GlobalHealthTrials.org

Research, Guidance, Training, Professional Development & Resources

Introducing **Global Health Trials -** your online specialist professional network

Part of:

The Global Health Network.org

supporting research through sharing methods and knowledge

TRIALS ARE HARD WORK!

Protocol

Case record forms

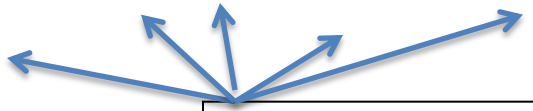
Data base

Regulatory submissions

QA

Analysis and report

Clinical conduct



Labs etc.

GlobalHealthTrials.org

Research, Guidance, Training, Professional Development & Resources

Who we are….

A free, open access collaborative programme to support clinical trials in developing countries.

Est. May 2010

The Aim….

To establish a mechanism for everyone working on clinical trials to have access to guidance, tools, resources, training – and each other

Why is this needed and how does it work?

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- Few trial steps, processes, methods or issues are truly specific to one disease
- There are initiatives providing clinical trial training but access can be problematic in resource-poor settings
- Need for more disease management trials to address local questions
- Global Health Trials works by knowledge and methods sharing across disease areas, staff roles and geographic regions

Features of Global Health Trials

- Member Profile and Connect Together system
- Discussion forums and blogs
- Guidance articles, tools and resources
- Regional faculties
- E-learning
- Professional membership scheme
- Bookmarks, events and opportunities

Why we think it is working

- All regions, all staff roles – ALL DISEASE AREAS
- Clear, clean and professional-looking space designed around the concept of encouraging a community
- Neutral, democratic – not belonging or located in any one institution; modeled on the Cochrane Group

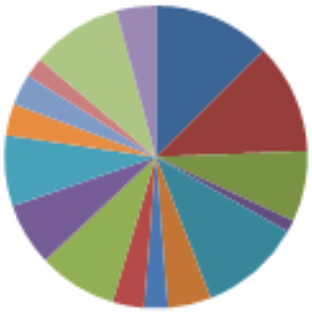
Website statistics as of 24th January 2013

45,878 people visited this site

- Visits: 92,714
- Unique Visitors: 45,878
- Pageviews: 520,540
- Pages / Visit: 5.61
- Avg. Visit Duration: 00:06:29

>110 developing countries visiting

Job roles of members



- Clinical Scientist
- Development
- Ethics
- Medical Officer
- Public Health
- Statistician
- Trial Coordinator
- Doctor
- Funding/development bodies
- Nurse
- Regulatroy Affairs/Governance
- Data Manager / IT
- Epidemiologist
- Lab
- Pharmacology
- Research Manager

GlobalHealthTrials

Search

Home | About | Get Involved | Community | Regional Faculties | Resources | Downloadable Tools and Templates | e-Learning Centre | Professional Membership | Noticeboard

The online community for clinical trials in global health for guidance, tools, resources, training and professional development

STUDENT | RESEARCH NURSE | LABORATORY STAFF | RESEARCH COORDINATOR | INVESTIGATOR

EDUCATION & TRAINING

eLearning Modules

CONTRIBUTE

Submit a guidance article
Start a discussion
Write a blog

GLOBAL RESEARCH NURSES

A collaborative professional network of international research nurses, funded by the Burdett Trust for Nursing

