12–15 SEPTEMBER | VIRTUAL CONFERENCE

TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

2023 AFRICA REGULATORY CONFERENCE

ORGANIZER IFPMA

PARTNERS leem les entreprises du médicament, IPASA, kapi KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY, arePI, LIPA

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Welcome to the 5th Africa Regulatory Conference

We will be starting soon …

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12–15 SEPTEMBER | VIRTUAL CONFERENCE

Conference Opening Remarks

Nevena Miletic

Regulatory Policy Head Eastern Europe, Middle East & Africa (EEMEA), Global Regulatory Policy

F. Hoffmann-La Roche

IFPMA ARN Co-chair

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TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

DAY 1 | How can the regulatory ecosystem in Africa be strengthened?

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THANK YOU FOR JOINING!
Participant guide

- The 5th AfRC conference is held in English.
- All participants are muted. We encourage you to use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also “like” that question.
- For some sessions, participants will have the opportunity to also engage with speakers through Mentimeter polls. To take part, a QR code will be displayed on screen and a link will be shared in the chat box.
- We encourage you to join all conference days.
- The 5th AfRC conference is recorded. All speaker presentations and videos will be made available on the africaregulatoryconference.ifpma.org website after the conference.

Présentations en anglais. Veuillez appuyer sur le globe pour avoir l’interprétation en français.
Apresentações em inglês. Clique no globo para interpretação em português.

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Keynote speech

Margareth Ndomondo-Sigonda

AMRH/AMA Advisor

AUDA-NEPAD & AUC

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OUTLINE

01. The New Public Health Order

02. The changing regulatory landscape in Africa

03. AMA Ratification & Operationalization - A Shared Responsibility

04. Conclusion

2023 AFRICA REGULATORY CONFERENCE

01. NEW PUBLIC HEALTH ORDER

COVID-19 Pandemic exposed the continent's vulnerabilities in ensuring access to vital drugs, vaccines, and health technologies.

- The African continent sidelined in the global rush for vaccines in 2021 and 2022—currently fewer than half of the African population has been fully vaccinated.

- The grappling health care delivery system and supply chain disruptions was a major limitation to access the needed quality health care services by majority of populations.

- The New Public Health Order strategy of the African Union calls for Africa to protect itself against the threat of infectious diseases, and has entrusted the Africa CDC with the responsibility of promoting the prevention and control of diseases in Africa.

01. NEW PUBLIC HEALTH ORDER…

Partnership for African Vaccines Manufacturing (PAVM)

- An off-shoot of the New Public Health Order - calls for Africa to protect itself against the threat of infectious diseases, including the need for expanded manufacturing of vaccines, diagnostics, and therapeutics.

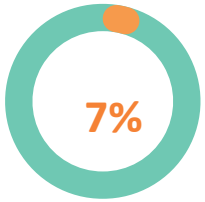
- The overall goal is to attain local production of 60% of vaccines needed on the continent by 2040.

- Regulatory systems strengthening is one of the key pillars of the PAVM Framework implemented under the African Medicines Regulatory Harmonization (AMRH) Initiative and eventually the African Medicines Agency (AMA), once operational.

- All these frameworks and initiatives are built on a firm foundation of the Pharmaceutical Manufacturing Plan for Africa (PMPA).

02. THE CHANGING REGULATORY LANDSCAPE IN AFRICA

- Prior to the establishment of AMRH, WHO reports showed that only:



of African countries NRAS have moderately developed capacity with more than

of NRAS having minimal or no capacity.

- The establishment of the AMRH Initiative in 2009 aimed to address weak and/or outdated laws coupled with fragmented regulatory systems on the African continent using regional structures.

- The AMRH Vision is to move from 55 national regulatory agencies operating separately, to a regional harmonization approach and eventual continental framework through AMA.

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02. THE CHANGING REGULATORY LANDSCAPE IN AFRICA…

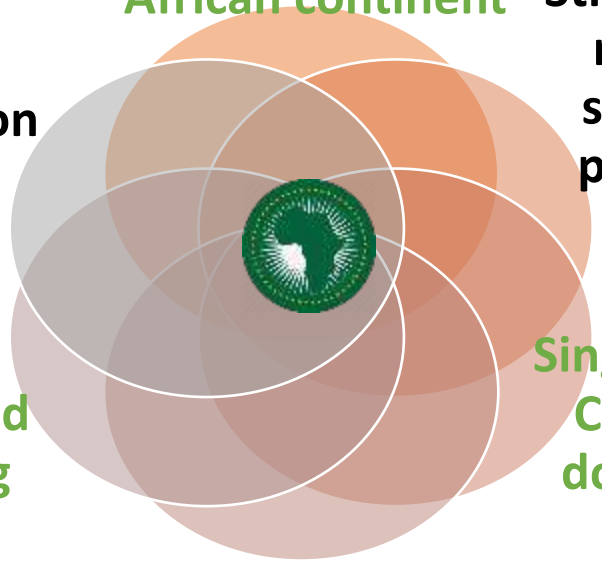
The AMRH vision 2009

Streamlined (harmonized) future

Faster registration

Resource pooling and information sharing

Between 5-7 regional economic communities (RECs) covering the entire African continent



Stronger, institutionalized regulatory capacity & systems strengthening programmes –training, twinning etc

Single set of requirements, Clear guidelines, Fewer dossiers to prepare (one per REC)

Transparent regulatory processes with clear timelines

Earlier approval of more medical products & vaccines

National > Regional > Continental

2.1. The African Medicines Regulatory Harmonization and the African Medicines Agency – Key Milestones

- **Strong legal frameworks through domestication of the AU Model Law for Medical Products Regulation**
  - Comprehensive medicines laws 17 countries
  - Autonomous agencies e.g. All 7 NRAs in EAC
  - Reliance provisions e.g. SAHPRA
- **Strengthened NRAs- 5 ML3 NRAs Egypt (vaccines producing), Ghana, Nigeria, Tanzania (Mainland), South Africa (vaccines producing) - to support less mature agencies as reliance NRAs**
- **Robust Regional Medicines Regulatory Harmonization Initiatives - EAC, SADC, ECOWAS, ECCAS, IGAD, AMU**
  - Harmonized standards, joint review & inspections
  - EWGs, Steering Committees, Heads of Agencies Forum
- **Strong AMRH Governance structure to support AMA Operationalization –NRAs, RECs, AMRC, Steering Committee, TCs, Partners, Secretariat**
- **Sustainable Regional Centres of Regulatory Excellence (RCOREs) to support regulatory capacity building – 8 regulatory functions**
  - Partnerships between NRAs & academia
- **AMRH - Partnership Platform providing technical, financial, policy advocacy support**

2.2. Regional Harmonization Initiatives – Updates

- ECOWAS Programme (2015): harmonized regulatory standards & practice, created a regulatory review process with 24 applications received to date. Formed several Technical Working Groups (TWGs) to develop technical regulatory harmonization .guidelines.

- The SADC Programme (2013): Built on a successful ZAZIBONA Scheme with harmonized regulatory standards & practice. 390 applications received to date, TWGs operational.

- The EAC Programme (2012): The first region to develop harmonized technical guidance, 235 applications received to date, TWGs operational.

- The IGAD Member States made a commitment in 2016 to establish a medicines regulatory harmonisation programme, to date 30 applications received, TWGs operational.

- The ECCAS - a collaborative framework for implementation of a medicines regulatory harmonization, developed an overarching regional pharmaceutical policy framework.

2.3. The AMRH TCs established/revived in support of PAVM & AMA

1. **The African Vaccines Regulatory Forum (AVAREF)**
   - Regulatory oversight on clinical trials and joint reviews of vaccines CT applications
2. **The African Medicines Quality Forum (AMQF)**
   - Quality controls and market surveillance
   - Network of Laboratories
3. **The African Blood Regulatory Forum (ABRF)**
   - Technical oversight on blood and blood products regulation
4. **The African Medical Devices Forum (AMDF)**
   - Technical oversight on medical devices and invitro diagnostics regulation
5. **Pharmacovigilance / Safety Surveillance**
   - Safety monitoring of medical products
6. **Good Manufacturing Practice (GMP)**
   - Continental guidelines & standards
   - Inspection of manufacturing sites including APIs
7. **Regulatory Capacity Development (RCD)**
   - Coordination of regional centers of regulatory excellence (RCOREs) & ACRSP*
8. **Medicines Policy and Regulatory Reforms (MPRR)**
   - Domestication of the AU Model Law on Medical Products Regulation
   - Coordinate reliance frameworks
9. **Information Management Systems (IMS)**
   - Support the operationalization of regulatory information management systems (RIMS)
   - Digitalization of regulatory processes
10. **Evaluation of Medicinal Products (EMP)**
    - Continental procedure for evaluation of priority medicinal products
    - Support/coordinate joint reviews, scientific opinion & recommendations for marketing authorization

2.4. RCOREs, ML-3 NRAs & POTENTIAL ROLE IN AMA

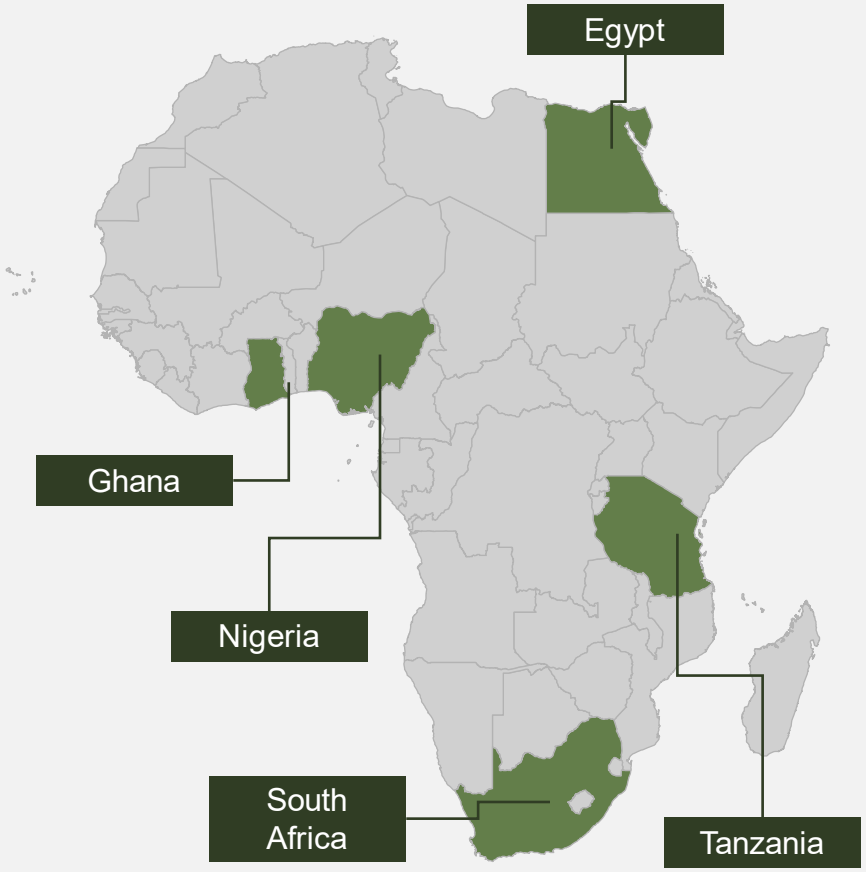
Existing RCOREs & Role

- **15 RCOREs since 2014:**
  - 11 for medicines regulation
  - 4 for vaccines regulatory oversight (with ML3 status)

RCOREs Role:

- Academic & technical training in regulatory science
- Skills enhancement thru' hands on training, twinning & exchange programs e.g. Ghana FDA, TMDA
- Practical training thru' placement
- Operational research to pilot new innovations & interventions to inform best practice

Existing ML3 status NRAs



Potential Role in AMA

AMA Treaty Article 6(e) Coordinate existing & new RCOREs

- **Can RCOREs serve as AMA Regional Centres?**

03. RATIFICATION & OPERATIONALIZATION OF AMA

- ‘A Shared Responsibility’

2023 AFRICA REGULATORY CONFERENCE

3.1 UPDATES ON AMA RATIFICATION PROCESS

As of 8th September 2023

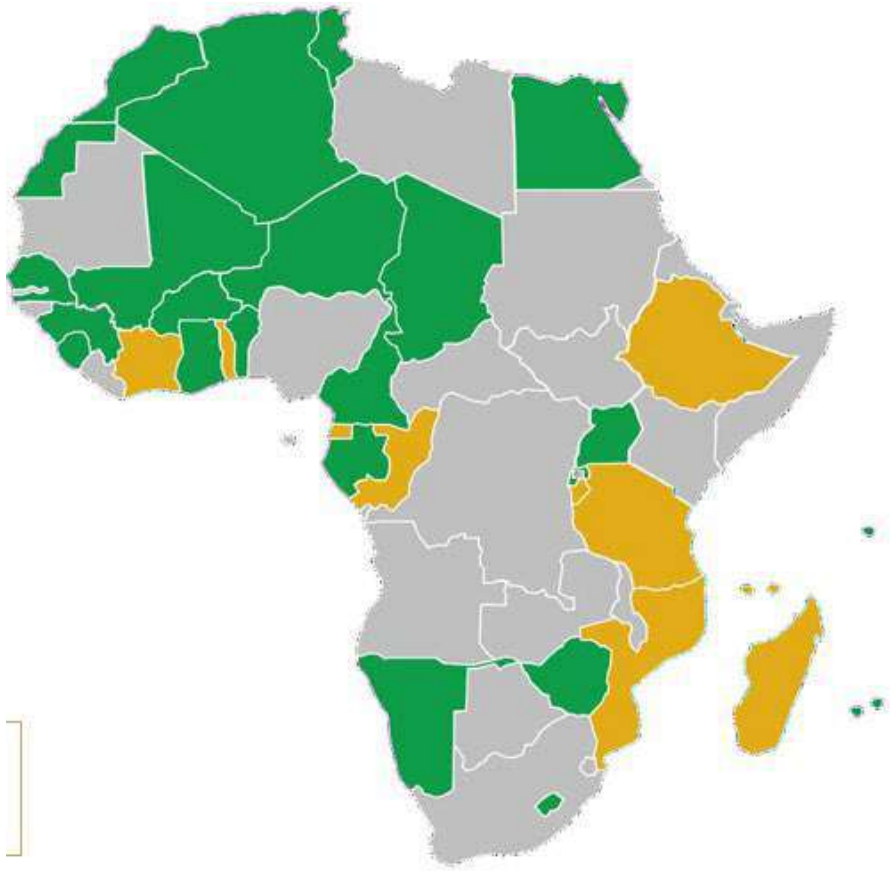
26 Number of Member States that have ratified the Treaty and deposited the instrument at the Commission

10 Number of Member States that have signed the AMA Treaty

19 Member States that have neither signed nor ratified

The AMA Treaty entered into force on 5th **November 2021** upon the deposit of the 15th instrument of ratification at the African Union Commission

The Headquarters of AMA is in Kigali, Rwanda



Member States that have only signed the AMA Treaty

1. Burundi
2. Comoros
3. Cote d'Ivoire
4. Ethiopia
6. Equatorial Guinea
7. Madagascar
8. Mozambique
9. Tanzania
10. Togo

Member States that have signed, ratified and deposited the instru- ment of ratification at the Commission

1. Algeria
2. Benin
3. Burkina Faso*
4. Cameroon
5. Cape Verde
6. Chad
7. Congo
8. Egypt
9. Gabon
10. Ghana
11. Guinea
12. Kenya
13. Lesotho
14. Mali
15. Mauritius
16. Morocco
17. Namibia*
18. Niger
19. Rwanda
20. Saharawi
21. Senegal
22. Seychelles
23. Sierra Leone
24. Tunisia
25. Uganda
26. Zimbabwe

*Ratification without signing

3.2 RATIFICATION & OPERATIONALIZATION OF AMA

➢ ROLE OF VARIOUS STAKEHOLDERS

Governments – advocacy, investment in regulation of medical products

Regulators – ensure effective and efficient regulatory services, avail competent experts, build robust regulatory systems and processes including digitalization.

Industry – advocacy, participation in the development of guidelines and standards

Patients and CSOs – advocacy, involvement in AMRH TC e.g. EMP-TC

04. IN CONCLUSION

- The African Medicines Agency can enable African people to live the healthier lives they deserve while boosting continental trade and economic development (Sidibé et al, 2023).

- AMA needs wider support and investment for it to be operationalized with urgency building on AMRH gains to provide an enabling regulatory environment for local production and trade among countries

- AMA has a key role in improving the health and wellbeing of Africans and provides an opportunity to design and implement a continental regulatory system, for African people, by African people, and leveraging African capabilities and talent.

THANK YOU!

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12–15 SEPTEMBER | VIRTUAL CONFERENCE

AfRC Track 01

Navigating the Maze: simplifying the path to efficient national registration of medicinal products

Session Moderator

Nevena Miletic

F. Hoffmann-La Roche, IFPMA ARN Co-chair

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EVOLVING REGULATORY LANDSCAPE IN AFRICA

National Regulatory Agencies (NRAs)

- RSS incl. development **of national well-functioning reliance pathways** (completed or under development)

Regional Economic Communities (REC)

- **Regional Joint Assessment Procedures (JAPs)**

African Medicines Agency (AMA)

- Foreseen to **coordinate joint assessments**, e.g. "highly complex" product dossiers (*tbc*)

Beyond Africa

- **WHO Collaborative Registration Procedures** (PQ, 'SRA'- approved)
- **Swissmedic MAGHP and MAGHP 'light'** procedure
- **EMA OPEN, EU-M4all**
- …

Many opportunities - how to choose optimal one?

2023 AFRICA REGULATORY CONFERENCE

Facilitated Regulatory Pathways

Introduction to Collaborative Registration Procedure (CRP) and Joint Assessment Procedures

Dr Mariana Roldao Santos
Technical Officer, Facilitated Product Introduction
Regulation and Prequalification Department
WHO

Enhancing Regulatory Reliance through Facilitated Product Introduction

Facilitated Regulatory Pathways (FRP) as a solution to NRAs

When timely access to quality-assured products is compromised…

NRAs carry great responsibilities in ensuring timely access to quality assured products to their population

Internal factors: low maturity of many regulatory systems, lack of resources and expertise in-house, and ack of collaboration between countries

External factors: increasing complexity of supply chains and global challenges, such as health emergencies

- Overwhelm NRAs - lengthy regulatory approvals of much needed medical products
- Patients' timely access to much-needed quality-assured medicines is compromised

FRPs, as a solution for NRAs and public health

FRP are a type of regulatory pathways available to NRAs, which are meant to facilitate and accelerate the regulatory decisions and the introduction of quality-assured products in countries, through the use of the concepts of reliance and collaboration. When well implemented:

What are Facilitated Regulatory Pathways (FRPs)?

- NRAs leverage on the work performed by others, improving efficiency of the regulatory systems by avoiding duplication of regulatory efforts and work
- NRAs optimize the use of human and financial resources and increase expertise and build capacities
- NRAs reduce the time nedeed to process a product application and reduce workload and backlog at NRAs
- NRAs perform science-based and transparent regulatory decision-making, while maintaining national independence on their decisions
- NRAs ensure timely access to priority quality-assured products in countries.

Organization

What are the FRPs available to countries and companies?

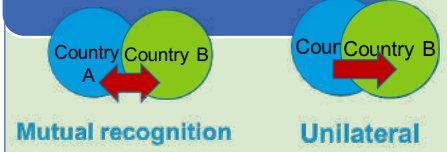
- WHA resolution 67.20, 2014 (model of Regulatory pathways available to NRAs to approve a product)
- WHO Good Reliance Practices, 2021

Level of collaboration, reliance and Regulatory efficiency

Level of effort, work, resources, expertise, time and duplication

Facilitated Registration Pathways

Recognition



Mutual recognition

Unilateral

E.g. Product approval based on "SRA" approval or WHO Prequalification. Verification of the sameness without further review or assessment of product information. - CRP

Abridged Review

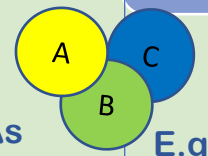
Abridged pathway using reliance

E.g. Secondary and abridged reviews of existing primary reports generated from "SRA" or WHO PQ – CRP and EU mutual recognition

Work-Sharing

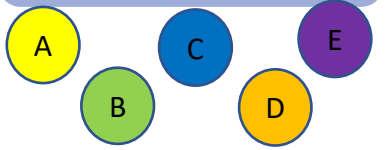
E.g. when it is agreed between 2 or more NRAs that only 1 NRA assesses (applying full review or reliance) and the remaining ones grant MA based on that assessment. - EU decentralized procedure

Joint Assessment



E.g. Assessment conducted jointly by 2 or more NRAs (applying full review or reliance) - EU centralised procedure, ASEAN JA

Full Assessment



Assessment of full product dossier conducted by the NRA - Standard National Procedure, Accelerated Procedure

FRPs, such as CRP, to be used not only during emergencies but also in the regular and routine regulatory activities of countries to improve efficiency of the regulatory systems

Collaborative Registration Procedure (CRP)

WHAT it is and HOW does it work?

