TDR Newsletter: Issue 2

October 2011

Dear Fellow

Welcome to the 2nd issue of the TDR website newsletter.

This month's newsletter features:

- Fellows' contributions from:
  - Abdullahi Ahmad
  - Aurel Allabi
  - Mahamadou Aly Thera
  - Dawit Ejigu
  - Zewdu Hurissa
  - Celine Mandara
- Up and coming Conferences and Meetings
- Details of the Professional Membership Scheme.
- The Global Health Trials website's 'e-Learning' and 'Discussions' areas.

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.

Best wishes

Mary

Training & Professional Development Coordinator

Fellows' Contributions

WHO/TDR Career Development Fellowship: The Fellow's Challenges

Report by: ABDULLAHI AHMAD
Home institution: Epidemiology unit, Ministry of Health, Kaduna State, Nigeria.

In the cause of acquiring the unique and specialised training offered by the TDR Clinical R&D Career Development Fellowship (CDF) Programme, the CDF fellows often encounter some challenges at various stages of their training. This short article, which briefly highlights some of the challenges faced by the fellows before, during and after their fellowship training, is being written from my experience as a current CDF fellow as well as from shared experiences of other past and present fellows.

Challenges encountered by the aspiring CDF fellow could be present as early as when the fellow decides to apply for the programme. The process of promptly obtaining an endorsement of the fellow's application and securing a guaranteed leave of absence from his/her home institution, which are requirements in the CDF application process, could turn out to be difficult tasks in some home institutions. This could be attributed to the fact that until recently, most health institutions in Disease Endemic Countries (DECs) tended to attach less priority to research and therefore do not readily see the need to support their staff in acquiring specialised trainings in research fields. It is therefore an important task for fellows returning to such institutions, upon completion of their fellowship, to use their acquired knowledge and skills in demonstrating how clinical research could be used as a valuable tool in generating scientific evidence capable of informing new health policies and decisions, innovating new health interventions and in building the capacity of health institutions in general.

Upon resumption within the host training institution, the fellow is soon faced with the challenge of having to successfully integrate within his/her new learning environment which often requires, amongst other things, understanding new policies, guidelines and procedures specific to the pharmaceutical industry. While this is very essential for the fellow's effective learning experience as well his/her ability to make valuable contributions to his host institution during his/her fellowship, it could be quite a demanding task especially when the fellow is not having any prior pharmaceutical industry or clinical research experience . Overcoming this challenge largely depends on how pro-active the fellow remains upon resumption and also on the host institution's ability to effectively and fully orientate the in-coming fellow.

Following successful completion of his/her training, the fellow is expected to make positive contributions to clinical research in his/her home country by joining and possibly leading clinical research groups. However, because clinical research is a relatively under explored field in most DECs, the fellow is bound to face the challenge of professional isolation. Added to this, the scarcity of resources for research in most DECs could make it difficult for the returning fellow to set up functional research units with ease. This challenge could even be more difficult to overcome for fellows returning to institutions that are not clinical research oriented. In order to overcome this challenge, the returning fellows should be proactive in making their acquired specialized knowledge and skills count by affiliating themselves with institutions that are actively engaged in research and participating in research activities as much as possible.

Continued interactions between fellows of the CDF programme as well as with other scientists met during the fellowship programme could greatly aid the fellow in overcoming the challenge of professional isolation and also serve as a good avenue for establishing future research collaborations.

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TDR Fellowship Placement: 6 month progress overview

Report by: AUREL ALLABI
Home institution: Faculte des Sciences de la Santé, Université d'Abomey-Calavi, Cotonou, Benin

In the past eight years, TDR has awarded a Clinical Research Career Development Fellowships (CDF), to nine researchers from Africa, to be trained by GlaxoSmithKline Biologicals. These past recipients are now making significant contributions to clinical research on infectious diseases in their countries and regions; their home institutions have been able to leverage their expertise to establish clinical research centre. In view of the success of this program, TDR received a grant from the Bill and Melinda Gates Foundation, to scale it up to 30-35 individuals to be trained in a three year period. In this context, I was selected and placed in Novartis Pharma as Fellow (First Round).

