The Global Health Network

National Skills Sharing Workshop

Managing the Laboratory Relationship

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

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UCT

Start up: Protocol development

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- Forge a mutually beneficial relationship with your analytical laboratory
- Facilitate open channels of communication
- Involve the laboratory in the protocol development

Prevent nasty surprises down the line

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Factors influencing laboratory selection

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- Accreditation
- Test availability
- Geographical location
- Past experiences
- Other or previous researchers experiences
- Previous audit findings

Researcher's aim: To perform the study within budget, delivering high quality data on time.

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The only source of knowledge is experience.

- **Albert Einstein**

Laboratory Accreditation

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- What is laboratory accreditation?
- Why do laboratories seek accreditation?
- Should you preferentially choose accredited laboratories?
- How do you evaluate accreditation certificates?

Key requirements

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- A documented management system that gives direction to the laboratory activities and directives to the staff to achieve effectiveness and efficiency in the laboratory;
- Ensures the qualifications, training and on-going competence monitoring of staff;
- Access to appropriate, serviced, calibrated equipment;
- The use of appropriate, controlled and validated methods;
- Specimen management;
- Environmental management;
- Confidentiality and professionalism.

Accreditation

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- Accreditation is the **best indicator** that the lab has the capability to do a **good** job.
- If any analysis is not performed in-house, all **supporting labs** should be accredited, as well.
- Accreditation is **not** proof of the quality of all of their data. It means that the lab is capable of providing accurate, representative, comparable, complete, and defensible data.

Search Site

News Categories

Select Category

Links

ILAC MRA Signatories
ILAC MRA Signatories
IAF MRA Signatories
Accreditation Body Membership of IAF
NLA
National Laboratory Association South Africa

Directory of Accredited Facilities

Each Facility contains a schedule linked in PDF format. Schedules can be viewed after selecting a specific laboratory or body.

Accredited Facilities

- Blood Transfusion Services
- Calibration Laboratories
- Forensic Laboratories
- Legal Metrology
- Medical Laboratories
- Pharmaceutical
- Testing Laboratories
- Veterinary
- B-BBEE Verification Agencies
- Certification Bodies
- Inspection Bodies
- Proficiency Testing
- GLP and GCP


ENQUIRE ABOUT ACCREDITATION


APPLY FOR SANAS ACCREDITATION

ACCREDITATION TIME FRAMES


CONTACT SANAS

Shortcuts

- Course Schedule 2014
- STC Meeting Calendar
- Accredited Facilities
- Publications & Manuals
- Current Tenders
- Assessor Conclaves
- Comms Meetings

Accreditation Schedules

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- A certificate of accreditation is not complete without the schedule of accreditation.
  - CERTIFICATE = Yes, we are accredited
  - SCHEDULE = We are accredited for X, Y, Z only.

M0346.08.14.pdf

Study design

Develop Study Protocol

8

Intervention and Laboratory organisation, supply and logistics

8

Intervention and Laboratory organisation, supply and logistics

Information

Laboratory tests are used in clinical trials to diagnose disease or rule out other underlying disease that could affect the results of a trial. They are also used to assess the efficacy of a medication or to monitor the effect of the trial drug on patients. It is therefore important that samples are collected appropriately and correctly to avoid any false positives or negatives which may affect not just the patients on the study but also potential patients to whom the results of the study will apply.

There are a number of factors that could influence lab parameters and they include:

- The choice of lab assessments and how they will be measured

Resources

Communicate during protocol development

Laboratory requirements

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- Sampling (tube) type, DBS?
- Label scheme and label type (storage)
- Printing
- Preparation of trial packs by whom?
- Documentation required and responsibility:
  - Laboratory manual
  - Request forms (PKW
  - “Time to freezer” forms
  - Shipping inventory
- On site storage and shipping instructions