CRP facilitates exchange of information to accelerate national registrations in countries through the provision to NRAs of detailed assessment and inspection reports generated by reference NRAs/PQ

Applicant

Single/Same product dossier

\+

Prod. Assessment Reports from SRA/PQ

WHO

To multiple CRP participating country(s) at the same time

WHO

Accelerated assessment and registration of quality-assured products in countries

Faster access to priority quality-assured products by the population

World Health Organization

CRP mechanisms and product scope

PQ CRP - products prequalified by WHO via full assessment:

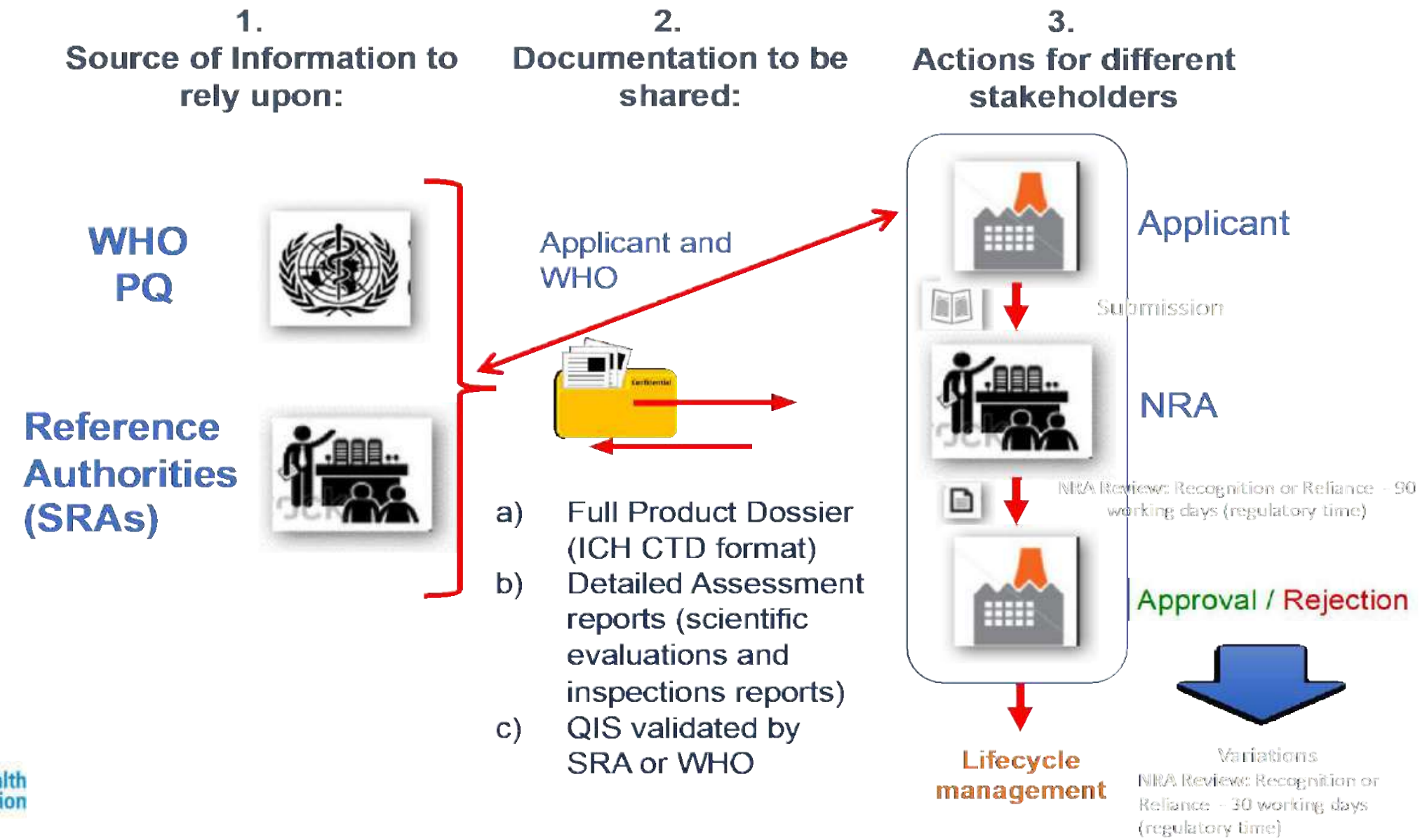
- Medicines
- Vaccines
- Biotherapeutics
- IVDs
- Applies to therapeutic areas in the scope of PQ

SRA CRP - any product assessed or approved by an SRA:

- **Innovative and generic products (chemicals or biologicals):** Medicines/Pharmaceuticals, multisource/generics, vaccines, biosimilars, biotherapeutics, etc.
- **Products Prequalified by WHO via Abridged review** (SRA approved)
- **Products approved by special routes or provided with positive scientific opinion: EU M4-all** (Article 58), **Swissmedic Marketing for Global Health Products**.
- Applies to any therapeutic area

World Health Organization

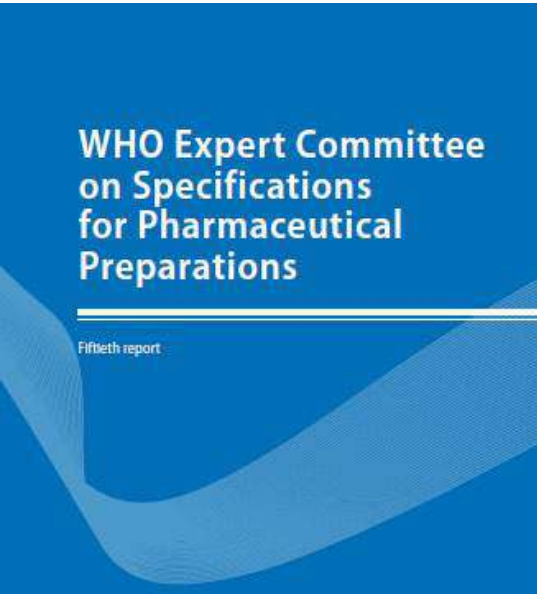
CRP Process (PQ CRP or SRA CRP)



World Health Organization

Relevant Tools and Resources

PQ CRP

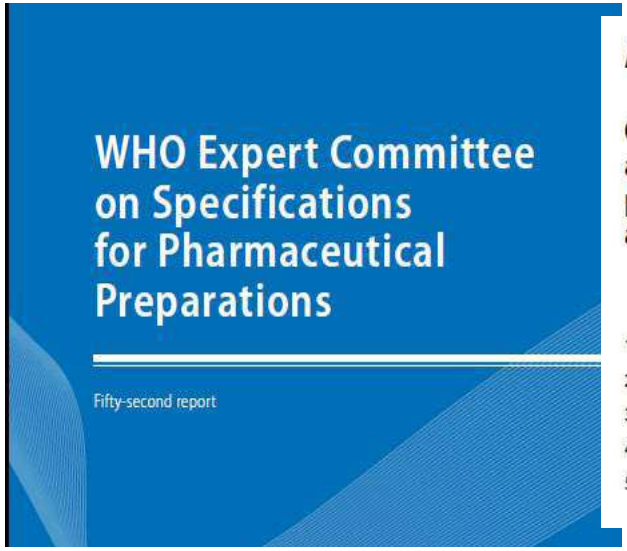


Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

SRA CRP



Annex 11

Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

https://extranet.who.int/pqweb/medicines/faster-registration-fpps-approved-sras

World Health Organization

PQ CRP

WHO PQ CRP applies to medicines and vaccines prequalified by WHO (fully assessment)

World Health Organization

PQ CRP for medicines and vaccines:
62 Participating NRAs, plus 1 Regional Economic Community

Angola
Armenia
Azerbaijan
Bangladesh
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
Cape Verde
*Caribbean Community (CARICOM)
Central African Republic
CHAD
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Gabon
Georgia
Ghana
Guinea
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Liberia
Madagascar
Malaysia
Malawi
Maldives
Mali
Mauritania
Moldova
Mozambique
Namibia
Nepal
Nigeria
Pakistan
Papua New
Philippines
Republic of Congo
Rwanda
Sao Tome and Principe
Senegal
Sierra Leone
South Africa
Sri Lanka
Sudan
Tanzania
Thailand
The Gambia
Timor-Leste
Togo
Turkey
Uganda
Ukraine
Uzbekistan
Yemen (Sana'a)*
Yemen (Aden)*
Zambia
Zanzibar
Zimbabwe

As of 30 October 2022:

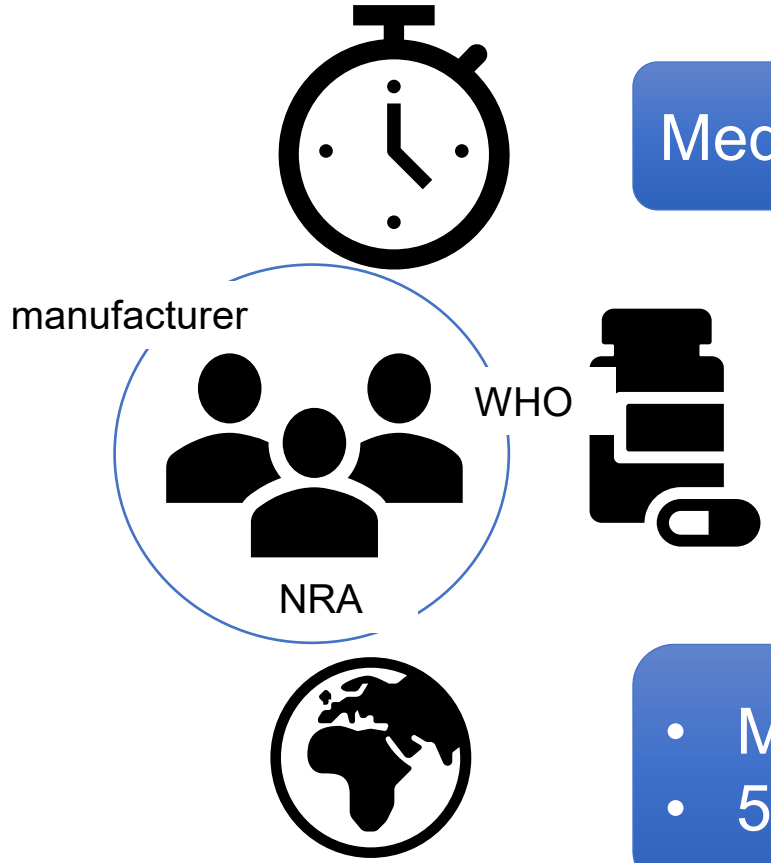
- **+14 countries** since last CRP Annual meeting 2021
- **+ 1 WHO region** represented (EMRO)

https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

World Health Organization

PQ CRP
Submissions and Countries Registrations in 2022:



Median = 90 days

- More than 1000 product submissions
- About 765 registrations

- More than 300 medical products
- 58 countries + CARICOM

SRA CRP

WHO SRA CRP applies to any product approved and/or assessed by an SRA

World Health Organization

Relevant Tools and Resources

List of SRAs as per current WHO Guidelines

TRS 1003 - 51st report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

WHO Technical Report Series 1003

14 June 2017 | Technical document

Overview

The WHO Technical Report Series makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

Based on the above interim definition, the following is the list of the countries whose NRAs are designated as SRAs.

Australia	Germany	Netherlands
Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Iceland	Romania
Canada	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Japan	Spain
Czech Republic	Latvia	Sweden
Denmark	Liechtenstein	Switzerland
Estonia	Lithuania	United Kingdom
Finland	Luxembourg	United States of America
France	Malta	Norway

World Health Organization

+ EMA

SRA CRP

53 Participating NRAs, plus 1 Regional Economic Community

Angola*
Bangladesh*
Botswana
Burkina Faso
Burundi
Bhutan*
CARICOM**
Cameroon
Cape Verde*
Central African Republic
CHAD
Comoros*
Cote D'Ivoire
Democratic Republic of the Congo
Eritrea *
Ethiopia
Gabon*
The Gambia
Georgia
Ghana
Guinea
Kazakhstan*
Kenya
Lao PDR*
Liberia
Malawi
Malaysia*
Mali
Mauritania*
Mozambique
Namibia
Nepal*
Niger*
Nigeria
Pakistan
Papua New Guinea*
Republic of Congo*
Rwanda
Senegal
Sao Tome and Principe*
Sierra Leone
Sri Lanka*
Tanzania
Thailand*
The Republic of South Africa
Timor-Leste*
Turkey*
Uganda
Ukraine*
Yemen (Sana'a)*
Yemen (Aden)*
Zambia
Zanzibar*
Zimbabwe

As of 1 December 2022:

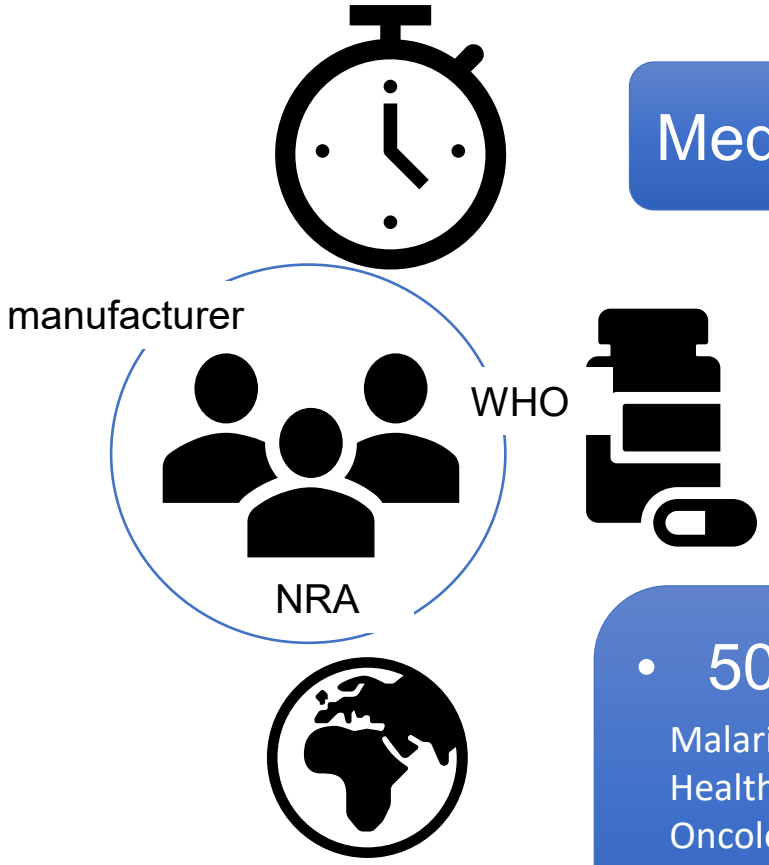
- **+25 NRAs/countries** since last CRP Annual meeting 2021
- **+ 3 WHO regions** represented (EMRO, SEARO, and WPRO) since last CRP Annual meeting 2021

https://extranet.who.int/pqweb/medicines/faster-registration-fpps-approved-sras

* New additions since last CRP Annual meeting 2021
** Caribbean Community, CARICOM
15 Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

World Health Organization

SRA CRP
Submissions and Countries Registrations in 2022:



Median = 120 days *(regulatory time + applicant time)*

- 230 product submissions *(approximately 80 from 2018 to July 2021)*
- 125 registrations *(approximately 50 from 2018 to July 2021)*

- 50 medical products *(16 products from 2018 to July 2021)*

  Malaria, HIV/AIDS, Tuberculosis, Rep. and maternal Health, Haemophilia, Pneumococcal vaccines, Oncology, Immunostimulants, Analgesics and Anaesthetics, COVID-19 therapeutics, Psycholeptics.
- 47 countries + CARICOM *(24 from 2018 to July 2021)*

World Health Organization

CRP win-win outcomes for all concerned stakeholders
Feedback from SRA CRP project evaluation 2020

NRAs

- Providing a **convenient tool and procedure for NRAs wishing to apply reliance,** allowing them to **leverage the work performed by other** authorities, and **making their registration system more efficient and responsive** to the country population needs
- Having access to **data well organized in line with international and stringent requirements** - Availability of detailed SRA/WHO assessment and inspection outcomes
- **Opportunity for well-informed and quality decision-making** at NRAs, **saving efforts, resources** (human and financial) and **time**, maintaining their national independency
- **Capacity Building component** – NRAs can learn from SRA/WHO assessment reports
- **Introduction of quality-assured products** in the country in a **faster** manner.

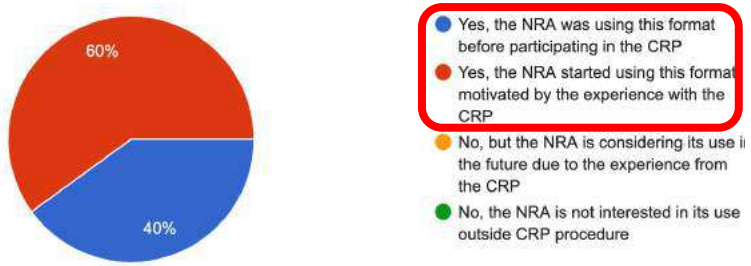
Applicants

- Providing a **procedure to facilitate and accelerate national registration processes,** with **appealing registration timelines**;
- **Only one single dossier for multiple countries** - harmonized data for national applications and registrations;
- **Reduced burden of duplicated national GMP inspections** to manufacturers and **laboratory testing prior to registration**;
- Enhanced and **facilitated collaboration, interactions and information exchange** with the NRAs, WHO and SRAs;
- **Savings on time and resources;**
- Allows **more efficient post-registration maintenance**.

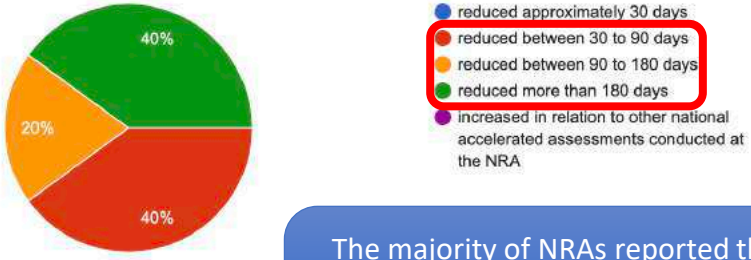
World Health Organization

Main findings and conclusions from CRP Evaluation 2020: Outputs from NRAs

28. Does your NRA use harmonized product dossiers based on international standards in its national product evaluations and registrations outside the CRP procedure (ICH CTD format)?

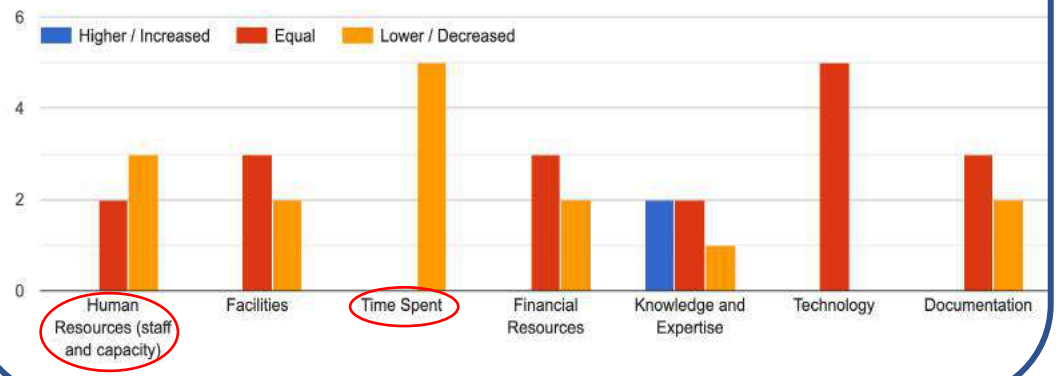


37. In comparison to your fastest national procedure for assessment and registration of new products outside CRP, through the use of CRP procedure the estimated total number of days needed to evaluate and register a new product at your NRA:



The majority of NRAs reported that: with the use of CRP the number of days for registration of products reduced to 180 days less, then when compared to national procedure outside CRP

38. What is the difference in resources dedicated by the NRA to the participation in the CRP programme in comparison to similar processes outside CRP?



Major reductions were seen in terms of time spent with the application and human resources needed (staff and capacity)

World Health Organization

EXPERT REVIEW OF CLINICAL PHARMACOLOGY
2022, VOL. 15, NO. 1, 11-17
https://doi.org/10.1080/17512433.2022.2037419

WHO collaborative registration procedure using stringent regulatory authorities' medicine evaluation: reliance in action?