Six months after the starting of this fellowship, there is a need to report the progress. This document gives a synopsis of the progress made in the first six months on Clinical Research CDF program.

Pace-setting: first weeks experience

Within the first few days of my arrival at Novartis Pharma in Basel, all the essential set up needed for my training were such as obtaining access badge was done by Dr Anne Claire Marrast and other members of the team. All Novartis administrative requirements and other administrative matters were done.

Introduction and one-to-one were organized with various members of the staff during the first three months. Familiarization with the company's environment (values and work ethics, organization, organograms, procedures, Novartis IT environment etc...) was done. Complete training required to access databases (CREDI training) was done and registration was followed.

Goals and Objectives were reviewed periodically with my supervisor, Dr. Anne Claire Marrast and me. Thereafter, the training program has progressed according to the fellowship objective plan and activities on-going, and has run smoothly.

P*rocess of training*

Interest and Interaction with supervisor and team members as well as external experts in the field:
Actor not a spectator; Training on-line; Training in class; Participation and contribution to all discussions (if no conflicting meeting); Attending internal meetings; Attending external meetings; and Specific activities.

Workshops & seminars included:

- Drug development at Novartis: module 1 "Appreciation"
- Drug development at Novartis: module 2 "Understanding"
- Drug development at Novartis: module 3- "The Novartis Café"
  Web based GCP Training (9 modules): overview of ICH GCP: Recruitment & Selection; informed consent; documentation requirements; investigational products; data collection and reporting; safety reporting; sponsor monitoring and audits and regulatory authorities
- PK-PD trainings
- Internal standard operations procedures related to Pharmacovigilance:
- Internal standard operations procedures related to Clinical trials

Congresses & meetings

- African Network for Drugs and Diagnostics Innovation (ANDI) meeting, 11-13 October 2010
- 10th ISOP Annual Meeting of International Society of Pharmacovigilance Accra, Ghana-3rd-6th Nov. 2010

- Clinical Trial Safety Training Course
- Risk Management Plan Training course
- Modeling and Simulation Applications to Healthcare in Africa Workshop, 20-21 January 2011, Cape Town, South Africa. I was sponsored by University of Cape Town, South Africa.

Specific activities

Activity 1: Riamet (Coartem) 20mg/120mg Dispersible Tablets-Response to the New Zealand Medicines and Medical Services Safety Authority dated 01 December 2009
Activity 2: Response to FDA Request for Information related to Lamprene
Activity 3: Contribution to PDCO Request
Activity 4: Participation to draft synopsis, CTPSL drafting, Protocol drafting
Activity 5: EU submission
Activity 6: B2401study: Preparatory activities including protocol finalization
Activity 7: B2303: Operational activities set-up, design of study
Activity 8: Pre-study contacts and potential investigators centers visits
Activities 9: Regular review of scientific literature
Activities 10: Monitoring activities related to B2401 (Meetings with Investigators/CRO, Update of the study etc...)
Activities 11: Pharmacovigilance activities related to B2401 study (Safety data reviews, SAEs checking etc.)
Activities 12: Modeling and Simulation activities
Activities 13: Attend Global Program Team meetings and provide input
Activities 14: Attend Medico-Market meetings and provide input

Scientific communication

1. Quique Bassat, Aurel Allabi, Marc Cousin, Srivicha Krudsood. Efficacy of artemether-lumefantrine (AL) in the treatment of blood stages of Plasmodium vivax (P vivax). ASTMH Poster November 2010.
2. Marouf Jules Alao, Aurel C. Allabi, Blaise Ayivi. Uncomplicated malaria in infants below 6 months of age and treated with Artemether Lumefantrine: retrospective analysis in HOMEL hospital, Cotonou, BENIN. ASTMH Poster November 2011.

