WORKING TOWARDS ACCREDITATION

The Global Health Network

October 2020

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PANDORA CANTAM

www.theglobalhealthnetwork.org

OBJECTIVES

- Licensure? Certification? Accreditation?
- Accreditation Process
- SLIPTA/SLMTA
- Benefits of accreditation

SCENARIO

- **The Minister of Health has asked you as the chief laboratory specialist how to improve recognition/acceptance of laboratory results throughout the country and internationally. How would you go about doing that?**

- What is a laboratory licensing?
- What is certification?
- What do we mean by accreditation?

LABORATORY QUALITY MANAGEMENT SYSTEM

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- Assessment or evaluation
- Quality management system can
  - Accurate
  - Reproduceable results
- Qualified organisation
- Compliance with international norms and standards

LICENSE

- **Licensure** — the granting of ability to practise, usually provided by a local governmental agency.

- License to practice

- Example: Health Professions Council South Africa.

CERTIFICATION

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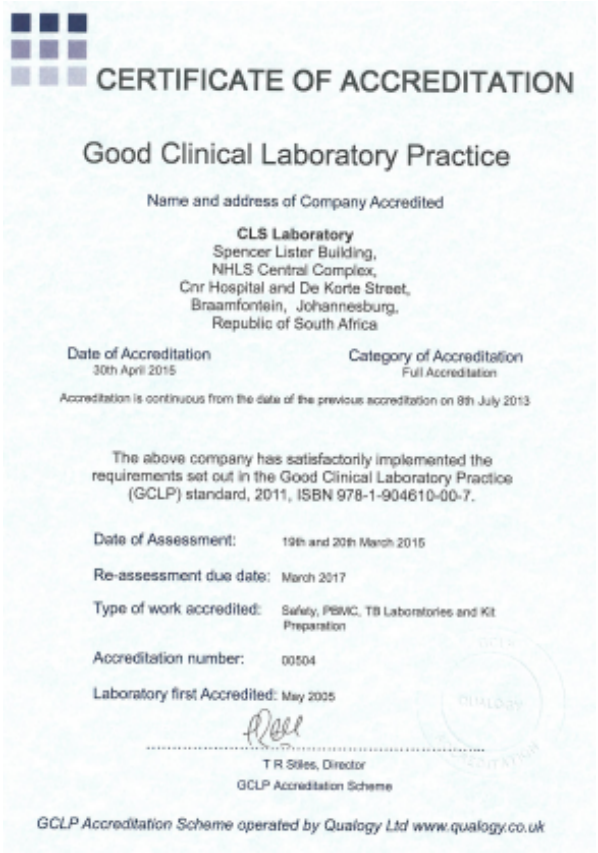
- **Certification** — the procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements.



CERTIFICATE OF ACCREDITATION

Good Clinical Laboratory Practice

Name and address of Company Accredited

CLS Laboratory
Spencer Lister Building,
NHLS Central Complex,
Cnr Hospital and De Korte Street,
Braamfontein, Johannesburg,
Republic of South Africa

Date of Accreditation
30th April 2015

Category of Accreditation
Full Accreditation

Accreditation is continuous from the date of the previous accreditation on 8th July 2013

The above company has satisfactorily implemented the requirements set out in the Good Clinical Laboratory Practice (GCLP) standard, 2011, ISBN 978-1-904610-00-7.

Date of Assessment: 19th and 20th March 2015

Re-assessment due date: March 2017

Type of work accredited: Safety, PBMC, TB Laboratories and Kit Preparation

Accreditation number: 00504

Laboratory first Accredited: May 2005

T R Stiles, Director
GCLP Accreditation Scheme

GCLP Accreditation Scheme operated by Qualogy Ltd www.qualogy.co.uk

ACCREDITATION

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- **Accreditation** — the procedure by which an authoritative body gives formal recognition that a lab or person is **competent** to carry out specific tasks.
- **Accreditation provides a higher level of assurance to those using the laboratory that its testing is reliable and accurate because it includes an evaluation of competency.**

sanas
South African National Accreditation System

CERTIFICATE OF ACCREDITATION

In terms of section 22(2) (b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-