Alexandra Vaz[a], Mariana Roldão Santos[b], Luther Gwaza[b], Elena Mezquita González[a], Magdalena Pajewska Lewandowska[c], Samvel Azatyan[b], and Agnès Saint-Raymond[a]

[a] International Affairs Division, European Medicines Agency, Amsterdam, Netherlands [b] Regulation and Prequalification Department [RPQ] World Health Organization, Geneve, Switzerland [c] International Collaboration, Urzad Rejestracji Produktow Leczniczych Wyrobow Medycznych I Produktow Biobojczych, Warszawa, Poland

INTRODUCTION The regulatory approval of medical products in countries with limited regulatory resources can be lengthy, which often compromises patients' timely access to much-needed medicines. To improve the efficiency of regulatory systems, reliance is being used. Reliance allows an authority to leverage the work performed by other authorities, such as scientific evaluations, to decide on medical products approval within their jurisdiction. This reduces duplication of regulatory efforts, resources and time, while maintaining national sovereignty.

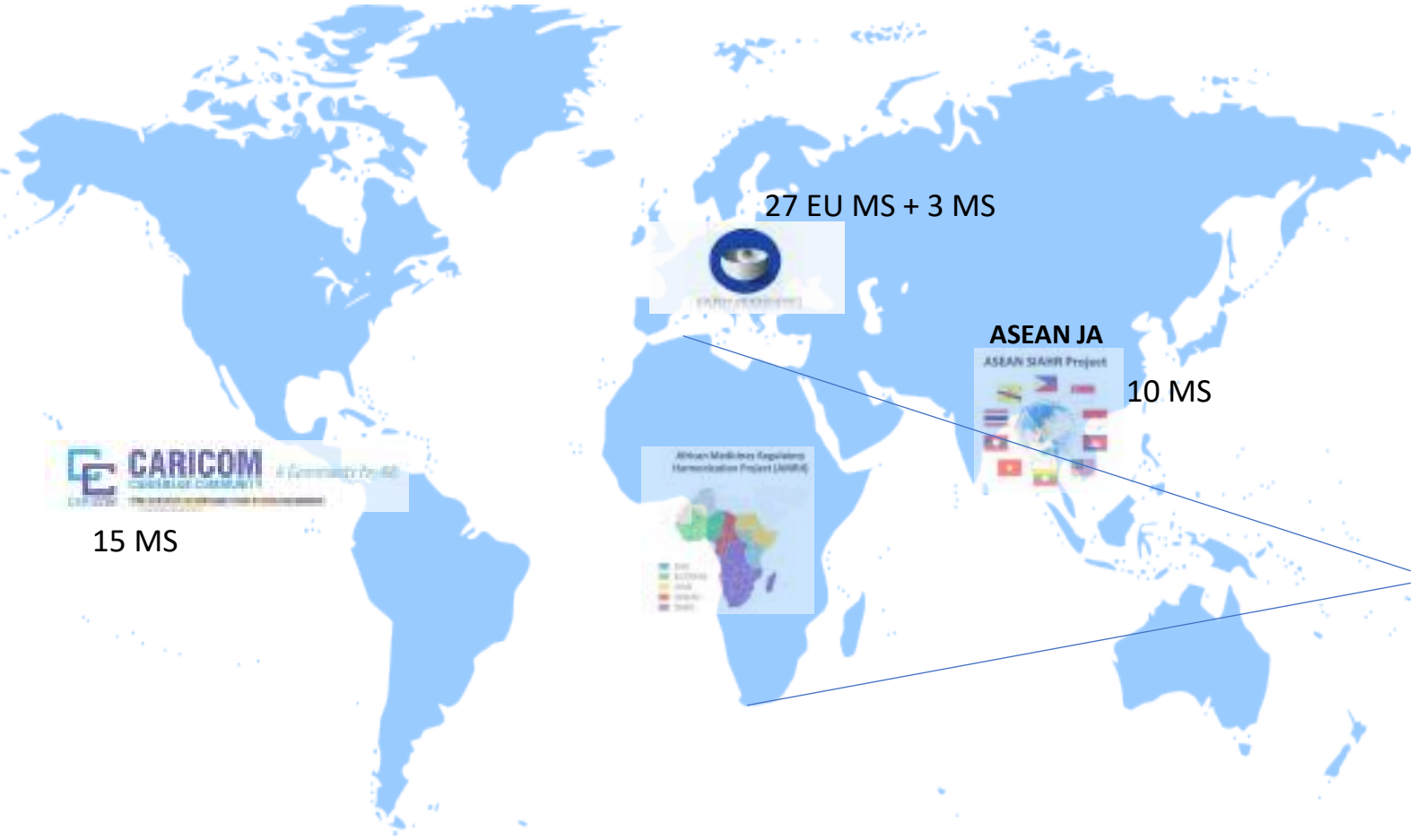
AREAS COVERED This article analyzes the outcomes and stakeholders' experience of using medicines assessments performed by Stringent Regulatory Authorities (SRA) in the Collaborative Registration Procedures (CRP). Since its establishment in 2015, 59 approvals were granted to 16 medicines in 23 countries through SRA CRP. Results show that the procedure is delivering on the intended benefits of access and speed, with long-term positive impact for resource-limited countries. The article concludes with recommendations on the need for guidance on management of post-approval changes, wider promotion of the procedure, and increased collaboration between authorities.

https://www.tandfonline.com/doi/full/10.1080/17512433.2022.2037419?journalCode=ierj20

Did the benefits of CRP programme (pilot) superseded the challenges?

Based on the experience from the pilot, how likely is that the organization will be able to continually participate and sustain its participation in CRP activities in the future (outside the pilot)?

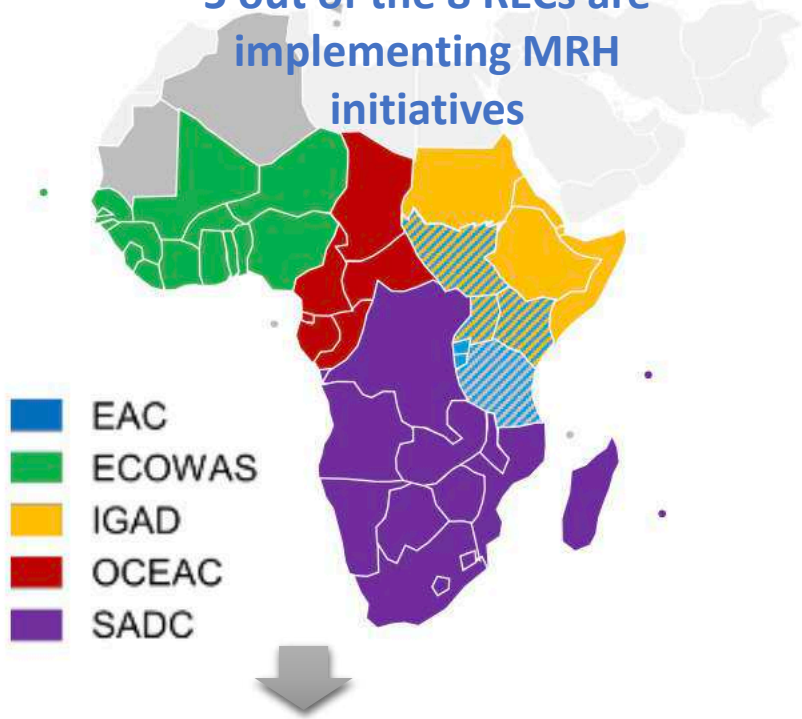
Examples of Joint Assessment Initiatives globally



World Health Organization

African Medicines Regulatory Harmonization Project (AMRH)

5 out of the 8 RECs are implementing MRH initiatives



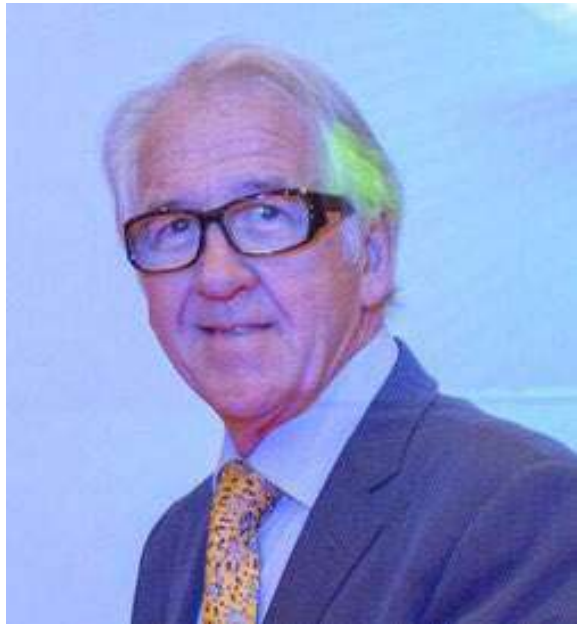
- **EAC MRH Programme:** since 2012
- **ECOWAS MRH Programme:** since 2015
- **IGAD MRH Programme**: since 2015
- **ECCAS/OCEAC MRH Programme**: since 2015
- **SADC MRH Programme and ZAZIBONA Initiative**: since 2011

FRPs, including CRP and JAs as key tools to to accelerate assessment and registrations of products in the region

Key Messages to bring Forward:

1. It is **overwhelming for NRAs at all maturity levels to fulfil all regulatory work alone** and independently from other regulators;
2. **There are several tools nowadays available to NRAs and Industry to facilitate the regulatory decisions (initial approval and post approval changes),** ensuring timely access to quality-assured products in countries and good regulatory-decision making. **FRPs such as CRP and JAs, are some of those tools available, using the concept of collaboration, reliance and work-sharing between NRAs, which is the future of medical products regulation.**
3. Applying those tools, **NRAs and industry are able to make the best with their available resources and time**, reducing duplication of efforts, workload and ultimately **accelerating the assessment and registration of their products** in countries in the region.

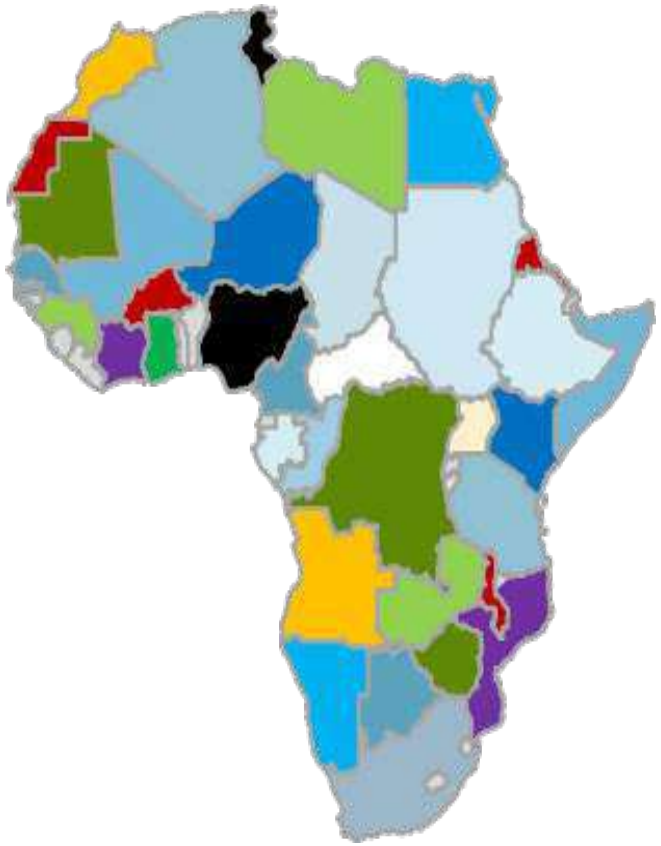
Navigating the Maze, Simplifying the Path to Efficient National Registration of Medical Products in Africa.

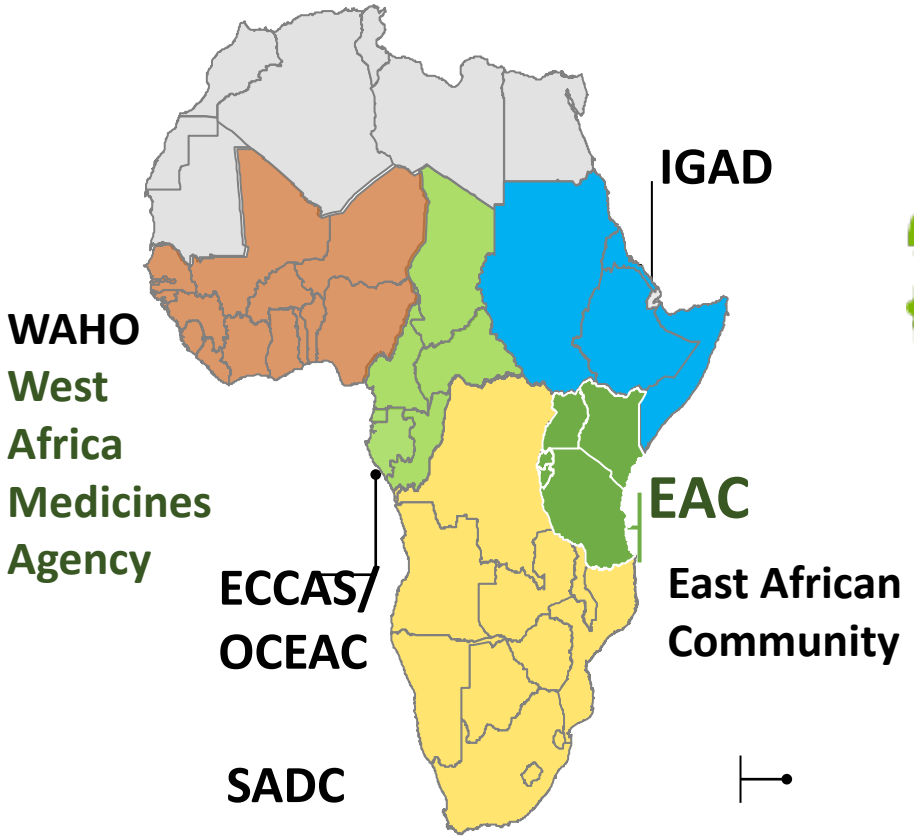


Professor Stuart Walker
Founder: Centre for Innovation in Regulatory Science.
Professor of Regulatory Science, University of Hertfordshire.
Honorary Professor, University of Witwatersrand , South Africa.
Academic Regulatory Expert. Center of Regulatory Excellence. Singapore.

Swalker@cirsci.org

African Union Vision (AUDA-NEPAD)

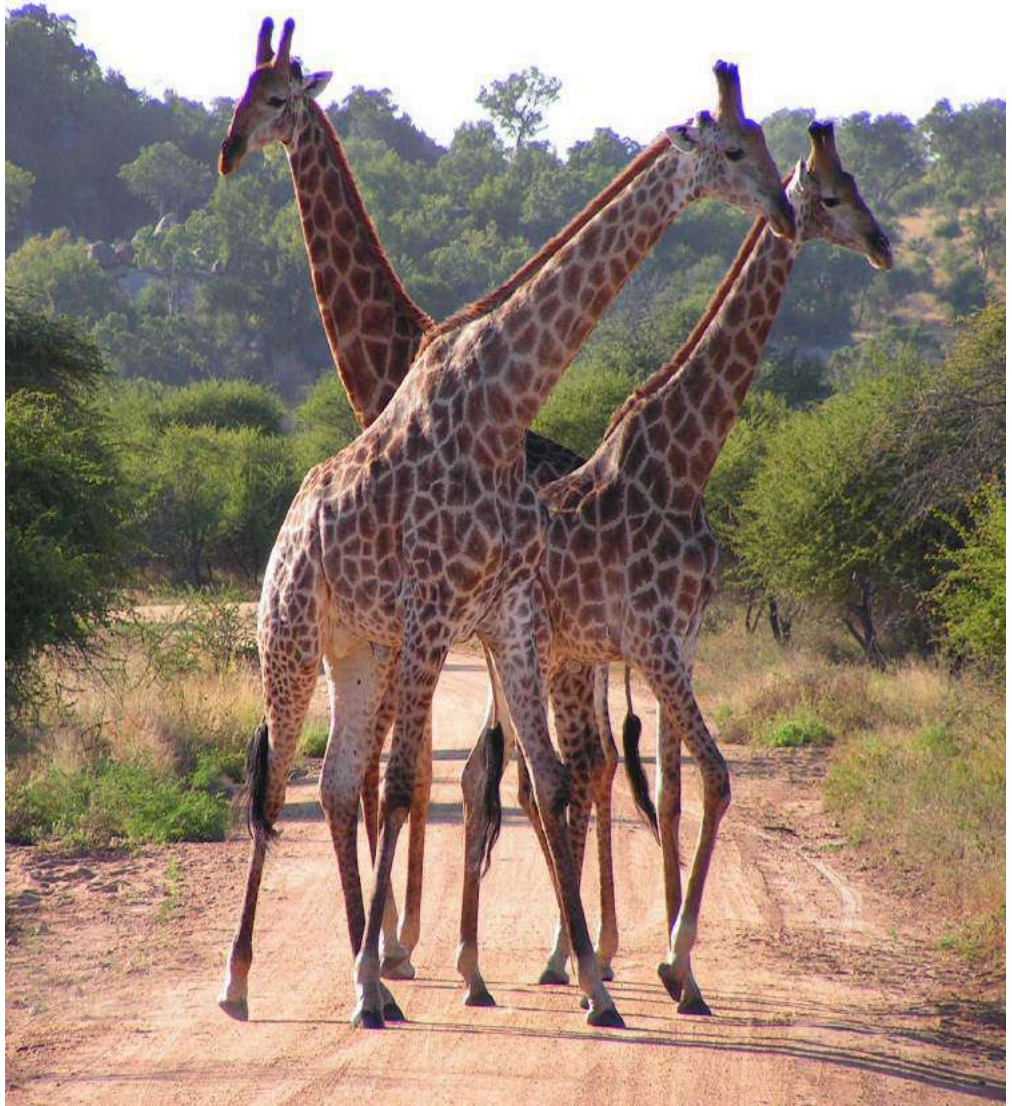




54 countries → **5 regions** → **1 continent**

Presented at the Heads of Agencies Meeting in Rwanda

Navigating the Maze, Simplifying the path to efficient, national registration of medical products in Africa.
Summary: 3 Key Messages



1. **THE AFRICAN MEDICINES AGENCY:**

   The Ultimate Goal

- **2. REGIONAL INITIATIVES IMPLEMENTED BY AFRICAN AGENCIES:**

  Strengths, Weaknesses, Opportunities.

- **3. THE IMPORTANCE OF RELIANCE BY 21 AFRICAN AGENCIES:**

  What works and what are the challenges?

African Medicines Agency

The African Medicines Agency creates an unprecedented opportunity for improved regulatory reliance and strengthening resulting in speeder access to medicines and vaccines for people throughout the continent

.