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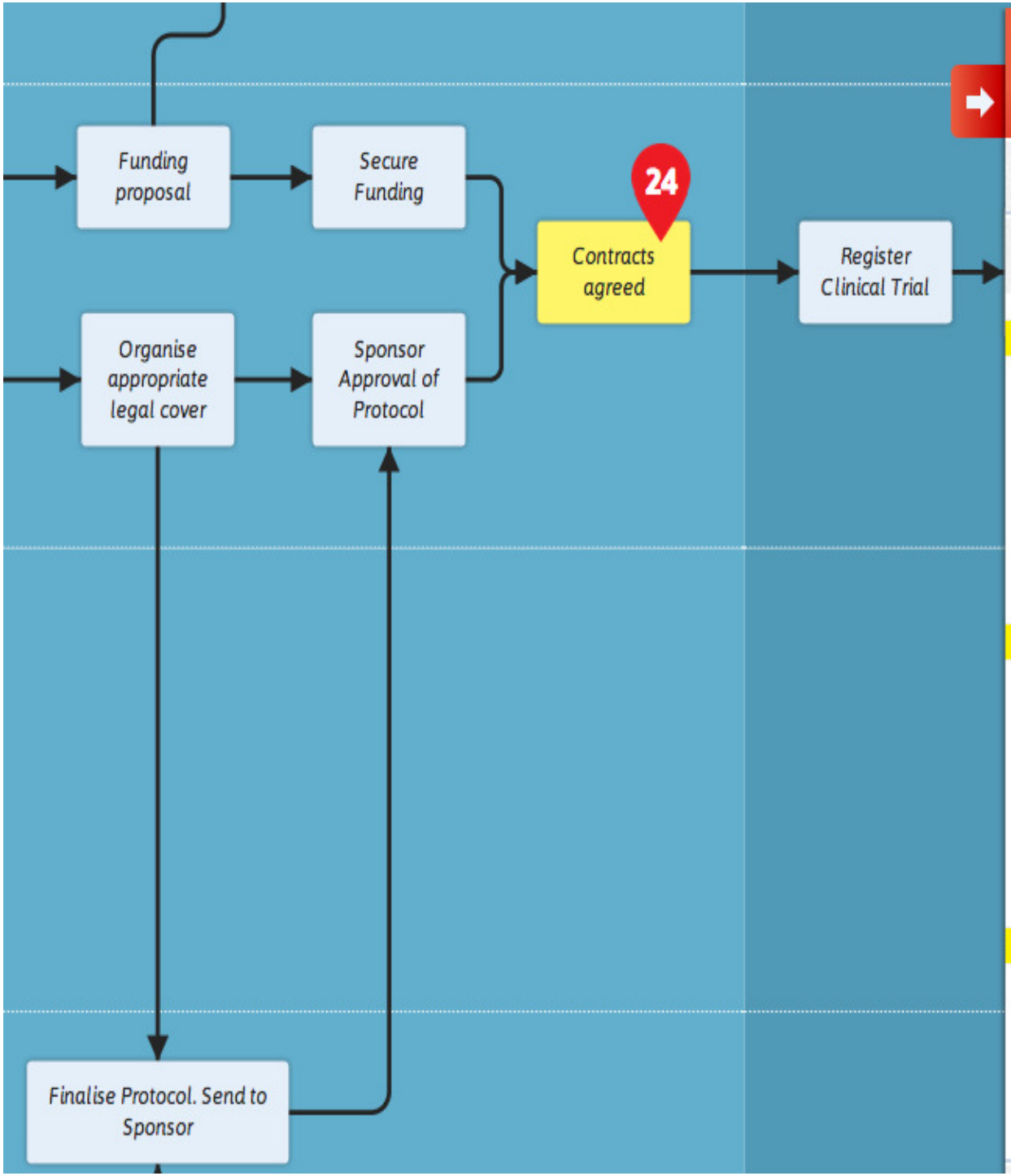
FOUND THE LAB

Obtained the sample specific instructions for the protocol (if needed)



24 Contracts agreed

Information

Resources

GLOBAL HEALTH TRIALS

Templates from an investigator-led trial in Cameroon: the CAMPS trial (also available in French)

During the setting up of our trial in Cameroon we met several operational issues that we needed to overcome. For some of these issues we developed some tools and we ...

