TDR Newsletter: Issue 3

November/December 2011

Dear Fellow

I hope you had a peaceful holiday season.

Welcome to the 3rd issue of the TDR website newsletter.

This month's newsletter features:

- Fellows' contributions from:
    - Qingyan Bo
    - Roma Chilengi
    - Marie Florence Makamche
    - Michel Mandro Ndahura
- Up and coming Conferences and Meetings
- Conference reporting
- The Professional Membership Scheme.
- The Global Health Trials website's 'Regional Faculties'

Please feel free 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.

This newsletter is designed for you, so if there is something you would like to see featured, please let us know.

Please let us know if you ever encounter any problems using the websites so we can make them as good as them can be.

Best wishes

Mary

Training & Professional Development Coordinator

Fellows' Contributions

Attending International Meetings

Report by: QINGYAN BO
Home institution: Clinical Pharmacology Dept, Affiliated Hospital of Nanjing University, Nanjing, Jiangsu, China

Meetings: DIA/FDA CDER/CBER Computational Science Annual Meeting (14 & 15 March '11) & Clinical Data Quality Summit (16 & 17 March 11)
Venue: Sheraton National Hotel Arlington, Arlington, VA 22204 USA

First of all, I wish to acknowledge the funding from the WHO/TDR providing the great opportunity allowing me to attend the two meetings to keep updated about current and future clinical data standards and FDA's initiatives to adopt the standards and improve the standards aiming at more efficient and effective review.

Drug Information Association (DIA) is the organizer for the meetings, and there were more than 200 attendees from the world (i.e., USA, UK, Sweden, China, Belgium, Netherland, Germany, Canada) including FDA officials, experts from academia and industry.

The key information I learnt from the two meetings are as follows:

1. Both CBER and CDER of FDA are working actively towards a standardized approach to acquire, receive, and analyze clinical study data. During last two years the FDA hired many statisticians and programmers to working this.
2. The FDA 's computational science initiatives currently mainly focused on the development of data standards and IT modernization, i.e, better data, better tools, and subsequently, better decision.
    a. Better data means eSubmission, standard data
    b. Better tools mean development, validation, and implementation of tools to check, retrieve and analyze submitted data
3. FDA Supports Development of Information Technology Systems for Tracking Medical Errors.
4. FDA Awards $2.5 Billion to Modernize Information Technology over 10 Years.
5. FDA plans to use CDISC standards for the foreseeable future, and pursuing a smooth evolution/convergence path of our CDISC work with HL7 standards development in order to Maximize reuse of standardized eSource information (e.g., in EHRs). In short, for data quality and efficiency gains pre-marketing study data and post-marketing safety data will be integrated in public health data warehouse of FDA after study datasets being standardized.
6. Certain therapeutic area data standards have been pioneered by some companies, e.g, TB and heart diseases.
7. Clinical data quality is still a not well-defined, different presenters had different understanding of data quality, and some broadened the concept of data quality to quality of clinical research conduction. No clear metric for evaluating data quality was suggested or agreed at the meeting.
8. It was agreed that clinical trial, using electronic tools, e.g, EDC (Electronic Data Capture, eRecuriting, eMornitoring, etc, and standardized database can facilitate data quality and quality check processes.

Overall, I feel that attending the two meeting really helps me a lot. I got insights through communicating with health authority directly, deeply understood their initiatives and knew where to find further information. Through communicating with the people from industry, I broadened my horizon, learning to achieve the purpose there might be different ways.

I really appreciate the support from TDR.

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What Does the TDR Fellowship Prepare You For?

Report by: ROMA CHILENGI
Home institution: Centre for Infectious Diseases Research in Zambia

Dear Colleagues

My name is Roma Chilengi, from Zambia, and I was the second fellow to tread the TDR Fellowship path now exactly ten years back. May 2001 to April 2002 is indeed a long time ago and reflecting on the programme, one may ask whether the" fellowship" really was worth the while? I guess only time answers such questions and so, my newsletter article this time is somewhat a personal reflection on the career journey that I have taken. I trust that in the process of reading the article, it will somehow be clear what value the fellowship added to my life. And if for no other value at all, I hope that some of the current and prospective fellows may be inspired by my experiences.

Presently, I am working for the Centre for Infectious Diseases Research in Zambia (CIDRZ), as Head for the diarrhoea programme. My principal role is to head the programme that is introducing a comprehensive diarrhoea control programme in Zambia, with a key focus on supporting the Ministry of Health to introduce Rotarix vaccine within the national EPI programme. Thus, my programme supports the Ministry in addressing the expansion of the national cold chain infrastructure, implement a clinical case management improvement programme for front line health workers as well as a community outreach programme to promote improved hygiene and better infant feeding practices; all for the goal of reduced under 5 mortality through reduction of severe diarrhoeal diseases.