Moreover, it represents, for many countries, the promise of the development of **local production**, and the development, across the continent of **centres of excellence for research**, the strengthening and security of supply chains, for the maintenance of a healthy environment and the **fight against falsified medicines.**

Dr Margareth Ndomondo-Sigonda

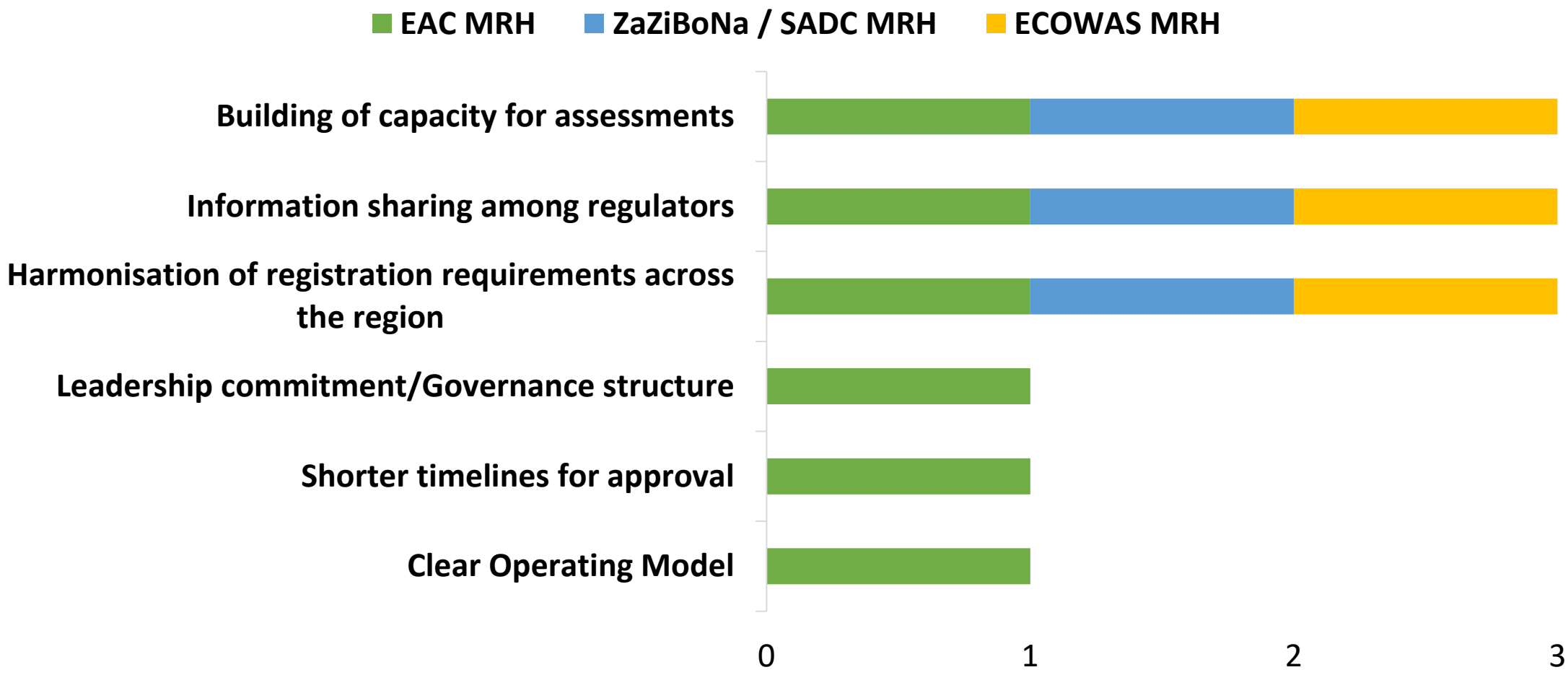
1.CIRS OPERA Tool Evaluating Regulatory Authorities in AFRICA

AFRICAN MEDICINES AGENCY

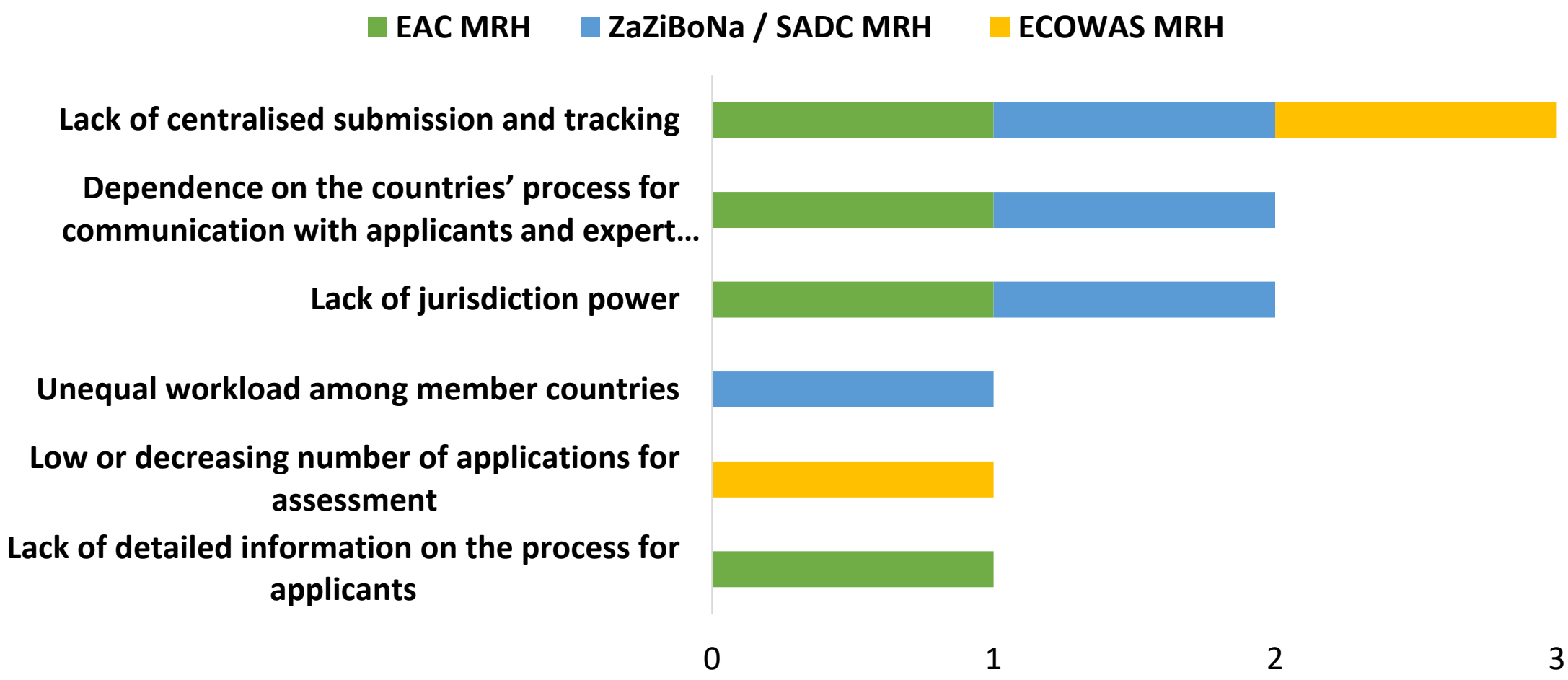
ZaZiBoNa	East Africa Community	ECOWAS
• Botswana • Mozambique • Namibia • South Africa • Tanzania • Zambia • Zimbabwe	• Burundi • Kenya • Rwanda • Uganda • South Sudan • Tanzania • Zanzibar	• Burkina Faso • Cote D'Ivoire • Ghana • Nigeria • Senegal • Sierra Leone • Togo

2. Process Effectiveness & Efficiency Rating Validated Questionnaire for three Regions

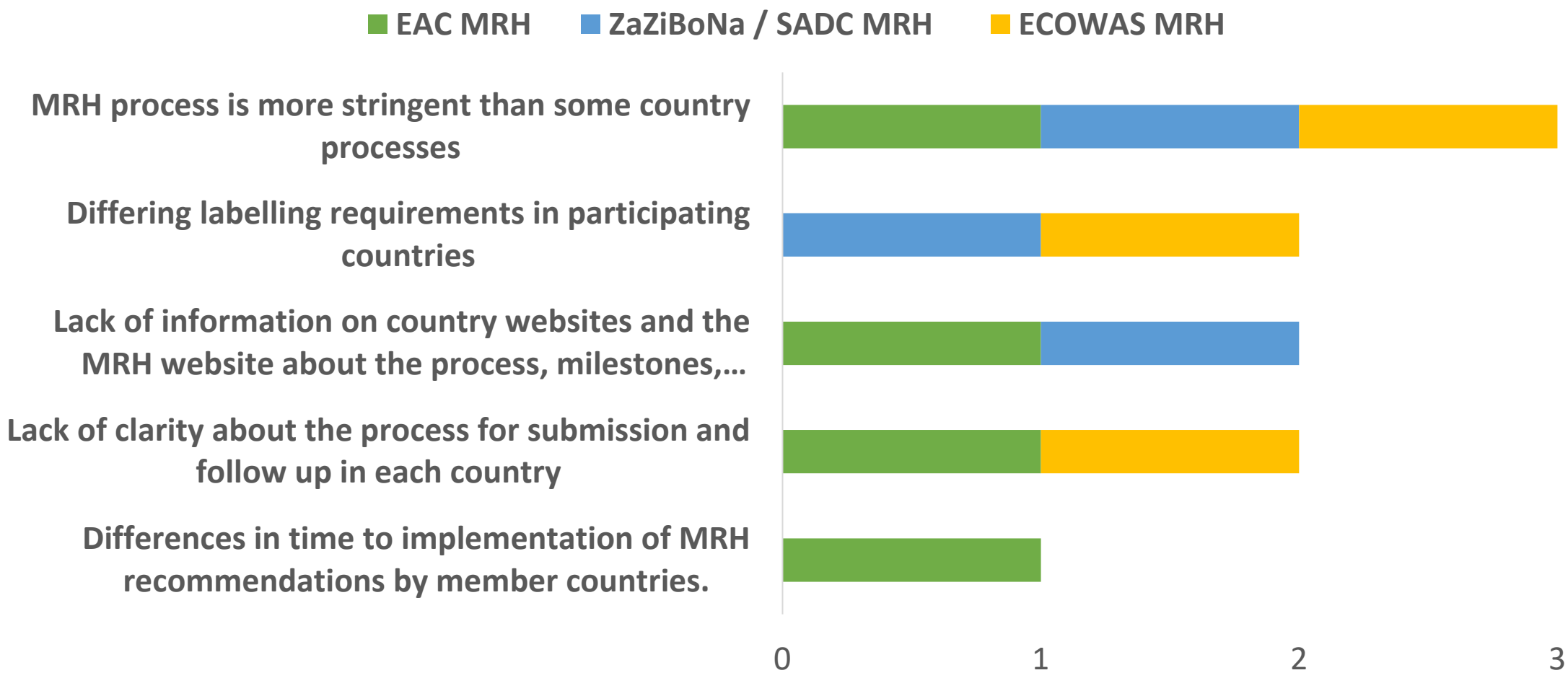
Strengths of the Three Regional Initiatives by Agencies

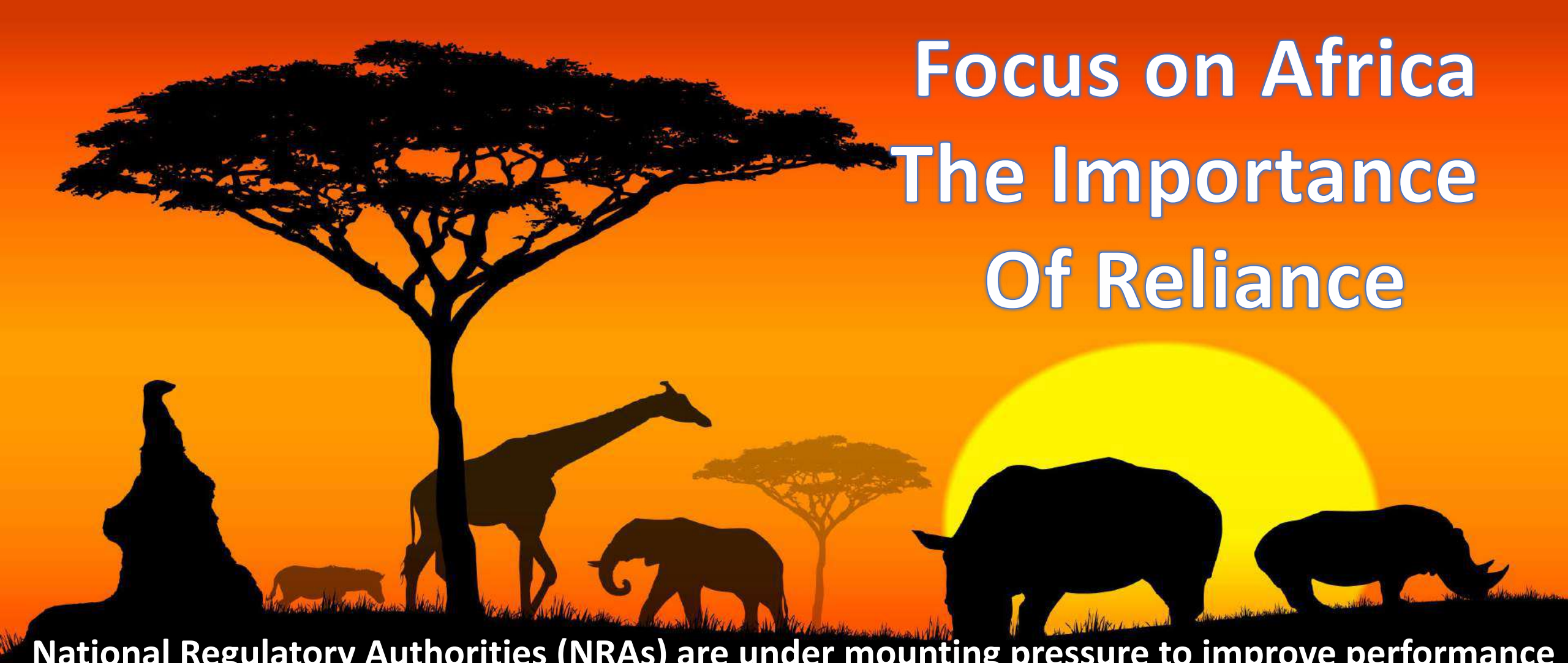


Weaknesses of the Three Regional Initiatives by Agencies



Challenges faced by Pharma Industry Applicants





Focus on Africa
The Importance Of Reliance

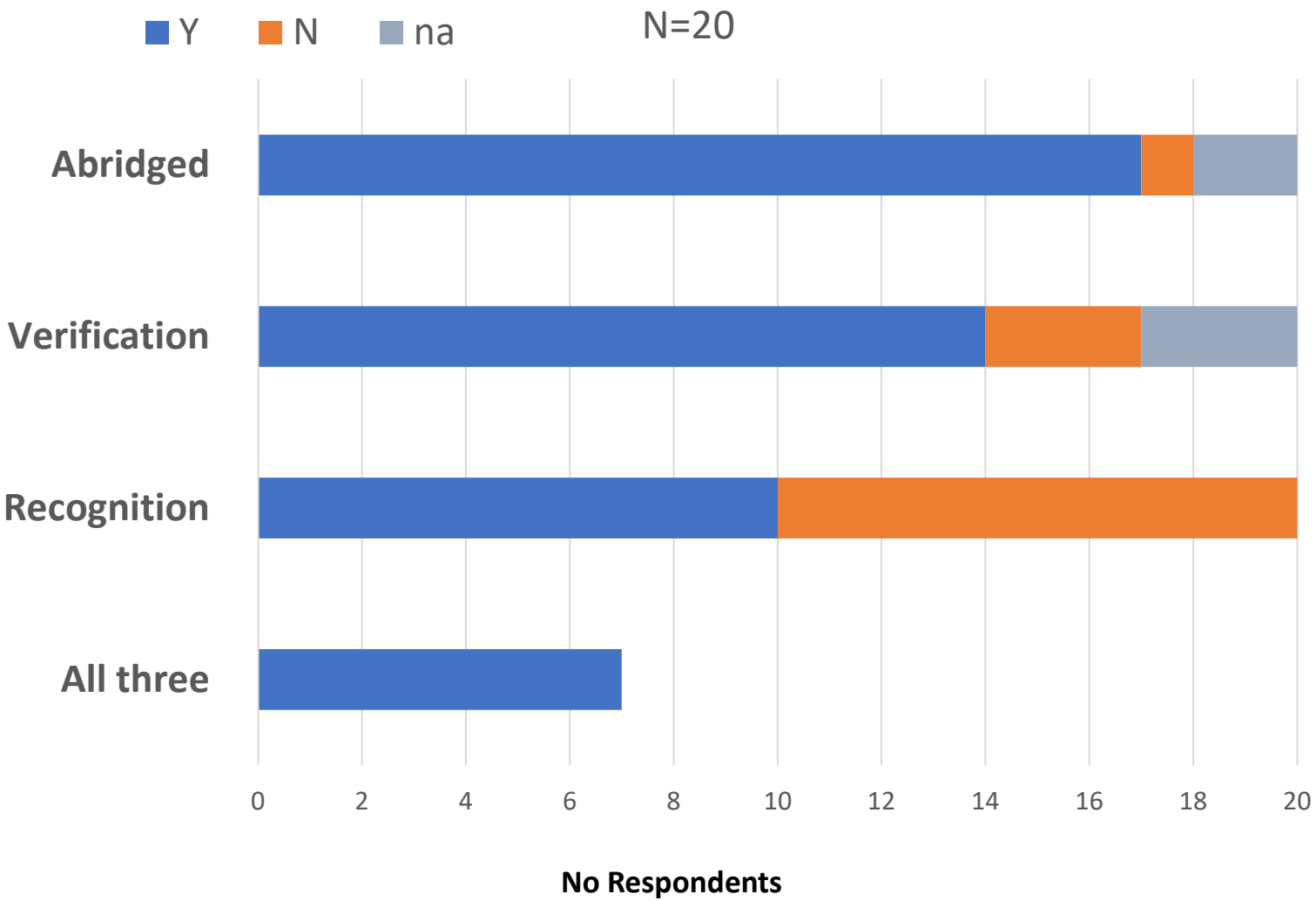
National Regulatory Authorities (NRAs) are under mounting pressure to improve performance and facilitate timely access to safe, effective and quality medicines as well as other health technologies

This task has become more challenging due to globalization, increasingly complex technologies and growing public expectations.

Reliance by 21 African Agencies

- 1. Identify which risk-based models agencies have been using for the regulatory approval of medicines.
- 2. Determine which frameworks agencies have in place to undertake or enable a risk-based approach
- 3. Provide insight into the future direction for risk-based models and how these can support the AMA.

What type of unilateral reliance model does your agency employ?



Abridged review – One in which the agency undertakes an abbreviated review focusing on local benefit risk assessment

Verification review - One in which the agency only verifies that the medicine is the same as that approved by a reference agency

Recognition review - One in which the agency recognises medicine approved by a reference agency

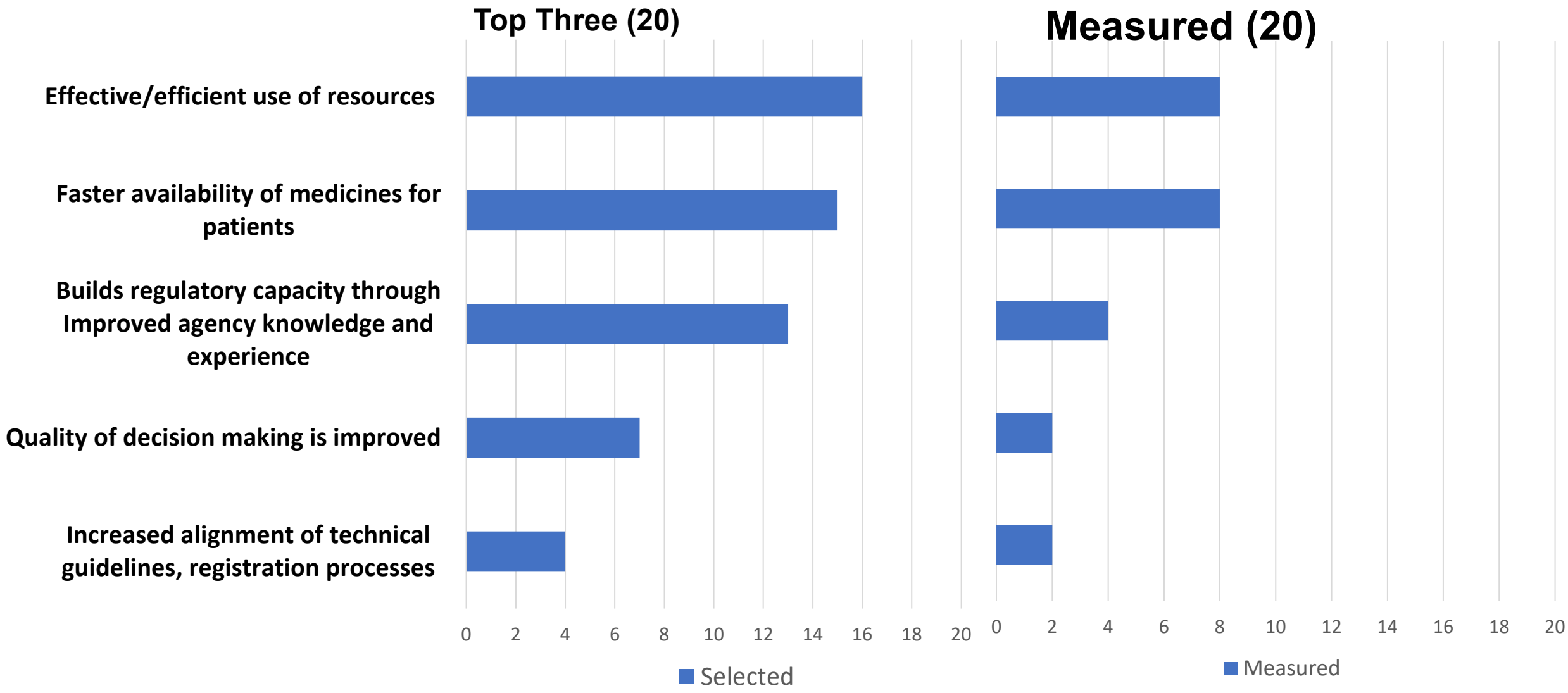
What activities/systems/frameworks are in place for each type of review

	Review Type		
ACTIVITY	Abridged (n=17)	Verification (n=14)	Recognition (10)
Legal Framework	11 (64%)	7 (50%)	5 (50%)
Strategy	8 (47%)	8 (57%)	5 (50%)
Transparent internal Criteria & Guidelines	12 (71%)	11 (79%)	5 (50%)
Transparent published Criteria & Guidelines	8 (47%)	5 (36%)	5 (50%)
Standard operating procedures	13 (76%)	10 (71%)	6 (60%)
Assessment template – specific to the review	13 (76%)	10 (71%)	6 (60%)
ALL OF THE ABOVE	4 (24%) Ghana, South Africa, Zimbabwe, Ethiopia	4 (28%) Ghana, South Africa, Ethiopia, Nigeria	2 (20%) Ghana, Ethiopia

For which products can a unilateral reliance model be utilised?