WITS HEALTH CONSORTIUM (PTY) LTD

Co. Reg. No.: 1997/015443/07
Practice No.: 5204240

CLINICAL LABORATORY SERVICES

Facility Accreditation Number: **M0536**

is a South African National Accreditation System accredited facility provided that all conditions and requirements are complied with

This certificate is valid as per the scope as stated in the accompanying schedule of accreditation, Annexure "A", bearing the above accreditation number for

MEDICAL TESTING LABORATORY
CHEMISTRY, ENDOCRINOLOGY, HAEMATOLOGY, MICROBIOLOGY, MOLECULAR BIOLOGY, SEROLOGY AND TUBERCULOSIS

The facility is accredited in accordance with the recognised International Standard

ISO 15189:2012

The accreditation demonstrates technical competency for a defined scope and the operation of a quality management system

While this certificate remains valid, the accredited facility named above is authorised to use the relevant accreditation symbol to issue facility reports and/or certificates

Mr R Josias
Chief Executive Officer

Effective Date: 07 November 2017
Certificate Expires: 06 November 2021

ELEMENTS OF ACCREDITATION

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- Accreditation body
- Standards
- Assessors
- Laboratory

SADCAS
SOUTHERN AFRICAN DEVELOPMENT COMMUNITY ACCREDITATION SERVICE

sanas
Testing Laboratory
T0812

ilac
Accreditation:
Delivering Global Confidence

ISO

ISO

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International Organization for Standardization

- world's largest developer and publisher of international standards

- standards are applicable to many kinds of organizations including clinical and public health laboratories

SLIPTA

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World Health Organization

- WHO guidelines **Stepwise Laboratory Improvement Process Towards Accreditation** in African region.

- Provides framework to **strengthen laboratory** quality

SLIPTA PHASE I

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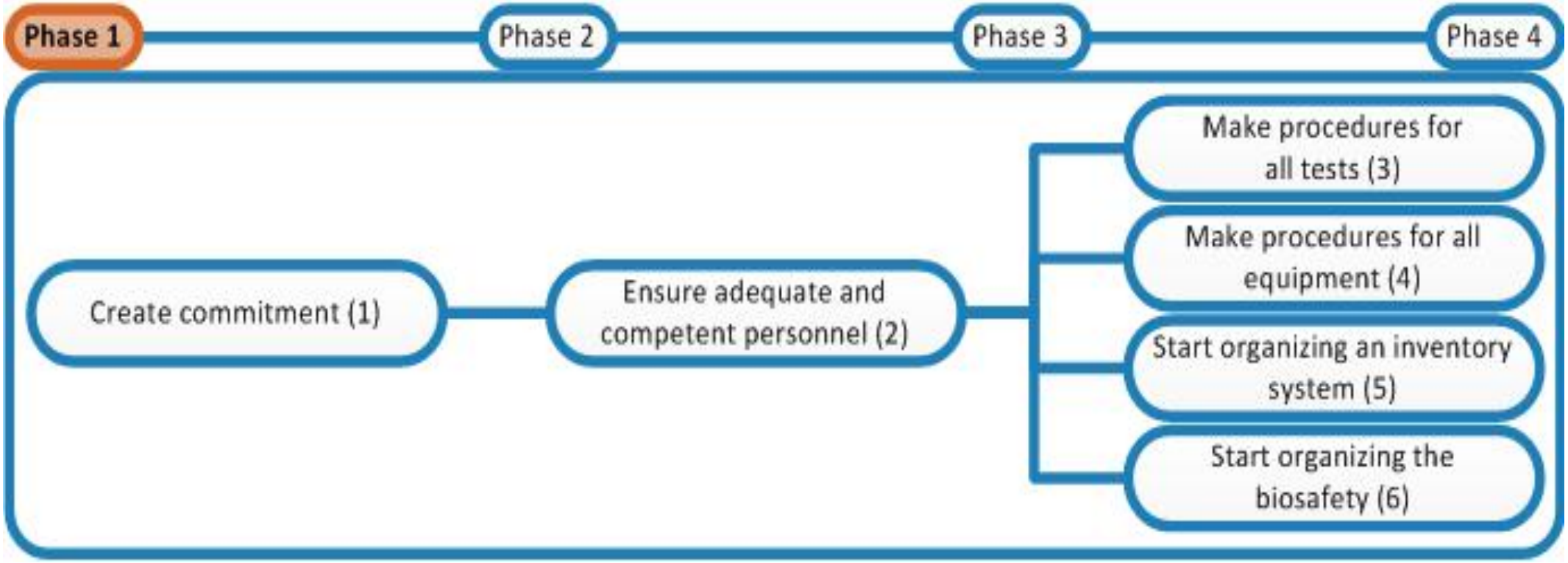