GLOBAL HEALTH TRIALS

Clinical Trial Governance

Clinical trial governance covers the following topics: Sponsorship Contracts Finance Confidentiality Trial insurance and professional indemnity Scientific and ethical review This section will provide guidance notes along with example and ...

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Downloadable Templates and Tools for Clinical Research

Here we provide a range of free, downloadable templates and tools for use in clinical research. These have been kindly shared by organisations who have developed them for use in ...

Regulatory Issues

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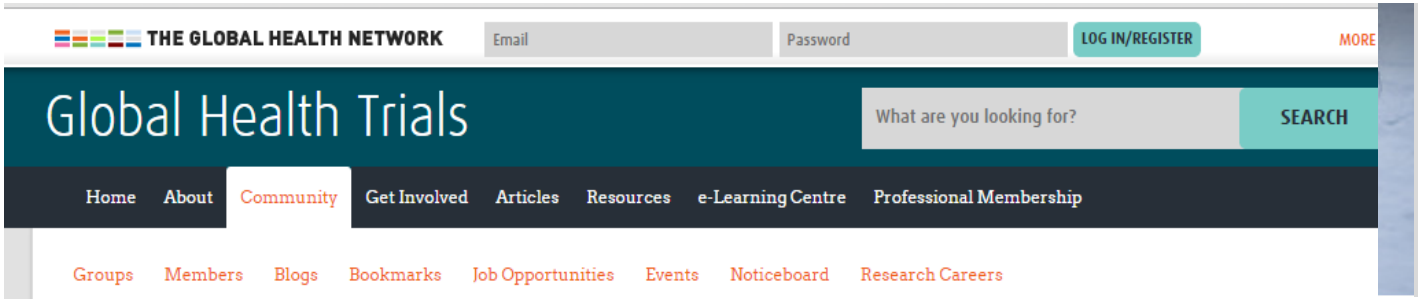
- Which regulatory guideline should be followed in the clinical laboratory?
- Accreditation = ISO (International Standard Organisation)
- Regulatory studies = GLP (Good Laboratory Practice)
- OECD and FDA GLP = Animal or non-clinical safety studies

!!GAP!!



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GCLP - The Regulatory Revolution

groups » Regulations and Guidelines » GCLP - The Regulatory Revolution

DISCUSSION STARTED BY

Peter Makuhunga
June 2, 2010

"As Good Clinical Laboratory Practice (GCLP) is based on GCP and Good Laboratory Practice (GLP), a brief history of both is important.
Up and until the early 1970s, many private and public laboratories applied GLP-type principles in one form or another. There were no national/industry regulations.
In 1972, New Zealand formally introduced GLP as a Testing Laboratory Registration Act, covering staff records, procedures, equipment, and facilities. In the same year, Denmark introduced a law to promote GLP.
In August 1976, FDA released a draft GLP document and published GLP regulations in the Federal Register. This resulted from violations noted by the FDA in an investigation of a pharmaceutical company. GLP violations included poor record keeping, data storage, inadequate personnel training, poor test facility management and fraud.
In December 1978, FDA published final GLP regulations and made compliance with them the law in the United States in June 1979. These regulations were collected in Title 21: "Food and Drugs" of the Code of Federal Regulations (CFR) as Part 58: "Good Laboratory Practice for Nonclinical Laboratory Studies.
Subsequently, FDA's Office of Regulatory Affairs (ORA) released two Guidance for Industry documents to ensure the proper and consistent interpretation of the directives by industry and by FDA's field investigators.
In September 1987, the FDA published its "Final Rule" - Compliance Program Bioresearch Monitoring: Good Laboratory Practices.
The Organization for Economic Co-operation and Development (OECD) Principles of GLP cover organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. A 1989 OECD Council Decision-Recommendation [C(89)87(Final)] established that OECD Member countries, in which testing of chemicals for purposes of assessment related to the protection of human health and the environment being conducted pursuant to the principles of GLP, shall establish procedures for monitoring compliance with GLP based upon facility inspections and study audits. In this regard, the Standards Council of Canada (SCC) established a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD. It functions in accordance with the OECD document Revised Guides for Compliance Monitoring Procedures for GLP (1995). Data generated in an OECD Member country in accordance with the OECD Principles of GLP is accepted in Member countries for purposes of assessment and other uses relating to protection of human health and the environment; that is, the Mutual Acceptance of Data (MAD).

