The Global Health Network

Lima – 11th June 2014



Enabling research by sharing knowledge

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www.theglobalhealthnetwork.org

What is it?

 A network which supports health research by sharing knowledge and methods.

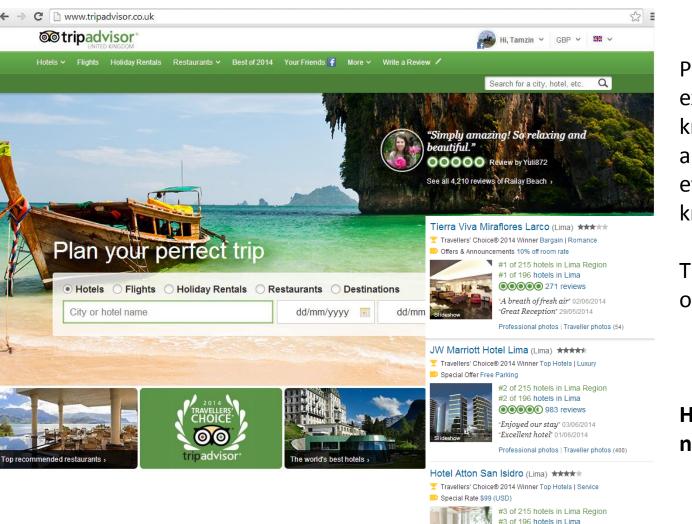
Health Research often occurs in isolated siloes.....



Researchers have to fight for funding, and don't share their ideas, methods, or results until publication.

The internet is changing the world in other fields.





People share their experiences and knowledge with one another, creating an evolving body of knowledge.

This is a 'Community of Practice'.

Health Research needs this!

#3 #3 ● Slidehow

#3 of 196 hotels in Lima

"Modern hotel in Lima" 03/06/2014 "Value, Class and Comfort" 01/06/2014

Professional photos | Traveller photos (385)

Clinical research involves many steps...

Samples & laboratories

Regulations & guidelines

Ethics / informed consent

Data capture and management

Protocols

Operating procedures

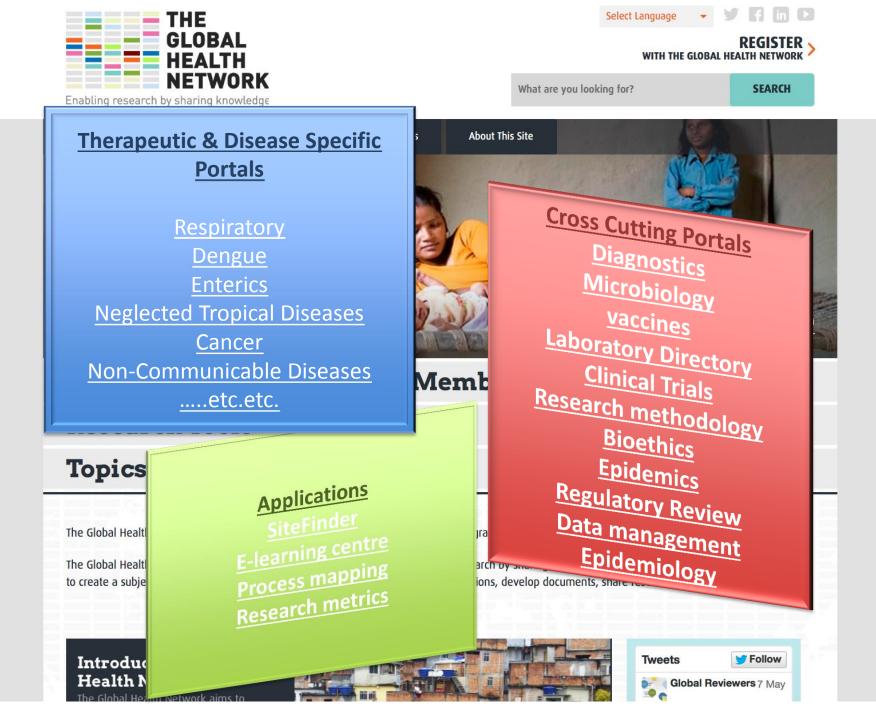
....that are largely similar irrespective of location, disease area or type of study

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

would bring....

