SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION

SALDA

SALDA – MDRC_SAHPRA MEETING

15 Nov 2023

SOUTHERN AFRICAN LABORATORY
DIAGNOSTICS ASSOCIATION

SALDA

The Southern African Laboratory Diagnostics Association is a body that represents laboratory medicine in Southern Africa. It is a unified voice around In Vitro Diagnostics (IVD) and a collaboration of multinational and local companies who distribute In Vitro Diagnostic tests/equipment. SALDA has a constitution and operates under a code of ethics.

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SALDA EXCO

TANYA WILSON - CHAIRPERSON
The Scientific Group - Local

MICHELLE BRONZE - VICE CHAIRPERSON
Diagnostech - Local

GREG NORTHFIELD
Separation Scientific - Local

SABINE HELLYER
Thermo Fisher- Multinational

THOMAS RAFUNDISANI
Beckman Coulter - Multinational

JAN KALJEE
SMM Instruments - Local

DUNCAN MACKAY
Becton Dickinson - Multinational

LOSHNEE VANDAYAR
Cepheid - Multinational

ANDISWA LAWANA
Roche - Multinational

SARAH COHEN
SALDA Executive Officer

KELEBOGILE LETSWALO
SALDA Marketing and Communications Officer

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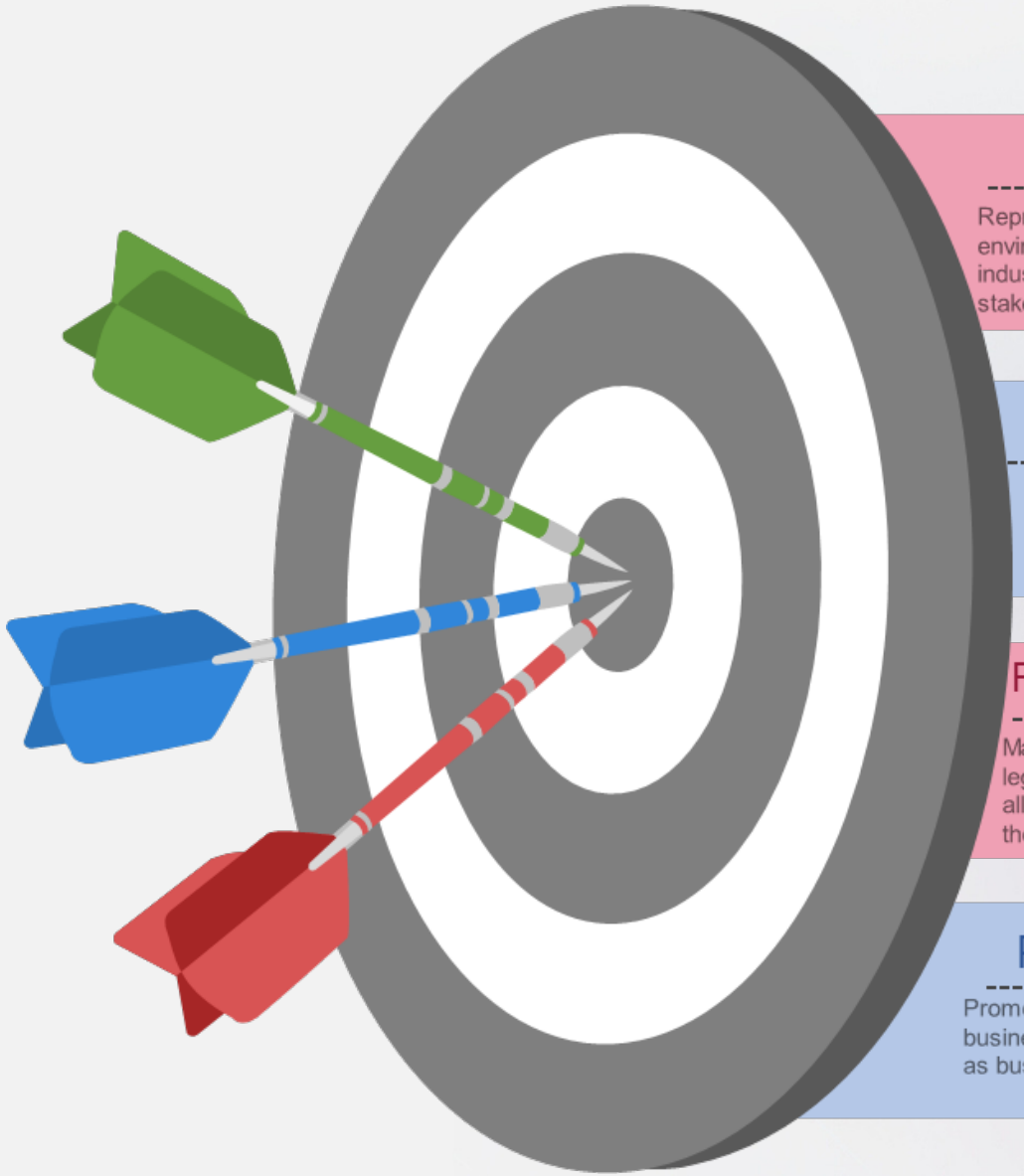
We believe IVDs are a key contributor to support and broaden universal healthcare coverage in resource-limited environments

