SACRA
SOUTH AFRICAN CLINICAL RESEARCH ASSOCIATION

8th Clinical Research Conference

2018 26-28 SEPT

Clinical Trial Updates and Collaborations

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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LAYOUT

1. Regulatory Authority: South African Health Products Regulatory Authority (SAHPRA)
2. Legislative framework
3. Stakeholders in Clinical Trials
4. Updates
5. Current Regulatory Challenges
6. Opportunities and Collaborations

SAHPRA

- The Medicines & Related Substances Act, 1965 Amended
  - Act 72 of 2008: **Establish SAHPRA**
    - Public Entity
    - Extended the mandate to include Medical Devices
    - Enacted: 01 June 2017, this also enacted Act 14 of 2015
  - Act 14 of 2015:
    - Appointment of a Governance Board
    - Expand oversight of Medical Devices to include *IVD*'s
    - Address transitional arrangements from MCC to SAHPRA
      - Work of the MCC
      - Staff
      - Assets and contracts
  - General Regulations published : 11 August 2017

SAHPRA (2)

Minister

SAHPRA – Public entity

BOARD

Board Committees

Acting CEO

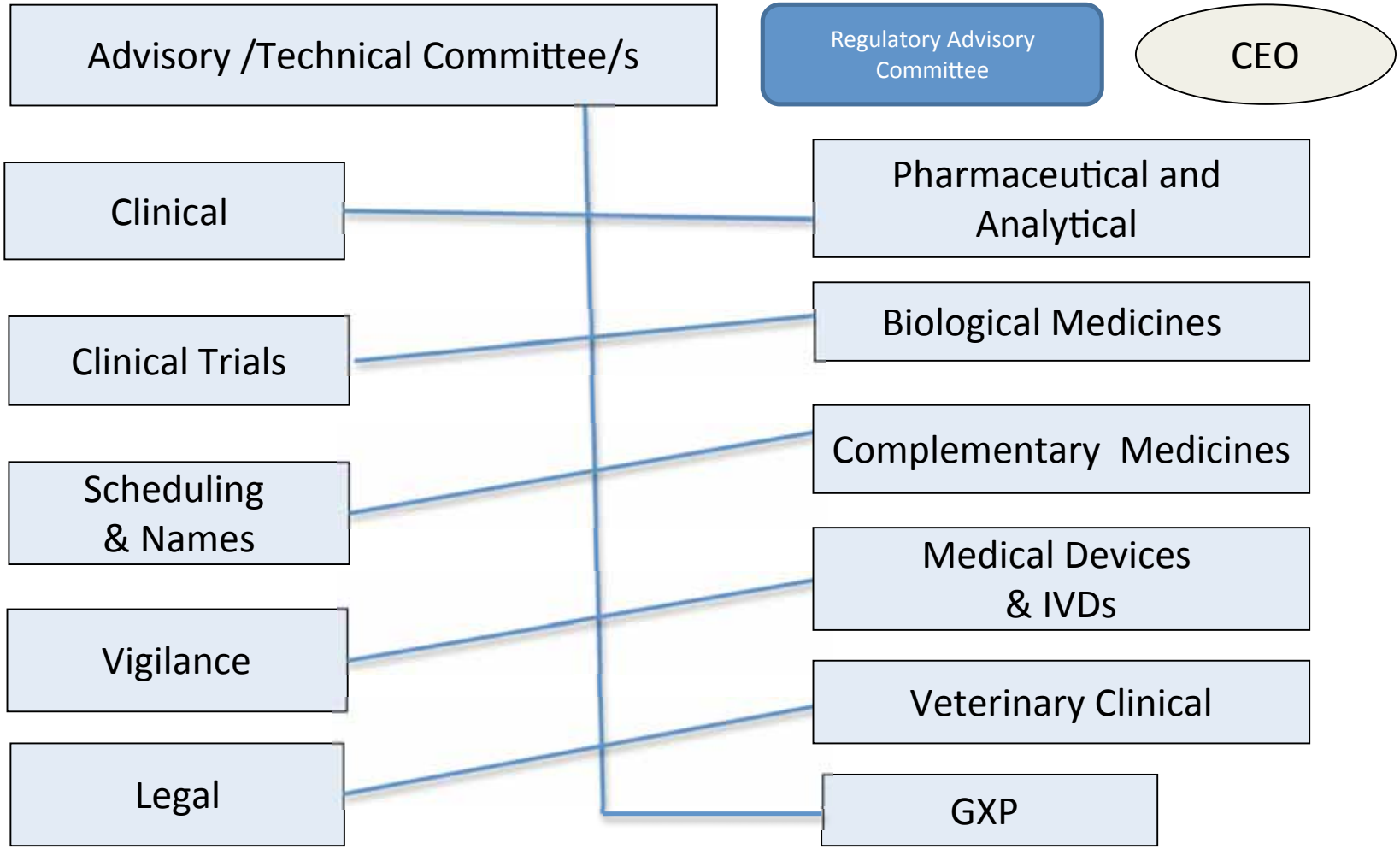
Authority

SAHPRA (3)