My story began at the turn of the decade in 1999, having completed my residency as a young physician. It was immediately clear to me that I needed to direct my career to something else, but I was never really sure of what that could be. I thus found myself looking around until I came across the opportunity at the Tropical Diseases Research Centre, which I quickly took on, and there began my research career. While I was conducting clinical trials, the opportunity for the TDR fellowship came up and I recall feeling extremely lucky to be the "one African" selected for the position. Back in the days, there were not many people one knew of who had successful research careers, at least not in Zambia. And so, the move to Belgium was both very exciting and very scary in that I could not imagine what I would do after completing the year-long fellowship. At Rixensaart, I was incorporated into the malaria team training as "Clinical Study Manager" for RTS,S trials then dubbed Mal 17, Mal 18, Mal 19.

The one month attachment to WHO/TDR in Geneva that followed in Belgium, was for me a great opportunity to see and learn R&D from other non-pharmaceutical industry contexts, and through that brief attachment, I joined the TDR monitors group. Although the Monitoring experience was later to be a key skill that opened doors for me, it was abundantly clear to me that the work of monitoring was only a necessary step and not a career in itself. During those times, there was a dearth of trained clinical monitors, and so a few of us were continuously involved with WHO monitoring activities even when I returned back to Zambia.

Indeed, at the recommendation of contacts in TDR, I was soon approached by the African Malaria Network Trust (AMANET), to consider a position as Clinical Trials Coordinator, and to be based in Tanzania. At that point, it appeared to me that the roles for the position where extracted from the "CSM" responsibilities, and therefore the job fit me like a glove. I therefore spent five exciting years running an "orphaned" malaria vaccine R&D programme and pan-African capacity building enterprise. During this period, I ensured that I took on academic studies through the London University and was lucky enough to complete the MSc in Epidemiology through the distance learning platform. This endeavour for me was not only the most challenging, but it was in every way the most difficult undertaking I had ever done; both intellectually and financially. Thus, the very helpful practical skills I had gained with inexplicably complemented by the knowledge from the Epidemiology training. As a result, I wound up with a new position as Head of Clinical Trials at the prestigious KEMRI-Wellcome Trust Research Programme in Kilifi, Kenya, and was employed by the University of Oxford in UK. My paths would again meet the RTS,S vaccine as co-principal Investigator now for Mal 55. Having worked with so many candidate vaccines over

the years, my knowledge and skills in the field of vaccine development has expanded in depth and scope. After living in Tanzania for five years and in Kenya for three years, the desire to return home was ever growing and when the opportunity for my current position arose, it was not a difficult decision to make.

However, this decision was a major one in that I had to make a shift away not only from the malaria to diarrhoea field, but it is also a step away from purely conducting research to programme implementation. This is a snapshot of the road I have walked over the past 10 years. Somehow, I know that I will again work with RTS,S vaccine especially if the phase III results will be positive. I am now walking another unfamiliar career which has to do with introduction of vaccines into the national programmes.

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The Overview of My Training Up to Now.

Reported by: MARIE FLORENCE MAKAMCHE
Home institution: Centre International de Référence Chantal Biya pour la Recherche et la Prévention et la Prise en Charge du VIH/SIDA (CIRCB), Yaoundé, Cameroon

I am very glad for this training on clinical research because it is of great importance for the African Society and most particularly for Cameroon, located in the Central Africa region where clinical trials are still a new concept.
Leaving my country to Belgium was not easy. The main problem was the Work Permit. I was supposed to leave in October 2010. After three months of waiting, I took the initiative myself to call the Belgian Embassy requesting with them if I need this work permit, because the pharmaceutical company had difficulties to get it from the Belgian authorities. The man who was on the phone told me that if I am involved in an international organization, I did not need a work permit. He told me to come with my file, after two weeks, the Belgian embassy gave me the visa. I was very glad.

I started the training in March 2011 at Tibotec-Virco Virology Bvba (Janssen Pharmaceutical Companies of Johnson & Johnson) located at Beerse 1 in Belgium. I quickly adapted myself to the environment, due to the sympathy of my supervisor (Wim Parys) and the staff of the department.