LATEST MEMBERS

ttsawayo
Jan. 24, 2013

yulinnkhine
Jan. 24, 2013

Dierickx
Jan. 24, 2013

DJOUMA NEMBOT Fabrice
Jan. 24, 2013

Mike Bitok
Jan. 24, 2013

Groups

GlobalHealthTrials.org

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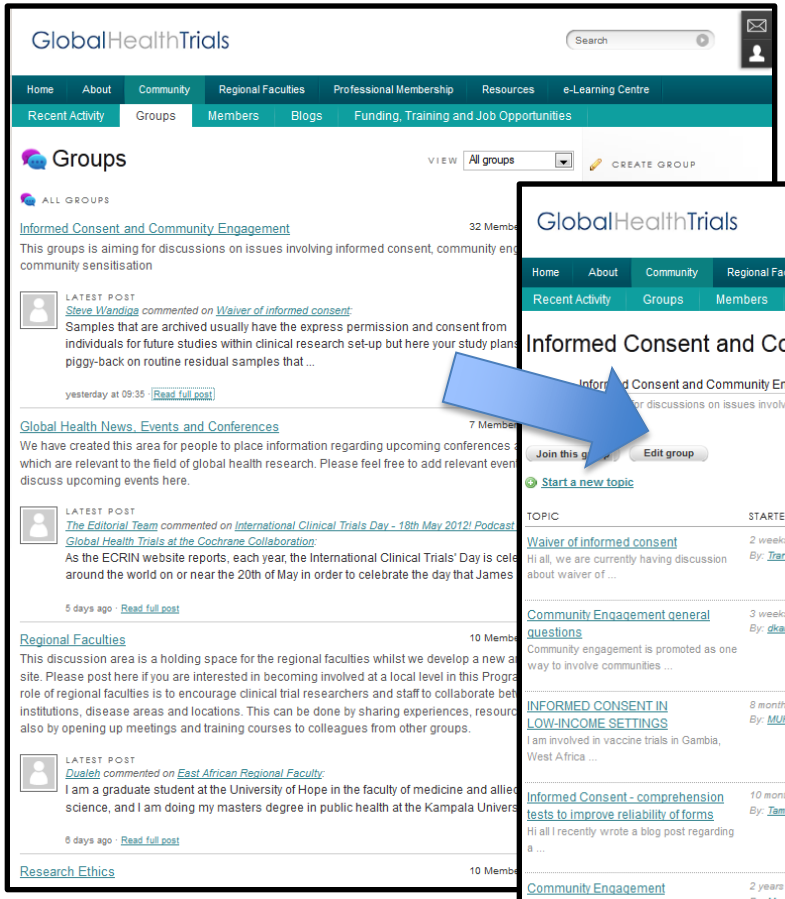
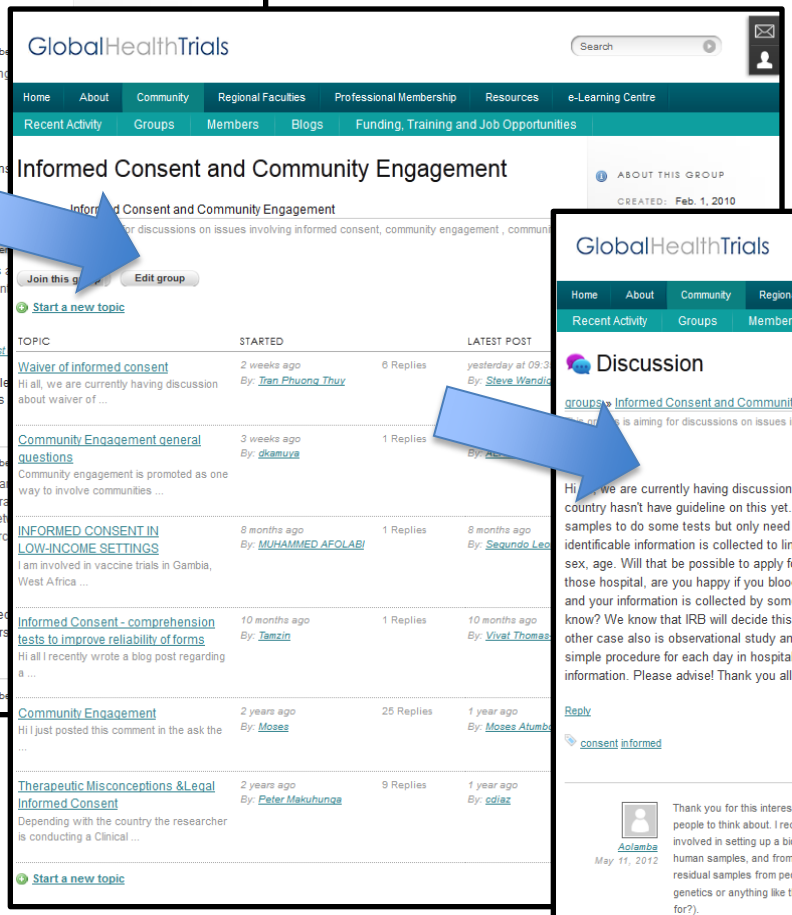
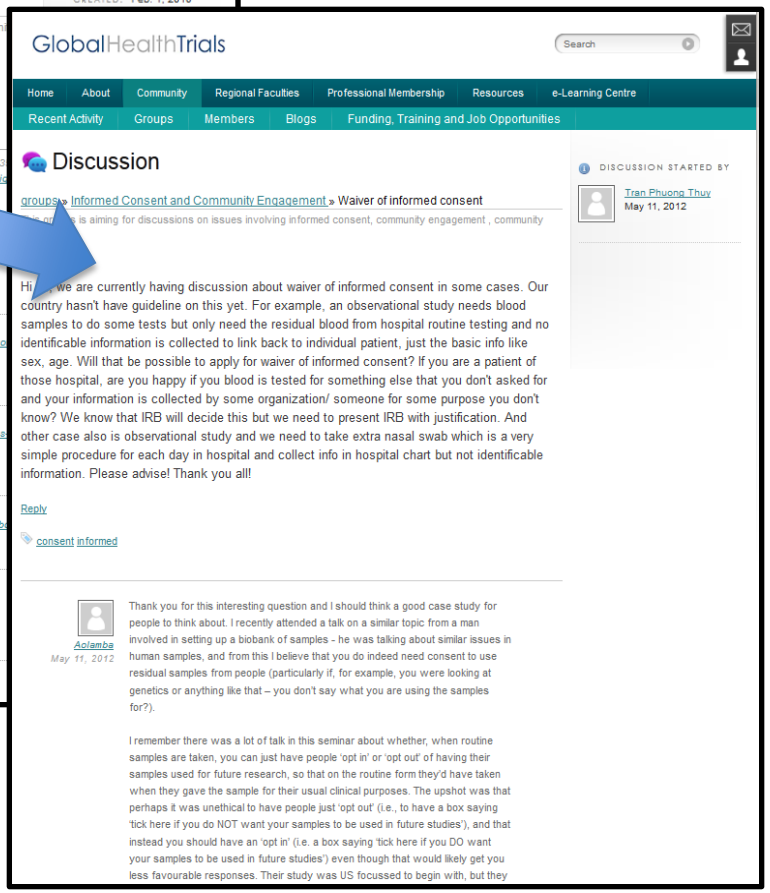