- **SAHPRA is responsible for**:
  Monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.
- SAHPRA will:
  - have **full-time in-house capacity** to support product review & approval and oversee all regulatory functions
  - establish **cooperation and information** sharing with other NRAs to support implementation of best practices and timely approval of products

SAHPRA (4)

Current Expert Committees



LEGISLATIVE FRAMEWORK (1)

Legislative framework governing Clinical Trials

- South African Constitution: Act 1996 (Act 108 of 1996) Sec 12(2) – Bill of Rights
- South Africa Health Products Regulatory Authority
- National Health Research Ethics Council
- Local Ethics Committees
- South African Good Clinical Practice Guidelines
- Other Acts and Regulations (Medicines and Related Substance Act, National Health Act, Children's Act, Mental Health Act, and other legislation outside of Department of Health)

LEGISLATIVE FRAMEWORK (2)

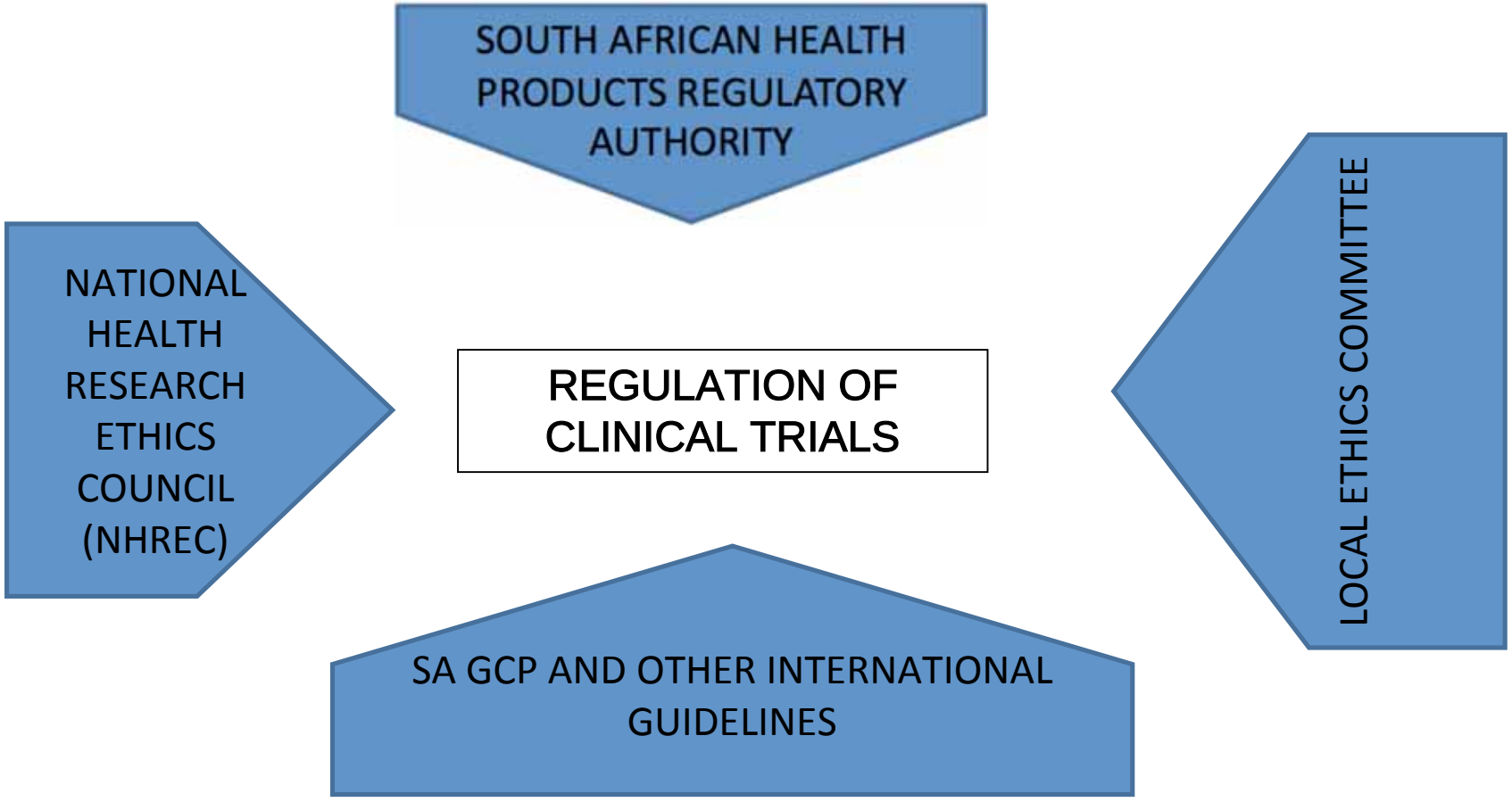
- International Guidelines e.g.
  - ICH Guidelines
  - ABPI Guidelines (Association of the British Pharmaceutical Industry)
  - CIOMS Guidelines
  - Declaration of Helsinki

- Before a clinical trial can be conducted in South Africa, the application must be approved by the South African Health Products Regulatory Authority, Local Health Research Ethics Committee and registered by the Department of Health on South African National Clinical Trials Register (SANCTR).

