An Assessment of the Capacity for Clinical Trials within INDEPTH member Centres

Kwaku Poku Asante

Rita Baiden

Bernhard Ogutu

Osman Sankoh

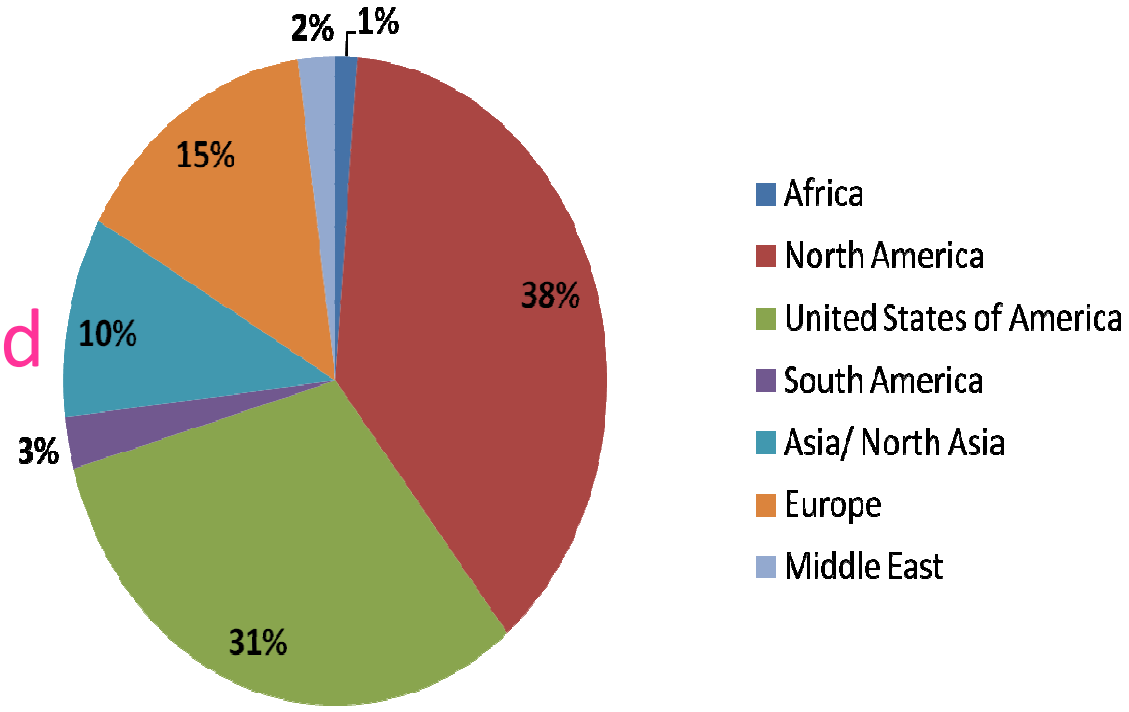
Seth Owusu-Agyei

Introduction

- Drug development is on the increase with improvement in technology.
- Communicable diseases such as malaria are endemic while non-communicable diseases such as diabetes and hypertension are on the increase.
- Developing countries need to position themselves to be able to meet the demands of clinical trials to evaluate new drugs and vaccines for existing and emerging diseases.

Introduction contd.

Currently, majority of clinical trials are conducted in the north compared to developing countries.



Introduction contd.

- Of the trials in Africa
  - 6.5 % are Phase 1
  - 25.6% are Phase 2
  - 52.6% are Phase 3
  - 15.0% are Phase 4
- There is the need to develop clinical trial capacity to be able to carry out early phase clinical trials

Introduction contd.

- The INDEPTH network is a non-Governmental Charitable Organization with the aim of providing health and demographic data based on research in developing countries to set health priorities and policies.
- Its member institutions in Africa and Asia conduct continuous follow up of human population in defined geographic areas known as Health and Demographic Surveillance System (HDSS)

Introduction

- This presents a good opportunity to conduct relevant clinical trials of regional and global benefit among these defined populations.