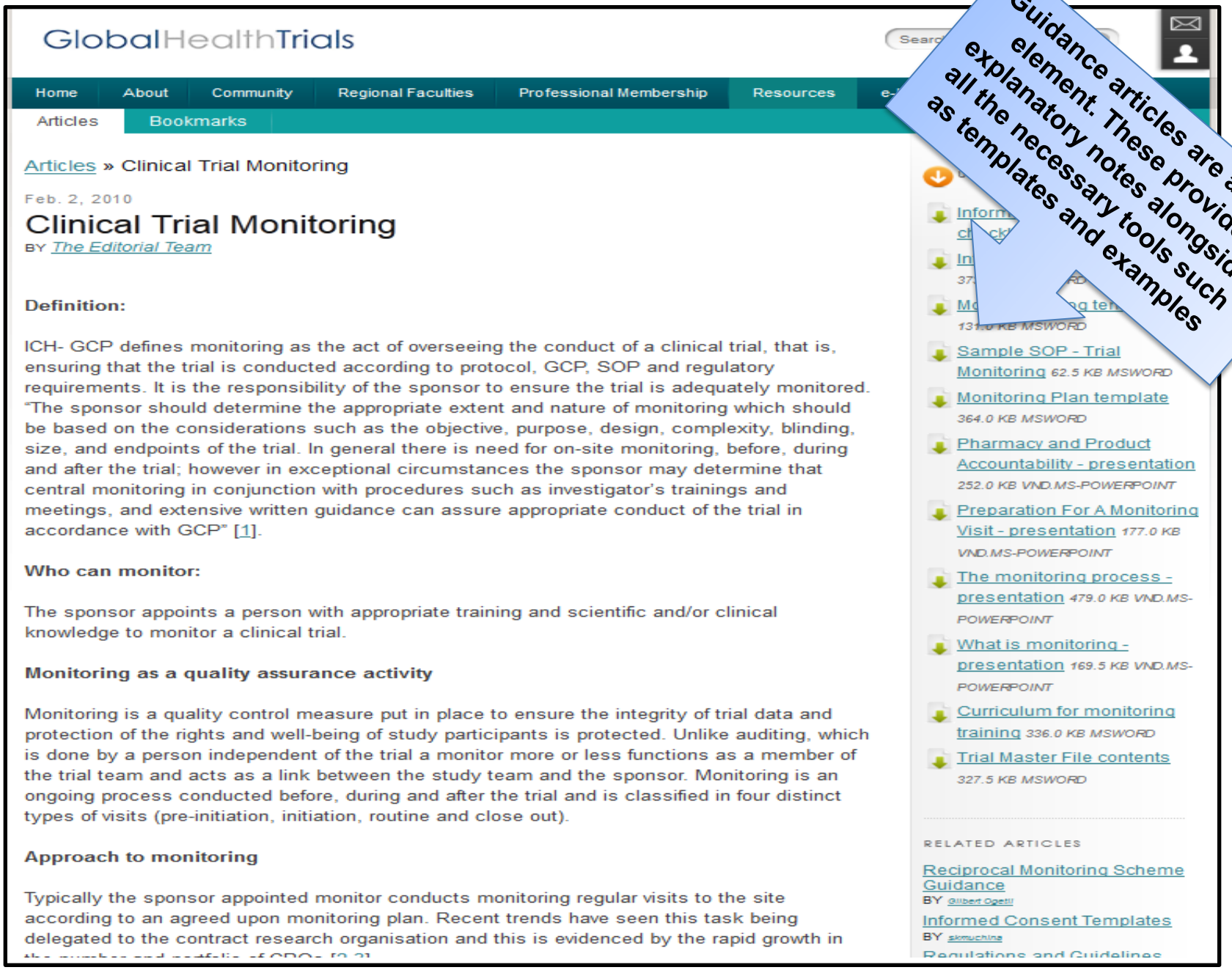
Topics



Discussion



Community Discussion Groups


GlobalHealthTrials
Home
About
Community
Regional Faculties
Professional Membership
Resources
Articles
Bookmarks
Articles » Clinical Trial Monitoring
Feb. 2, 2010
Clinical Trial Monitoring
BY The Editorial Team
Definition:
ICH- GCP defines monitoring as the act of overseeing the conduct of a clinical trial, that is, ensuring that the trial is conducted according to protocol, GCP, SOP and regulatory requirements. It is the responsibility of the sponsor to ensure the trial is adequately monitored. "The sponsor should determine the appropriate extent and nature of monitoring which should be based on the considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is need for on-site monitoring, before, during and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigator's trainings and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP" [1].
Who can monitor:
The sponsor appoints a person with appropriate training and scientific and/or clinical knowledge to monitor a clinical trial.
Monitoring as a quality assurance activity
Monitoring is a quality control measure put in place to ensure the integrity of trial data and protection of the rights and well-being of study participants is protected. Unlike auditing, which is done by a person independent of the trial a monitor more or less functions as a member of the trial team and acts as a link between the study team and the sponsor. Monitoring is an ongoing process conducted before, during and after the trial and is classified in four distinct types of visits (pre-initiation, initiation, routine and close out).
Approach to monitoring
Typically the sponsor appointed monitor conducts monitoring regular visits to the site according to an agreed upon monitoring plan. Recent trends have seen this task being delegated to the contract research organisation and this is evidenced by the rapid growth in
Sample SOP - Trial Monitoring 62.5 KB MSWORD
Monitoring Plan template 364.0 KB MSWORD
Pharmacy and Product Accountability - presentation 252.0 KB VND.MS-POWERPOINT
Preparation For A Monitoring Visit - presentation 177.0 KB VND.MS-POWERPOINT
The monitoring process - presentation 479.0 KB VND.MS-POWERPOINT
What is monitoring - presentation 169.5 KB VND.MS-POWERPOINT
Curriculum for monitoring training 336.0 KB MSWORD
Trial Master File contents 327.5 KB MSWORD
RELATED ARTICLES
Reciprocal Monitoring Scheme Guidance
BY Gilbert Ogetii
Informed Consent Templates
BY skmuchina
Guidance articles are a core element. These provide explanatory notes alongside all the necessary tools such as templates and examples

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Home | About | Get Involved | Community | Regional Faculties | Resources | Downloadable Tools and Templates | e-Learning Centre | Professional Membership

Downloadable Tools and Templates

This is a page showing *HOW TO* ...

These resources are all taken from the e-learning site on Global Health Network; for ease of access they h
free to use and can be adapted for use in your studies.

This page provides links to tools and templates and also articles explaining the research process. You can
information in the e-Learning Resources section of this website.

If you have examples to add, please get in touch.

Adverse experiences This is a form to use or adapt, for parents and guardians of a child taking part in a study, to record a
study.

Concept Protocol This document can be used by a group, to develop a protocol. It provides a format to record discussions
to stakeholders.

Information Sheet and Consent Form for parent/ guardian of achild taking part in a study. This is an example o
guardian of a child taking part in a study.

Informed Consent Templates On this link are templates for Patient Information Sheets and Consent Forms for several types

Generic SOP This template demonstrates how you might document Standard Operating Proceures when setting up a study

Study CRF Case Record Form; An example of a Case Record Form, used for data collection.

CRF Tracking A sample Tracking Form, used as a record showing that all data have been correctly recorded.

Study protocol An example of how a study protocol can be constructed.

TRAINING

Explaining the research process:

Safety reporting

What is a clinical trial

Global Health Network

Supporting research in Global Health by sharing knowledge and methods

Concept Protocol

This is a seed document for a concept Protocol – this is usually used to begin discussion on a proposed protocol to introduce it to collaborators, sponsors and funders.