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

...& WOULD SPEED UP RESEARCH !



Global Mother Child Research

What are you looking for?

١١

SEARCH

MORE ~

WELCOME, THE EDITORIAL TEAM 🗸

13 Retweeted by





The Global Health Regulatory Requirements Database

Provides information on international regulatory requirements for product development plans.

GO TO SITE

Gide

Global Health Technologies Coalition

Thailand

Advanced search

The Global Health Regulatory Requirements Database is designed to help researchers and regulatory affairs professionals access the information they need to develop effective strategies for gaining approval to conduct clinical trials and market products. The database provides high-level information on regulatory requirements, timelines, costs, and other basic information required to create product development plans for new tools.

Search

Find key information on the regulatory environment within a specific country by using the Search function.

THE GLOBAL HEALTH TECHNOLOGIES COALITION

The Global Health Technologies Coalition is a group of more than 25 nonprofit organizations working to increase awareness of the urgent need for tools that save lives in the developing world.



TO THE WEBSITE

THE GLOBAL HEALTH NETWORK

The Global Health Network is a collection of websites that are aiming to support research by sharing knowledge and methods.



TO THE WEBSITE

GLOBAL HEALTH REVIEWERS

Global Health Reviewers is a resource for all those involved in the ethical and regulatory review of research, particularly in resource-limited settings. A variety of materials and forums are provided to assist committee members from Ethics Review Committees, Institutional Review Boards, and Food and Drug Administration regulatory committees.



TO THE WEBSITE

GLOBAL HEALTH TRIALS -DISCUSSION FRAMEWORK FOR CLINICAL TRIAL DATA SHARING: GUIDING PRINCIPLES, ELEMENTS, AND ACTIVITIES

Data sharing is one of the most important current issues in clinical trials. If conducted in the right way, sharing data could help facilitate faster and better generation of evidence to bring new interventions and improve disease management.

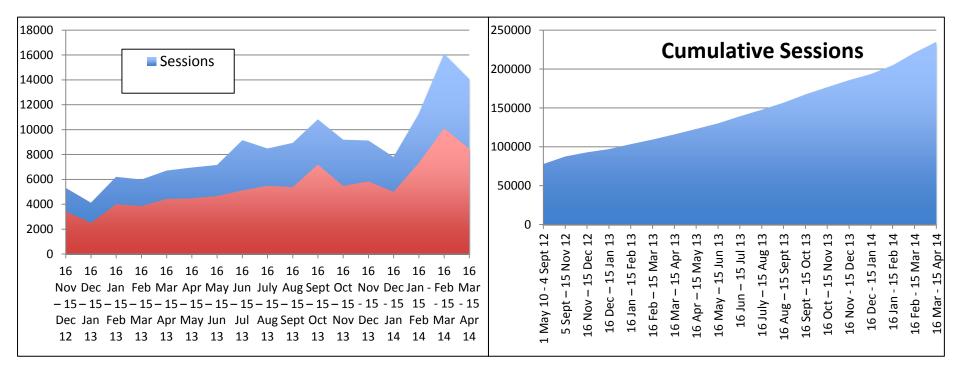


JOIN THE DISCUSSION

Statistics



- Over 230,000 visits since May 2010
- Double what it was a year ago
- 17,087 site memberships





Global Health Trials



Upcoming (on website):

