# The Global Health Network

Lima – 11th June 2014



Enabling research by sharing knowledge

# **Tamzin Furtado**

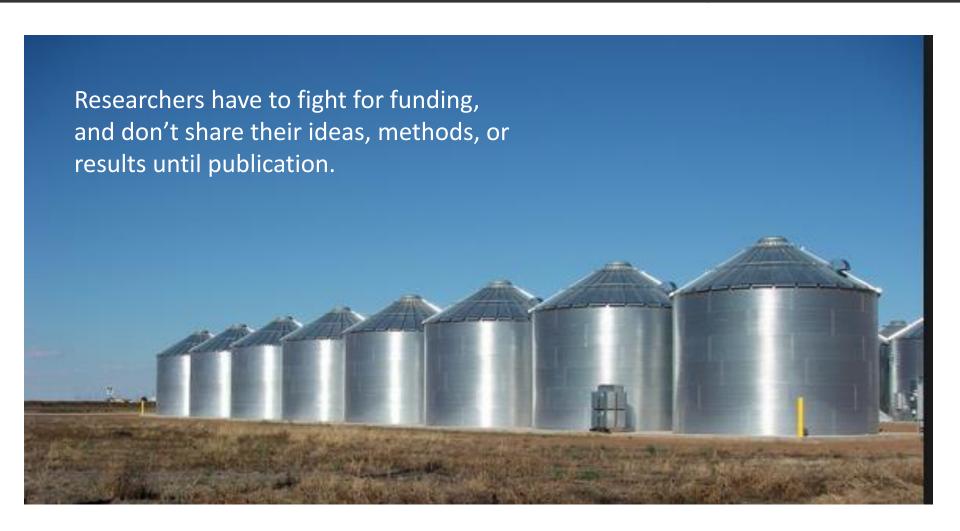
Project Manager
The Global Health Network

www.theglobalhealthnetwork.org



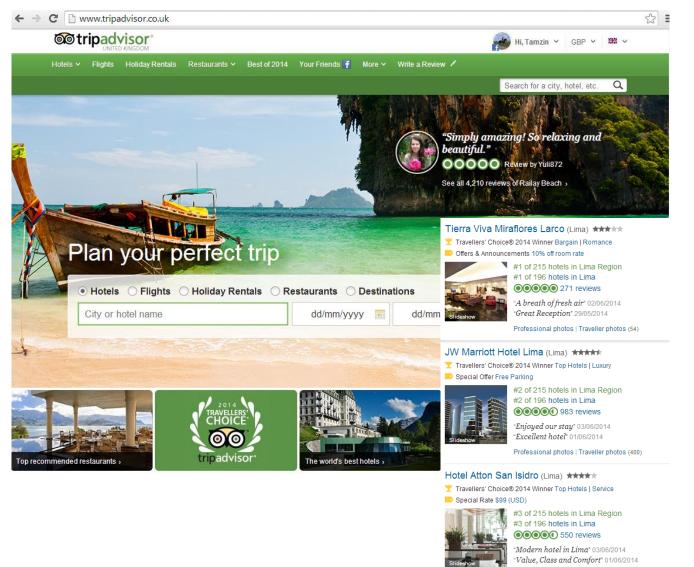
# Health Research often occurs in isolated siloes.....





# 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!

Professional photos | Traveller photos (385)

# Clinical research involves many steps...

Samples & laboratories

Regulations & guidelines

Ethics / informed consent

Data capture and management

**Protocols** 

Operating procedures

irespective of 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









What are you looking for?

SEARCH

# **Therapeutic & Disease Specific Portals**

**GLOBAL** 

Enabling research by sharing knowledge

NETWORK

Respiratory

Dengue

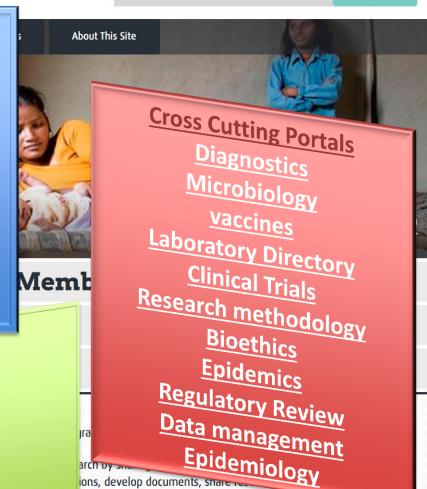
**Enterics** 

**Neglected Tropical Diseases** 

Cancer

Non-Communicable Diseases

.....etc.etc.