Study Title			
Sponsor		Investigators	
Period & Duration		Site(s) - Location	
ves			
Population & sample size		Estimated Budget & funding source	
Potential risks			
Potential benefits			
State strategic implications of the research			
Brief description			

e-Learning Centre

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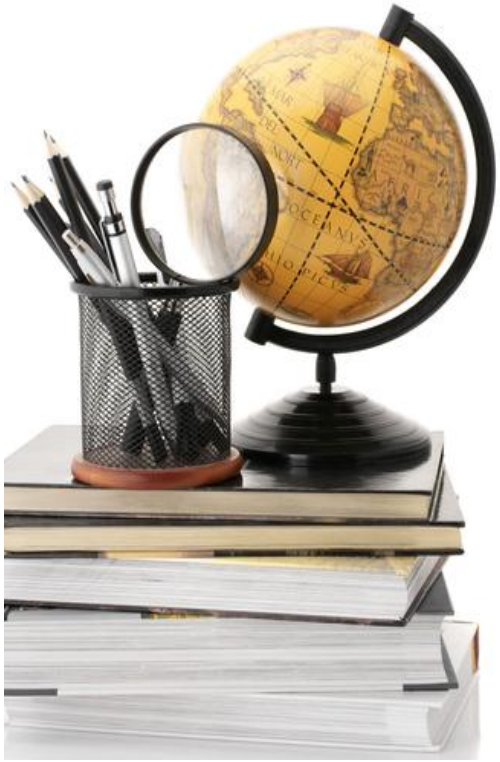
- Cross cutting ‘how-to’ skills training for all roles of staff, all disease areas and all regions
- Simple concept of taking good face to face courses and adapting them into e-learning material
- Sharing training material



Our philosophy is quite simple….

- Take these great training resources you have all developed and share them by creating e-learning courses!

e-Learning Short Courses

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Home | About | Community | Regional Faculties | Professional Membership | Resources | e-Learning Centre

Introduction To Clinical Research

Save & Exit ✕

DOWNLOAD

18%

Why Do We Perform Clinical Research (a)?

Clinical research is undertaken to collect data on usual and unusual events, conditions, and population groups to allow us to:

- observe treatment and health management practices so that we learn how they can be improved upon
- test interventions to develop new drugs and vaccines and to find new uses for existing therapies
- learn more about specific diseases so we can better understand how to manage, treat and prevent them

Ultimately the aim is to better understand how, with clinical research, we can improve health outcomes.

During the 20th century the huge improvements seen in global health were mainly a result of the knowledge gained through clinical research, examples include:

- 1920s: research found that improving childrens' nutrition helped combat rickets and other childhood diseases.
- 1950s: epidemiological research proved that cigarette smoking caused lung cancer.
- 1980s: trials proved that giving folic acid to high-risk women resulted in a reduction of babies born wi
  bifida.
- 1990s: clinical trials showed that the progress of AIDS could be delayed by combining antiretroviral drugs.

◀ How Does Clinical Research Differ From Standard Care?

Why Do We Perform Clinical Research (b)? ▶

WWARN

EACCR

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Hereby Certifies that

Innocent Mbuagbaw

has completed the e-learning course

INTRODUCTION TO CLINICAL RESEARCH

with a score of

100%

on

16/08/2011

WWARN

EACCR

The Global Health Trials e-Learning Centre
globalhealthtrials.org/elearning

GlobalHealthTrials.org

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Home | About | Community | Regional Faculties | Professional Membership | Resources | e-Learning Centre

e-Learning Short Courses | e-Seminars | Other e-Learning Links | e-Learning Resource Library

Global Health Trials e-Seminars

Below are a series of e-seminars on topics related to conducting clinical trials in the field of Global Health. They are MP3 (audio) and MP4 (video) files. You will need a media player to play them. If you do not have a media player installed try Quicktime, which is free and runs on PCs and Macs.

An Introduction to Clinical Trials

George Warimwe, the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Kilifi, Kenya.
Audio Version
Video Version (requires high-speed internet)

The Story of ICH-GCP: An introduction for investigators and site staff

Dr Roma Chilengi, Head of Clinical Trials at the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Kilifi, Kenya.
Audio Version
Video Version (requires high-speed internet)

Introduction to Research Ethics

Dr Roma Chilengi, Head of Clinical Trials at the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Kilifi, Kenya.
Audio Version
Video Version (requires high-speed internet)

Clinical Trial Protocol Development

Dr Phaik Yeong Cheah, Head of Clinical Trials at the Mahidol-Oxford Research Unit in Bangkok, Thailand.
Audio Version
Video Version (requires high-speed internet)

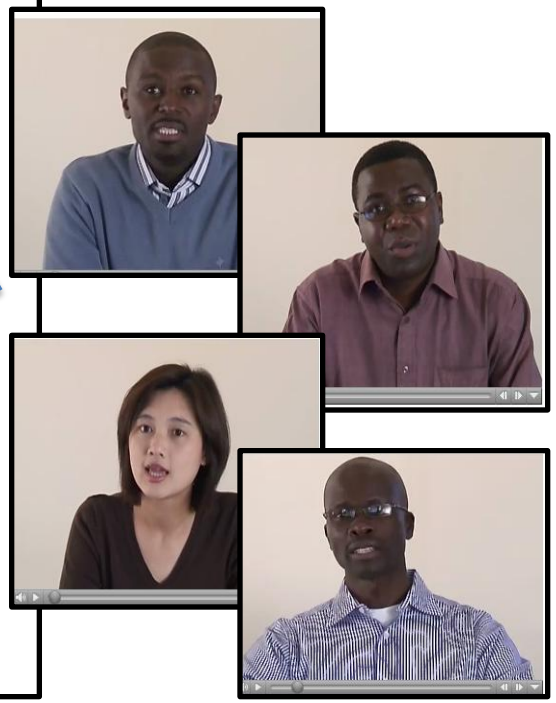
Data Safety Monitoring Boards: Their Place and Role in Trials

Dr Roma Chilengi, Head of Clinical Trials at the Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Kilifi, Kenya.
Audio Version
Video Version (requires high-speed internet)