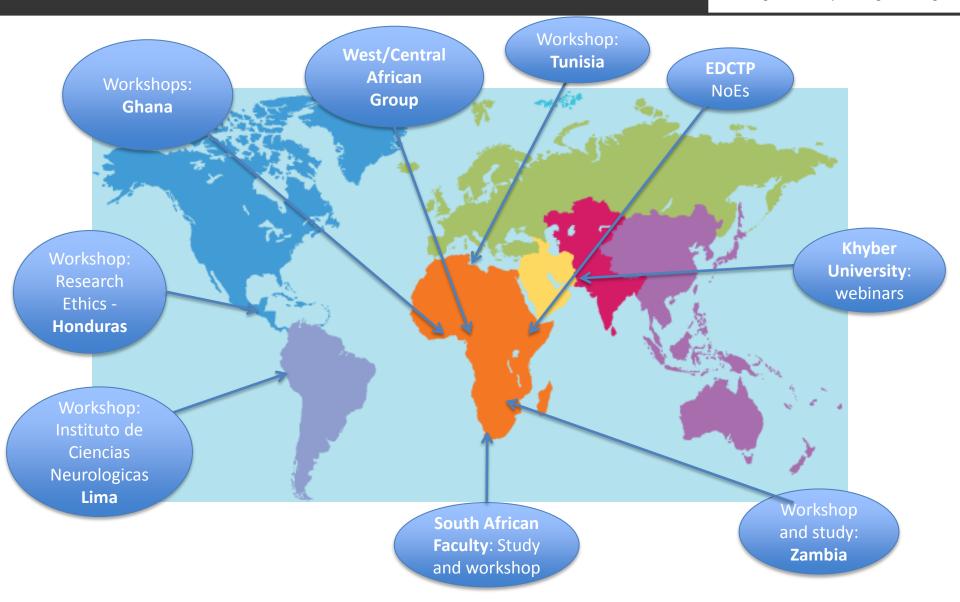
- Issue of the Month: Focus on Children in Research
- Trial Management Month
- SPIRIT Guideline-compliant protocol template
- Roles within Research toolkit
- Rapid Ethical Appraisal Toolkit
- Continued publishing of WHO toolkits

And the Process Map

Regional Faculties & Workshops



Enabling research by sharing knowledge



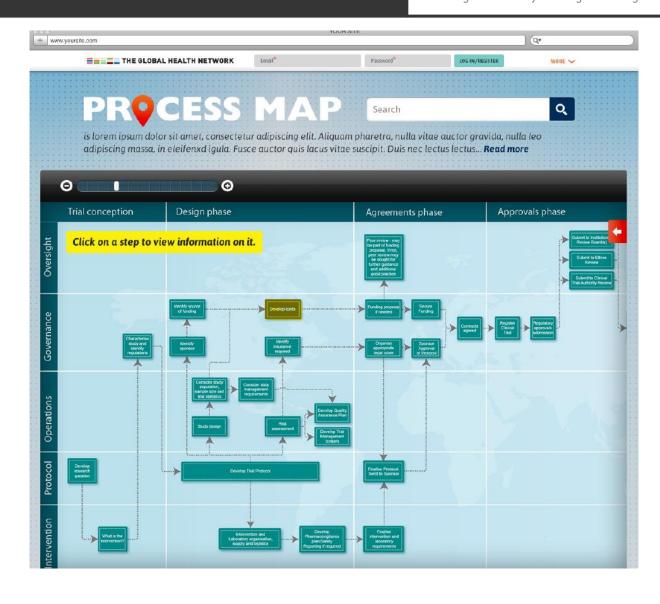
The Process Map

Enabling research by sharing knowledge

- Fully interactive and flexible layout
- Serves as a structural way of organising information across the Global Health Network
- Powerful search

Each item links to:

- Formal written information from trialists
- Other links and resources
- Relevant eLearning
 courses
- Discussions and blogs





 Powered by Curvels Translate Select Language

Research sites Studies seeking sites

e Zeck to results

University of North Carolina Project-Malawi

Experience

20 years of conducting large clinical and community based trials in infectious diseases including HIV, other screally transmitted diseases, TB, Malaria, cancer, obstetrics and gyine; trauma and others.

Beararch interests

NTH Division of AIDS HIV Clinical trials network; Malaria Vaccine Initiaitye.

