

The Diagnostics Advisory Committee(DAC): Accelerating Access to Diagnostics for the health security of Africa.

Dr Noah Takah Fongwen
Coordinator, Diagnostics Access
Division of Laboratory Systems
Africa Centres for Disease Control and Prevention
Addis Ababa, Ethiopia

**AMDF/MDRC/US FDA Meeting:
6-9 November 2023
Nairobi, Kenya**



Slow Introduction of Laboratory Diagnostics

Major Reasons for Slow Introduction

- Paucity of data on performance, impact and cost effectiveness of the technology
- Time lapse in conducting evaluation studies
- Capacity limitation to conduct standard evaluation studies
- Lack of systems for sharing data on the evaluation of diagnostics
- Challenges related to registration of laboratory diagnostics



Africa Collaborative Initiative to Advance Diagnostics (AFCAD)

Launched in 2018 with the following objectives:

- Promote local manufacturing of diagnostics
- Capacity Building for Centres of Excellence (biobanking networks)
- Facilitate harmonization of regulatory processes
- Global market negotiation

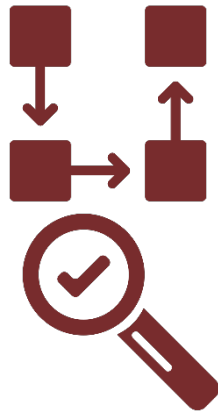


AFCAD Consultative Meeting Sept 23-24, 2019

Proposed Model for AFCAD



- Establish Diagnostics Advisory Committee



- Develop a generic protocol
- Identify centers of excellence in Africa and strengthen their capacity
- Work with regulatory authorities for registration of diagnostics



The Diagnostics Advisory Committee

1. Purpose

To provide guidance on the selection, evaluation, validation/verification, and adoption of laboratory diagnostic technologies and facilitate data sharing.

2. Objectives

- Provide technical support at all stages during the multi-site evaluation of laboratory diagnostics
- Review data on diagnostics performance and provide recommendation on adoption of technologies
- Advise Africa CDC on all issues related to diagnostics availability and accessibility
- Facilitate sharing of laboratory diagnostics performance data across Member States
- Support cooperation and communication with stakeholders on the adoption of diagnostics
- Provide technical support for the development of strategies, guidelines, protocols and standard operating procedures

DAC Meeting in Dakar

- The DAC was Formed during the face-to-face meeting in Dakar, Senegal, August 15-17, 2023.
- Members of DAC identified
- ToR reviewed and finalised
- Synergize with AMRH/Africa Medical Device Forum
- Africa Medicines Agency (AMA)





AFCAD
Africa Collaborative
Initiative to Advance
Diagnostics

Joint Meeting :
Africa CDC Diagnostics
Advisory Committee (DAC) and Africa Medical Device
Forum (AMDF) Technical Committee