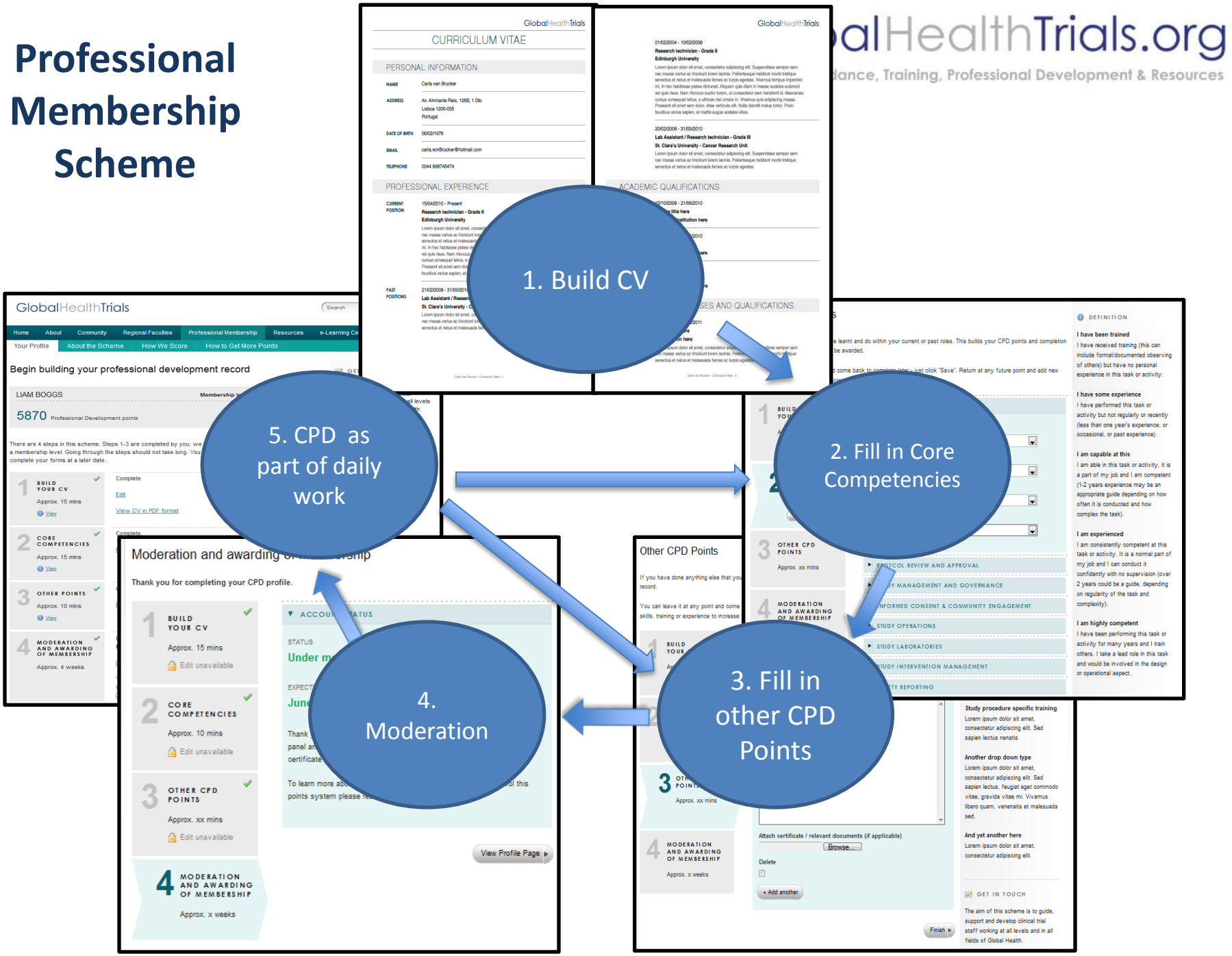
The Role of Laboratory in Clinical Trials

Ken Awuondo, Clinical Trials Laboratory Manager, Kenya Medical Research Institute (KEMRI)/Wellcome Trust Research Programme, Kilifi, Kenya.
Audio Version
Video Version (requires high-speed internet)

e-Seminars are available in both audio (MP3) and video (MP4) and are delivered by experienced clinical trial researchers



Professional Membership Scheme



The Professional Membership Scheme:

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Research, Guidance, Training, Professional Development & Resources

- Creates awareness that this is a valid career path with wide opportunities
- Provides feedback and recognition
- Allows researchers to identify appropriate and targeted training opportunities
- Audited and moderated (annual review) for quality and validity
- Information very secure
- Professional looking CV and training record.
- Helps research study leaders and institutions support, manage and develop their staff

Southern Africa Regional Faculty

Global Health Trials – Southern African faculty page

We launched a Southern African faculty of GHT in June 2012 at a clinical trials course in Cape Town that was attended by clinica countries (including South Africa, Malawi, Zambia and Botswana).

We have spent the time since launch raising awareness of GHT locally in South Africa by presenting the initiative and distributing plans going forward are to continue to respond to requests to give such talks, to facilitate relevant local skills-sharing workshops, -relevant resources on the new dedicated web page (including training opportunities, regulatory and ethical requirements etc.) an about conducting research in this region to find it. In order to achieve this, and to expand our offering, we would welcome people than South Africa to contact us with a view to collaborating.

Coordinating members:

Elizabeth Allen: I trained as a pharmacist in the UK and have worked primarily as a Project Manager within clinical trials (pharm industries, and currently at an academic clinical site) in the UK and Africa since 1994. After completing an MPH in epidemiology methodological research in the field of pharmacoepidemiology (drug safety).

Cordelia Reddy: I am a trained registered nurse and cut my teeth in nursing in paediatrics and primary health care. Currently I a Organisation as a clinical monitor. I am interested in supporting study personnel, with a focus on nurses in their role in clinical re

Recent Workshops

- **Abuja**, Nigeria
- **Dar es Salaam**, Tanzania (with six subsequent seminars)
- **Yaounde**, Cameroon (heavily oversubscribed!)
- **Lilongwe** and **Blantyre**, Malawi (Global Research Nurses)
- **Cape Town!**

Upcoming workshops

- **Entebbe**, Uganda (14th February) – collaboration with MUTHI
- **Lagos**, Nigeria (March) – in collaboration with Global Research Nurses
- **India** – Thiruvananthapuram, Erode, Bangalore (February - in collaboration with Global Research Nurses)

Training Courses

Global Health Trials Regional Faculty Training Course Scheme

To aid in the career development of research staff and in capacity development, Global Health Trials regional faculties are working courses in clinical research, to open up those courses to additional members who could attend free of charge. Courses could inc courses in monitoring, GCP or GCLP, the various aspects of quality trial conduct or specific methodologies.