Our Mission

IVDs contribute to more than 70% of all medical diagnosis and can be used to decrease overall healthcare costs. We believe that broader access to innovative diagnostic tools will drive and support the healthcare paradigm.

Our association aims to lead and highlight the relevance and impact of IVD, influence patient lives and wellbeing, improve access, propel the market within Southern Africa. We actively engage with necessary stakeholders, public, private, advocacy, patient groups about the value industry brings to patients.

SALDA OBJECTIVES



Industry Representation

Represent the interests of its members in the laboratory and IVD environment and participate at all relevant forums: health sector industry bodies, government departments and health sector stakeholder and industry collaborations

Engage

Respond to health sector and business environment changes affecting the interests of its members.

Regulatory & Legislative Advocacy

Make representations to legislative authorities where legislative and regulatory frameworks are proposed and bring all legislative and regulatory issues affecting its members to the attention of appropriate authorities.

Promote the value of IVD

Promote the field of IVD in the health sector and broader business community, to interact with other health sectors as well as business stakeholders as may be required from time to time

Stakeholder Engagement

national regulator for
compulsory specifications

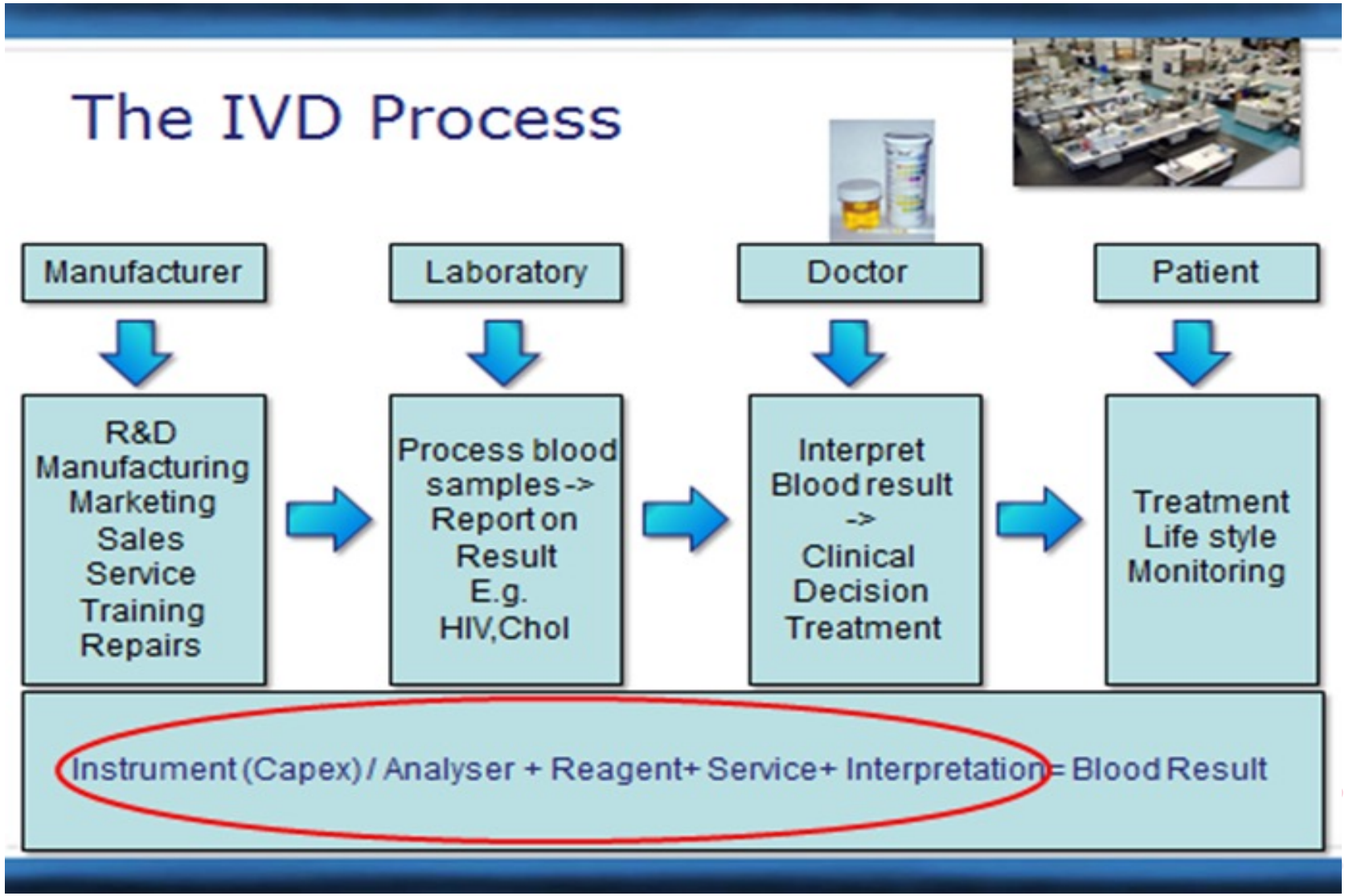
National Economic Development
and Labour Council