# **Topics**

The Global Healt

The Global Healt to create a subje **Applications** 

**Process mapping** 

Research metrics

Introduc Health N

Tweets



# Global Mother Child Research

What are you looking for?

**SEARCH** 





The Global Health Regulatory Requirements Database

Provides information on international regulatory requirements for product development plans.

GO TO SITE



Thailand

Search

0

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.

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.

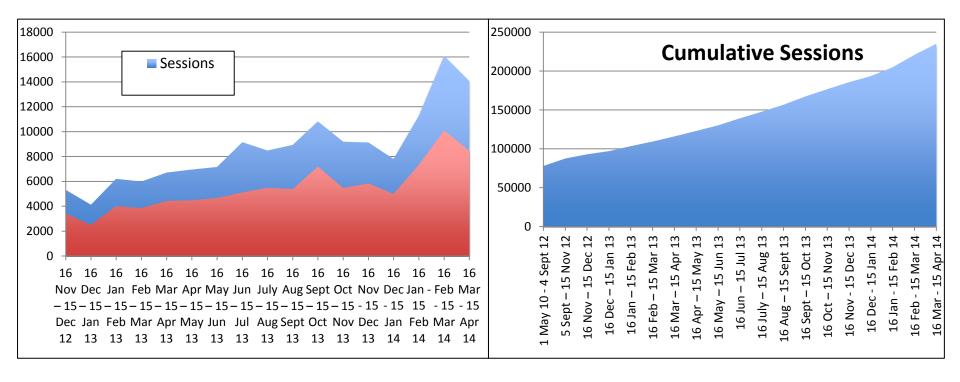


JOIN THE DISCUSSION

# **Statistics**



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



#### Guidance articles e.g.

- how to do a back translation review for ICFs
- Monitoring
- introduction to data management,
- how to manage a trial.....

Hundreds of resources, tools, downloadable SOPs and templates, etc

Everyone can get involved, whatever your location and role in research

## Global Health Trials

What are you looking for?

SEARCH



### Welcome

Waleome to the new look Global Health Triats. The new portals below should help you to find what you're looking for across the network, as well a new and featured articles, discussions and elearning courses. Any comments? Let us know.

#### News

# ctions/Audits - a Free Online Short



The Global Health Network is proud to announce the launch of a new e-learning short course: How to Conduct GCP Inspections/Audits at the Clinical Investigator Site. This course is intended to benefit regulatory good clinical practice (GCP) inspectors and sponsor ... READ MORE

#### Join Global Health Trials

Become a contributor - wherever you are



This is the opportunity for you to become involved in Global Health Trials, wherever you are. Global Health Trials is a community of researchers, and it's run by a community of researchers too - from across the world. We need ...

#### Vaccinology in Africa - a five-day Master's level course (bursaries available)



this course will be run on 13-7th October 2014, in Nairobi, and will cover the main aspects of vaccinology, the vaccine development process, biomanufacturing and well as regulatory and

#### Discussions

#### Group: THE ZAMBIAN CLINICAL RESEARCH FORUM

What are some of the expectations and challenges of working in a

#### research team?

LATEST REPLY: MAY 7, 2014

#### Group: REGION AL PACULTIES

#### Tunisian Regional Faculty

Following the inaugural Tunisian Research Skills workshop held on 20th April 2014, please use this space to introduce yourselves, comment on the workshop, and discuss ...