Places will be offered on these courses if the participant:

- Works for a non-profit organisation (such as a charity, MoH, and including Universities)
- The course must not be covered by the organisation's study or project budget.
- The course will add benefit to the career of the applicant in clinical research
- The applicant would add benefit to colleagues, or site/programme through the knowledge gained from the course

To apply for the courses, you need to email info@globalhealthtrials.org, explaining why you would like to attend the course, and letter from your Head of Department.

Global Health Trials Southern African Regional Faculty is delighted to announce the first course provider to sign up t Research, Education, and Development), in South Africa. To find out about the training courses run by Crede, please

To apply for one of CREDE's courses, please email info@globalhealthtrials.org, explaining why you would like to be

CREDE

Clinical Research Education and Development

Teaching Clin

"What is r
date with
William F

About

CREDE (Clinical Resea
Development) is an i
provides GCP and ot
education and devel
the clinical research
and the rest of Africa
unique because they
and accredited.

"Experto crede" is a l
faith in experience."
clinical research. Our
wide experience in th
knowledge.

Our Programmes

GCP Beginner

Good Clinical Practice

This course will provide you with an overview of clinical research, various concepts of research and

GCP Refresher

Good Clinical Practice

This is a 1 day course with 6 hours teaching time. At the end of the course a written assessment is done

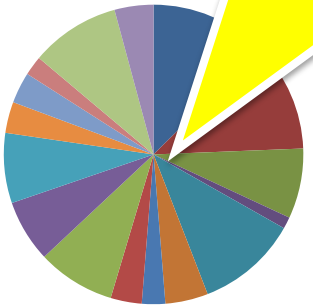
Global Health Trials is engaging and supporting researchers

GlobalHealthTrials.org
Research, Guidance, Training, Professional Development & Resources

GlobalHealthTrials.or… …cs September 2012	
Members	3252
…	74,634
Unique…	…
Number of di… …tries of origin of visits	140
Returning Visi…	53%

Professional Memberships Scheme members: 170

E-Learning Courses Taken: 2000+



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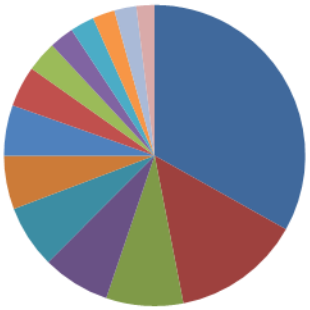
- Clinical Scien…
- Development
- Ethics
- Medical Officer
- Public Health
- Statistician
- Trial Coordinator
- Doctor
- Funding/developmen…
- Nurse
- Regulatroy Affairs/Governance
- Epidemiolo…
- Lab
- Pharmacology
- Research Manager

