical trials on the field of HAT.
These initiatives are facing to enormous challenges among whom:

1. Obtention of approbations to perform clinical trial
   Most of endemic countries have no ethics nor regulatory autority working normaly.
   The process of approbation obtention depends on country and it can take from few weeks to several months.

2. Site accessibility (patients accessibility)
   HAT is a rural seeckness, to perfom clinical trial on sleeping seekness you neeed to go to those rural,remote areas where patients are.
   Health center or hospital are far from urban areas; some time you spend many hours on bad roads to reach the study site.
   You can take a plane to reach study site but most of air plane companies in those area are black listed. The only option remaining is humanitarian flies, but access to those flies are very restricted.

3. General condition of Heath center
   Most of those hospital /health center are in worst state and under equiped .There is a need of rehabilitation and equipment before starting a clinical trial.

4. Team in the health center
   Staff members don't know Good Clinical Practice.
   Most of time It's their first participation to a clinical trial. Training the staff on GCP, the basics of clinical trial,the study protocol is mandatory

5. Profil of patients (vulnerable population)
   Sleeping seckness patients are poor and less or not educated. There is a serious issue to have an inform consent.

   Regarding inform consent, patient usually has three attitudes:
   - Suspicious: patient find it bizarre that he is asked to sign a document before starting his treatment. This is not in habit and at this time patient can circullate some false informations about the study and this is very bad for the study.
   - Trust : patient trust the staff, he agrees on all with out reading and understanding the study. Everything coming from the staff is ok because he trust the staff.
   - Opportunisme :patient agree to be enrolled on the study because he won't pay any fees , he will be totally in charge of the study (sponsor)

6. Follow up of patients after treatement
   In WHO guideline for clinical trial on HAT, the decision of success of treatment is made 18 months after tthe end of treatment.
   You need to imagine the best way to have patients at the 18 month follow up.This is not easy because patients come spontaneousely at the first follow up (at 6months) and then after they don't come fearing the lumbar ponction or because they can't leave their activities (agriculture).

Despite those challenges,clinical trials on HAT have some good consequences on all the stakeholders (HAT patients,health staff,regulatory and ethics autorities).

- For patient: hope of having a new treatement well tolereted.
- For the health staff, participating to a clinical trial improuve the way of working, it breaks routines and bad habits.
- For the healh center/hospital: it is rehabilited , equipeted and by participating to a clinical trial it become more visible.
- For regulatory and ethic autorities , every protocol is a good exercise ofr them and it's a call for improving their work for reach the international standard.

Thanks to all those who work on the field of clinical trial on HAT.

Wilfried MUTOMBO KALONJI,MD

PNLTHA / RDC

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Up and Coming Conferences & Meetings

RSTMH 2012 biennial meeting

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

- Student hall accommodation is bookable directly via Warwick conference office.

International Congress for Tropical Medicine and Malaria (ICTMM) and Congress of the Brazilian Society for Tropical Medicine

23rd – 27th September 2012
Royal Tulip Hotel, Rio de Janeiro, Brazil
Contact: http://ictmm2012.ioc.fiocruz.br/

The Second Global Symposium on Health Systems Research "Inclusion and Innovation Towards Universal Health Coverage"

31st October - 3rd November 2012
Beijing China
Contact: http://www.hsr-symposium.org/index.php

ASTMH 61st Annual Meeting

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

For more information please contact info@globalhealthtrials.org

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/ .

Call for Applications

Stars in Global Health

This unique program enables innovators in low- and lower-middle-income countries and Canada to develop their **bold idea with big impact** to improve global health conditions.

We are seeking ideas that reflect the full spectrum of global health including drug discovery, medical devices and diagnostics, vaccine development, health and medical education, maternal and child health, non-communicable diseases (including mental health and cancer), information communication technologies, health-related water and sanitation, and agriculture.

Awards are initially valued at $100,000 CAD for up to 12-18 months to demonstrate proof-of-concept of the idea. Upon successful review of proposals at 12-18 months after the initial award is granted, scale-up grants of up to $1 million CAD may be awarded with potential linkages to private sector investments.

We are looking for innovative ideas to address complex real-world challenges that involve a scientific or technological solution (new or existing) alone or in combination with social and/or business innovations. We call this approach *Integrated Innovation*.

Application Deadline: September 5, 2012 3:00 p.m. EDT

For further information and to apply please visit the link below:

http://www.grandchallenges.ca/grand-challenges/gc1-stars/stars-program-information/

The Global Health Network Update

The Global Health Network

The Global Health Network is expanding all the time and now encompasses 16 websites that are all connected by a shared digital hub:

- Global Enterics Research
- Global Dengue Research
- Global Epidemic Research
- Global Health Bioethics
- Global Health Cancer
- Global Health Diagnostics
- Global Health Epidemiology
- Global Health Microbiology
- Non-Communicable Diseases
- Global Health Reviewers
- Global Health Trials
- Global Neuroinfections
- Global Research Nurses
- ISARIC
- Mother Child Link
- Tropical Disease Research Fellowship

In the past couple of months both **ISARIC** and **Global Research Nurses** websites have been launched and are fully operational.

ISARIC is a global initiative aiming to ensure that clinical researchers have the open access protocols and data-sharing processes needed to facilitate a rapid response to emerging diseases that may turn into epidemics or pandemics.

Global Research Nurses is setting out to raise the profile of nurses in research and to guide and support nurses as they develop their careers in medical research, irrespective of the level or type of role that they have. This network is for nurses working in any capacity - in any form of research involving human subjects and across all diseases areas and regions.

Each user name and password for the TDRf website allows access to all the resources and information that is shared across the entire network. Please feel free to make use of these valuable resources and if you have colleagues or friends that would find a specific area of the network useful then please inform them.

Quoc Dat Vu suggested that if each of the TDR fellows placed a link to the Global Health Network on their home institutions websites then we could disseminate this information to a vast number of people within the field of global health.

Regional Faculties

In the previous TDRf newsletter there was an article about The Regional Faculties in which we described how they 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.

In addition to the current regional faculties; West Africa, East Africa and Central Africa, the Southern Africa faculty (including RSA, Malawai, Zambia and Botswana) has now launched. Currently the Southern Africa faculty is being coordinated by members of the website based at the University of Cape Town but other members are welcome to join and assist in the coordination of the faculty. To join in the Southern Africa faculty discussion please visit the link below:

http://globalhealthtrials.tghn.org/community/groups/group/faculties/topics/195/

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/

For more information on regional faculties please contact admin@globalhealthtrials.org