The first month of my training was devoted to:

- the introduction on Project Management
- the introduction of Hepatitis C Virus Virology
- a visit of the Department of Hepatitis C Virus Virology
- a visit of the Laboratories of Developing Drugs; meeting with my Supervisor
- practical issues (office, badge)
- administrative issues (residence permit)
- reading material on Good Clinical Practice (GCP) and best practices when managing Clinical Trials, Global Clinical Operations (GCO) and Investigator safety training (e-learning)
- discussion with experts of the pharmaceutical company

I received many documents on clinical research from Patricia Van Rompuy. I also had access to the GCO portal Homepage which allowed me to read many procedural documents and to follow Clinical Trials films. Reading these documents allowed me to identify the different key players in the Clinical Trial set up; and to understand the composition of each key player and the responsibilities and roles allocated to each of them in accordance with ICH-GCP. It also helped me in the understanding of the Clinical Development Plan (CDP), the study preparation (study design), to be familiar with the Clinical Trial Protocol, the Inform Consent process, the study feasibility and site selection, the understanding of Clinical Trial methodology, and the writing of Standard Operating Procedures (SOPs).

Tibotec works in partnership with GCO (which is another department of Johnson & Johnson located at Beerse 2); a partner for the delivery of clinical studies worldwide and it enables the development and lifecycle of all Johnson & Johnson health care products. My supervisor has appointed two coordinators from Tibotec (Jens Van Roey and Jos Noben) and one from GCO (Patricia Van Rompuy) for the coordination of this training. Working with GCO gave me the opportunity to have discussions with the Senior Manager of GCP and Quality, the local Trial Manager and Site Manager, and to learn more on clinical research.

I attended the practical workshop for implementing procedural documents in May at Turnhout, Belgium. The overall learning objectives of this workshop were: to manage the conduct of a Clinical Trial successfully by applying GCO SOPs, ICH-GCP guidelines, and Food and Drug Administration (FDA) Code of Regulations; to locate and access applicable resources and apply them 100% of the time in conducting Clinical Trials.

This workshop allowed me to learn more on study implementation and conduct (pre-study contacts, study initiation and monitoring); study reporting (study reports); and medical safety and regulation (reporting and management of safety, production of safety documents). The workshop also triggered my interest for more applicable learning, specific to implementation at the Chantal Biya Institute, Cameroon. I did the site visit with the site manager. The aim of this visit was to see how the site is organized and how a monitoring visit is conducted.

Everything I learned allowed me to write a document with the help of Patricia Van Rompuy. The document is titled "How to set up an investigational clinical site". This document is a preliminary step to setting up an investigational clinical site and to seeing if the site is ready to conduct a Clinical Trial. Six topics have been identified on the Johnson & Johnson Site Feasibility Questionnaire (a trial-specific questionnaire based on a standard template that is developed by the Global Trial Manager in conjunction with the Protocol owner or representative and completed by all potential Investigators):

1. staff and experience
2. subject recruitment
3. equipment or facility requirement
4. data collection
5. Independent Ethics Committee/ Institutional Review Board
6. Pharmacy and Investigational Drug

The document will help to identify what is theoretically needed, the actions to be taken, and propositions to meet the requirements. This document will help us in the setting up an investigational Clinical Site at the Chantal Biya Institute in Cameroon.

I also did:

- Trainings online
- Practical training on the Electronic Case Report Form (eCRF)/ Electronic Data Capture (EDC).

I started the second part of my training with Biosafety training and Lab training in the Tibotec-Virco Resistance Testing Lab (Virco Diagnostic Lab Operations). This is a fully accredited Clinical Sample Testing Laboratory. The goal was to have an overview of the organization of materials, maintenance of equipment, documentation, and the monitoring of quality; in summary the Quality System needed in place for accreditation of a clinical lab.

I also attended the Sixth EDCTP Forum in October at Addis Ababa, Ethiopia on the Strengthening of Research Partnerships for better health and sustainable development. The aims of the forum were to:

- promote African and European Leaders' support for research in HIV/AIDS, Tuberculosis and Malaria
- increase awareness of the need for Clinical Trial activities in Africa
- provide a platform for bridging partnerships by bringing together member states and third party partner
- support engagement between African and European scientific communities, as well as partners from other regions in order to shape an effective and appropriate research agenda.

I would like to thank the WHO Special Programme for Research and Training in Tropical Diseases and Janssen Pharmaceutical companies of Johnson & Johnson for the great opportunity they gave to me for learn and better understand clinical research.

A Starting Fellow at Novartis

Reported by: MICHEL MANDRO NDAHURA
Home institution: District Sanitaire de Bumia, Université de Bumia, Dem. Rep of Congo.

