INDUSTRY LIAISON FORUM

ILF Thematic Roundtable on HIV Diagnostics: Addressing challenges of EID and POC diagnostics

Tuesday, 19 July 2016, 18:00 – 21:00
The Royal Hotel, Prince Alfred Suites, 267 Anton Lembede Street, Durban, South Africa

CONCEPT

The International AIDS Society's (IAS's) Industry Liaison Forum (ILF) is pleased to invite you to a thematic roundtable on *HIV Diagnostics: Addressing Challenges of Early Infant Diagnosis and Point of Care Diagnostics*.

In line with UNAIDS 90-90-90 targets, by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART), and 90% of all people receiving ART will achieve viral suppression. Early infant diagnosis (EID) and the use of point of care (POC) diagnostics make integral parts of a strategy to achieve the first of the three 90s (testing).

Part I: EID evaluation

Reducing duplication of evaluation requirements
The WHO/CDC/NHLS Common Quality Assessment Mechanism for IVDs is a mechanism focused on simplifying how new diagnostic laboratory assessments of IVDs are performed by the partner agencies. In this harmonized approach, all partners agree on evaluation protocols, and the evaluations are jointly conducted to avoid duplication of efforts. Alignment between WHO Prequalification of HIV-related IVDs and USAID under a common quality assessment mechanism reduces duplication of efforts specifically for the performance evaluation component, and allows for USAID to leverage dossier review and site inspections conducted by WHO. This is intended to lead to the creation of a single list of approved products for procurement by UN agencies, as well as USAID-funded procurement through the Supply Chain Management System and PEPFAR. Two POC EID devices have received CE marking in 2015 and are currently being evaluated through this mechanism.

Fast-tracking clinical trials
The EID Consortium brings together investigators, laboratories and partner organizations to address the difficulties in the clinical evaluation of diagnostic devices. With the introduction of Option B+, fewer infants are born with HIV, therefore making it increasingly difficult to evaluate the clinical performance of diagnostic tools. Indeed, as a result of the lower HIV prevalence, individual countries may require long periods to identify sufficient numbers of infants to estimate the sensitivity of a device. The EID Consortium is made up of multiple independent sites in Africa, all of which are encouraged to use a common evaluation protocol so that data can be aggregated to accelerate evaluation of IVDs for EID that may be used at or near POC. Through these collaborations the EID Consortium aims to accelerate the adoption of new technologies for EID, and decrease infant mortality through early treatment initiation.

The meeting will provide an opportunity to highlight the progress and challenges of these initiatives aiming to remove some of the barriers for access to POC EID devices.

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Part II: POC diagnostics quality assurance

POC diagnostics devices, if they meet the appropriate specificity and sensitivity criteria, have the potential to substantially reduce delays between testing and the delivery of results, thereby allowing for earlier initiation of treatment and reduction of infant mortality. However, there are some challenges with the inclusion of POC solutions in existing laboratory frameworks. As diagnostics are decentralized, quality assurance (i.e., monitoring the quality of IVDs and the testing event) and epidemiologic surveillance (i.e., monitoring the results) become more difficult as the numbers of both users and sites (often in remote areas) substantially increase. In this context, a quality assurance programme that can monitor the users and the surrounding testing environment is important.

Connectivity is one important aspect of a POC quality assurance programme. Instrument connectivity is gradually being relied upon not only to capture data to cover patient and population-level information, but also for monitoring instrument performance and supply chain management. Instruments are often out of service for long periods as service plans are unlikely to be a priority in diagnostics budgets; this is a common issue when warranties end, generally after one year of implementation. As for challenges in the supply chain of POC diagnostics, these are often linked to poor transport networks and remote locations of implementing sites. This often leads to stock-outs of kits and reagents. Again, a quality assurance programme capable of monitoring testing events can raise alerts and guide corrective actions and optimization of systems.

The meeting will provide an opportunity to discuss the role of quality assurance to support accurate testing data and epidemiologic surveillance.

Objectives of the meeting

The main objectives for this discussion are therefore to:

- Follow up on some of the issues highlighted at the *ILF/CIPHER Thematic Roundtable on Paediatric HIV Diagnostics: Early Infant Diagnosis and Beyond* (July 2015, Vancouver, meeting report available online), in particular:
  - Challenges and progress in the area of clinical trials for EID devices
  - Challenges related to the use of POC diagnostics and the role and challenges of connectivity
- Provide a platform for further brainstorming, exchange and discussion, highlight potential synergies, and catalyse collaboration among attendees from different backgrounds.

Thank you for your interest.

Sébastien Morin, PhD
Research Officer, Industry Liaison Forum, International AIDS Society, Switzerland

About the Industry Liaison Forum

The ILF highlights the perspective of the HIV biomedical industry and catalyses multi-stakeholder dialogue and engagement as well as reflections and actions to address barriers along the HIV cascade of prevention, diagnostics and treatment. Challenges around cross-cutting issues affecting industry's contribution to the HIV response are also of central importance. The ILF performs this role by bringing together stakeholders and by highlighting key data and points of view. The work of the ILF is guided by a strong, multi-stakeholder advisory group, which is composed of industry and non-industry representatives. The ILF is grateful for the unrestricted support received from its Gold Partners (Gilead Sciences, MSD and ViiV Healthcare), its Silver Partners (AbbVie, Alere and Janssen) and its Bronze Partners (Abbott, bioLytical Laboratories, Cepheid, Cipla, Female Health Company, Omega Diagnostics, Roche Molecular Systems and Sysmex Corporation). This discussion is sponsored by ILF Gold and Silver Partners.