#### 3 REPLIES

LATEST REPLY: MAY 6, 2014

#### Group: THE LAMBIAN CLINICAL RESEARCH FORUM

#### Quantification of the amount of TDF/FTC/EFV (atripla) excreted in breast milk.

Looking at the new ART guidelines which advocate for ininitiation of full HAART to children born from reactive mothers who also start HAART regardless of

#### 4 REPLIES

LATEST REPLY: MAY 5, 2014

#### Group: THE JAMBIAN CLINICAL RESEARCH FORUM

#### Clinical Research

Discuss how clinical research can improve the quality

### GHN\_EDITORS

Build your professional profile and CV

#### MEMBERS HIP LEVEL

#### SUBMISSION REQUIRED

PROFESSIONAL DEVELOPMENT

### **SiteFinder**

A free, open-access tool to link research sites with collaborators planning research.

#### Find a research partner now.

GO TO SITE



### Tweets

y Follow GlobalHealthNetwork 1h

# @Info\_TGHN Marcus Rijken, of Utrecht University the Netherlands. presents a lecture in Oxford on

Free and open access eLearning

Discussion boards overseen by experts; featured discussions such as 'ask the expert'

> Up to date news and events

> > Track your continued professional development

Opportunities for research sites

# 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





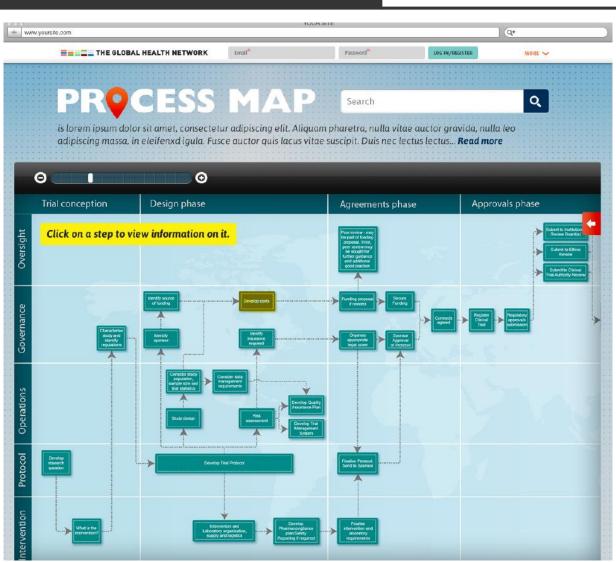
# The Process Map



- 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





# **SiteFinder**

GO TO ADVANCED SEARCH

Log out x

0

Scarch

The Editorial Team Y

Home About Us How to Register. Mep of Sites. Funding Opportunities. Regulatory Requirements. Contact

Select Language

▼ Powered by Curiglo Translate

#### Research sites Studies seeking sites

e Back to results



\* Enter a Site

#### University of North Carolina Project-Malawi

#### Experience

20 years of conducting large clinical and community based trials in infectious diseases including HTV, other screelly transmitted diseases, TB, Malaria, cancer, obstetrics and gyne; traums and others.

#### Beararch interests

NIH Division of AIDS HIV Clinical trials network; Malaria Vaccine Initialty e

#### Disease areas

- Malaria
- · Montal Health
- · Newborn Health
- Socially Transmitted Diseases (STDs)
- TB

#### Other information

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

#### Photos





description of infrastructure

# **OVERVIEW**

#### Size and scale

Multiple sites, one location

#### Type of site

#### Affiliation

MaH University

#### Location

Lilengwe, Malawi

#### Working language

### English

Laboratory

Research Facilities

Community advisory

Research eversishs

Regulatory support

Lead researcher:

Center of Excellence

Ministry of Hoslin.

partnering with Malawi

Irving Hoffman

Trial operational

Clinical research

laboratorica

governance

management

boards

Data management capacity

Community language

#### Chichews/English

- Clinical Facilities
- Outration's clinics Maternity clinics
- Adult in patients Page in patients
- Community clinica
  - - Maternal Health
    - Marcal Realth

    - Pedecoslasts.
    - Reminstony Diseases

Outgatients citrics

### Advanced Search

We currently list 108

#### \* Required fields

Research Sites.