- To explore this huge potential for clinical trials, we assessed the capacity of the INDEPTH member sites to conduct clinical trials to international standards

Methodology

- A pre-tested questionnaire was sent to all INDEPTH member institutions by email
- Completed responses were sent to investigators by email.
- Phone calls were made for further clarifications on completed forms

Findings

- There were in total, 33 INDEPTH member institutions we emailed.

- 18 of the 33 INDEPTH members conduct clinical trials.
-
- 13 out of 18 member centres that conduct clinical trials responded to the questionnaire.

  – 9 members from Africa; 3 from Asia and 1 from Oceania

Respondents	Country	Population
Bagamoyo Research and Training Centre of Ifakara Health Institute	Tanzania	75,497
Dodowa Health Research Centre	Ghana	108,025
Kintampo Health Research Centre	Ghana	125,945
Kilifi - KEMRI-Wellcometrust Research Programme Clinical Trial Facility	Kenya	220,000
USAMRU-K/KEMRI KOMBEWA SITE	Kenya	60,000
Manhica Health Research Center (Centro de Investigação em Saúde da Manhiça CISM)	Mozambique	84,217
Navrongo Health Research Centre	Ghana	151,000
Centre National de Recherche et de Formation sur le Paludisme (CNRFP)/ Sapone DSS	Burkina Faso	78,701
Centre de Recherche en Santé de Nouna (Nouna Health Research Center)	Burkina Faso	78,701
CHILILAB	Vietnam	65,000
FilaBavi	Vietnam	250,000
Vadu Health and Demographic Surveillance System, Shirdi Sai Baba Rural Hospital	India	81,543
Wosera HDSS & IMR Madang	Papua New Guinea	76,000

Profile

- The oldest institution was established about 100 years ago and the youngest about 5 years ago.
- However clinical trials experience of all institutions has been of recent
- The HDSS populations in these institutions totaled about 1,463,544.
  - This large population could be part of clinical trials of long term follow up using the advantage of HDSS

Institutions research interest

- The research areas of the institutions mirror the pattern of diseases common in the populations.

- All the institutions have research interest in at least one of the following diseases –
  - Malaria,
  - HIV/AIDs,
  - Pneumonia, and
  - diarrhoea diseases.

- 4/13 institutions have interest in non

Human Resource

- All the institutions have high quality scientific leadership with PhD degrees and have had between 5 – 20 years of clinical trials experiences

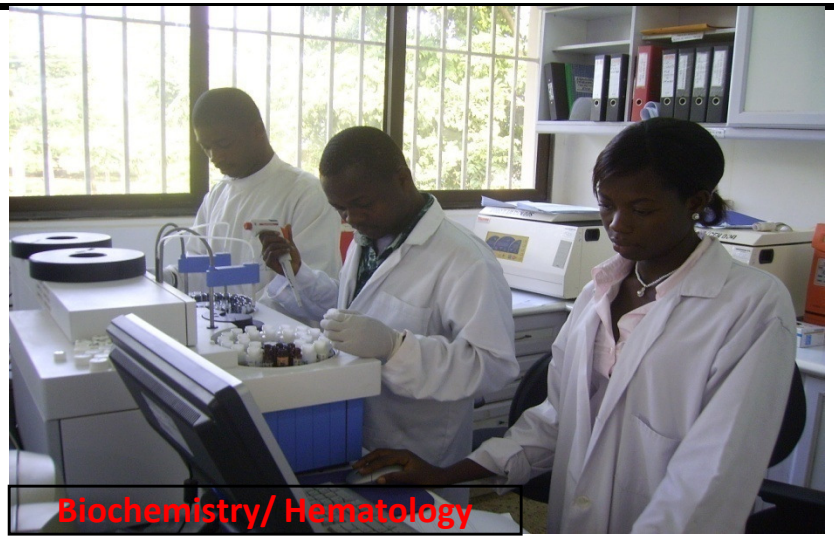
- Other key staff required for the conduct of clinical trials present at the sites included:
  - Clinicians
  - Nurses
  - Laboratory personnel
  - Data Mangers

- Trained clinical trial coordinators were uncommon.