A great article on Global Health Trials Website!

Good **CLINICAL** Laboratory Practice

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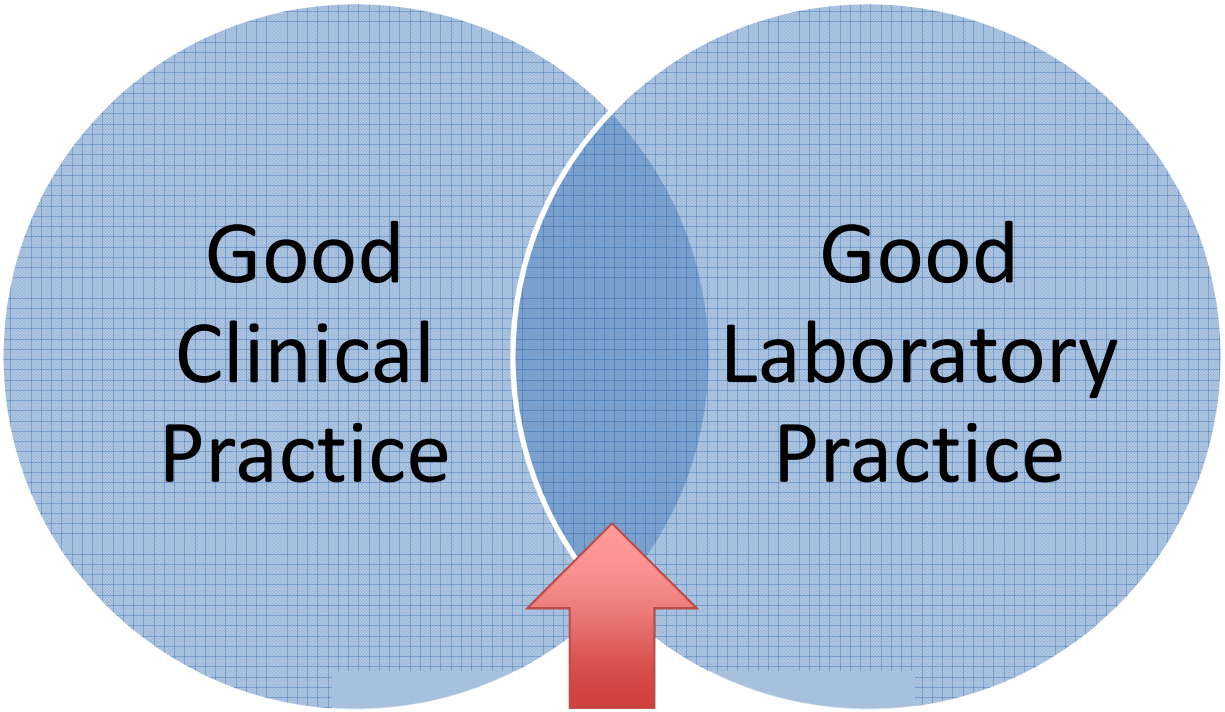

Good Clinical Laboratory Practice

- Two guidances in existence:
  1. BARC
  2. WHO TDR
- Not recognised by FDA

Regulatory Audits... A Word

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- There is no GLP accreditation.
- ISO affords an accessible and workable system for a Quality Management System
- There is no regulatory requirement to use an accredited lab.

An insurance policy

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The single biggest problem in communication is the illusion that it has taken place.

- George Bernard Shaw