WER LIST

- Disease Cancer
- Charge
- Ctolera
- Dangue
- Extend director
- 500
- Malmorator
- Influence
- Laterbroaducts
- I Malaria

- Neglected Tropical Diseases (NTDs)
- Neuro Infections
- Newform Real to

- Sexually Transmitted Diseases (STDs)

#### Clinical facility

Materially clinics



Enabling research by sharing knowledge

Search



Select Language

# **Site Finder**

GO TO ADVANCED SEARCH 0

The Editorial Team w Log out x

How to Register Map of Sites Funding Opportunities Regulatory Requirements Contact



▼ Powered by Google Translate

This is a multicentre, randomized, double-blind, 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.

#### Disease areas

Enteric diseases Other

#### Study types

Phase III Especially India

#### Appropriate sites

District hospital Regional hospital Clinic Single investigators Other

Must be able to recruit 25 patients as specified.

#### Facilities needed

Clinical Research

Staffing needs



### Advanced Search

### \* Required fields

Disease Cancer

Chagas

Cholera Dengue

Enteric diseases HIV

Helminths Influenza

Leishmaniasis

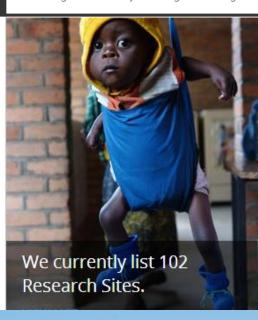
Malaria Maternal Health

# Site-Finder

THE
GLOBAL
HEALTH
NETWORK
Enabling research by sharing knowledge

- 110 Research Sites
- 20 studies (fluctuating)
- Since July 1<sup>st</sup> 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







# 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





Enabling research by sharing knowledge

Hereby Certifies that

# LIAM BOGGS

has completed the e-learning course

# INTRODUCTION TO INFORMED CONSENT

with a score of

100%

on

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

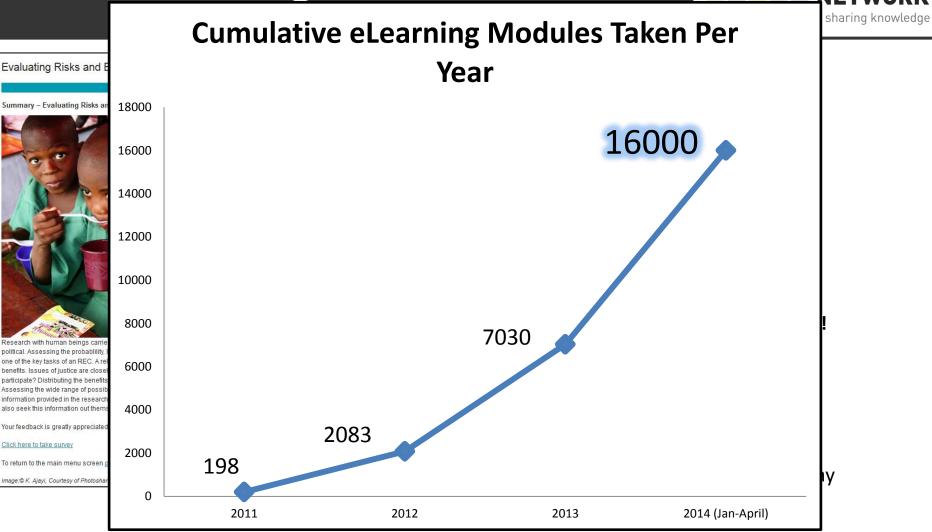
### **Short Courses:**

- 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)

