An Introduction to Global Health Trials

<u>Your</u> online facility for career development, training and guidance

GlobalHealthTrials.org

Research, Guidance, Training, Professional Development & Resources

GlobalHealthTrials.org

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What is it?

Global Health Trials is an open access collaborative programme to support clinical trials in developing countries. Many partners are involved

What is it for?

A mechanism for everyone working on clinical trials to have access to
tools, resources, training, continuing professional development – and each other!

What can it do for me

…career development support

…skills and knowledge training

…access to peers and experts all over the world

Clinical research involves many steps…

- Samples & laboratories
- Regulations & guidelines
- Ethics / informed consent
- Data capture and management
- Protocols
- Operating procedures

A mechanism for sharing methods and resources between groups, disease areas and regions

would bring….

- Standardization
- Better research practices
- Immediate access to knowledge & information
- Enable data sharing
- Use of same terminology
- Increased collaboration
- Peer support & networking

…& WOULD SPEED UP RESEARCH !

Features of Global Health Trials

- Peer reviewed articles with downloadable resources
- Discussion area – very popular!
- Document development / sharing facility
- Profiling, members and network
- Professional membership scheme
- E-learning
- Regional faculties

Coming very soon….

- Interactive study set-up tool
- Interactive clinical trial site and collaborator registry
- Decision tree tool for risk assessment of trials

GlobalHealthTrials

Search

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

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

Global Health Trials was launched in May 2010 as a simple, open space for supporting clinical trials in developing countries by sharing tools and knowledge