Outcomes of the DAC Meeting

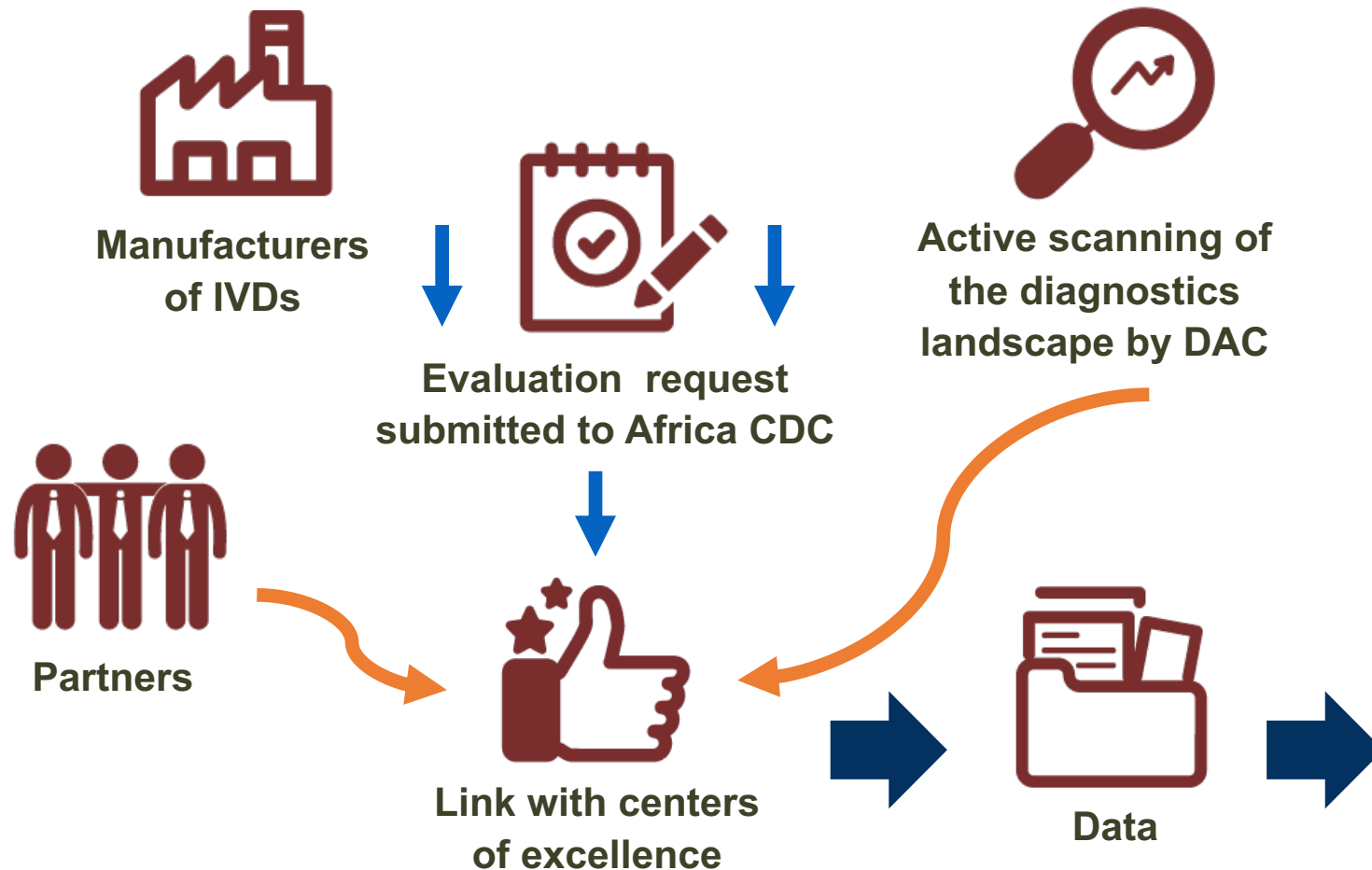
- Alignment of the DAC and the AMDF Tc/AMRH
- ToR reviewed and finalised
- Chair and co-chair elected for the next 2 yrs
- Key next steps: in a press release
- Follow up activities for the DAC



Press release: Joint Africa CDC/AUDA NEPAD

1. Develop a list of diagnostics for priority diseases in Africa for evaluation and regulatory approval
2. Establish an African System under AMRH and through AMDF for assessment and certification of IVDs
3. Support African NRAs to register diagnostics recommended by the AMRH, AMDF and WHO Prequalification process and create list of AU suitable/certified diagnostics for Africa priority diseases
4. Support mapping, identification, and capacity building of a network of accredited laboratories for the validation of IVDs in Africa
5. Promote a robust African Union procurement mechanism for priority diagnostics in Africa
6. Expand global price negotiation efforts by the African Union
7. Support existing efforts in creation of an enabling environment for local manufacturing of diagnostics in Africa.