Overall appraisal

During this one year of fellowship, I received systemic training, participated in the conduct of clinical projects and contributed to the team's work in clinical development. I participated to activities related to planning, execution and reporting of clinical trials or other activities. I participated to the development of trial related documents (e.g. protocols, case report forms, data analysis plan, publications etc.). I participated to the development of presentation material for trial-related advisory boards (e.g. Franchise board, etc.).

I got more familiar with medical marketing activities (promotional material, symposium, advocacy, Congress planning etc...) by attending medico-marketing meetings and participating. I interacted with internal (Clinical team, Global program team, Franchise staff, Novartis malaria staff in Africa and other line functions) and external (e.g., Health Authorities, key opinion leaders etc...) partners. I contributed to the development of clinical sections of regulatory documents such as responses to Health Authorities questions, submission documents, briefing books, safety updates.

Finally, this training permits me to be more knowledgeable in the area of Malaria and particularly in the area of antimalarials developments, pharmacokinetic and pharmacodynamic of antimalarials, developing practical knowledge/skills in clinical studies. Training on Ethical and regulatory requirements of conducting clinical trials were also followed.

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My Progress So Far

Reported by: CELINE ISAACK MANDARA
Home institution: National Institute for Medical Research, Department of Epidemiology, Tanga, Tanzania

I am a Medical doctor qualified from Tumaini University of Kilimanjaro Christian Medical College, Moshi, Tanzania and also I have done my masters in clinical research at the same University.

Currently I am working with the National Institute for Medical Research and I am based in Tanga Centre. I have joined this Institute since July 2004 and we are dealing with medical research including Malaria, HIV/AIDS, TB and non-communicable diseases.

Once I saw this call on the internet, I was so excited and thought this will really broaden my research capacity and be able to alleviate diseases that have troubled us for quite some time. I was so glad to hear that I have been among the rest to be nominated for the course.

My fellowship was to start in April 2011 but up to this moment I have not yet started due to some obstacles. I had a lot of communications with the administrators of the course and promise to start by October and now the month is almost over.

Luckily I managed to contact Flora Rutahakana who has been of great help in making sure that all the steps are known to me and in case I have any queries I was free to ask her and she gave me the clues. So far I am expecting a LoA which is on the way by DHL to my home Institution.

As for now I have done a refresher course on GCP and obtained a certificate and finishing up a field work on efficacy study of Malaria in children from 6-59 months.

So I have been waiting for quite a long time to start the training but sooner or later I will so hopefully I will have more to contribute in the coming reports.

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Harnessing TDR/Industrial fellowship

Reported by: DAWIT EJIGU
Home institution: Faculty of Medicine, Addis-Ababa, Ethiopia

Being the first TDR/GSK fellow on Tuberculosis (TB) vaccine development, I was placed in GSK-Bio Rixensart, Belgium from 2007 to 2008. The hands-on experience in GSK- Bio was excellent. The working environment is well organized and the quality standards in the form of SOPs, guidelines, policies and so on are so efficient. Once one acquaints himself/herself with the standards and the environment in the company, the projects start to roll smoothly. No doubt experience in an industrial set-up such as GSK-Bio will give more than the basic requirement for running clinical trials. However, one needs to be curious to know if the fellows in such programs can easily fit in the leadership positions for product development in Africa and other developing countries. This is worth considering since the aim of such programs is also to strengthen Research and Development (R&D) capacity in developing countries.