Organisation Activities Phase I

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- Quality Management team
- Make action plan with SMART
- Organise staff meetings (Weekly)
- Appoint Biosafety officer
- Appointment Equipment officer
- Stock management officer
- Make organogram

SLIPTA PHASE II

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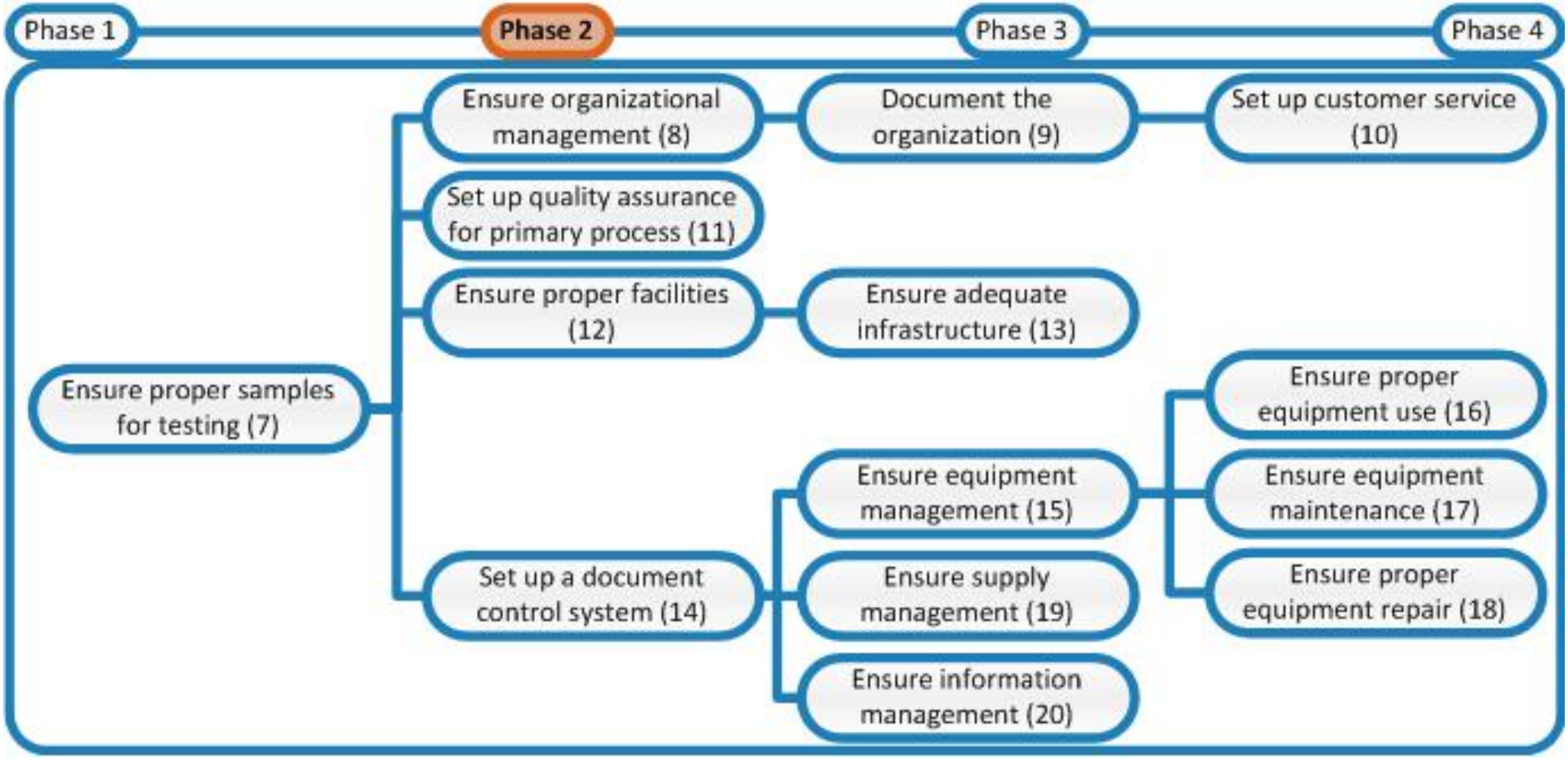