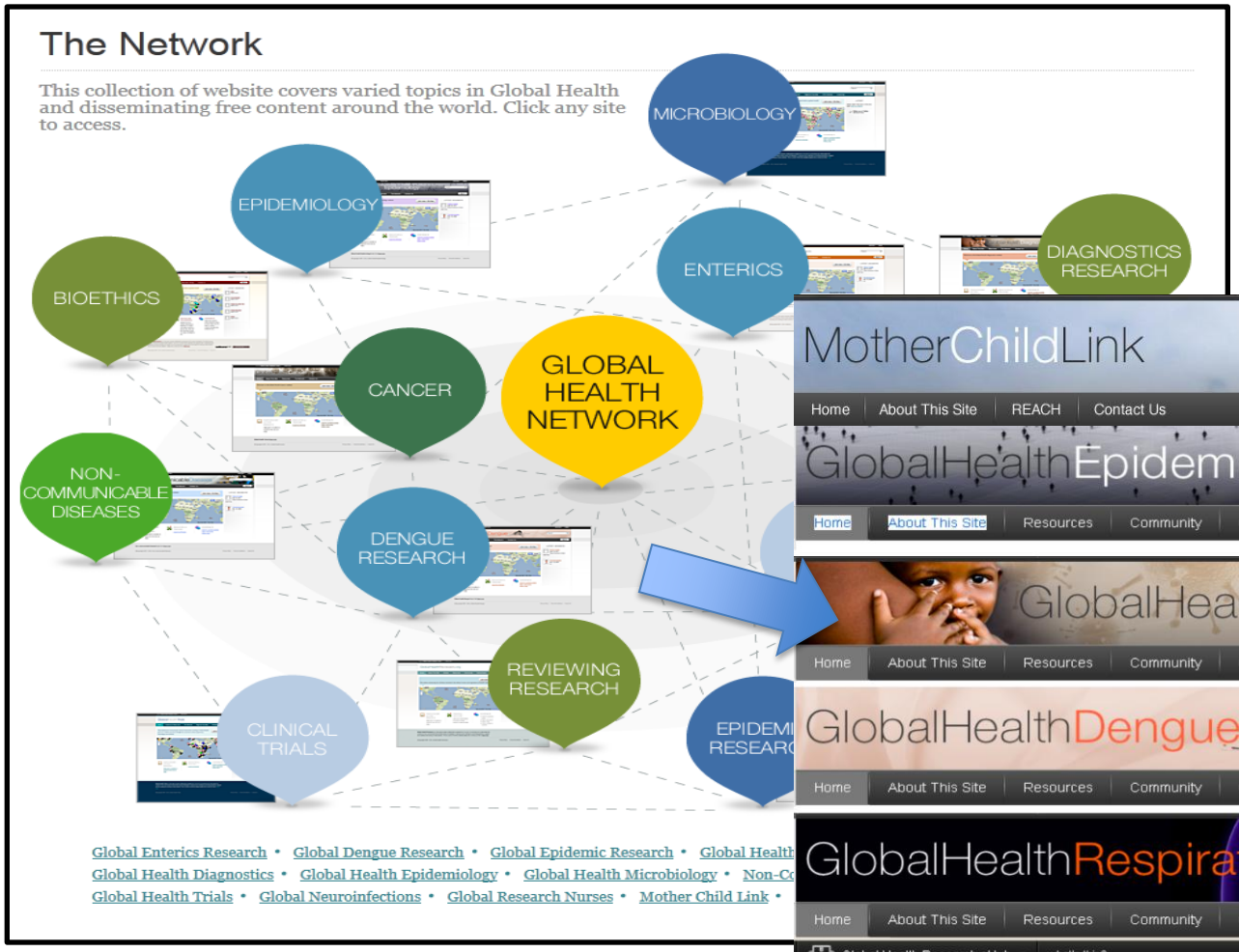


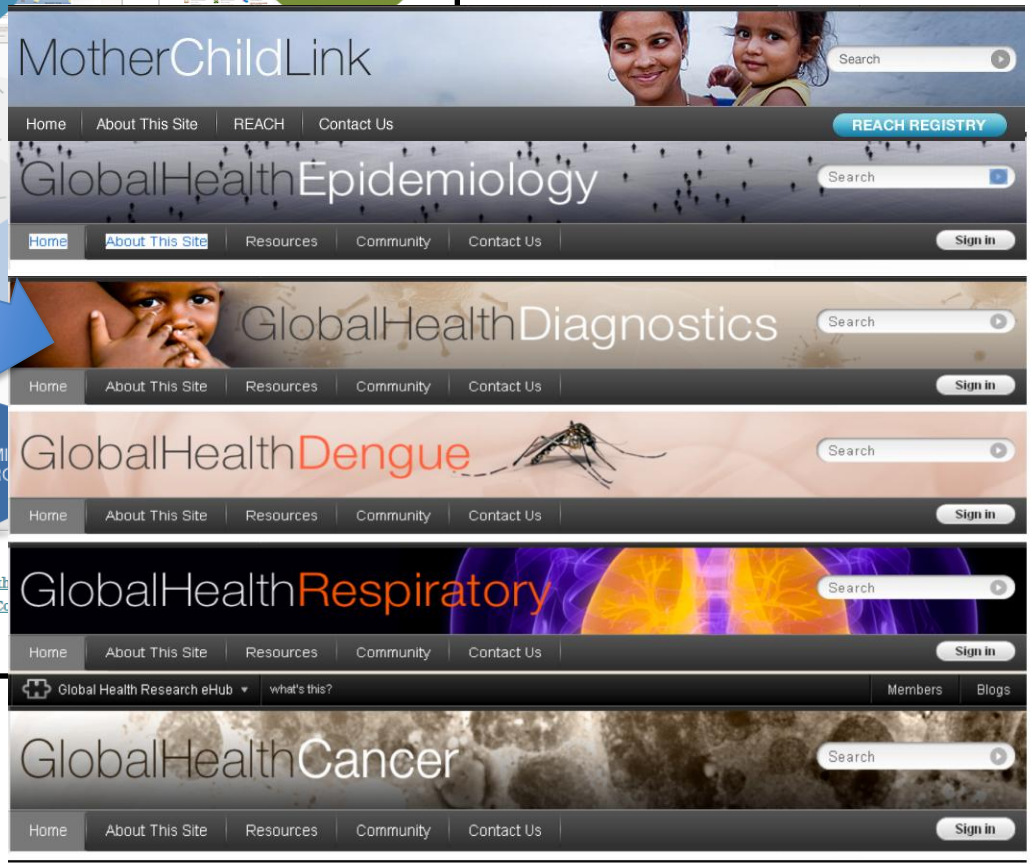
Most visits from LMIC

- Kenya
- India
- Ghana
- South Africa
- Nigeria
- Uganda
- Tanzania
- Vietnam
- Thailand
- Uzbekistan
- Ethiopia
- Philippines
- Cameroon
- Gambia

The Global Health Network.org

supporting research through sharing methods and knowledge





GlobalResearchNurses

A member of the Global Health Network

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Featuring Network Participants | Tools & Templates

WORKING TOGETHER FOR GLOBAL HEALTH

A collaborative professional network of international research nurses, funded by the Burdett Trust for Nursing

