



## **Pan-African Harmonization Working Party Regulatory Forum and Workshop**

**Saturday December 3, 2016, 1-5 pm**

**International Conference Centre, Room 1.61-1.62  
Cape Town, South Africa**

### **Background**

The pathway from diagnostic test development to regulatory approval and deployment normally takes more than 10 years. As the world faces increasingly frequent and serious threats of infectious disease outbreaks and antimicrobial resistance, there is an urgent need for the development of better diagnostic tests to combat disease outbreaks and to reduce inappropriate antibiotic prescriptions. Once tests are developed, countries need to be able to expedite regulatory review and approval processes so that tests can be deployed without delay.

Universal access to quality-assured diagnostics is also critical in helping countries achieve disease control and elimination targets. For example, the introduction of self-testing to increase access to HIV testing is important in helping countries to achieve the first 90 of the 90-90-90 targets set by UNAIDS. Safeguarding the quality of malaria rapid diagnostic tests sold is crucial for malaria control programmes to achieve elimination.

Shortening the time from diagnostic tool development to impact will require public and private sectors to work together. This Regulatory Forum and Workshop aims to provide a neutral platform whereby the Pan African Harmonization Working Party (PAHWP), ASLM, industry and public health programmes could explore collaborative mechanisms to accelerate test evaluation, regulatory review, approval and implementation. PAHWP, in collaboration with interested stakeholders, will establish a Task Force to coordinate activities towards achieving this goal.

Regulatory capacity building using harmonization approaches underpins the important goals of accelerating the diagnostic tool development to impact initiative. This session will include a workshop on the review of clinical performance and understanding risks and benefits in the assessment of health impact of diagnostic tools.

### **Forum and Workshop Objectives:**

1. To provide an update on activities from PAHWP and diagnostic alliances from other regions
2. To explore mechanisms for collaboration to accelerate test evaluation, regulatory review, approval among interested stakeholders
3. To build capacity on regulatory science in understanding risks and benefits in assessing the performance and potential impact of diagnostic tests

**Agenda:**

Time	Agenda items	Speakers
1:00-3:00 pm Regulatory Forum:	1. Welcome 2. Update from PAHWP on activities in Africa 3. Updates from global and regional diagnostic alliances (10 min. each)	PAHWP Executive: Agnes Kijo, Tanzania FDA Patience Dabula, NHLS, South Africa  Members of the Global Diagnostic Alliance: - Shireen Haroon, Alere, USA - Carlos Gouvea, Latin American Alliance for IVD (ALADDIV) - Koshiba Michikazu, Mitsubishi UF J Research Consulting (MURC), Japan
	Round Table Discussion: <ul style="list-style-type: none"> <li>• The need for streamlining and harmonizing test evaluation, regulatory review and post-market surveillance</li> <li>• Collaborative mechanisms to shorten time from tools to impact and assure quality</li> <li>• The way forward</li> </ul>	- ASLM: Ali Elbireer - HIV self-testing project, STAR - US Pharmacopedia: Farouk Umaru  Open Discussion
3:00-3:30pm	Break	
3:30-5pm Regulatory Workshop	1. Review of clinical performance data 2. Understanding risks and benefits in assessment the performance and impact of diagnostics	R. Peeling, LSHTM/IDC

**Forum Outcomes:**

1. Consensus on the need for public-private sector collaboration to ensure the quality of *in-vitro* diagnostics in Africa
2. Establishment of a Working group or Task Force to explore a joint Tools to Impact initiative focused on regulatory capacity building and acceleration of regulatory approval of diagnostics in Africa to combat global health threats and improve health outcomes
3. Development of a framework for inter-regional collaboration on regulatory harmonization and post-marketing surveillance

**Learning Outcomes:**

At the end of this Workshop, the participants will know:

1. Diagnostic tools are urgently needed as the world faces increasingly frequent and serious threats of infectious disease outbreaks and antimicrobial resistance
2. Public and private collaboration is critical in developing mechanisms to ensure the timely approval and deployment of quality-assured diagnostics in Africa to combat global health threats and improve health outcomes in Africa. PAHWP will coordinate a task force to advance this cause with all interested stakeholders.
3. How to assess potential impact of diagnostics through understanding risks and benefits in the review clinical performance data on diagnostic tests