PHASE II PERSONNEL ACTIVITIES

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- Competency Assessments
- Induction programme
- Performance appraisals
- Staff files

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SLIPTA PHASE III

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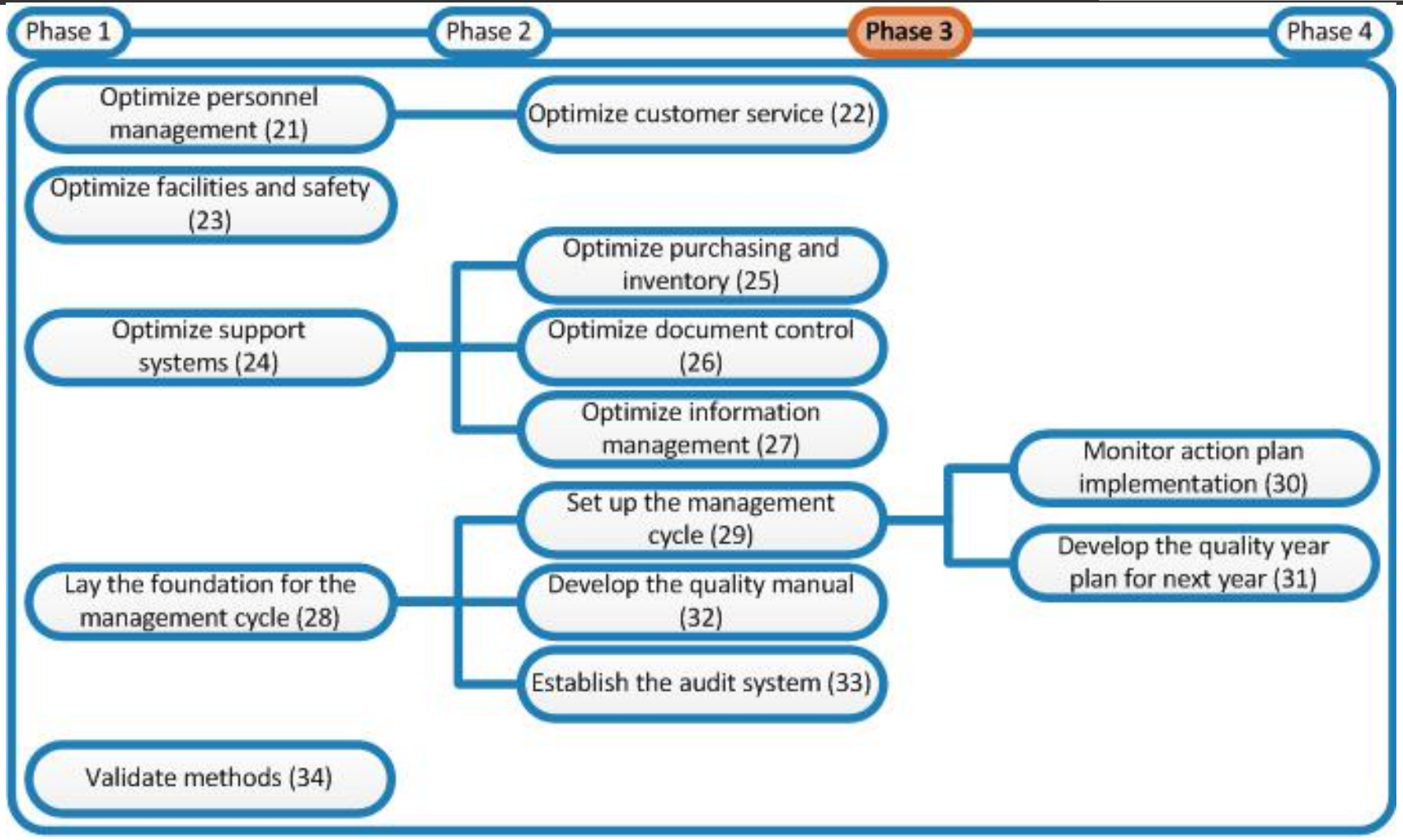