Background

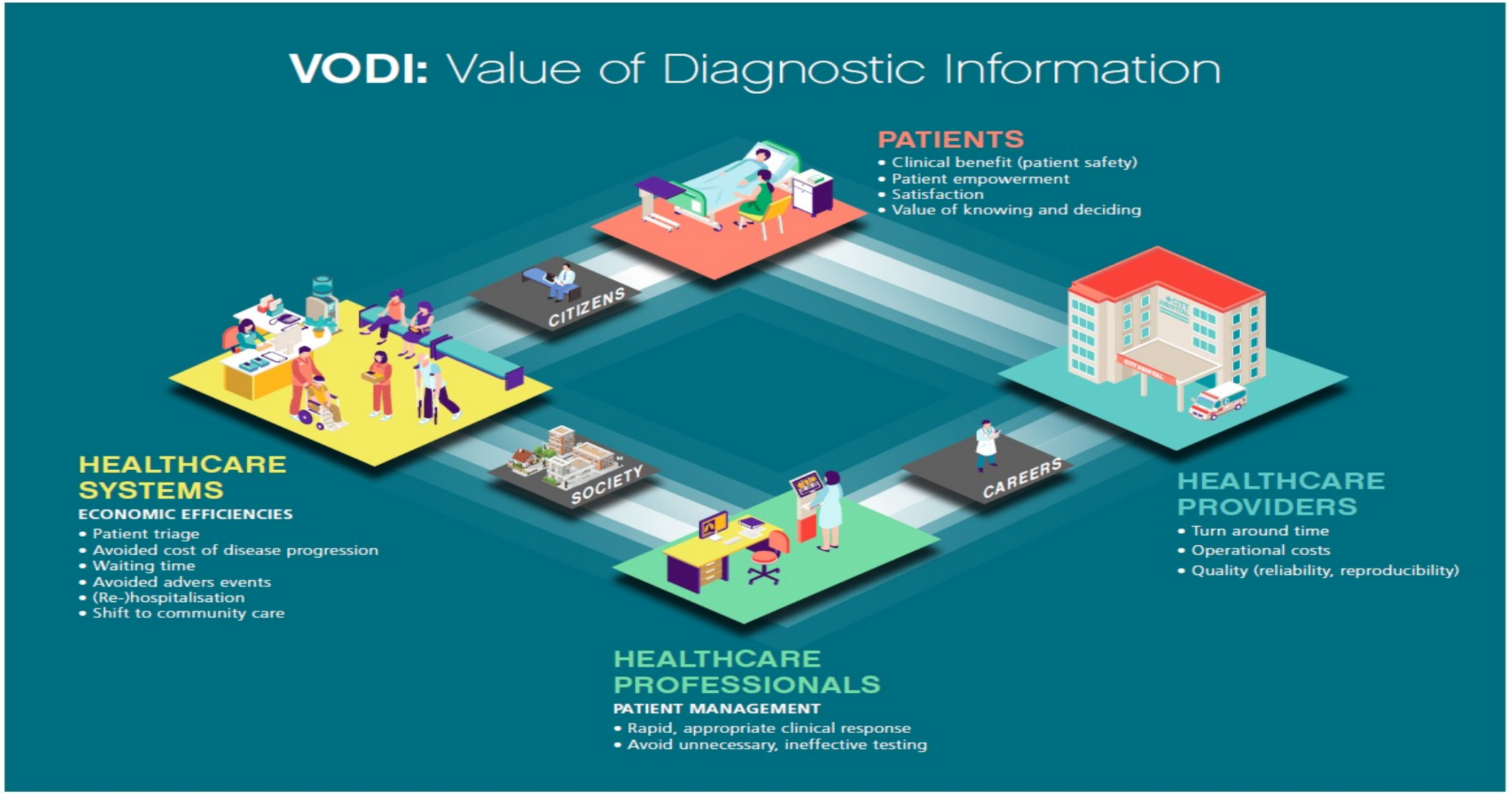
In Vitro Diagnostics are made up of various disciplines:

- Each of these is a specialisation on its own, many have requirement for quality compliance and cold chain management
- Includes Research and Development and Clinical trials/evaluation

IVD Process


The IVD Process
Manufacturer
Laboratory
Doctor
Patient
R&D
Manufacturing
Marketing
Sales
Service
Training
Repairs
Process blood samples -> Report on Result E.g. HIV,Chol
Interpret Blood result -> Clinical Decision Treatment
Treatment Life style Monitoring
Instrument (Capex) / Analyser + Reagent+ Service+ Interpretation = Blood Result

Value of Diagnostic Information



Wurcel et al. (2019)[4], modified illustration

IVD Applications

- In the field of medicine, precise and rapid diagnostics are crucial for identifying diseases, monitoring treatment responses, and guiding therapeutic decisions.
- In vitro diagnostics (IVD) play a vital role in modern healthcare by enabling accurate and timely detection, monitoring, and management of various diseases and medical conditions.
- These diagnostic tests are conducted outside the living organism, typically in a laboratory setting, using patient samples like blood, urine, tissue, and other bodily fluids.
- IVD has revolutionized medical practice, leading to earlier diagnoses, personalized treatment plans, and improved patient outcomes.