Numerous challenges are characteristics of the R&D environment in developing countries in Africa and elsewhere. These challenges may not come out clearly during the fellowship training probably owing to the well-established set up in industries which more or less addresses the issues. In the absence of an industrial Sponsor, clinical trials are usually conducted in consortia using public funds. In such circumstances challenges such as conflict of interest, collective decision making, ownership, harmonization of data collection, capacity building,

issues related to ethics/regulatory reviews and others become the main hurdles hampering implementation of R&D projects. Therefore, TDR fellows must be well equipped not only with the necessary experiences to implement trials in a convenient environment but also with the knowhow of tackling untamed challenges which are part of the R&D atmosphere in developing countries. This will give the fellows a better chance of fitting in the R&D endeavors of developing countries. The fellowship trainings also need to be more flexible to provide additional meaningful exposure to the fellows on these aspects.

In my opinion, experience sharing/the learning process should not be confined to the period of the fellowship training. Experiences of TDR fellows or other colleagues in various institutes and in multifarious fields should rather form a common pool of knowledge/experience which can be deployed for the betterment of R&D activities in Africa and elsewhere. In order to do so we need functional network and collaborations within TDR fellows and outside the TDR fellowship circle. One possible means of forging such functional collaboration within this TDR fellows group could be embracing the TDR fellows in a consortium and securing a research grant. Such a consortium needs to aim at contributing towards the R&D endeavors and harnessing the conspicuous experiences of the TDR fellows. I believe TDR is well positioned to coordinate the application for such grants owing to its networks, vast experiences in such matters and as pioneer of this fellowship program. This consortium may eventually host the future fellows as part of their training and help them get the kind of experience that will be required to enable them fit in the R&D environment of Africa and beyond.

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What I Learned From My Fellowship

Reported by: Mahamadou Aly Thera
Home institution: Université du Mali, Faculté de Medecine, Bamako, Mali

At the end of my fellowship back in 2000, I was interviewed by TDR News [http://apps.who.int/tdr/publications/tdrnews/pdf/TDRnews-issue-64.pdf]. Before writing this paragraph I took a look at what were my feelings 11 years ago. I realised how unique this kind of fellowship was and how perfectly it embodied the concept of Public Private Partnership, particularly in the field of capacity development. It was for me the initial steps of a wonderful journey which took our teams to major achievements. The fellowship definitively shaped my approach to clinical research and my future in this field.

I remember that the initials days were made up of a succession of surprises. It was a totally new professional environment I had to adapt to. Around me, everybody was struggling with time, deadlines to meet, milestones to achieve and numerous meetings to attend. Luckily, I was efficiently mentored by an accomplished Clinical Study manager (CSM) and a bright Clinical Development Manager (CDM).

I had to remain aware that despite the training nature of my presence I was working on real life issues. I learned precious lessons at the interface of the clinical trial-focused CSMs point of view on clinical research and the more comprehensive medically oriented approaches of CDMs. I was exposed to the know-how of a leading pharmaceutical company where the credo was “We are the best and we must deliver only the best of products”. Immediately after the fellowship I was ready for the malaria vaccine trials challenge in Mali. My home institution was also preparing to undertake malaria vaccine trials. I was therefore lucky to return home and start working immediately in a research environment prepared to address the challenge.

Given the academic nature of my home institution, I needed the experience and know-how gained during the fellowship to have an accompanying academic grade so that it would have contributed to my academic career. In parallel with the fellowship, I followed then a Master degree course on Biostatistics and Clinical Research.

There are two lessons I believe useful to further improve the fellowship program. The ‘learning by doing’ approach brings incredible practical experience and know-how. A theoretical basis on clinical research may help

make it stronger. Now that the fellowship is expanded, it might be worth considering a degree conferring scheme for those African researchers based at academic institutions and the classical non-degree learning by doing approach for all others.

By nature the industry work is fractionated and team work is a key component for success. Fellows need a favorable environment after their training to nurture, grow and express all their potential. Another approach, quite challenging to implement, but worth being considered is the training of small teams from the same research institutions. This could translate into the recruiting of three to four researchers from the same institution with the following profiles: clinical investigator, clinical coordinator, clinical lab manager, biostatistics and data management. Such an approach would be more useful in the case of home institutions with clear vision and concrete plans to engage into clinical development of products.