LEGISLATIVE FRAMEWORK (3)

- **SAHPRA**: Established in terms of the section 21 Medicines and Related Substances Act 101 of 1965, as amended and regulation 30 of the Act, to regulate the conduct of clinical trials in South Africa
- **National Health Research Ethics Council:** Established in terms of the National Health Act 2003 (*Act No 61 of 2003*) to promote and monitor good ethical research in the RSA. It registers all Ethics Committees
- **Local Health Research Ethics Committees**: Also established in terms of the National Health Act 2003 (Act No 61 of 2003) to review research protocols and grant approval for those that meet ethical standards

LEGISLATIVE FRAMEWORK (4)



LEGISLATIVE FRAMEWORK (5)

South African Health Products Regulatory Authority:

- Has statutory obligation to ensure that medicines available in the country fulfill the requirements of safety, quality and efficacy
- That clinical trials on human participants are designed according to sound scientific and ethical standards within the framework of Good Clinical Practice
- That the rights, safety and well being of research participants are protected
- Has authority to terminate a clinical trial for reasons of SAFETY or where there is evidence of gross GCP violations

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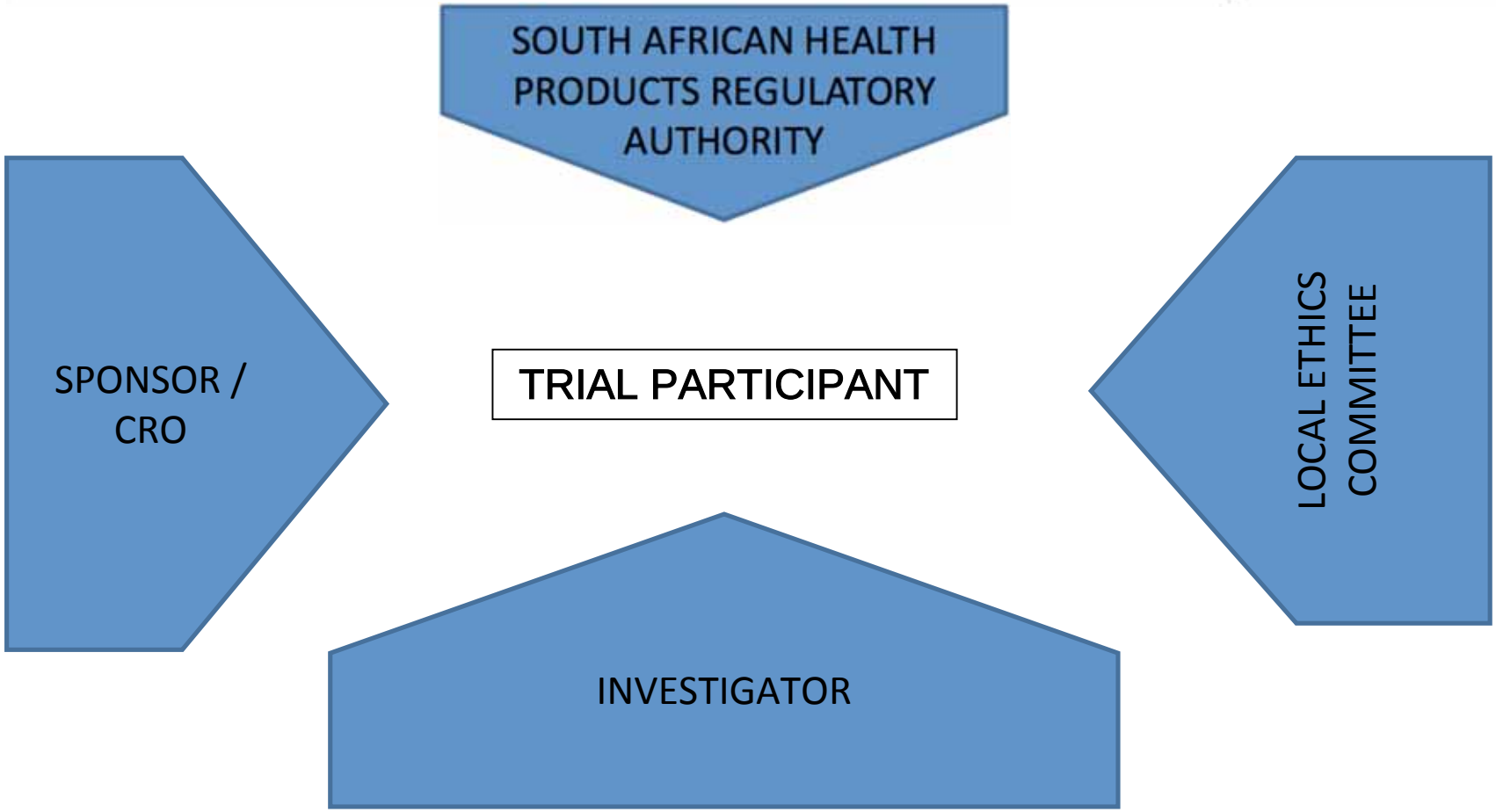
LEGISLATIVE FRAMEWORK (6)