In Vitro Diagnostics (IVD) has a **wide range of applications** across various areas of medicine and healthcare due to which it can witness tremendous growth in the coming years. **These include**:

- - Disease Diagnosis
- - Monitoring Disease Progression
- - Personalised Medicine
- - Drug Development and Clinical Trials
- - Blood Banking and Transfusion Medicine
- - Fertility and Pregnancy Testing
- - Point-of-Care Testing (POCT)..Etc

Laboratory Environment – South Africa

- Public – National Health Laboratory Services – Diagnostics, Research and Surveillance
- Private – National Pathology Group/Laboratory Medicine Group - Diagnostics
- Academic – Linked to Universities – research and innovation
- Basic research and development facilities
  - Genomics
  - Vaccine
  - Local manufacture

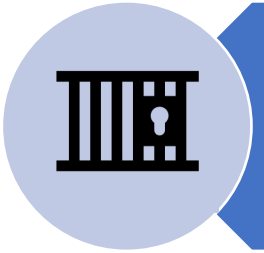
- Accreditation – South African National Accreditation System(SANAS)
  - ISO15189
  - GCLP (Good Clinical Laboratory Practice)
  - ISO17025
  - ISO 13485

Challenges and Opportunities

Regulatory Compliance

- Revised regulations /Fees
- Licensing
- ISO13485

NB . Product Registration -PENDING

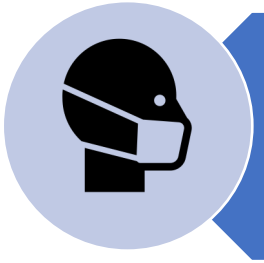


Detainments (Port Health)

- Export /Import requirements (NDOH)
- Animal products (Dept. of Agriculture)

Footprint in Africa

- Opportunities to engage with other countries (Mecomed, GMTA, MedTech Europe) as an industry
- Understanding, consolidating, standardising regulations/ trade in each country (especially in SADC region)



Pandemic Readiness

- Lessons from COVID to apply to other disease outbreaks, pandemics
- Opportunity to grow our industry

NB . Public Private Partnerships

Pre-Qualification of IVDs - World Health Organization (WHO)

- Less structured regulatory framework for IVDs in the past

WHO – use of IVDs to guide clinical decision making

  - WHO pre-qualification – aim to focus on quality and performance of IVDs
  - Access to safe, efficacious products and diagnostic technologies of good quality per standard requirements
  - Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings

- Pre-Qualification assessment encompasses following :

✓ Dossier review (conforms to essential principles of safety and performance of MD/IVDs)

✓ Manufacturing Site inspection – QMS Functional - Critical areas

❖ Instructions for use

❖ Stability of products

❖ Training

❖ Complaints handling

✓ Laboratory evaluation

✓ Labelling review based on internationally recognized standards and WHO guidance and specifications.

Once evaluated, if the products are deemed compliant, they are listed as eligible for procurement on the public website.

Laboratory Evaluation

- Performance and Operational Characteristics
- Meet acceptance criteria
  - Sensitivity
  - Specificity

Details provided in the report :

- Product provided for evaluation
- Specimen panels tested
- Reference results
- Data Analysis
- Results
- Appraisal by laboratory personnel
- Appendices containing data generated during the evaluation

* Product eligible for procurement if it passes the criteria above.

Post –Market Surveillance

- Safety
- Quality
- Performance

✓All critical once placed on the market and is the obligation of the manufacturer

✓Need strengthened post-market vigilance process to protect patients

Barriers to Trade and other obstacles

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- Regulations not streamlined across the continent. Need good regulatory practices ; Reliance
- Heavily regulated under IVDR
- Patient Impact – surge of Antimicrobial Resistance hence new technologies required
- Access to IVDs: Financial disparities in SA linked to access – rural vs urban; WHO Resolutions – strengthening diagnostics capacity
- Knock on effect of COVID-19 – lack of testing for TB/HIV etc. has led to increased cases globally impacting the IVD/ diagnostics market
- POC testing /self-testing/near-patient testing/RUO

Recommendations

- Good Regulatory Practice – Regulate only what is strictly necessary to fulfil the mandate
- Define the practical steps to regulate and group products to reduce application costs
- Determine the organisational capacity required at the company and the regulator – i.e., skills and capacity building
- Use available expertise from the industry; what about innovation
- Reliance – accept certification from selected regulators without requiring dossiers that require additional intense review
- Estimate fees required to support the planned process of registration (consider SMEs and possible banding structure)
- Adjust fees and requirements to do no harm to the sector
- Protect the access to IVDs for all South African patients

Any Questions ?