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Fellowship and Travel Challenges

Reported by: ZEWDU HURISSA DADI
Home institution: University of Gondar, Leishmaniais Research and Treatment Centre, Gondar, Ethiopia

Dear Fellows

I just want to share with you all what has actually happened to me with my travel after I have been awarded the WHO/TDR fellowship with GSK Biologicals in Belgium. I was first notified of the fellowship award in July 2010 with probable date of starting the training in September 2010. However, I was communicated from GSK Biologicals that I have to be in Belgium by 03 Jan 2011 and start my visa process by the earliest time possible. It was at this point that I told my boss exactly when I will leave office so that a replacement to my position was made for a year in Jan 2011. My initial date of visa application was in November 2010 but has waited until the first week of March 2011 to have the first response from the embassy. The outcome was 'refusal' stating either I have to submit a work permit, or document that shows registration as a regular student at the Government University (in our case it is the Institute of Tropical Medicine) since GSK in private company.

This time, one of my colleagues with whom we applied during the same period from Nigeria received his visa joining GSK Biologicals. After communicating with TDR and GSK about the outcome of visa, it was decided to re-apply with some more documents that clarify about the fellowship training scheme and I therefore made my second visa application by the end of March 2010 and I am still waiting for the outcome.

The challenge was me being out of work since my position has been replaced until end of the year 2011. In fact, this was probably one of the most difficult times in my career. I know, some of the fellows have similar experience but I think this is probably the worst case scenario. As you are all aware, it isn't possible to influence the embassy at individual level but can only be done through the sponsor of the training. WHO/TDR was therefore actively engaged to facilitate the process but didn't come easy.

As a solution, it is important that TDR as well as the host institution or pharmaceutical company make the necessary communication about the exact date when the fellow should arrive or depart from his/her home country. Communication should also involve the fellows institution at all levels. It is also important to outline other possible alternatives as an option in case one fails with regard to difficulty of receiving a visa for the destined country. Mine would be a wonderful example when one might be out of work for a year; months which I really believe plan B should be implemented or otherwise would create problems with the fellow institution as well as frustration to the fellow. I also believe WHO/TDR should be able to support the fellow in such unprecedented circumstances both with financial matters and trying its best in facilitating looking for alternatives and implementation of it.

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Up and Coming Conferences & Meetings

The 7th World Congress of the World Society for Pediatric Infectious Disease

Melbourne, Australia
15th – 19th November 2011

WSPID 2011, the 7th World Congress of the World Society for Pediatric Infectious Diseases, provides thousands of specialists in the field a world forum for sharing the latest knowledge and receiving updates on the treatment and prevention of pediatric infectious diseases.

Organized by the World Society for Pediatric Infectious Diseases (WSPID), this biennial congress is the largest gathering of paediatricians in the field of infectious diseases. Participants will receive a fully comprehensive scientific program featuring internationally renowned experts, sponsored and plenary symposia, free papers, poster sessions, and networking opportunities.

For further information please visit:
http://www2.kenes.com/wspid/Pages/home.aspx

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American Society of Tropical Medicine and Hygiene 60th Annual Meeting

Philadelphia, USA
4th – 8th December 2011

The ASTMH 60th annual meeting will be held in Philadelphia this year.

Global Health Trials director Dr Trudie Lang is delighted to be chairing a symposium at the meeting. The ASTMH aims at promoting global health through preventing and controlling disease, and the global health symposium chaired by Trudie will be entitled 'Harnessing the Web to Support and Enhance Research into Global Health'. The symposium will include five talks in diverse areas surrounding this topic. We will post slide sets of the presentations and, if possible, audio clips on the GHT website after the symposium.

The draft schedule and further information can be found at:
http://www.astmh.org/Schedule_at_a_Glance.htm

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TDR CDF Annual Meeting

Geneva, Switzerland
25th - 27th January 2012

The annual TDR CDF meeting will take place in Geneva from the 25th to the 27th of Jan. 2012.