# e-Learning 2014 so far!



THE

**GLOBAL** 

14 courses – 31 modules – 20 translations

# e-Learning in Progress





**Good Clinical Laboratory Practice** 

Influenza Outbreak + Laboratory Response





Laboratory Quality Management System &

Biorisk Management

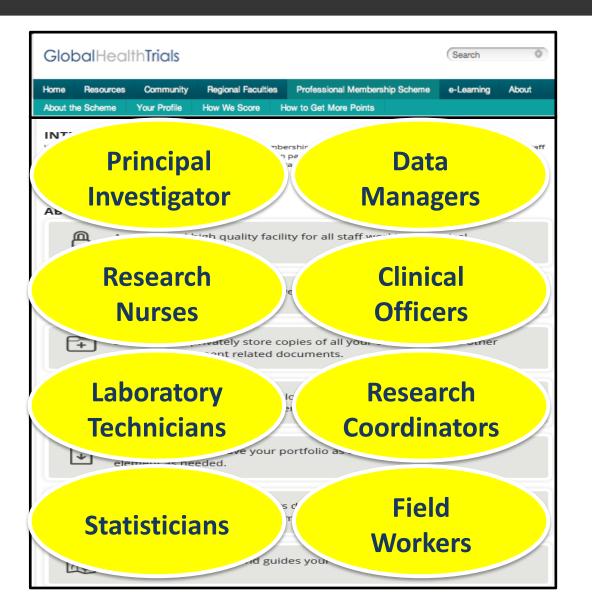
NoEs - Gold Standard GCP/GCLP





# 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

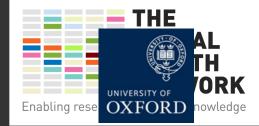
# Steps involved in awarding a professional membership

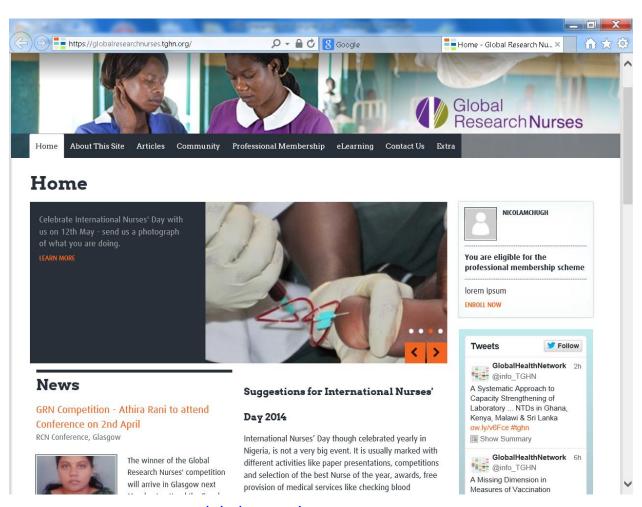




- Creates awareness that this is a valid career path with wide opportunities
- Provides feedback and recognition
- Track Development
- Audited and moderated for quality and validity
- Information very secure
- Professional looking CV and training record.
- Helps research study leaders and institutions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







Burdett Trust for Nursing



# GlobalHealthLaboratories

Search



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Working Groups Global laboratory directory ASLM Contact Us

# Resources

#### Standard Operating Procedures

by Karla Lam

A general overview of Standard Operation Procedures (SOPs).

25th February 2014 · 0 comments

#### Five keys to improving research costing in low- and middle-income countries

by ESSENCE on Health Research Initiative

ESSENCE on Health Research have created a good practice document on research costing. It includes a review of the funding practices related to the definition and funding of direct and indirect costs.

18th December 2013 - 0 comments

#### Implementation Research in Health: A Practical Guide from the WHO

by The Editorial Team

This guide, developed by the WHO and released in December 2013, aims to facilitate implementation research in LMICs.



We welcome contributions from members. Please submit an article for review by our editorial team.





Clinical Trial Laboratories (2)

Clinical trials (1)

Disease-specific Guidance (8)

Funding (1)

Health Inequality (1)

Infectious diseases (5)

Microbiology (1)

Publications (1)

Regulations and Guidelines (3)

Reports (1)

Resources (18)

Sampling (1)

SOP (2)



Home About This Site Getting Started Resources Categorised Downloadable Documents Community

Working Groups Global laboratory directory ASLM Contact Us

- 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 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 **Data Storing & Sharing**
- Ongoing refinement and upgrades

### 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

### 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

### 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

### 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

**Data Management** 

### Stage C = Launch Data Storage and Release tools

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

# The Process Plan

Year 1 (pilot funding) Year

Year

Year

Year

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