My Announcement of WHO Clinical Research Fellow joining the Established Medicine Franchise
(communication from EM, 04.11.11):

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).

Questions: Where am I?
As soon as I received this announcement it aroused in me the question to know exactly where am I in this new environment of the research for so high level.

My first experience and my commitment.
During my first Fellowship month in this Global Program Team of Malaria Initiative:

- I had introduction meetings with the members of the GPT and members of Malaria initiatives.
- I have followed some lectures and conferences (e.g. “Roll Back malaria”,” Shrinking malaria map”....),
- I have gone through certain Protocols of Studies on Malaria sponsored by Novartis
- I was also called to complete a considerable number of on-line courses on GCP, new internal processes for conducting clinical research programs, and on the Code of Conduct.

These activities began to make me collect elements of answers to my question; which urged me to look out farther and to find finally the answer to my question.

I left my hospital in the northeast of the Democratic Republic Congo having worked for six years in an environment where malaria remains the first cause of death and morbidity (which means we had experimented with malaria under all its forms); at the same time as having worked for three years as a CRA acting on a sponsor's behalf.

I understood that I am a mix of a very low level of Clinical Research and Clinical Monitor (Clinical Research Associate: CRA) acting on a sponsor's behalf, with a high level of Research (Global Program Team (GPT) of Malaria Initiative, part of ‘Establishes Medicines Development Franchise’). And after this one month experience in the Malaria Initiative GPT Coartem team, I finally knew that I am going to cross my entire training in a department which specialises in Malaria.

Now I am involved for a year in the team of Novartis Malaria Initiative, a holistic approach to best serve patients’ needs which develops four pillars of activities:

1. Treatment-In the front ranks of a change in the treatment of malaria:
    - Novartis has been in the front ranks of a revolution in the treatment of malaria, ever since it launched Coartem® in 1999.
    - Coartem®, with a cure rate of over 95% and a demonstrated safety profile, is the first fixed-dose artemisinin-based combination therapy (ACT) brought to market
2. Access- Improving affordability and availability of medicines:
    - Novartis Malaria Initiative continues to spearhead programs to expand access.
3. Capacity building-Empowering patients and healthcare professionals:
    - Beyond treatment, the Novartis Malaria Initiative offers best practice sharing workshops, training materials, logistics management and others types of technical expertise to empower local populations to care for their health. All these elements are critical to ensure long-term health impact.

4. Research & Development -Leading the path to malaria elimination: Novartis is applying his expertise in drug discovery to the next generation of malaria treatments, also exploring innovative interventions to decrease disease transmission.

The feeling that I had by seeing all the artilleries that a big company pharmaceutical as Novartis is spirit to implement in the fight against Malaria and in front of the complexity of the real situation of Malaria that we have experimented throughout our daily work on ground in the malaria endemic Countries, I think I should be proud of. Not everyone has the chance to work for a company that literally saves lives of the people who suffer from a disease that we particularly experimented, and I think this is an opportunity offered to me during my twelve months of Fellow in Novartis.

I took a firm commitment to bring the maximum of what I can in this noble spot of Novartis so that one day the population of these endemic countries do not die any more from the malaria.

Especially, as a Clinical Research Fellow, by finding the answer to my question of the beginning of my training, I also took the firm resolution to take advantage at most opportunities which offers me this new work location to reach the objectives at the end of my training course.

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Up and Coming Conferences & Meetings

IX International Giardia and Cryptosporidium Conference

January 30-February 3, 2012
Wellington, New Zealand
Contact: www.cryptogiardia2012.org

The aim of the IGCC is to promote dialogue and facilitate the exchange of information and ideas between groups involved in research and practice pertaining to these parasites. The IGCCs are international events in which the research, voice and friendship of all the delegates matter and genuine networking is encouraged.

ASTMH 61st Annual Meeting

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

- *Call for Symposia*
  Proposal submission deadline: March 6
  Download the Call for Symposia.
  Submit your symposium proposal here beginning February 1.

- *Call for Abstracts*
  Submission deadline: May 1
  The Call for Abstracts will be available in mid-March. The abstract submission site will open in mid-March. The abstract submission deadline is May 1.

- *Travel Award Applications*
  Application deadline: April 3
  The travel award application guidelines will be available in late February. The travel award application deadline is April 3.

Conference Reporting

We would like to encourage each of the fellows to write up and submit a report and a photo if possible, on each conference they attend. 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

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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

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/

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