Clinical Trials Committee of SAHPRA:

- 16 Members and evaluators who have their primary job elsewhere.
- ***Expertise:*** General Medicine, Oncology, Psychiatry, Paediatric, Pulmonology, Cardiology, Public Health, Biostatistics, epidemiology, pharmacology, virology, microbiology, immunology, ophthalmology, GCP, ethics and quality.

Stakeholders in Clinical Trials



UPDATES (1)

Documents Published for Implementation:

- Emergency Procedures for Clinical Trial Sites
- Post Clinical Trial Access
- Oversight and Monitoring in Clinical Trials
- Clinical Trial Participant Time, Inconvenience and Expense Compensation Model
- Revised Clinical Trial Form 1
- Notification Studies: Phase IV
- Six-Monthly Progress Report Form for Clinical Trials
- Electronic Submission of Clinical Trial Documents
- Clinical Trial Investigators
- Safety Reporting in Clinical Trials

UPDATES (2)

Documents Published for External Comment:

- Capacity Building and Transformation
- Quality of medicines Used in Clinical Trials

Documents Published for Internal Comment:

- Workload
- Liability Insurance for Clinical Trials
- Clinical Laboratory Competence For Clinical Trial in SA

UPDATES (3)

Documents Under Review:

- Clinical Trial Application 2 (amendments)
- General Guidance Document
- Proposed Template for meetings with external stakeholders
- Policy on Rehabilitation (GCP Violation)
- Conditions for first in human studies
- Good Clinical Practice Guideline

UPDATES (4)

Operational/Regulatory Systems:

- EDMS underway for entire organisation
- Improved timelines
- Some reviews done in-house
- Independency as some decisions are taken in-house
- Accountability team
- Training underway
- Housing of SAHPRA staff
- Transfer of staff to SAHPRA

UPDATES (5)

- Executive Positions advertised and interviews already started

Current Regulatory Challenges (1)

Clinical Trials Unit of SAHPRA:

- Processes in place but no electronic system yet
- Still receive loose documents or incomplete documents
- Applicants not adhering to submission requirements which delays the process further
- Lack of proper planning from Applicant

Clinical Trials Committee of SAHPRA:

- Harmonization and collaboration
  - Minimal harmonization and collaborative efforts
- Complexities of studies
  - Complex study designs
  - Cancer studies- although holds potential but other patients with co-morbidities are excluded
  - Genes and genomic studies and stem cell studies

Current Regulatory Challenges (2)

- Lack of understanding in completion of clinical trials protocol and documents – particularly investigator initiated trials – protocol development done elsewhere
- 16 Members and evaluators who have their primary job elsewhere.
- Lack of standardization of GCP course (No agreement on course content and method of assessment)

Regulator:

- Electronic system not in place yet
- Transitional processes
- Still housed in NDOH Building

Opportunities & Collaboration (1)

- Electronic system to applicants to capture information themselves to avoid errors
- Documents to be submitted electronically
- Independency

Opportunities & Challenges (2)

Regulatory Collaboration & Networking

- Work sharing and exchange of information with other recognised regulatory authorities
- Joint review and co-evaluation of applications
- Abridged methods that avoid duplication of effort – Reliance mechanisms
    - Reliance: ZAZIBONA – Collaborative review platform for review of dossiers for registration
    - AVAREF: provide regulatory authorities with expertise, information sharing and capacity building; and Joint review of clinical trials applications

Opportunities & Challenges (3)

Regulatory Collaboration and Networking

- CTC working closely NHREC
- Bi-annual Stakeholder Meeting
- *Adhoc* Policy Task Team

Contingency measures during go-slow action

- Off site activities
- Interim electronic system – automation
- Building (assistance from National Treasury to comply with PFMA
- Electronic submission of investigators and listing

THANK YOU