The Approach to accelerating access



Africa CDC recommendations

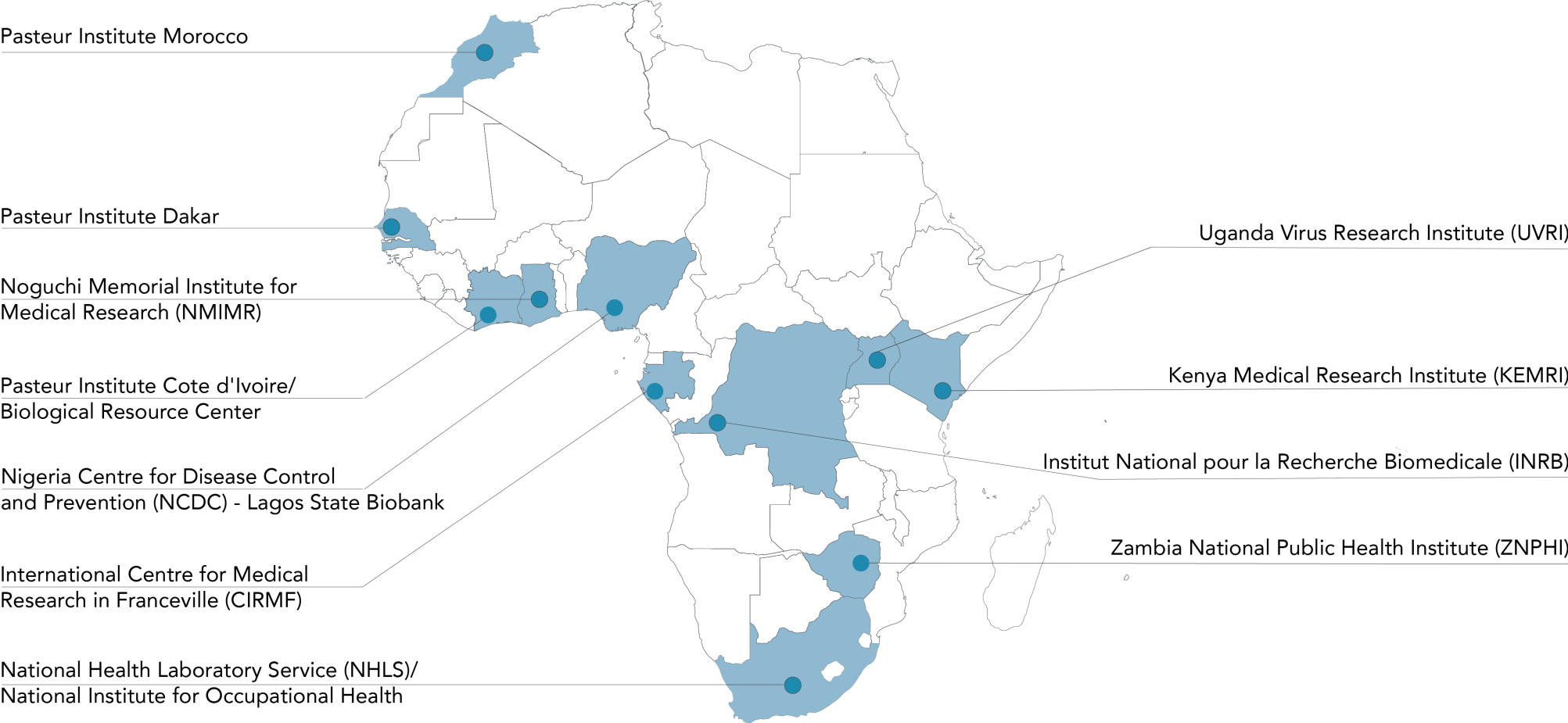
AMRH programme/AMA: Continental approval

Manufacturers (to register diagnostics in other regions)

Partners (procurement)

Member States (in-country registration and use at programme level)

Mapping Centres of Excellence for Diagnostics Evaluation



KEY NEXT STEPS FOR THE DIAGNOSTICS ADVISORY COMMITTEE

- Development of the five-year work plan- Meeting to be held in Nairobi(15-17 November 2023).

- Key elements in the workplan:
 - Priority list of diagnostics
 - generic protocol for diagnostic evaluation
 - mapping and capacity building for centres of excellence
 - local manufacturing.
 - Collaboration with PEPFAR to pilot the mechanism

- Continuous engagement of the DAC with the AMDF and AUDA NEPAD to support regulatory harmonization efforts and engagement with ministries of health and governments.

Acknowledgements

- Special thanks to:
 - The members of the DAC
 - The Laboratory Systems Division at Africa CDC
 - Colleagues in the AMDF and AUDA NEPAD



THANK YOU