Discase areas

- Cancer
- HTV
- Malaria Montal Health
- Newborn Health
- · Other
- Sciually Transmitted Diseases (STDs)
- TB

Other information

350 cmmlerrees with 3 clinical trial sites, 10 cc nat faculty from the university of North Carolina, extensive lab and infrastructure to conduct traisl of any size.

Photos



Documents description of infrastructure



We currently list 108 Research Sites. VIER LIST

Disease
Cancer
Cugar
Cicleta
🖯 Dengue
Ditteric direases
o an
🖸 Helminthz
🔁 Indianza
🕒 Lefebreantante
🕜 Malaria
📴 Matemal Health
🔄 Mantal Hasith
🕘 Neglacted Tropical Diseases (VTD
💽 NeuroInfections
Newborn Real th
🖸 Other
🕛 Podoconiasta
Registory Diseases
Security Transmitted Diseases (\$7
B TE
🕒 Vallow Paver
Clinical facility
Outpatients clinics
Materility clinics



Research sites Studies seeking sites

· Back to results

01110 30 OCT 2013 8X4815

Gastroenterology (Duodenal Ulcer) Phase III study

Details

prospective, placebo controlled, three arm, parallel group comparison trial, evaluating the clinical bioequivalence of generic sucralfate oral suspension, 1g/10 mL with Carafate® suspension in patients with duodenal ulcer. The primary endpoint is the percentage of patients with endoscopically assessed DU healing after 56 ± 2 days of treatment (approximately 8 weeks); the secondary endpoints include percentage of patients with endoscopically assessed DU healing after 28 ± 2 days of treatment (approximately 4 Weeks), the use of antacid rescue medication, ulcer pain scores and occurrence of adverse events. Total sample size: 575

Inclusion Criteria

Patients meeting all of the following criteria can be enrolled: 1. Patients of ≥18 and ≤65 years of age 2. Patient must have endoscopically confirmed active duodenal ulcer of at least 3 mm in diameter and not exceeding 25 mm. Patients may have up to a maximum of two duodenal ulcers 3. Patients must be confirmed H.pylorinegative. Absence of H.pyloriwill be confirmed by rapid urease test and microbiology. Patients can be enrolled if found to be H.pylorinegative by rapid urease test performed locally. However, final confirmation will be done by biopsy specimen culture and histology at the central laboratory.



THE

GLOBAL

Enabling research by sharing knowledge

HEALTH

NETWORK

AdvancedSearch * Required fields

кеqu	
Disease	
Cancer	
🔲 Chagas	
🔲 Cholera	
🔲 Dengue	
🔲 Enteric dis	eases
🔲 HIV	
🔲 Helminths	
🔲 Influenza	
🔲 Leishmani	asis
🔲 Malaria	
Maternal I	Health

MeH University Location Lilongwe, Malawi Working language

English Community language

Type of site

Affiliation

Other

Chickeys/English

Clinical Facilities Outratients clinics Maternity clinics Adult in patients Paod in patients Community clinics Laboratory

Research Facilities

Data management capacity Clinical research. Isboratorica Community advisory boarda Research oversight / rovernance Trial operational management Regulatory support

Lead researcher: Irving Hoffman Center of Excellence

partnering with Malawi Miniatry of Health



Advanced Search

* Required fields

1	Disease
k	Cancer
ŝ	Chagar
6	Cholans
F	Dengue
ŝ	Diteric direases
ŝ) RIV
6	Helminth:
F) Influence
ŝ	Lafahmaniasis
ŝ	Malaria
6	Matemal Health
F	Mantal Realth
ŝ	Neglected Tropical Diseases (NTDs)
ŝ	NeuroInfections
6	Newborn Real to
1	Cither
ŝ	Podocovlasta
ŝ	Respiratory Diseases
6	Security Transmitted Diseases (STDs)
F) TE
K	Vallow Pavar





