Using digital technology to support and enhance clinical trials in resource limited settings

EDCTP forum
Trudie Lang  October  2011
Who we are....
Global Health Trials is an open access collaborative programme to support clinical trials in developing countries. Many partners are involved.

The Aim....
A mechanism for everyone working on clinical trials to have access to tools, resources, training – and each other.

What we have achieved...
The site was released in May 2010. Not yet advertised or promoted (early days still). We have 14,000 users from 56 developing countries 20% of whom have visited the site over 50 times.
• There are initiatives providing clinical trial training BUT majority at a trial, disease or regional level

• Few trial steps, processes, methods or issues are truly specific to that disease or location. Even specific lab assay’s most problematic steps are generic (tracking and transporting samples, for example)

• There is a need for more disease management trials addresses local questions as well as product development trial to support new product registration. Sites COULD and SHOULD diversify into more and different trials

• Could be addressed by knowledge sharing and tactic learning across disease areas and within locations¹

¹ Advancing Global Health Research Through Digital Technology and Sharing Data

T Lang

Science 11 February 2011: Vol. 331 no. 6018 pp. 714-717

Time for globally sensible guidelines

Lang, Cheah, White

The Lancet, 21 Feb 2011
The professional community for clinical researchers working in Global Health. Join over 12,000 users from 58 different countries to share experience, knowledge and methods.
Features of Global Health Trials

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

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 the Cochrane Group
Aug. 10, 2010

The Trial Protocol Tool

BY The PRACTIHC Collaboration

The Trial Protocol Tool: a tool to help researchers to write a high quality protocol for a randomised controlled trial

Introduction
A high quality protocol is the starting point for running a randomised controlled trial. The Trial Protocol Tool makes it easier for researchers in low and middle-income countries to produce a high quality research protocol. Despite the existence of guidelines and individual tools to help with this these are spread across hundreds of journals, websites, books, conference proceedings and software tools. The strength of the Trial Protocol Tool is that it packages existing materials from journals, websites, books, conference proceedings and software tools into a single easily accessible and practical tool. It was developed in an EC-funded project called PractiHC (http://www.practihc.org/index.htm) (EC grant ICA4-CT-2001-10019).

The help you need in a single package
The Trial Protocol Tool was developed along the lines of a Help system, which means

USEFUL RESOURCES

Trial Protocol Tool 1.3 KB HTML
Trial Protocol Tool (Español) 1.3 KB HTML

RELATED ARTICLES

Developing a protocol
BY The Administrator

MOST POPULAR TAGS

sop (6)  ich-gcp (4)  training (3)  ethics (3)
community (3)  logistics (2)  safety (2)
sponsor (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)
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 the trial. The monitoring team may consist of one person, or multiple people, depending on the size of the trial. The monitoring team may include individuals such as the study monitor, data monitor, and clinical monitor. The role and responsibilities of each individual will be defined in the monitoring plan. The monitoring plan should specify the frequency and nature of monitoring activities, as well as the criteria for identifying and reporting any deviations from the protocol or GCP.
Bamlak Tessema
Wevesa
May 31, 2011

what an incredabel idea is it ?my current experience in clinical coordinater and also research nurse working in ahri ethiopia .it will be good in collabrating developing and developed countery in their experience of research nursing

regad

bamlak tessema from ahri ethiopia

Rose Malya
May 31, 2011

That is a wonderful idea!!I have worked in research unit as a research nurse for about 3 years which is a short period of time, I had mastered lots of things,of which in these few months am working as a Trial manager.Actually, this forum will be helpful to nurses since research nurses are contributing much in clinical trials despite of their low theoretical aspect of understanding in research issues.

Jemal
June 2, 2011

Its really a very good idea and initiation,from my experience what i have in (TB Vaccine) clinical trial here in Ethiopia AHRI(Armawer Hanson Research institute)compliance with GCP and successfully completed, it will be a good opportunity to share my experience for the other research nurses who are working in a clinical trial and to learn their experiences as well.
Please keep it up.
Jemal Ahmed
AHRI
The Global Health Trials Professional Membership Scheme

- Increase professional recognition of trial staff
- Comprehensive
- Valid and high quality
- Expert review panel
- Only other schemes are in US and EU – commercial
- Aim to build partners
- Discussing with universities
- Building partnership recognition scheme
The Global Health Trials e-learning Centre

• There is some fantastic training being delivered
• The trouble is they often focus one disease (or protocol!)
• Often only small number of staff can gain – limited by travel
• However most steps, processes and issues are the same

Our philosophy is quite simple....

- Take these great training resources you have all developed and share them!
Welcome to the Global Health Trials e-Learning Centre

The aim of this area of the Global Health Trials website is to provide clinical study investigators and clinical study staff with 'how-to' training on designing, planning, operationalising and reporting clinical studies. We deliberately say 'study' rather than 'trial' as these courses apply to most types of clinical research studies – including clinical trials.

Our e-learning short courses are designed to cover every step, process, and issue, that needs to be understood in order to conduct a high quality clinical study. These 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.

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).

Global Health Trials e-Learning Short Courses

Live:

Introduction to clinical research
Introduction à la Recherche Clinique
Setting the Research Question
The Research Protocol: Part one
The Research Protocol: Part two

Currently out for peer review:

1. Data Safety Monitoring Boards
2. Reporting and Collecting Adverse Events
3. Introduction to Consent
4. Introduction to Good Clinical Practice

The 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 Warnme, the Kenya Medical Research Institute (KEMRI)/Welcome Trust Research Programme, Kiifi, Kenya, presents an introduction to clinical trials.

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)/Welcome Trust Research Programme, Kiifi, Kenya gives an introduction to ICH-GCP.

Audio Version
Video Version (requires high-speed internet)
To summarise

- 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

We have taken the latest digital technology to tackle these through an open collaborative professional community.

Please register – please get involved!
Division of Pharmacology, Department of Medicine, University of Cape Town
European Developing Country Clinical Trials Alliance (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

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