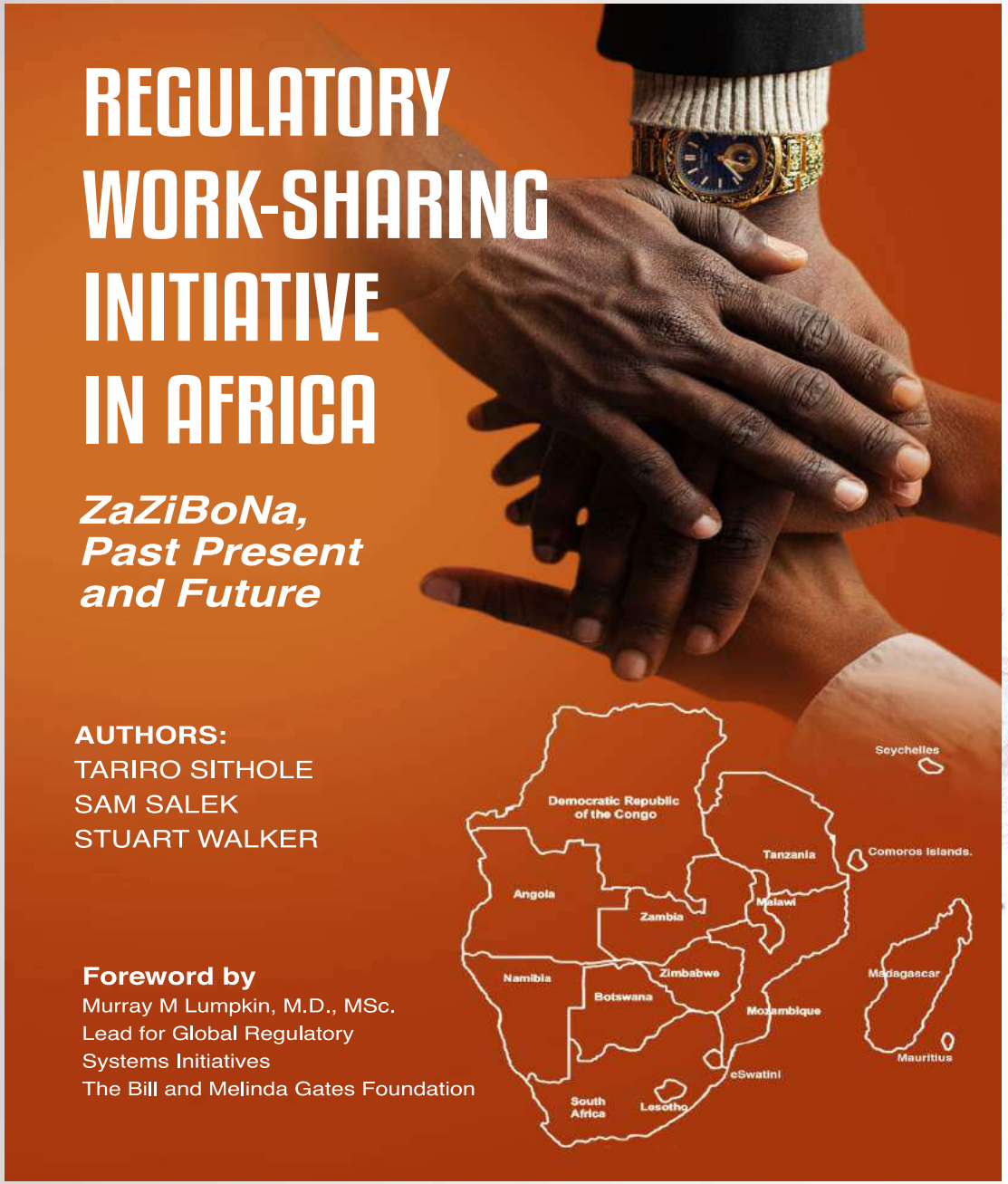
	Review Type		
TYPE OF PRODUCTS	Abridged (n=17)	Verification (n=14)	Recognition (10)
Generics	15 (88%)	12 (86%)	7 (70%)
Chemical entities	16 (94%)	10 (71%)	7 (70%)
Biologic/Biotechnology	15 (88%)	12 (86%)	7 (70%)
Biosimilars	14 (82%)	12 (86%)	8 (80%)
Priority/essential medicines	16 (94%)	11 (78%)	7 (70%)
Covid treatments	14 (82%)	12 (86%)	8 (80%)
ALL	13 (76%)	10 (71%)	7 (70%)

Key incentives/benefits to undertake a unilateral reliance?



REGULATORY WORK-SHARING INITIATIVE IN AFRICA

ZaZiBoNa, Past Present and Future



AUTHORS:
TARIRO SITHOLE
SAM SALEK
STUART WALKER

Foreword by
Murray M Lumpkin, M.D., MSc.
Lead for Global Regulatory Systems Initiatives
The Bill and Melinda Gates Foundation

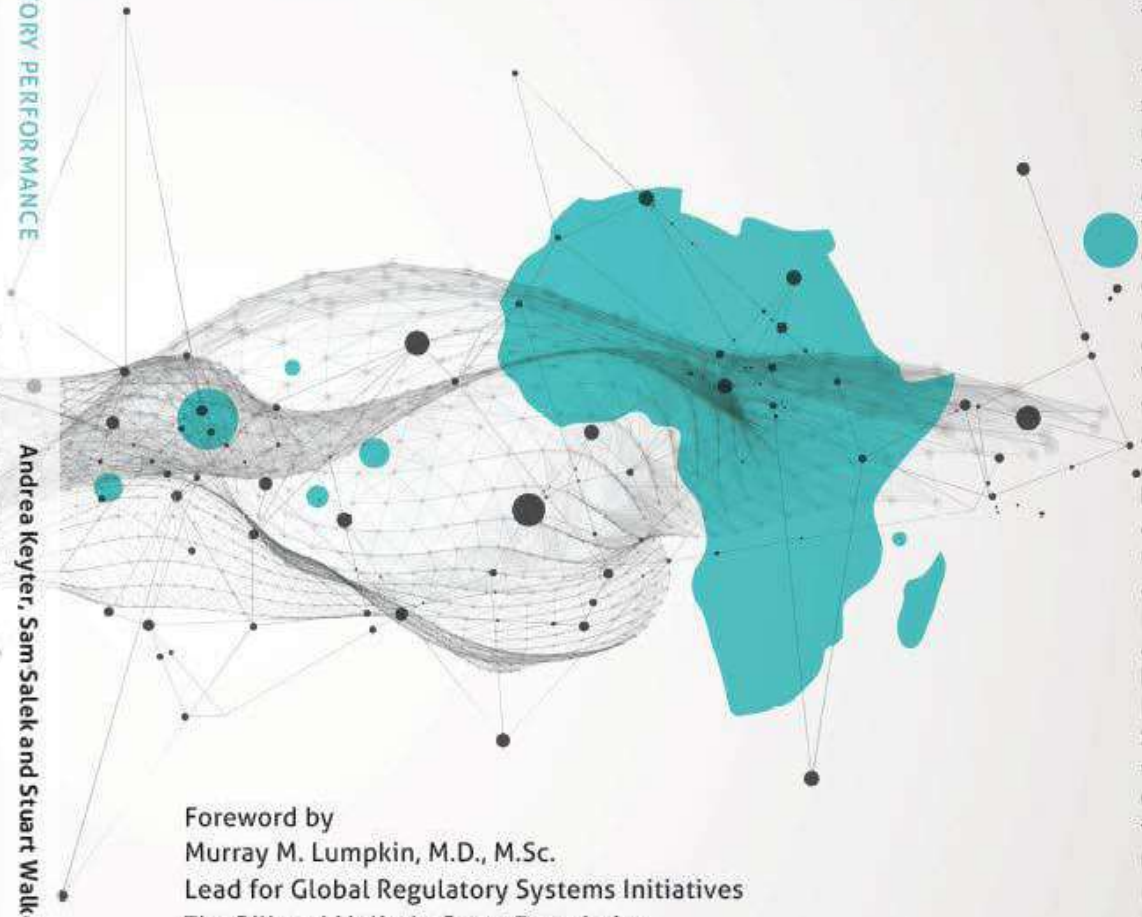
ROADMAP FOR REGULATORY PERFORMANCE

Andrea Keyter, Sam Salek and Stuart Walker

ROADMAP FOR REGULATORY PERFORMANCE

South Africa's Experience in Enhancing the Pharmaceutical Review Process

Andrea Keyter, Sam Salek and Stuart Walker



Foreword by
Murray M. Lumpkin, M.D., M.Sc.
Lead for Global Regulatory Systems Initiatives
The Bill and Melinda Gates Foundation

Dr Andrea Keyter is a pharmacist with over 10 years of experience in regulatory system strengthening, the regulation of medical devices, GMP inspection, quality management systems and the production of pharmaceutical and complementary medicines. She has worked extensively with the World Health Organization (WHO) in these areas and has participated as a WHO assessor in the benchmarking of national regulatory authorities, using the WHO global benchmarking tool. Dr Keyter has been an active member of a number of Pharmaceutical Inspection Co-operation Scheme (PIC/S) committees and is currently the Chair of the African Medical Device Forum and a member of the African Medicines Regulatory Harmonization (AMRH) steering committee.


CONTINUOUS
IMPROVEMENT
&
OPERATIONAL
EXCELLENCE

RECOMMENDATIONS FROM CIRS STUDY

1. **Aligning the operating models to improve efficiency:** The operating models of the MRH projects should be fully aligned to improve efficiency in supporting the African Medicines Agency.

2. **Legal framework:** All three Regional Economic Communities (RECs) should develop regional legally binding framework, if possible, to allow for the establishment of a centralised procedure.

3. **Information Management Systems (IMS):** The RECs should invest in robust information management systems to rectify the challenges identified in this study and to allow for the tracking and monitoring of performance

4. **Reliance:** The RECs should support the strengthening of the capacity of their member states by implementing a reliance strategy and using the WHO Global Benchmarking Tool (GBT) assessments to facilitate inter-country and inter- REC reliance.

CONCLUSIONS

The results of these comparisons allow for the three regional harmonisation initiatives to learn from each other.

The implementation of these recommendations will bring about a greater alignment and efficiency in the regional operating models, thereby strengthening the foundation of the soon to be operationalised African Medicines Agency.

The Centre for Innovation in Regulatory Science has tools which are linked to the WHO GBT indicators, are of value to agencies and the regions who wish to assess their Regulatory Performance when supporting the AMA.

PANEL DISCUSSION

Nevena Miletic
Regulatory Policy Head
Eastern Europe, Middle East & Africa (EEMEA), Global Regulatory Policy,
F. Hoffmann-La Roche

Sakhile Dube
Co-ordinator for the SADC MRH Project
Southern African Development Community (SADC)

Christelna Reynecke
Chief Operations Officer
South African Health Products Regulatory Authority (SAHPRA)

John Mwangi
Head, Regulatory Affairs - East & West Central Africa
Bayer

Sybil Nana Ama Ossei-Agyeman-Yeboah
Principal Professional Officer, Public Health
West African Health Organization

2023 AFRICA REGULATORY CONFERENCE

PANEL DISCUSSION

- **What is your experience regarding facilitated regulatory pathways currently available on the continent?**

Strengths, Challenges, Opportunities of regional JAPs and CRP

- **How reliance is implemented in practice? What works and what are the opportunities?**

Importance of collaboration and reliance mechanisms

- **How to efficiently translate the outcome of CRP & JAP into a national registration? Recommendations for improvements**

Way forward: opportunities for the Africa Medicines Agency

The ECOWAS Joint Assessment Procedure (ECOWAS JAP)

The ECOWAS Joint Assessment Procedure (JAP) is a collaborative initiative among 15 National Regulatory Agencies (NRAs) in West Africa that ensures harmonized and streamlined market authorization of medical products across the region.

Upon approval notification by the West African Health Organization (WAHO), the applicant has 2 years to apply to the 15 ECOWAS Member States that will grant marketing authorization within a maximum of 60 days.

1. Benin
2. Burkina Faso
3. Cape Verde
4. Côte d'Ivoire
5. Ghana
6. Guinea
7. Guinea-Bissau
8. Liberia
9. Mali
10. Niger
11. Nigeria
12. Senegal
13. Sierra Leone
14. The Gambia
15. Togo

ECOWAS Secretariat Headquarters

Key Features for Success

- Expression of Interest (EOI) all year round
- Pre-submission meetings
- Pre-admission screening and dossier validation
- Expert participation from across the region
- Joint evaluation with WHO, Swissmedic, and EMA (technical partners)

Objective

Increase access to and affordability of good quality, safe, and efficacious medicines

Through:
- Harmonized regulatory requirements
- Transparent and efficient regulatory processes

Timeline† (DAYS)

- **133** without queries
- **196*** including a single round of questions

This timeline does not consider the time needed for applicants to reply to the comments and list of questions

Scope of Products under the ECOWAS JAP

- WHO Essential Medicine List
- Programme Medicines
- Public Health Emergencies
- WHO Prequalified and Stringent Regulatory Authorities (SRAs) Approved†
- Life Saving Commodities
- Biological Products and Blood Products (Including Vaccines)
- WAHO Listed Medical Devices Covered in Calls for EOI
- Priority Medical Supplies Determined by WAHO

†*For WHO Prequalified and Stringent Regulatory Authority (SRA) approved products the ECOWAS JAP procedure takes only 60 days.*

ECOWAS JAP Process Flow

How the joint assessment procedure supports an efficient registration of medicinal products

ECOWAS-JAP Preliminary phase | ECOWAS-JAP Regular process | ECOWAS-JAP Decision-making | ECOWAS-JAP Stop outcome | ECOWAS-JAP Extended timeline | National Market Authorization Procedure

Screening fee payment — *Evaluation fee payment*

START

- **STEP 1** Expressions of Interest (EOI)
- **STEP 2** Pre-submission meeting
- **STEP 3** Submission and dossier validation (screening)

30 DAYS

- Letter of Deferral
- Letter of Acceptance

14 DAYS

DAY 0
- **STEP 4** Dossier assignment for review

DAY 45
- **STEP 5** Phase I: Technical Evaluation — VIRTUAL
- Draft technical report and preliminary list of questions (LoQ#1)

DAY 66
- **STEP 6** Phase I: Joint Evaluation (by EWG & Technical Partners) — VIRTUAL or FACE-TO-FACE
- Endorsement and finalization of proposed technical report

Outcome notification and list of questions (LoQ#1) delivery

- APPROVAL
- Development of answers

DAY 101
- **STEP 8** Phase II: Technical Evaluation — VIRTUAL
- Draft technical report 2 and, if applicable, preliminary list of questions (LoQ#2)

OPTIONAL
- **STEP 7** Joint GMP Inspection and Quality Control

DAY 138
- **STEP 9a** Phase II: Joint Evaluation (by EWG & Technical Partners) — VIRTUAL
- Endorsement and finalization of proposed technical report
- APPROVAL

DAY 139
- **STEP A1** EWG member comments to applicant answers
- Outcome notification and list of questions (LoQ#2 or N) delivery
- Development of answers

DAY 169
- **STEP A2**** Joint Evaluation (by EWG & Technical Partners)
- Draft technical report #N and, if applicable, list of questions (LoQ#N)
- Additional questions
- APPROVAL

DAY 152
- **STEP 9b** Development of the final report by EWG
- FINAL REPORT

DAY 182
- **STEP 10** Report validation by WA-MRH Steering Committee

Beginning of NMAP

DAY 196 — End of JAP
Recommendation by WAHO

Screening: *USD 500* *(as of March 2023)*

Evaluation fee: (as of March 2023)
- Applicants in the West Africa Region will pay USD 8,000
- Applicants in other regions of Africa will pay USD 10,000
- Applicants outside Africa will pay USD 12,000

Decision-makers
- EWG
- ECOWAS-JAP Steering Committee
- NRA Assessors
- Lead Coordinating Authority*
- Technical Partners

Actors involved
- Applicant
- ECOWAS-JAP Secretariat
- EWG Chairman

*On a rotational basis, one of the 15 NRAs acts as a Lead Coordinating Authority (LCA). As of March 2023, the Nigeria regulator serves as LCA.
If dossier is found unacceptable after **STEP A2, a re-submission will require an additional payment of 50% of the evaluation fee.

A win-win solution for the applicants and the NRAs:

- ✓ Transparency, efficiency and predictability
- ✓ Streamlined administrative procedures
- ✓ Single point of contact during product assessment
- ✓ Faster and harmonized regulatory approvals
- ✓ Timely access to any of the 15 ECOWAS Member State markets
- ✓ Use of reliance-based procedures

Tips for Success

- Attend pre-submission meeting
- Submit dossiers that meet regulatory requirements in ECOWAS CTD format
- Submit complete and timely responses to the LoQs

Abbreviations

CTD	Common Technical Document
ECOWAS	Economic Community of West African States
EMA	European Medicines Agency
EOI	Expression of Interest
EWG	Experts Working Group
GMP	Good Manufacturing Practice
LoQ	List of Questions
NMAP	National Market Authorization Procedure
NRA	National Regulatory Agency
WAHO	Western African Health Organization
WHO	World Health Organization

Useful resources

- ECOWAS JAP initiative portal
- ECOWAS JAP EOI portal
- Information on the WAHO Guidelines for GMP
- Information on the ECOWAS-WAHO eCTD & eSubmission
- African Medicines Regulatory Harmonization Programme

Contact information

WAHO - West African Health Organization
01 BP 153 Bobo-Dioulasso 01 / Burkina Faso
(226) 20 97 01 00 / (226) 20 97 57 75
(226) 20 97 57 72
https://www.wahooas.org/web-ooas/
wahooas@wahooas.org

IFPMA
http://www.ifpma.org/

https://waho-essmed.org/WAMRH

Scan the QR code and visit the interactive infographic

PANEL DISCUSSION

- **What is your experience regarding facilitated regulatory pathways currently available on the continent?**

Strengths, Challenges, Opportunities of regional JAPs and CRP

- **How reliance is implemented in practice? What works and what are the opportunities?**

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Way forward: opportunities for the Africa Medicines Agency

INTERACTIVE POLL

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Mentimeter

Instructions

Go to

www.menti.com

Enter the code

5142 3986

Or use QR code

QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

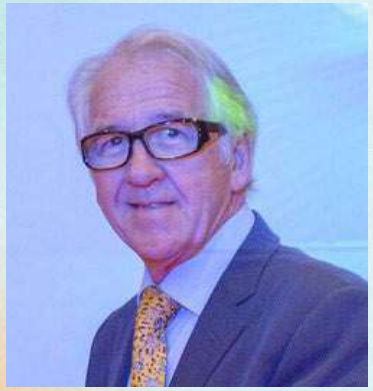
If a question you would like to ask has already been raised, you can also “like” that question. "

2023 AFRICA REGULATORY CONFERENCE

Questions and Answers

Nevena Miletic
Regulatory Policy Head Eastern Europe,
Middle East & Africa (EEMEA),
Global Regulatory Policy,
F. Hoffmann-La Roche

Mariana Roldao Santos
Technical Officer,
Facilitated Product Introduction
World Health Organization



Stuart Walker
Founder of Center for Innovation for regulatory Science

Christelna Reynecke
Chief Operations Officer
South African Health Products Regulatory Authority (SAHPRA)

John Mwangi
Head, Regulatory Affairs - East & West Central Africa
Bayer

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Co-ordinator for the SADC MRH Project
Southern African Development Community (SADC)

Sybil Nana Ama Ossei-Agyeman-Yeboah
Principal Professional Officer, Public Health
West African Health Organization