RESEARCH NURSE AT A HEALTH CLINIC

ARE YOU A REGISTERED GHN USER? LOG IN HERE

Your email

Your password

Sign in

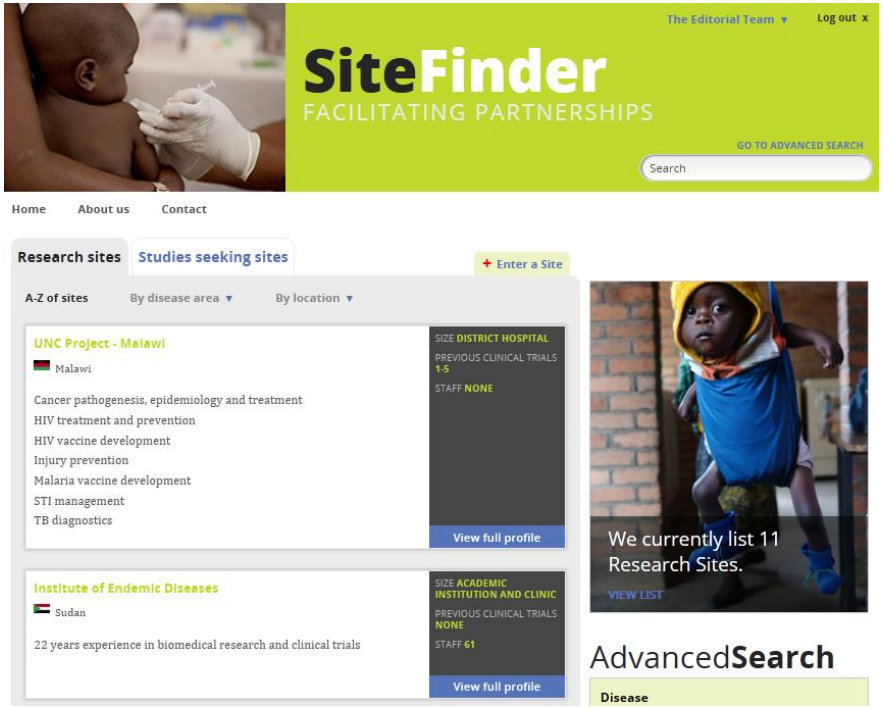
Don't have an account? Register here

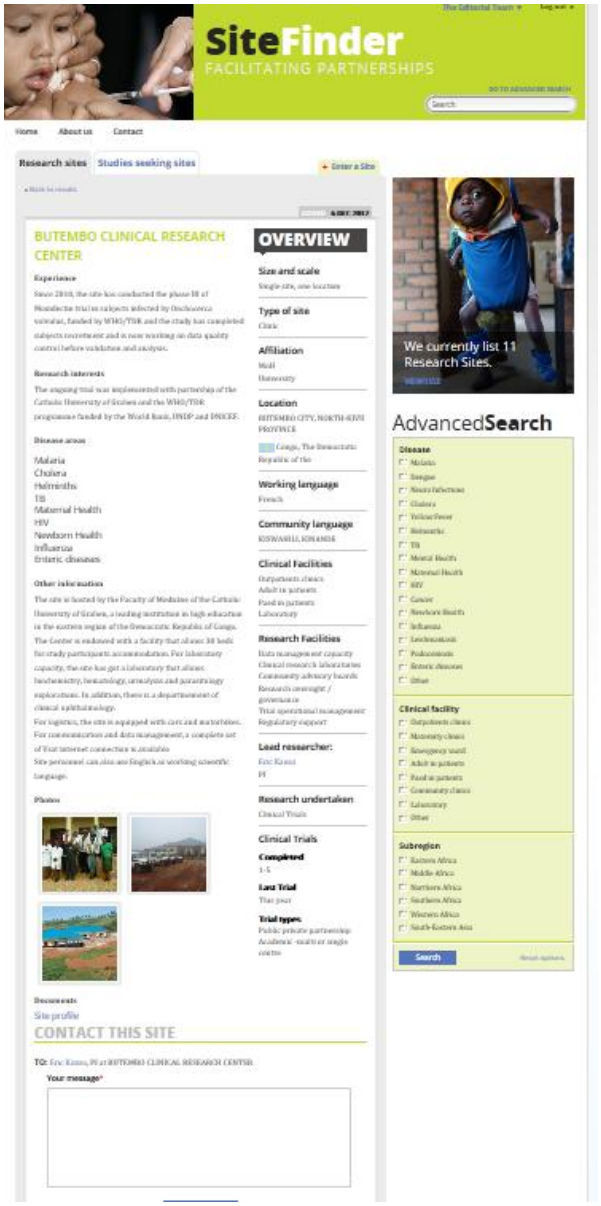
SITE SEARCH

SEARCH

POPULAR TOPICS

SiteFinder Post-Launch Update





- Site is being well-populated
- Researchers are making use of the functionality to add pictures and documents
- So far we have a wide range of types of site
- Excellent feedback from sites

Plans for future: on website

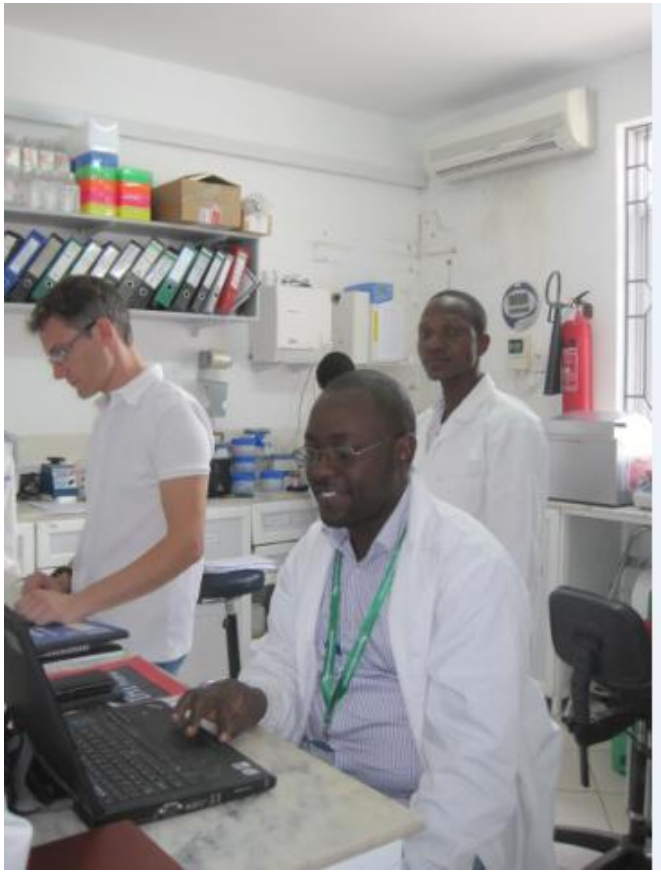
Revamp of website - Front pages more news-like, add events diary

Guidelines and resources

- How to establish a research laboratory
- Accreditation in laboratories
- Basic statistics for clinical researchers
- DSMBs

Toolkits for specific tasks e.g. monitoring

Webinars



Plans for future: South Africa

Continue meetings, workshops, events

- Give local talks about GHT
- Facilitate local workshops based on feedback of needs

Develop other resources

- South African-relevant (training opportunities, regulatory and ethical requirements etc.)
- Grow training provider scheme
- Help those who need advice to find it
- Foster links within Southern Africa

Please volunteer!

To summarise:

GlobalHealthTrials.org
Research, Guidance, Training, Professional Development & Resources

- We could all help each other by sharing our successes
- Solutions to most trial challenges can be applied globally
- We need to increase access to training and knowledge
- We need to be better at supporting ALL our trial staff

Please register – please get involved!

www.globalhealthtrials.org

The Global Health Network is funded by The Bill and Melinda Gates Foundation

THANK YOU, THANK YOU, THANK YOU

- Tamzin and GHT
- Regional volunteers (Lesley, Havana and Cordelia)
- Meeting volunteers (Rae, Shireen, Faikah and Jenny)
- GSH and UCT facilities
- Karen Barnes and Marc Blockman
- BMGF