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

LATEST MEMBERS

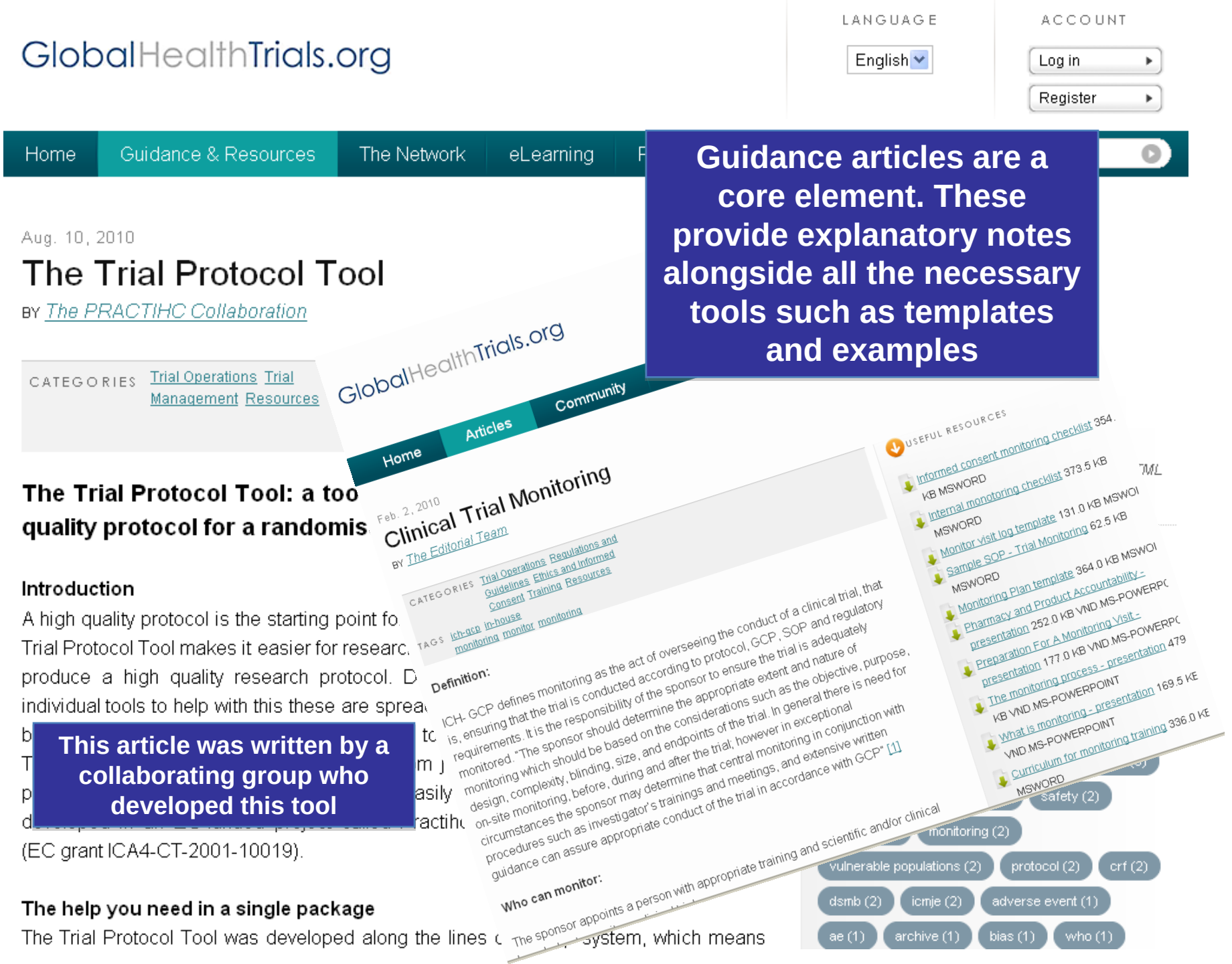
Neil Young
Sept. 26, 2012

PATIENCE KOMBA
Sept. 26, 2012

Dhelio Pereira
Sept. 26, 2012
Professor at UNIR - Universidade Fedra de Rondônia

Kenneth Mworozi
Sept. 25, 2012

Gilles COTTRELL
Sept. 25, 2012


GlobalHealthTrials.org
LANGUAGE
English
ACCOUNT
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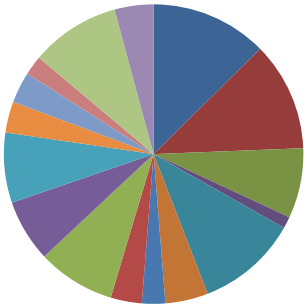
Register
Home
Guidance & Resources
The Network
eLearning
Guidance articles are a core element. These provide explanatory notes alongside all the necessary tools such as templates and examples
Aug. 10, 2010
The Trial Protocol Tool
BY The PRACTIHC Collaboration
CATEGORIES Trial Operations Trial Management Resources
The Trial Protocol Tool: a too
quality protocol for a randomis
Introduction
A high quality protocol is the starting point fo
Trial Protocol Tool makes it easier for researc
produce a high quality research protocol. D
individual tools to help with this these are sprea
This article was written by a collaborating group who developed this tool
(EC grant ICA4-CT-2001-10019).
The help you need in a single package
The Trial Protocol Tool was developed along the lines
GlobalHealthTrials.org
Home
Articles
Community
Feb. 2, 2010
Clinical Trial Monitoring
BY The Editorial Team
CATEGORIES Trial Operations Regulations and Guidelines Ethics and Informed Consent Training Resources
TAGS ich-gcp in-house monitoring monitor monitoring
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
USEFUL RESOURCES
Informed consent monitoring checklist 354.
KB MSWORD
Internal monotoring checklist 373.5 KB
MSWORD
Monitor visit log template 131.0 KB MSWOI
MSWORD
Sample SOP - Trial Monitoring 62.5 KB
MSWORD
Monitoring Plan template 364.0 KB MSWOI
MSWORD
Pharmacy and Product Accountability - presentation 252.0 KB VND.MS-POWERPC
Preparation For A Monitoring Visit - presentation 177.0 KB VND.MS-POWERPC
The monitoring process - presentation 479
KB VND.MS-POWERPOINT
What is monitoring - presentation 169.5 KE
VND.MS-POWERPOINT
Curriculum for monitoring training 336.0 KE
MSWORD
safety (2)
monitoring (2)
vulnerable populations (2)
protocol (2)
crf (2)
dsmb (2)
icmje (2)
adverse event (1)
ae (1)
archive (1)
bias (1)
who (1)

Global Health Clinical Trials is support researcher staff in all roles and is the professional network for finding help and tools

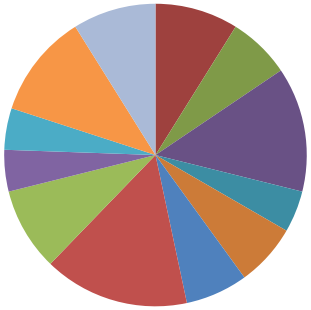
GlobalHealthTrials.org metrics February 2013	
Members	**12,532**
Visits	**97128**
Number of different developing countries of origin of visits	**56**
Returning Visits %	**59%**

Job roles of members



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

Location of users providing content



- Ghana
- Kenya
- S.Africa
- China
- Rwanda
- Sudan
- India
- Peru
- Pakistan
- Brazil
- Gambia

- There are various essential roles working in clinical research – nurses, doctors, coordinators, data managers and lab staff
- They are gaining skills and experience but they are not captured nor rewarded… nor valued?
- The barriers are access to training, peer support and professional recognition
- In the US and EU there is better recognition

- In Europe and the US research is a supported and well recognised career option for all types of roles
- There numerous professional networks such as ICR and ACRPI
- These people are developing their careers and making a highly valued contributions to research
- We need to catch up here! We need professional recognition!

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Research, Guidance, Training, Professional Development & Resources

Division of Pharmacology, Department of Medicine, University of Cape Town
European & Developing countries Clinical Trials Partnership (EDCTP)
Institute of Infection and Global Health, University of Liverpool
The PRACTIHC Collaboration
East African Consortium for Clinical Research (EDCTP funded)
Africa Malaria Network Trust (AMANET)
Malaria Consortium, Uganda
Medical Research Council, Clinical Trial Unit
International Vaccine Access Center, John Hopkins
MRC, The Gambia
Malawi-Liverpool WT Research Unit
Swiss Tropical Institute
The Malaria Centre, LSHTM
Drug for Neglected Diseases Initiative (DNDi)
Liverpool Centre for Tropical Medicine
London School of Hygiene and Tropical Medicine
Imperial University Centre for Tropical Medicine
Institute for Tropical Medicine, Antwerp
Facultad de Salud Escuela de Salud Pública Maestría en epidemiología Colombia
Centre for Paediatric Research, Lucknow, India
Medical Research Unit of the Albert Schweitzer Hospital, Lamberene,Gabon.
KEMRI-Wellcome Programme, Kenya
World-Wide Antimalarial Resistance Network (WWARN)
Mahidol-Oxford Tropical Medicine Research Unit, Bangkok, Thailand
Oxford University Clinical Research Unit, Ho Chi Minh City, Vietnam
Nuffield Department of Medicine, Centre for Tropical Medicine.
Sri Jayewardenepura Teaching Hospital Sri Lanka
Clinical Trials Transformation Initiative, Duke University. USA
KEMRI/Centre for Disease Control, Kisumu. Kenya.
Clinical Trial Laboratories, Kintampo Ghana
CSH Medical University Uttar Pradesh, India
Consortium for National Health Research, Nairobi, Kenya

List of collaborators

for

Global Health Trials