2023 AFRICA REGULATORY CONFERENCE

KEY TAKEAWAYS– AfRC Track 01

The ongoing harmonization - basis for the collaboration

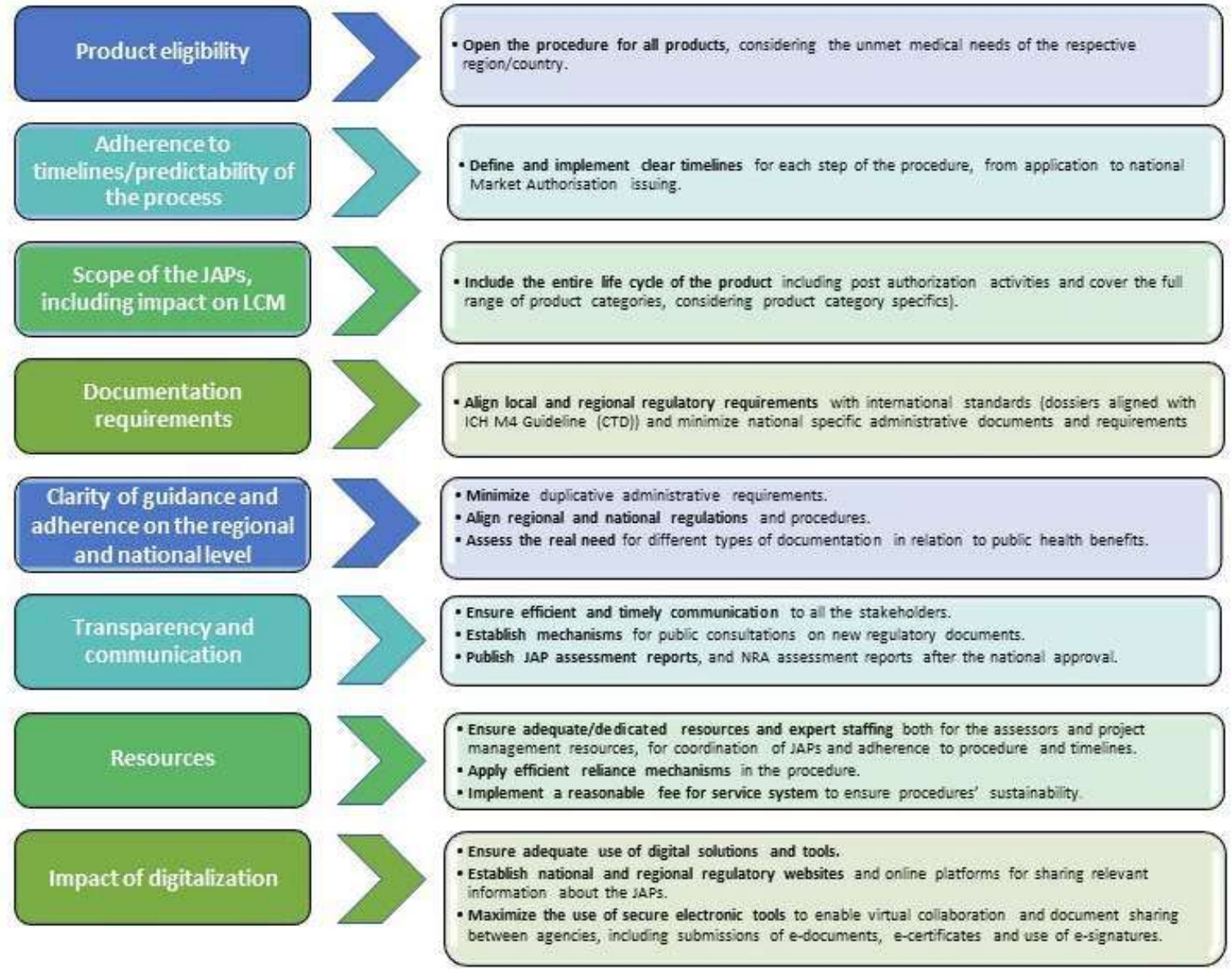
Work-sharing and reliance led to more efficient use of resources and faster product registrations

Positive aspects of JAPs: **Shorter timelines** / Generally **predictable appointment**/ assessment meetings /**Flexibility to assess** products

Important: **Clarify the scope** and responsibilities of the three regulatory layers in the African regulatory ecosystem (national, regional and continental), to **avoid duplication** and redundancy

Consistent and sustainable approach: **appropriate regional provisions** in official guidance and procedures to be implemented nationally

AREAS FOR COLLECTIVE IMPROVEMENT



Miletic N, Adam S, Acquah J, Aziz Z, Joos A and Mwangi JM (2023) What makes joint assessment procedures attractive to the innovative industry: successes, challenges, and proposed improvements. Front. Med. 10:1207954. doi: 10.3389/fmed.2023.1207954

Next steps– AfRC Track 01

Under development/ongoing

Common procedures for variations handling
Proposals for sustainable financing models
Establishment of common digital platforms for submission, collaboration and follow up

Pilot projects, early involvement of all stakeholders

Legal/regulatory basis implemented on all 3 levels (National, Regional and continental)

Ongoing work of continental TWGs and TCs (e.g. eligibility of products for continental assessment defining), to clarify scope, roles and responsibilities

Industry commitment

- Continue raising awareness
- More systematic use of JAPs/CRPs

THANK YOU!

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ORGANIZER IFPMA

PARTNERS leem les entreprises du médicament, IPASA, kapi KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY, arePI, LIPA

Virtual coffee/tea break

We will be back at **14h45 CEST**

AMA publication

JAP publication

12–15 SEPTEMBER | VIRTUAL CONFERENCE

AfRC Track 02

Clinical Trials & Research Ecosystem in Africa: Optimization for the Future

Session Moderator: **Kelly Chibale**

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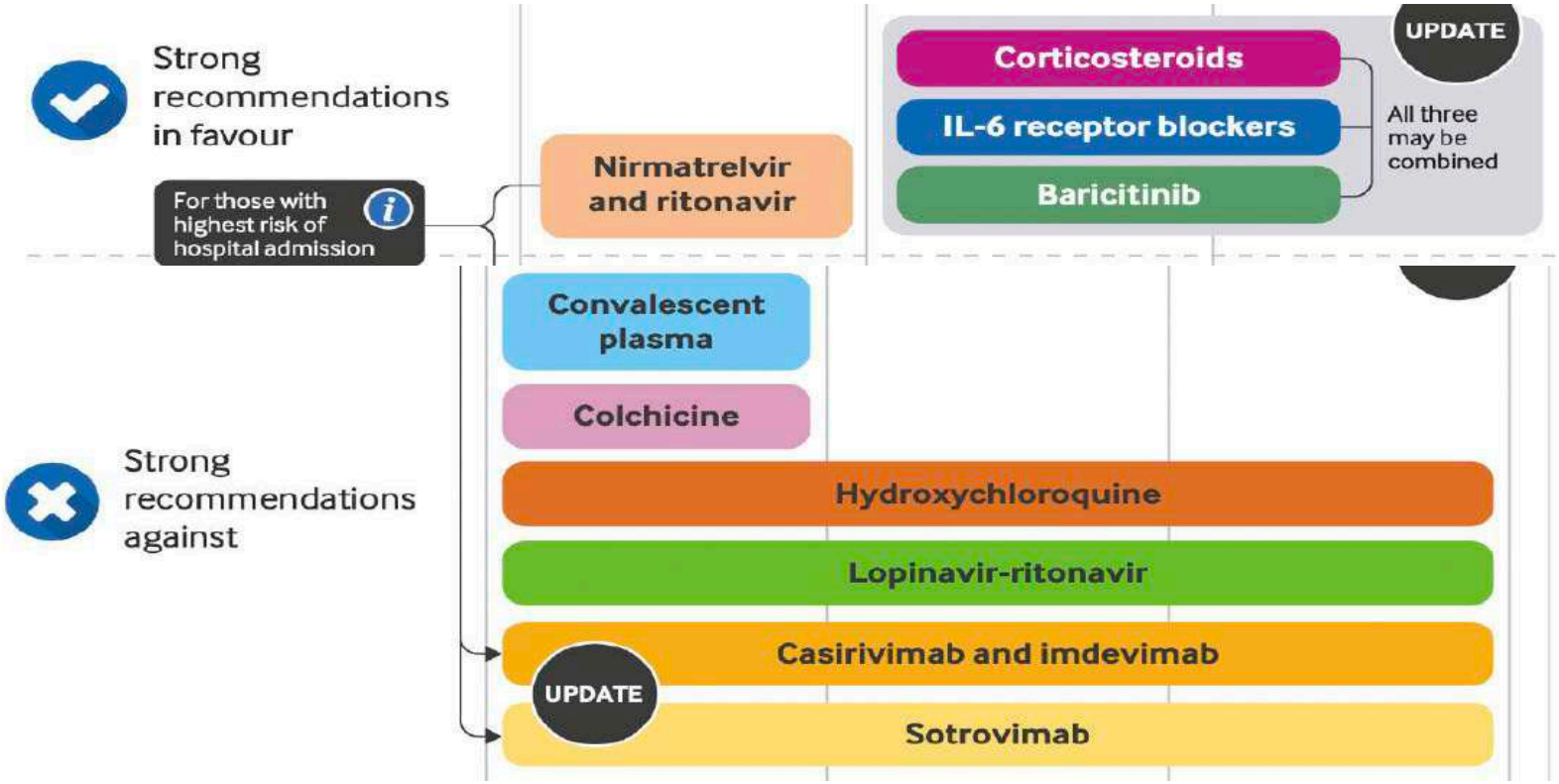
World Health Assembly 2022 resolution on Clinical Trials:

What is WHO doing to enable quality evidence generation from the trials ecosystem?

Vasee Moorthy MA BMBCh FRCP PhD
Senior Advisor
WHO Research for Health Department
Science Division
WHO Geneva

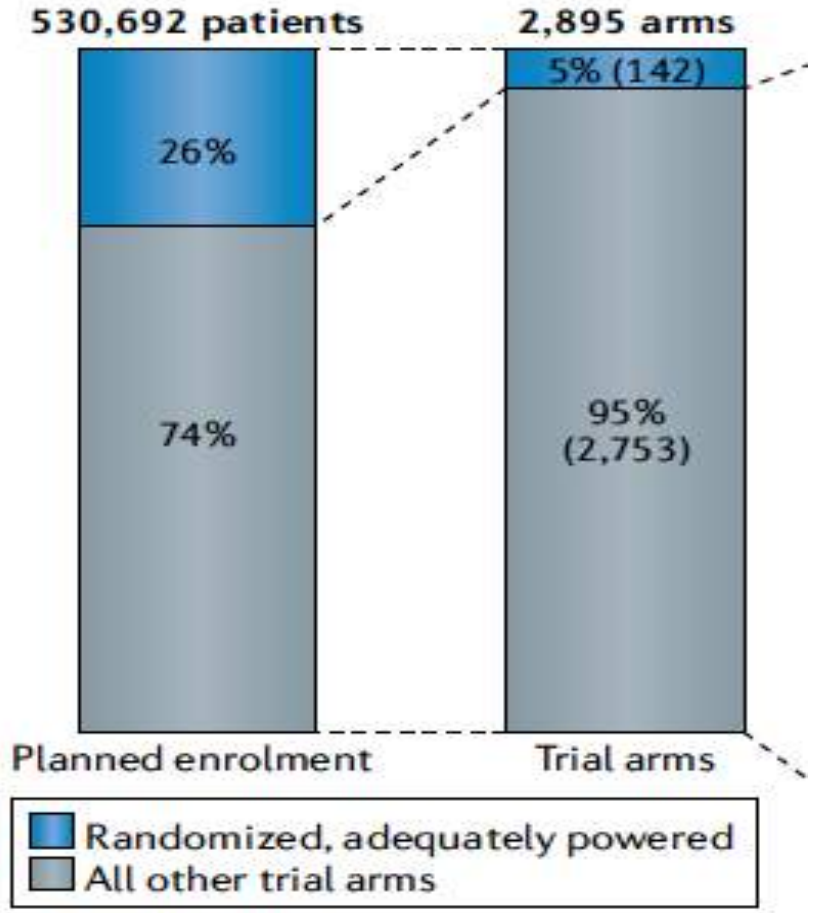
World Health Organization

A few large trials generated much useful evidence and changed global practice



World Health Organization

1000s of trials were low quality



Ref: Nat Rev Drug Discov . 2021 Apr;20(4):254-255. Bugin & Woodcock.

World Health Organization

WHA75.8: Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

Problem statement

Gaps in current ecosystem in enabling high quality trials that produce actionable evidence

Inadequate clinical trial capabilities; Excessive bureaucracy; Research waste;

Scope all clinical trials capabilities for priority use cases in “normal times”, rapidly deployable in times of emergency
All diseases and conditions

Several actions listed in the resolution

World Health Organization

Guidance

- TAG review
- Public consultation Deadline Sep 15
- Training materials in coordination with ICH, Ethics, Funders

Mapping

- Networks
- Funding
- National Regulations
- Sites/institutional capacities

Consultations

- Member State consultations
- Private sector consultations
- Regional consultations PAHO, SEARO, AFRO, EMRO later this year
- Ongoing consultations with other key stakeholders including clinical researchers, ethics, regulatory, funders, patient, community

World Health Organization

Can we facilitate addressing key barriers to clinical trials ?

- A framework for **improving clinical trial capabilities and infrastructure**
- How best to **identify key needs/research gaps for clinical trials to inform policy and practice**
- How to ensure **quality of research including protocol design**
- **Enabling environment for innovative trials** – models for efficient international trials
- Greater **integration of RCTs into healthcare delivery** including digital, patient-centricity
- **Addressing data gaps in under-served populations** (eg children, pregnant and lactating women, global south)
- Better clarity on **roles of different national and international stakeholders**
- **Better inter-agency coordination** eg where multiple approvals are needed

World Health Organization

A practical example of how trials can start with gaps in evidence and rapidly change policy

- Lack of clarity about role of antenatal steroids in reducing preterm infant mortality in certain settings
- This was an identified gap and research need called for in WHO guidelines
- Group of relevant stakeholders conceptualized and designed trial to inform this question
- 4 countries in Africa and Asia took part in trial
- Results confirmed that use of antenatal glucocorticoids reduced preterm infant mortality in these resource limited settings[1]
- WHO and national guidelines were updated to reflect this[2]
- Introduction into policy saves many lives at very low cost

World Health Organization

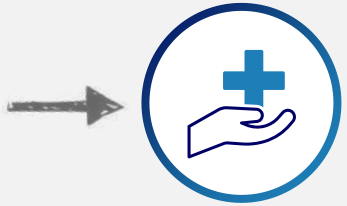
[1]NEJM 2020; 383:2514-2525
[2]www.who.int/publications/i/item/9789240057296

African Vaccines Regulatory Forum

AVAREF (African Vaccine Regulatory Forum) connects regulators and ethics committees from African countries

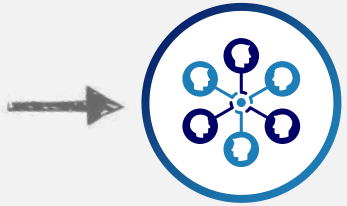
All 55 countries in Africa are members of AVAREF.
AVAREF aims to **harmonise** regulatory practices, **strengthen** collaboration, **build** capabilities and **shorten** timelines to country decisions through joint-review processes

AVAREF offers and facilitates **three main services to PDPs**, using (fromQ4 2023) a fees for services model



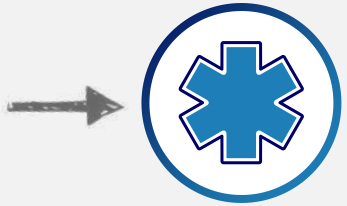
Clinical Trial scientific advice

- Platform for PDPs to engage with experts from across Africa to obtain regulatory and ethical advice about the design of clinical trial in African countries



Multi-country review of Clinical Trial application

- Facilitated joint-reviews for PDPs willing to conduct clinical trial in multiple African countries, coordinating regulators and ethics committee for timely and efficient review



Emergency Use Authorisation facilitation

- Facilitated multi-country technical workshops and joint-reviews for PDPs willing to obtain EUA in multiple African countries using the WHO EUL recommendation for candidate vaccines

All services are available for vaccines, medicines and medical devices, for products addressing a public health emergency, a neglected disease, an unmet medical needs, or involving a novel technology

Visit AVAREF **website**
to view guidance, templates and tools

Subscribe to our **newsletter**

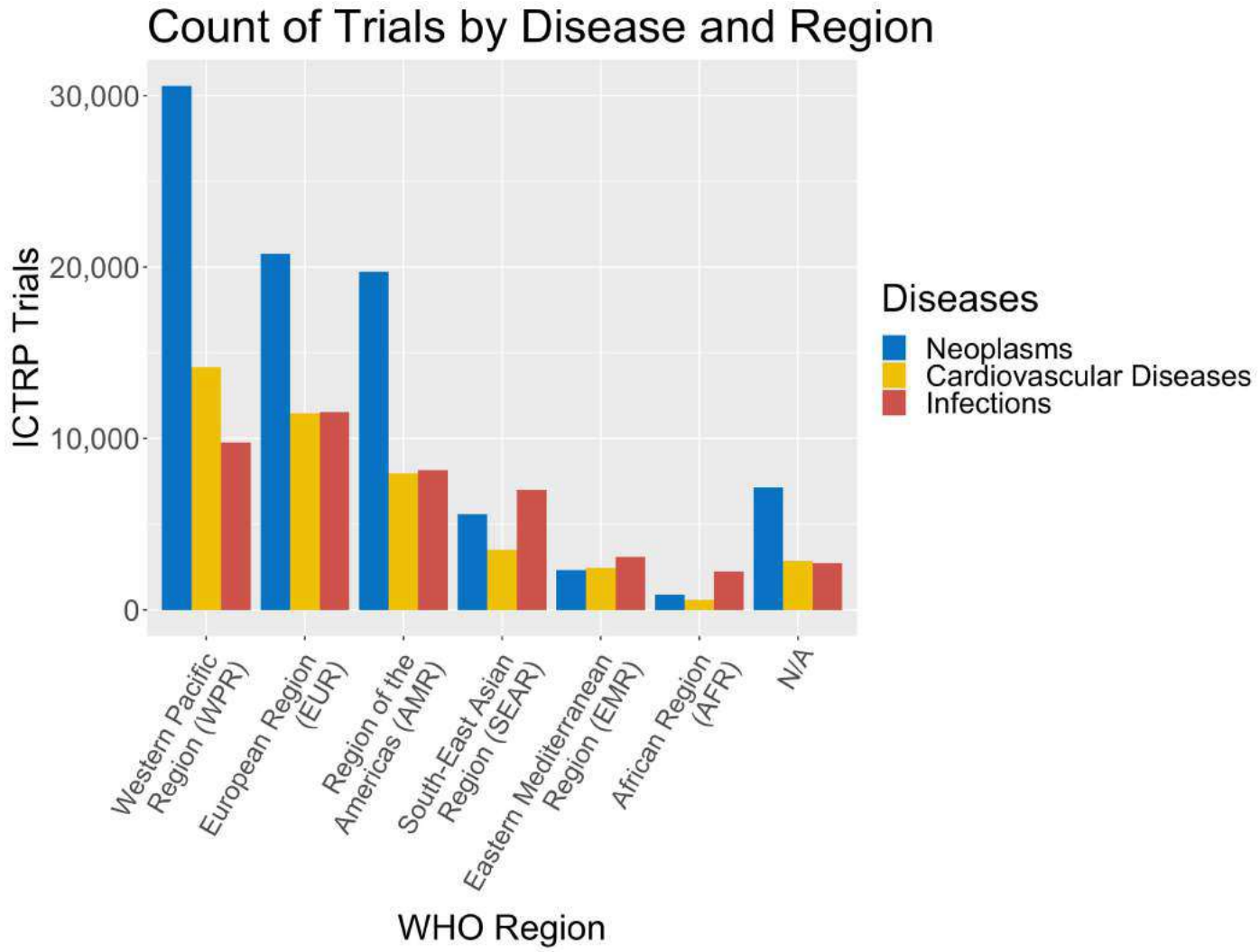
Contact AVAREF Secretariat for information and enquiry: maigad@who.int ; rodgersj@who.int

Mapping of clinical trials by disease area and region (PRELIMINARY)

Clinical trials were mapped to WHO regions as well as the disease areas neoplasms, cardiovascular diseases, and infections

Disease areas were defined using Medical Subject Headings (https://www.ncbi.nlm.nih.gov/mesh/)

2018-2022



World Health Organization

Mapping of clinical trials legislation (preliminary)

Defining

11 key aspects of clinical trial governance were identified.

Searching

A comprehensive search of legislation, standards, and guidance documents was conducted, sourced from:

- Governmental and Ministry of Health websites
- US International Compilation of Human Research Standards 2021
- Clinregs.com
- Legal and academic databases

Summarizing

Source text from the associated legal document was captured to confirm if the country has a legislative requirement for each clinical trial aspect.

89

- Legislation from **89 WHO member countries** has been located.