PHASE III PROCESS MANAGEMENT ACTIVITIES

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- Determine TAT
- Monitor adherence to TAT
- Validation SOP
- Validate all processes

QUALITY AUDIT

- ISO 15189 and 17025 emphasise internal audits
  - Must have audit programme
  - Auditors independent of activity
  - Document audits
  - Retain audit reports
  - Report audits to management
  - Promptly address findings
- Audit training for QM/auditors
- 12 months audit programme
- Conduct audits
- Formulate action plan
- Write an internal audit SOP

SLIPTA PHASE IV

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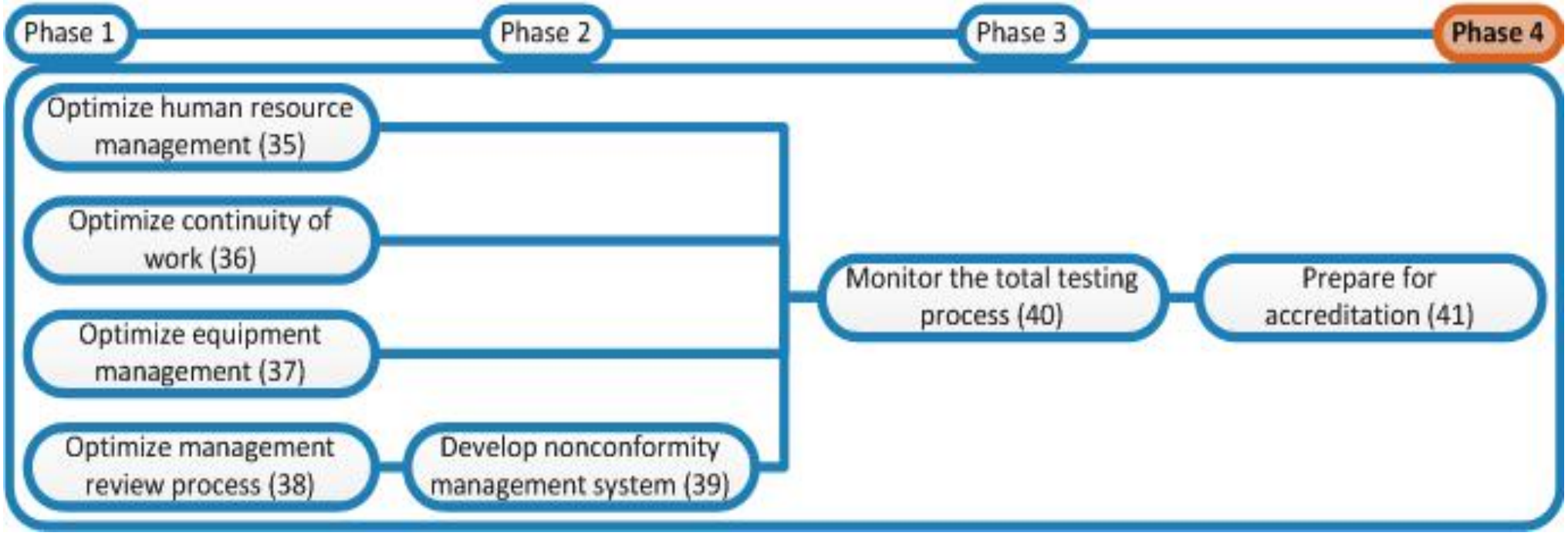

PHASE IV PERSONNELACTIVITIES

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- Staff complement
- Procedure for new staff
- Education needs
- Continuous professional development
- Failure mode effect analysis (FMEA)

ACCREDITATION PROCESS

- Formal recognition that a testing or calibration laboratory is competent to carry out specific tests or calibrations

Competent”

Specific tests or calibrations

- Accreditation is having a Management System and demonstrating competency

- Laboratories are accredited for specific tests or calibrations and particular products and test or calibration specifications

COMMON STANDARDS

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- CERTIFICATION
  - ISO 9001:2015
  - ISO 14000
- ACCREDITATION
  - ISO 17025
  - ISO 15189:2012
- REGULATIONS
  - USA CLIA
  - French GBEA
  - UN Transport of Dangerous Goods