Enter a Study

OVERVIEW Sristek Clinical Research

This is a multicentre, randomized, double-blind,

Especially India Appropriate sites

District hospital Regional hospital Clinic Single investigators Other

Organization

Disease areas

Enteric diseases

Study types

Phase III

CRO

Other

Must be able to recruit 25 patients as specified. **Facilities** needed Clinical Research

Staffing needs



OVERVIEW Size and scale Multiple sites, one location

28 JUN 2012

+ Enter a Site

Site-Finder

- 110 Research Sites
- 20 studies (fluctuating)
- Since July 1st 2013, 6,300 visits from 3,800 visitors
- Sites and Studies contacting one another: over 30 contact requests since January this year
- Monthly news and funding opportunities sent to sites





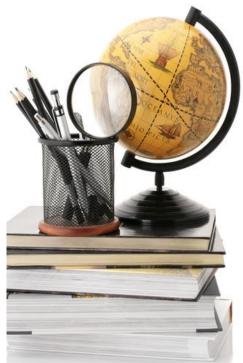


We currently list 102 Research Sites.

e-Learning Centre



- Most steps, processes and issues are the same
- 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 Courses







has completed the e-learning course

INTRODUCTION TO INFORMED CONSENT

with a score of

100%

25/11/2013

This e-learning course has been formally recognised for its quality and content by the following organisations and institutions



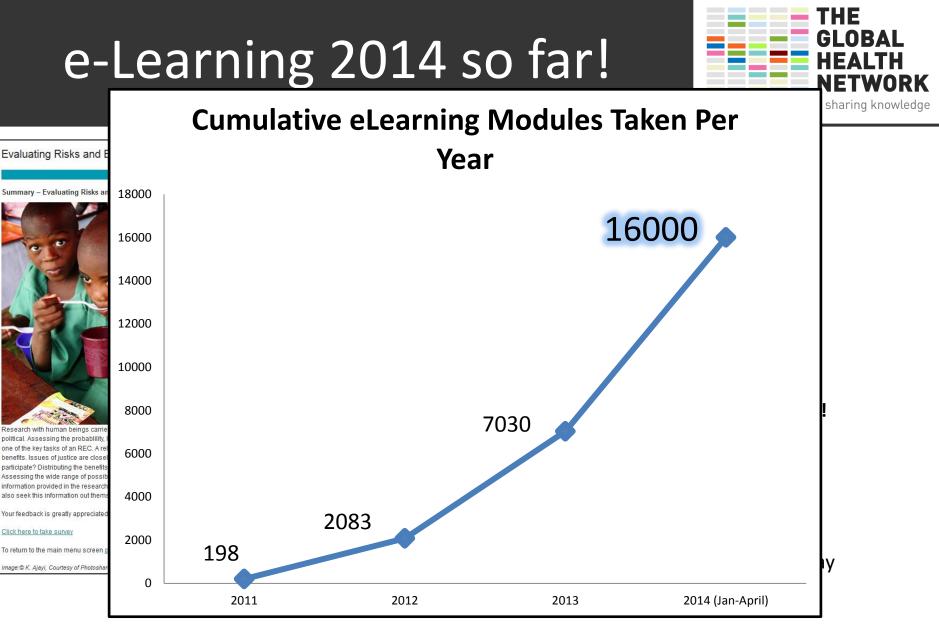
The Global Health Trials e-Learning Centre globalhealthtrials.org/elearning Certificate Number 7769

Short Courses:

- 1. Introduction to Clinical Research
- 2. ICH Good Clinical Practice Course
- 3. Setting the Research Question
- 4. The Research Protocol: Part one
- 5. The Research Protocol: Part two
- 6. Data Safety Monitoring Boards for Clinical Trials
- 7. Introduction to Consent
- 8. Introduction to Data Management For Clinical Research Studies
- 9. Introduction to Collecting and Reporting Adverse Events in Clinical Research
- **10.** Introduction to reviewing Genomic Research
- 11. The Retrospective Treatment Outcome Study
- 12. How to Conduct GCP Inspections/Audits...