Breakdown by WHO regions:

- Africa – 20
- Americas – 15
- Eastern Mediterranean – 3
- Europe – 36
- South-east Asia – 6
- Western Pacific – 9

Breakdown by World Bank income groups:

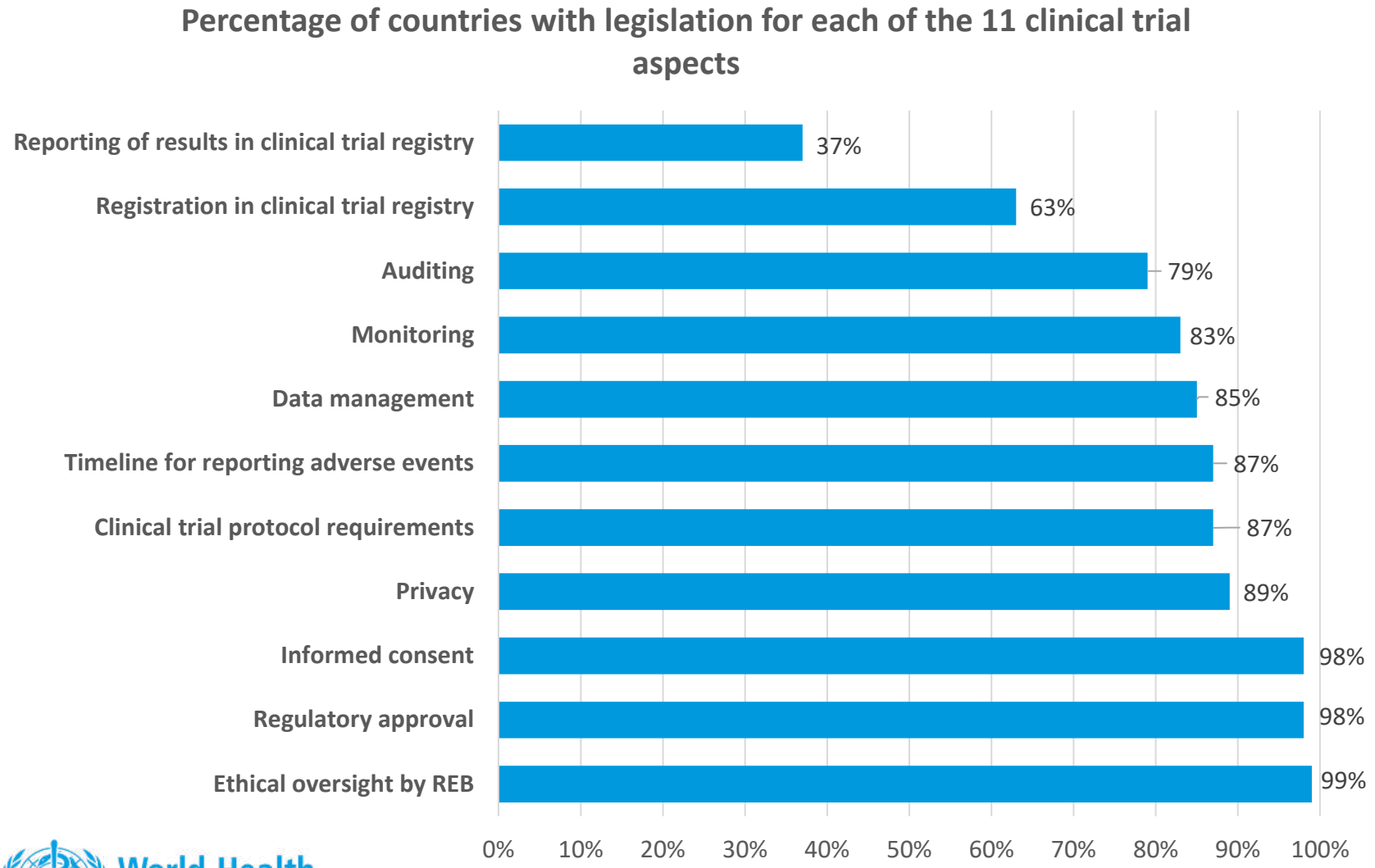
- High – 40
- Middle – 16
- Low-middle – 12
- Low – 21

39

- Legislation for an **additional 39 countries** has been identified, although direct text access remains unavailable.

World Health Organization

Mapping of clinical trials legislation (preliminary)



- **98-99%** of countries have legislation relating to **informed consent, regulatory approval** and **ethical oversight.**
- **63%** of the 89 countries mandate **registration in a registry** before commencing clinical trials.

World Health Organization

Questions?

- What are the key barriers impacting generation of high quality evidence, efficiently and ethically?
- Once the barriers are agreed, how best to advance the areas of focus?
- What would be most useful in terms of a public mapping resource in clinical trials? Is anything further needed in terms of mapping?

World Health Organization

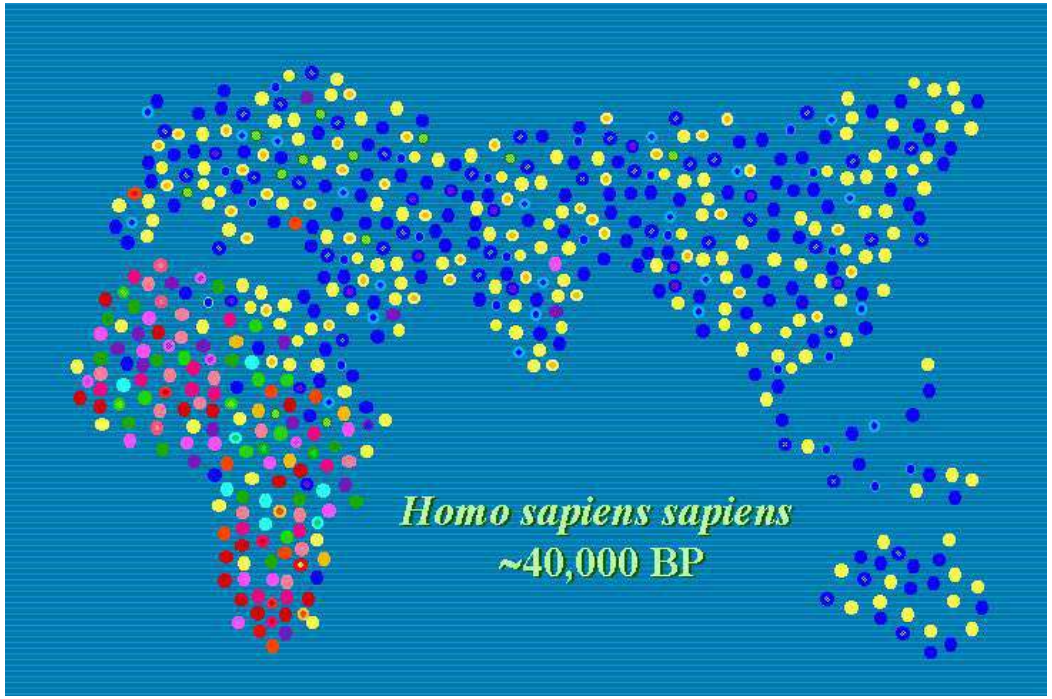
Funding Acknowledgement

World Health Organization

Overview of clinical research/trial in Africa

Dr Thomas Nyirenda
EDCTP Africa Office, Cape Town.

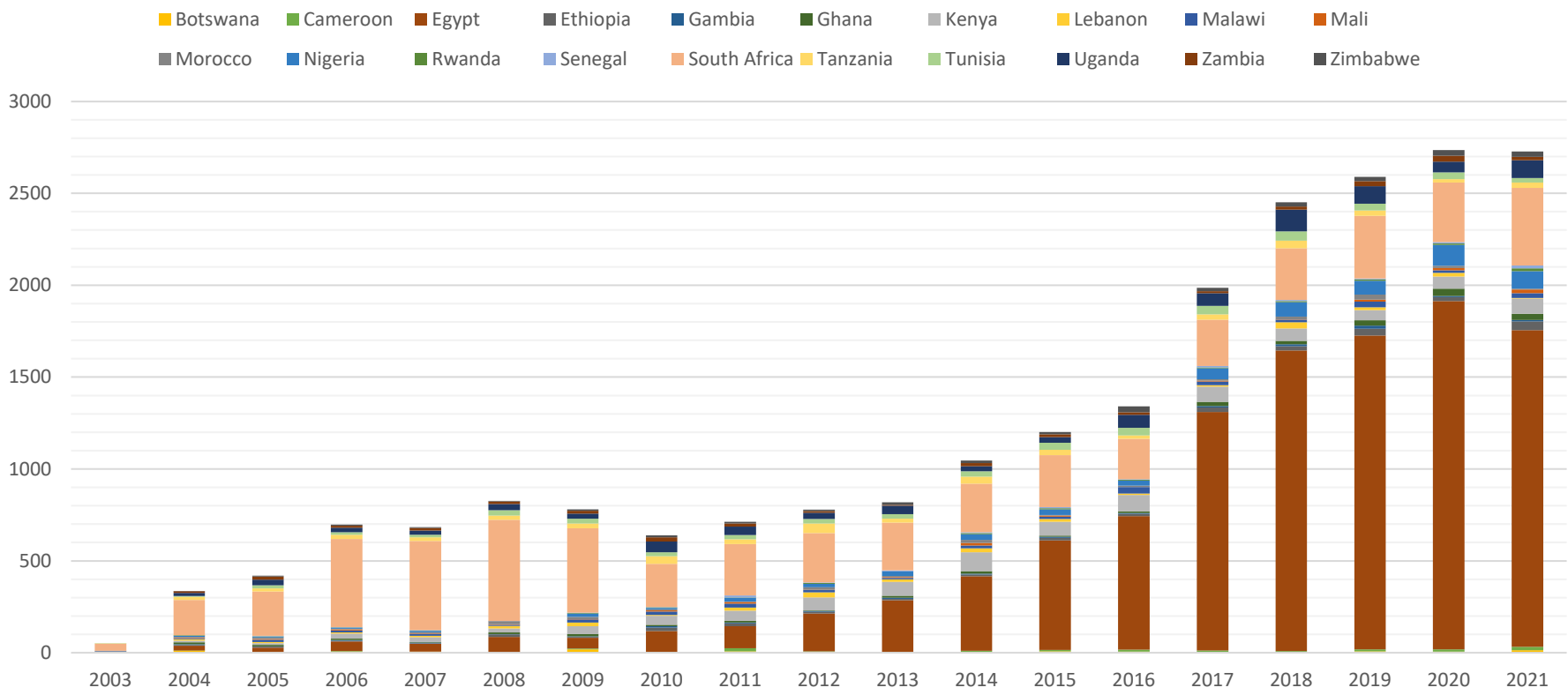
Any clinical trial of disease of global importance should be first done in Africa: Humans originated from Africa



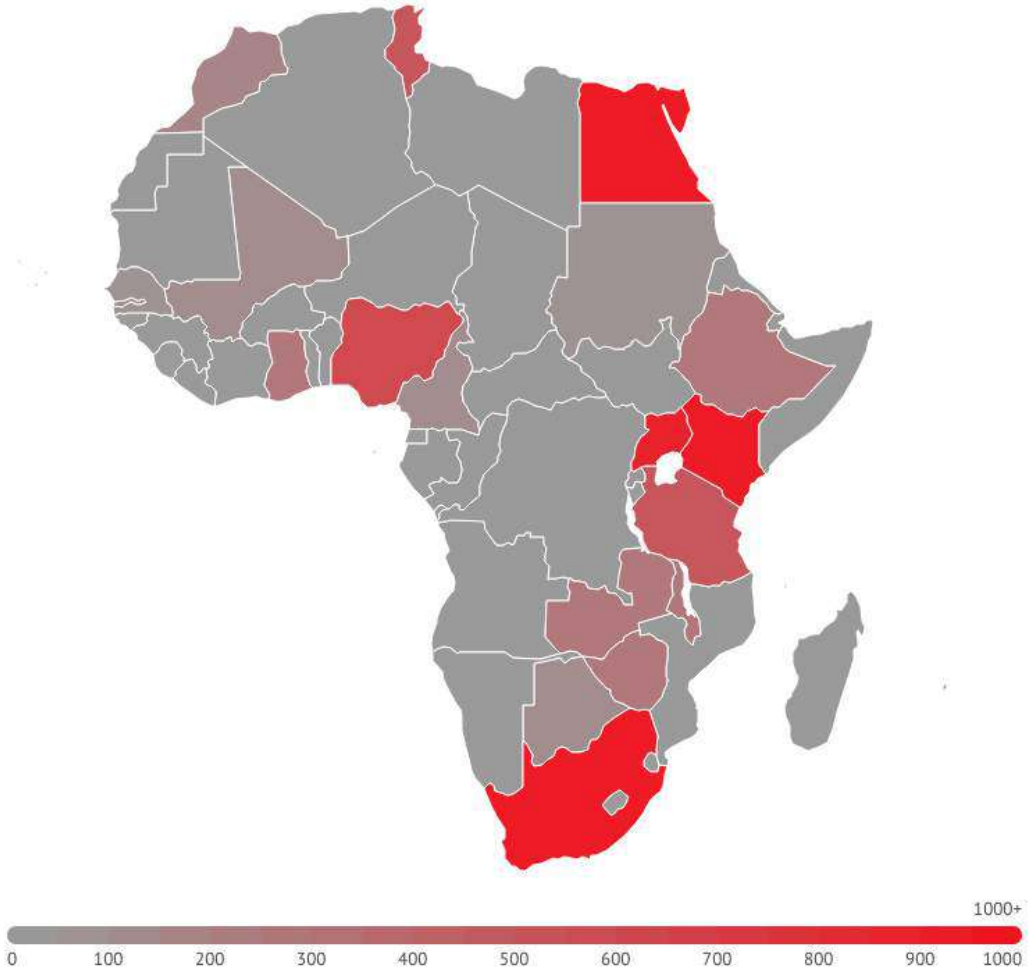
Source: African Society of Human Genetics

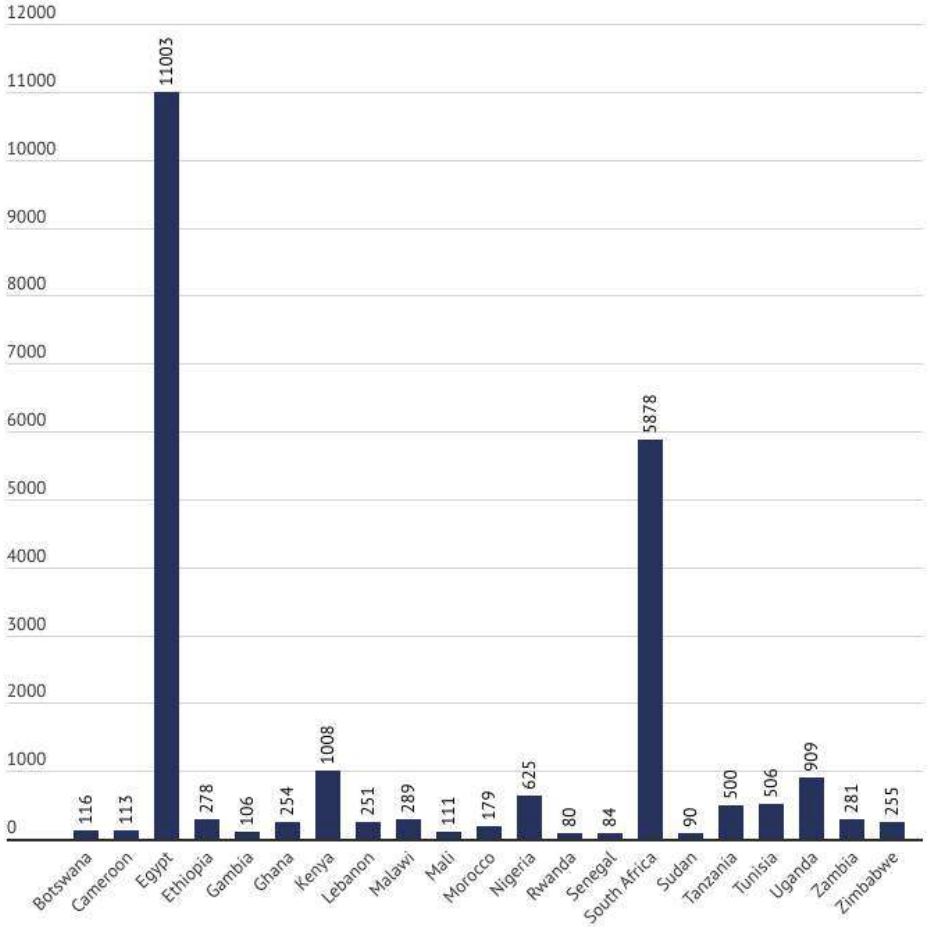
http://tools.medicine.yale.edu/kidd/www/point.html

Number of Clinical Trials Per Year per Country in Africa (Top 20)



Total Number of Studies in Africa between 2003 & 2021 (Top 20)



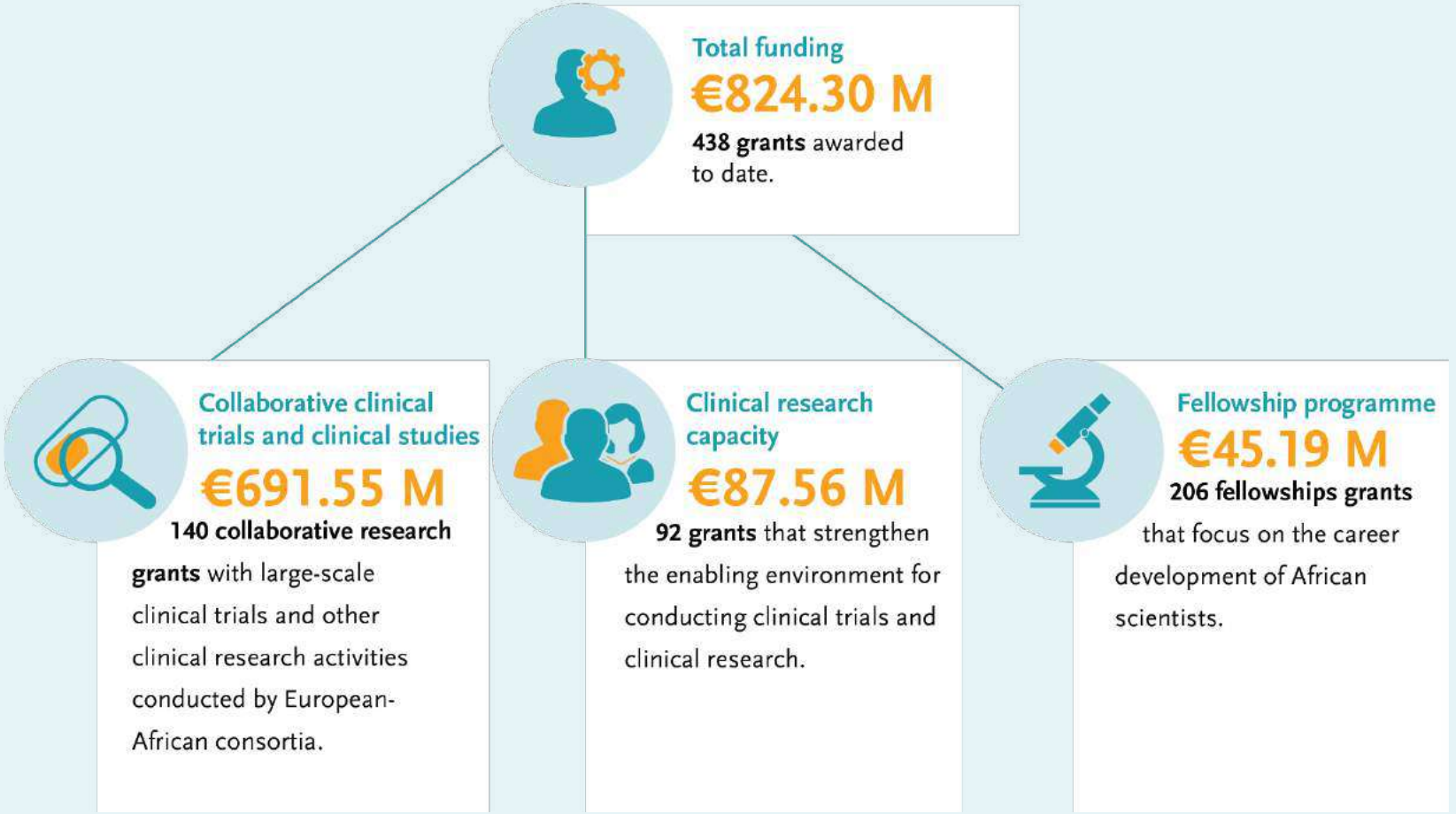


EDCTP

DATA Provided by CLINICAL TRIALS COMMUNITY

EDCTP2 grants contribution

2014-2023



EDCTP-supported activities (#63 countries)