Further information will be posted on the TDR/GHT website once it becomes available.

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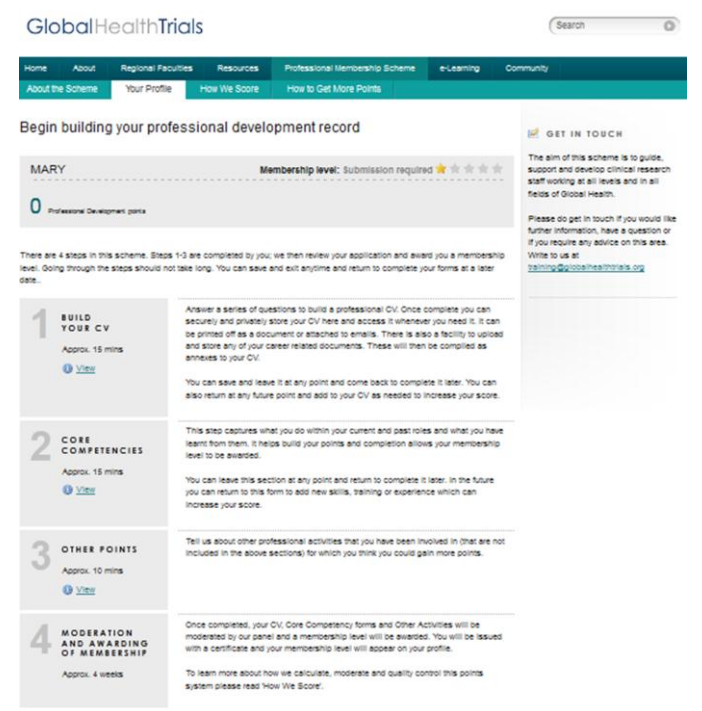
Professional Membership Scheme

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 only 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 for you, which can be used for job applications, is stored in your profile and can be updated regularly.

When you have completed all of the relevant sections, 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. To find out about how we score see: https://ght.globalhealthehub.org/cpd/scoring/.

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 and that the report from this review is submitted to the scheme. This is so the user involves their employer in the professional development scheme in order to gain the employer's support in their 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

e-Learning Centre

The Global Health Trial website's free, certified e-learning modules are designed to be used as quick 'how-to' training sessions on designing, planning, operationalising and reporting clinical studies. They can also be used as a means of gaining points towards the Professional Membership Scheme. The courses should take about 45 minutes to complete and a certificate is issued on completion. Every course is written to be globally applicable, so for all diseases and all regions. They are also highly pragmatic and adaptable. Each course is carefully researched to provide up to date and high quality material that is peer reviewed and regularly reviewed and updated.

Request for help with e-Learning Course Translations

To make the materials more widely available we would like to translate the courses into other languages. Currently we have two available in French with another three going up by the end of November.

We are asking collaborators and members who are fluent in a widely applicable language e.g. French, Spanish, etc. to help translate some of the courses for us. If you have a relevant language and would like to translate a course for us, we would be very grateful for your help. If you are interested please email me at: mary@globalhealthtrials.org.

These courses are built through the support and partnership of the Bill and Melinda Gates Foundation, the World-Wide Antimalarial Resistance Network (www.wwarn.org) and The East African Consortium for Clinical Research (www.eaccr.org).

To learn more, visit the website at: http://ght.globalhealthehub.org/elearning/

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Groups' Area

The Global Health Trials website 'Groups' area contains the wide variety of the different discussions that take place on the site. Each discussion is broken down into relevant topics under that discussion heading. Anyone can start a topic or respond to a topic started by someone else. Discussions include areas such as:

- Research Ethics
- Informed Consent & Community Engagement
- Training and Career Development
- Data Management & Statistics

To find out more visit: https://ght.globalhealthehub.org/community/groups/

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