Laboratory Infrastructure

- Basic laboratory infrastructure exist in majority of the sites.
- Laboratories that have been supported by the INDEPTH-MCTA project were much more advanced.
- Only 3/13 laboratories have capabilities in carrying out pharmacokinetic studies which may be crucial for early phases of clinical trials.

Laboratory Capacity in an INDEPTH-MCTA supported Institution



Such labs have local and international certification for QA/QC systems supported by Malaria Vaccine Initiative

Data Management/IT infrastructure

- All institutions have internet facilities for communication
- 8/13 sites have internet services that support remote data entry system.
- There is however local data management expertise that operates on various software platforms such as Microsoft Access, Visual fox pro and Oracle

Data Management Centre -Chililab

Regulatory environment

- All 13 institutions have regulatory structures for conducting clinical trials. These include:
  - Institutional ethics committees
  - National ethics committees
  - National food and drugs authorities
- Majority of the 13 institutions require submissions to multiple committees which has the potential of delaying clinical trials.
- Consenting is required at all institutions and the process requires community involvement; witnesses (if applicable); and individual consenting.

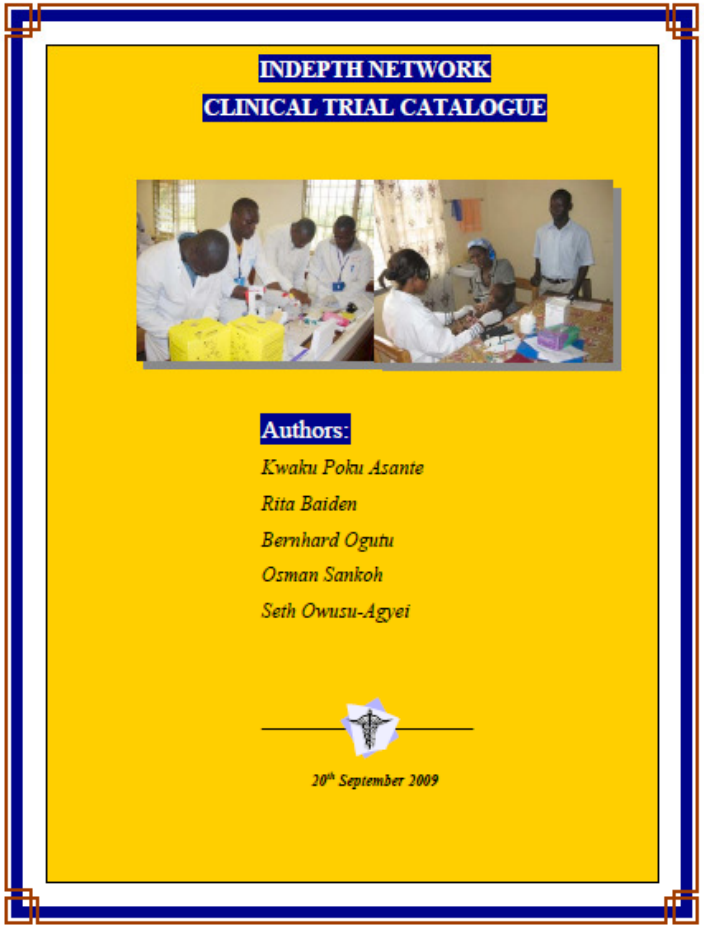
Collaborations

- Majority of the institutions collaborators are northern institutions
- Very few south-south collaborations.
- There is the need strengthen south-south collaborations to conduct multicentre clinical trials as is being done under various initiatives of INDEPTH
  - Reproductive health group
  - Antibiotic resistance working group

Conclusions

- A huge potential exists for multicentre clinical trials among INDEPTH sites given the common interest that exist.
- There is the need to share knowledge and best practices among sites.
- The infrastructure developed with the support of INDEPTH-MCTA and other partners could leverage for the conduct of clinical trials into existing diseases and emerging diseases such as hypertension and diabetes.

Publications



- A catalogue has been developed
- Will be available on INDEPTH website
- Regular updates will be required

Acknowledgements

- INDEPTH Network
- INDEPTH-MCTA
- All member Centres that provided information
- Kintampo Health Research Centre