Modular Courses:

- 1. Basic Malaria Microscopy (5 modules)
- 2. Research Ethics Online Training (14 modules)



14 courses – 31 modules – 20 translations

e-Learning in Progress





Good Clinical Laboratory Practice

Influenza Outbreak + Laboratory Response





Laboratory Quality Management System & Biorisk Management

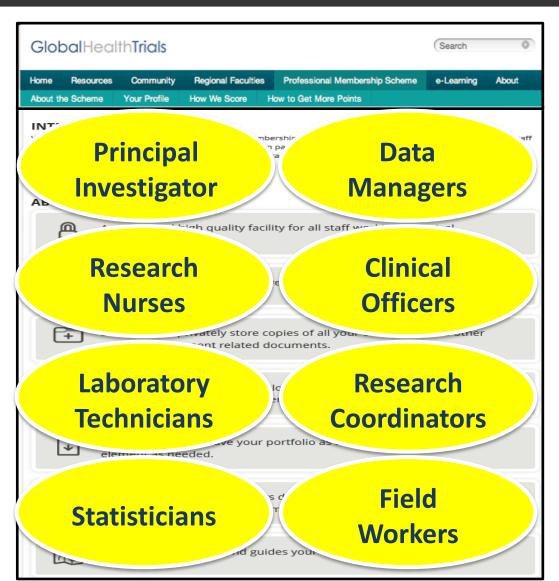
NoEs - Gold Standard GCP/GCLP





Professional Membership Scheme





- Bill & Melinda Gates funded partnership between GHT & WHOTDR
- Professional membership for all levels of clinical research staff.
- This scheme increases professional recognition and tracks development
- It is free, comprehensive, validated and high quality
- Good for sites provides a mechanism for staff review
- Good for individuals provides own record and highly motivational

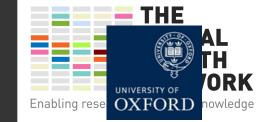
Steps involved in awarding a professional membership



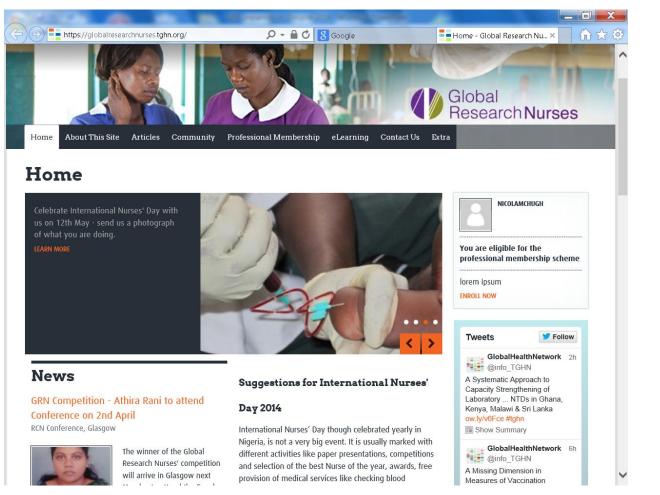


- Creates awareness that this is a valid career path with wide opportunities
- Provides feedback and recognition
- Track Development
- Audited and moderated for quality and validity
- Information very secure
 - Professional looking CV and training record.
- Helps research study leaders and institutions support, manage and develop their staff