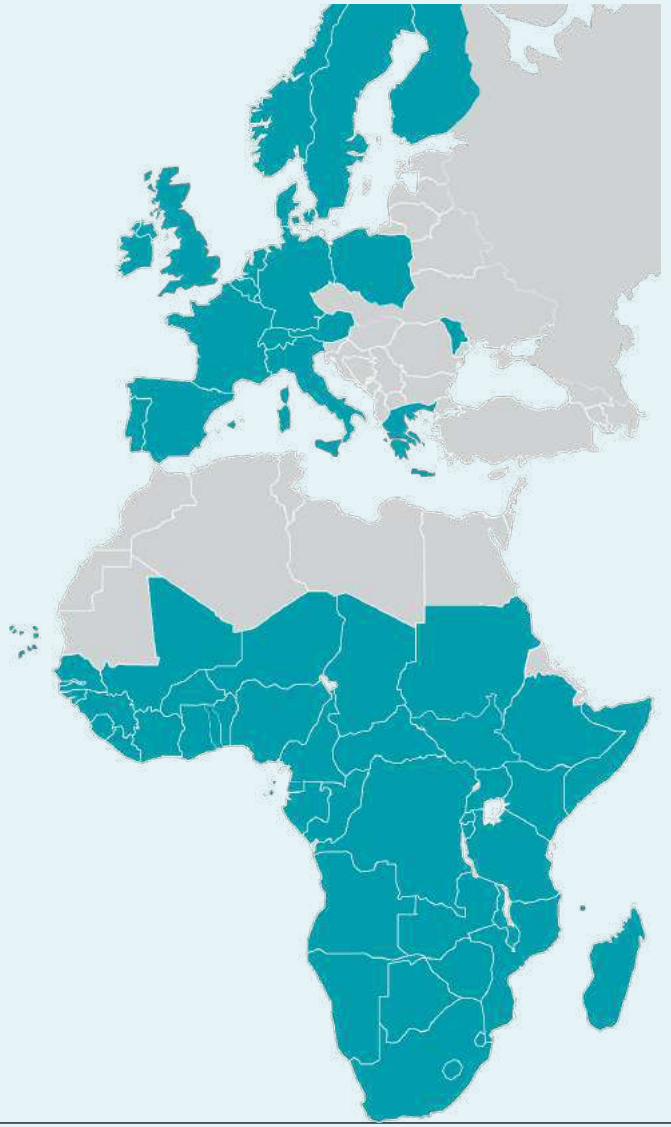
2014-2023

European countries

1. Austria
2. Belgium
3. Denmark
4. Finland
5. France
6. Germany
7. Greece
8. Ireland
9. Italy
10. Luxemburg
11. Moldova
12. Netherlands
13. Norway
14. Poland.
15. Portugal
16. Spain
17. Sweden
18. Switzerland
19. United Kingdom

African countries

1. Angola
2. Benin
3. Botswana
4. Burkina Faso
5. Burundi
6. Cabo Verde
7. Cameroon
8. Central African Republic
9. Chad
10. Comoros
11. Congo
12. Democratic Republic of Congo
13. Equatorial Guinea
14. Ethiopia
15. Eswatini
16. Gabon
17. The Gambia
18. Ghana
19. Guinea
20. Guinea-Bissau
21. Ivory Coast
22. Kenya
23. Liberia
24. Lesotho
25. Madagascar
26. Malawi
27. Mali
28. Mozambique
29. Namibia
30. Niger
31. Nigeria.
32. Rwanda
33. São Tomé and Príncipe
34. Senegal
35. Sierra Leone
36. Somalia
37. South Africa
38. South Sudan
39. Sudan
40. Tanzania
41. Togo
42. Uganda
43. Zambia
44. Zimbabwe



EDCTP

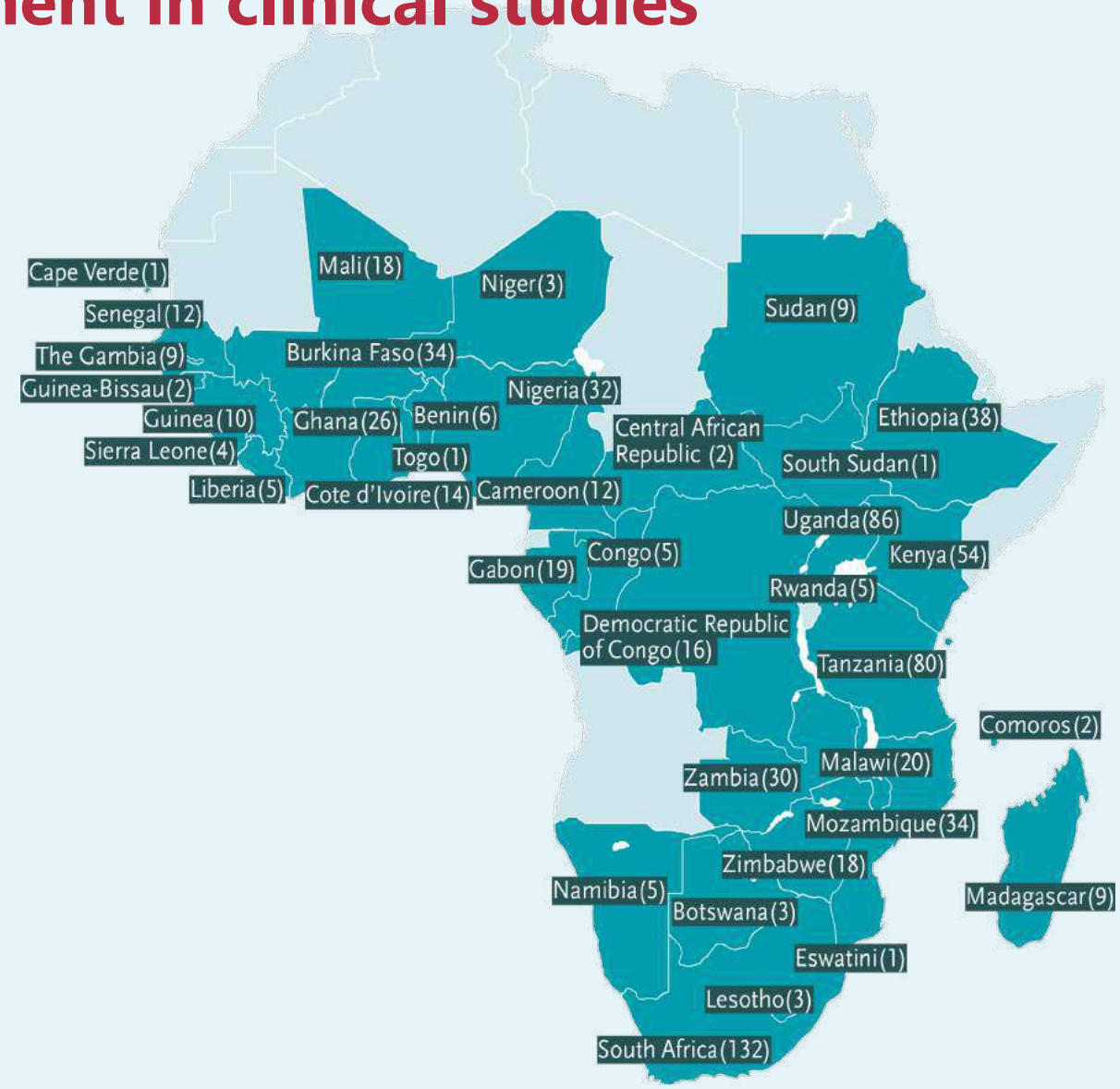
DATA Provided by CLINICAL TRIALS COMMUNITY

EDCTP Country involvement in clinical studies

2014-2023

38 sub-Saharan African countries

- **375** clinical studies, including **225 (60%)**, diagnostics trials and interventional trials of drugs, vaccines and broadly neutralising antibodies (bNAbs)
- **63%** of interventional studies are in phase II-III



EDCTP

DATA Provided by CLINICAL TRIALS COMMUNITY

EDCTP's contribution towards strengthening ethics and regulatory capacity in Africa

2014- 2023

EDCTP-supported ethics and regulatory projects are being conducted in **37 sub-Saharan African countries**

WHO maturity level 3 NRAs

- **Egypt**
- **Ghana**
- **Nigeria**
- **South Africa**
- **Tanzania**.

EDCTP

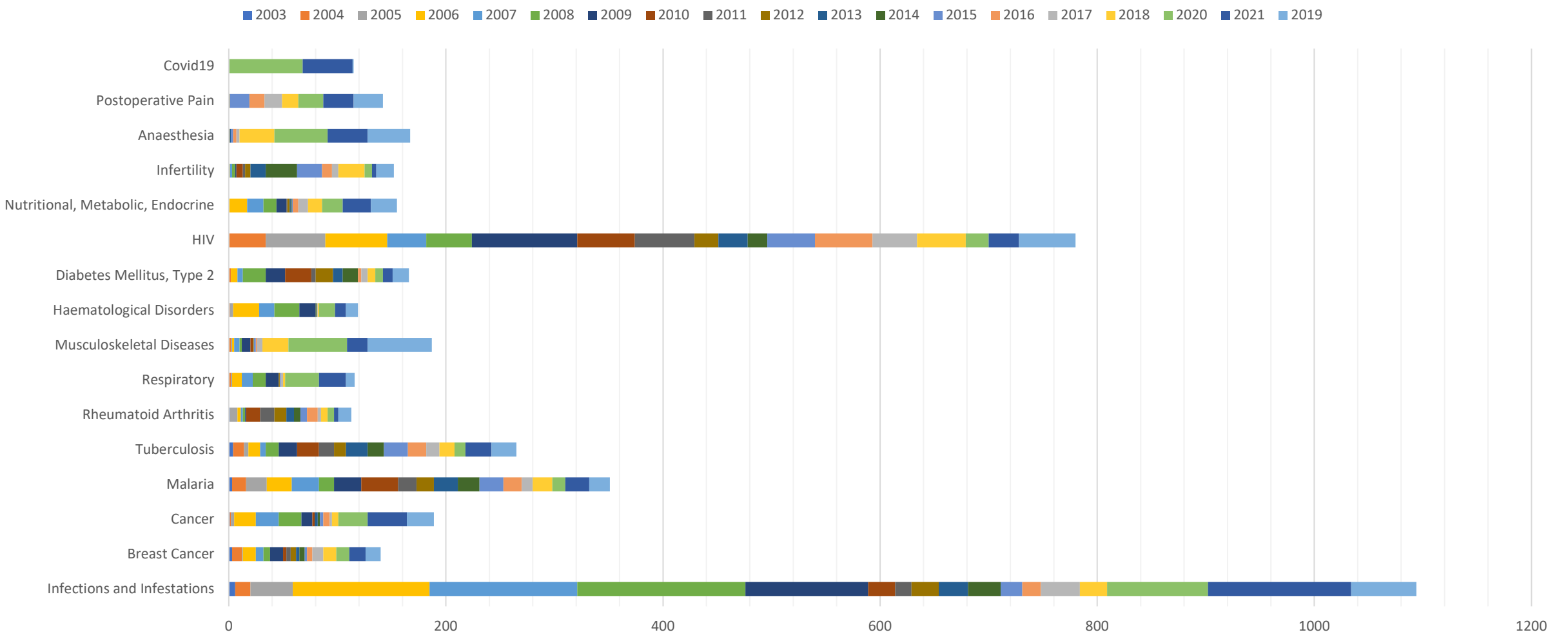
DATA Provided by CLINICAL TRIALS COMMUNITY

So what?

- We should all support the young clinical trial Ecosystem in Africa, for the betterment of science
- Ethical and regulatory oversight strengthening in Africa require joint effort
- Together we can build one healthy global village.

Thanks for your attention

Number of African Clinical Trials per Condition per Year (Top 15)



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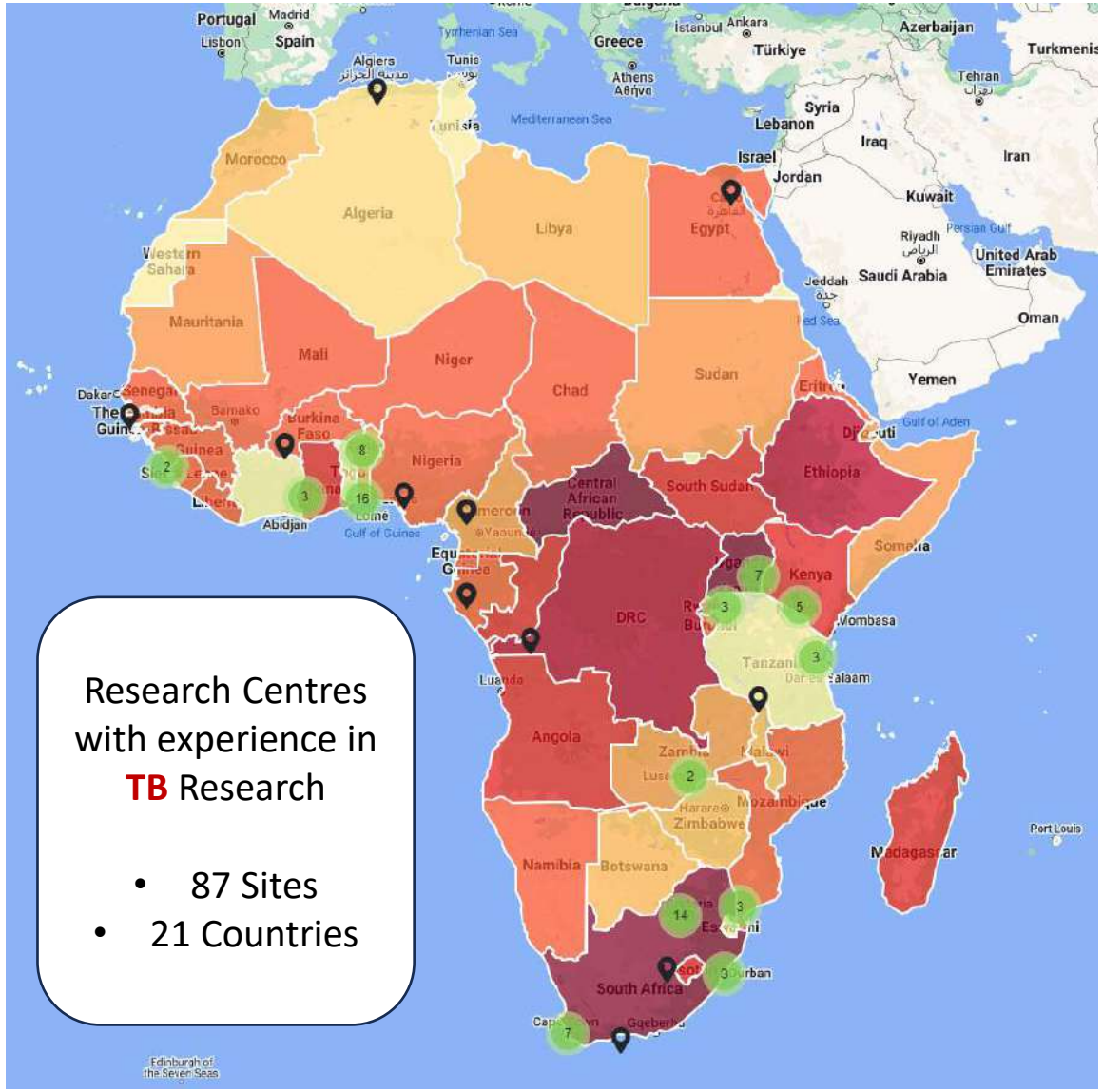
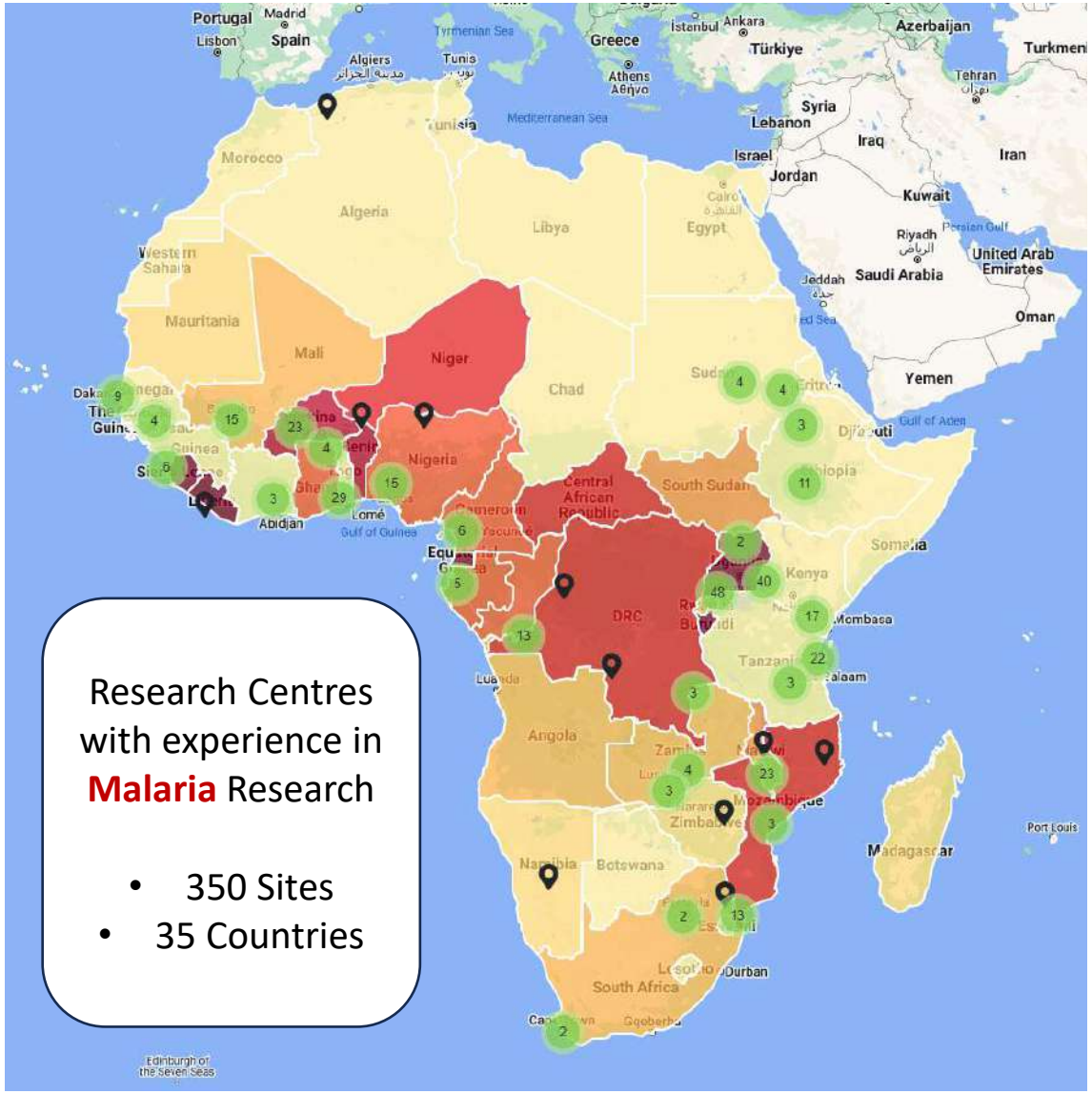
Experience in Africa: TB & Malaria Research





EDCTP

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PANEL DISCUSSION

Kelly Chibale
Neville Isdell Chair in African-centric Drug Discovery & Development
H3D

Thomas Nyirenda
Strategic Partnerships and Capacity Development Manager & Head of Africa Office, EDCTP

Vasee Moorthy
Senior Advisor World Health Organization

Dirk Gillé
Head Capacity Development J&J, Global Public Health R&D, Janssen Research & Development

Jacqueline Rodgers
AVAREF Secretariat World Health Organization

Shingai Machingaidze
Ag. Chief Science Officer Africa CDC

2023 AFRICA REGULATORY CONFERENCE

QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question. "

2023 AFRICA REGULATORY CONFERENCE

KEY TAKEAWAYS – AfRC Track 02

- The **number of clinical trials** in Africa has increased from less than 100 in 2003 to more than **2500** in 2021.
- Opportunity to continue growing the clinical trial and research ecosystem in Africa; including **capacity building in ethics and regulatory oversight**.
- WHO implementation of WHA 75.8 aiming to address **best practices** for clinical trials (design & implementation) and generation of **quality evidence**, while improving **international coordination**, prioritization and links with health policy.
- Reminder of the importance of **clinical trial infrastructure** to both pandemic preparedness and **boosting R&D capacity** in Africa.

THANK YOU!

2023 AFRICA REGULATORY CONFERENCE

Join tomorrow for AfRC Day 2

How can regulatory collaboration help achieve patient-centric impact?

13:00 -16:00 CET

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