ISO/IEC 17025

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- Enables laboratories to demonstrate they:
  - Operate competently
  - Generate valid results
  - Testing and calibration
  - Does not cover safety operations

ISO 15189:2012

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- Specify requirements for:
  - Medical Laboratories
  - Quality Management processes
  - Technical processes
  - Administrative systems

ACCREDITATION STEPS

- Application
- On-site assessment
- Deficiencies
- Proficiency testing
- Accreditation decisions
- Annual review
- Re-assessment/Renewal of accreditation

BENEFITS OF ACCREDITATION

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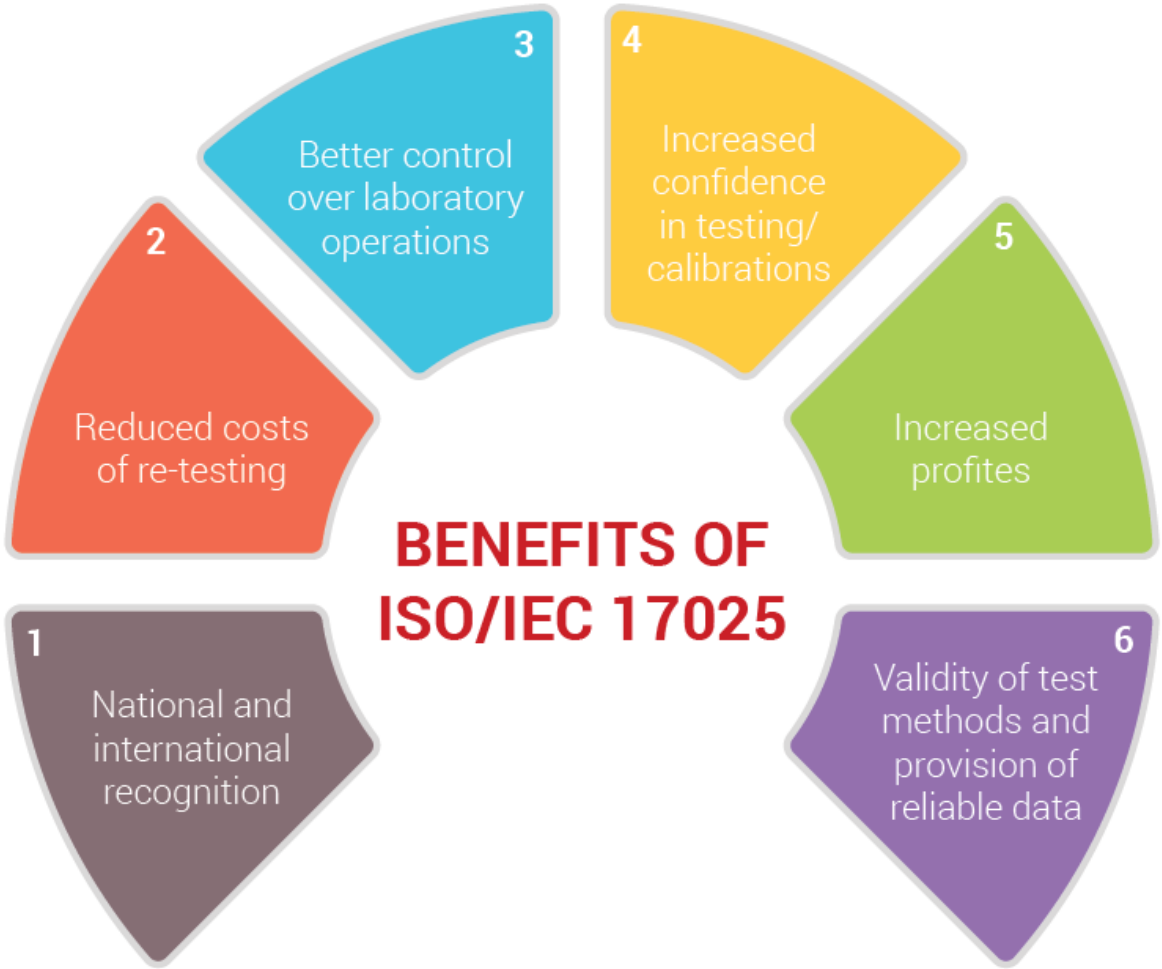

Acknowledgements

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Director, The Global Health Network

The Global Health Network Operational Team:

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