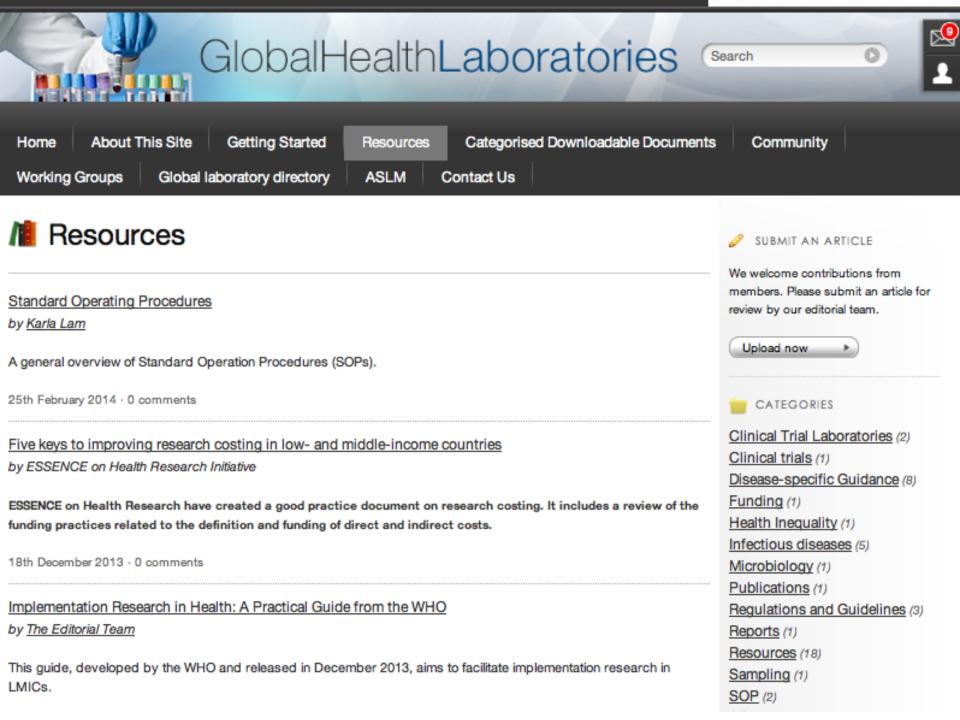




Burdett Trust for Nursing



www.globalresearchnurses.org



GlobalHealthLaboratories Search

Home	About T	oout This Site Getting Started		Resource	s Categorised Downloadable Documents Community
Working	Groups	Global laboratory directory		ASLM	Contact Us

2

- Introduction and Background
- GCLP Course objectives
- Laboratory Organization & Personnel
- Laboratory Facilities
- Laboratory Equipment
- Standard Operating Procedure
- Laboratory Reagents, Kits & Materials
- Lab Procurement & Inventory
- Laboratory Sample Management
- Good Documentation Practice
- Lab Quality Control
- Lab External Quality Assessment
- Laboratory Validations
- Lab Information Management System.
- Lab Corrective Action Preventive Action

Global Health Data Box An Open-Access Data Quality, Management, Storing and Sharing Solution

Stage 1 = DEFINE

- •Define current situation: How do researchers manage their data?
- Characterize Target User groups
- Determine Target User needs
- Technical SWOT analysis of existing tools
- Select DM toolset to take forward
- Establish consortia and governance structure
- Define baseline for impact measurement
- Define current data storage and sharing practices and needs

(pilot funding)

Year 1

Stage 2 = REFINE

- Refine the DM tools
- Field test the DM tools
- limited release of DM toolkit
- Build decision tree application
- Develop trust and community of users
- Incorporate CDISC data standards
- Develop training resources
- Online support systems

Year

2

Stage A = DEFINE

- •Working with the the consortia and users group to:
- Identify best practices in data standardization and data sharing tools with in consortia
- Determine level of support and engagement of users groups
- Technical SWOT analysis of existing tools and technical opportunities

Year

Stage 3 = Release toolkit

- Full release of open access DM toolkit
- impact measurement
- Publicize to target user groups
- Measure impact and uptake in user group
- Establish need for extending to facility to data storage and sharing
- Ongoing refinement and upgrades/

Stage B = REFINE

- Select data storage solutions
- Refine data storage systems
- Select sharing storage solutions

•Refine data storage system

- Develop training resources
- Online support systems
- Refine the data sharing tools
- Refine data stands tools
- Develop

The Process Plan

5

Year Year

Data Storing & Sharing

Data Management

THE

GLOBAL

HEALTH NETWORK

research by sharing knowledge

Stage C = Launch Data

- publicize to target user groups
- Measure impact and uptake
- Storage and Release tools
- develop impact measurement tools

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