MISSION AND GOALS

The ILF promotes and facilitates the full contribution of the biomedical industry to the global HIV response. It focuses on expediting development and approval of diagnostics and medicines for HIV and related infectious diseases, thereby contributing to accelerated access for populations most in need. The ILF collaboration platform takes advantage of its strong, multi-stakeholder advisory group composed of industry and non-industry representatives.

Goals:

• Maintain a multi-stakeholder platform, including a broad industry contribution to improve collaboration across sectors.

• Fast track the development of paediatric HIV medicines (focusing on the most-needed paediatric ARV formulations).

• Improve regulatory approval processes for timely access to quality HIV diagnostics and medicines by populations most in need.

In 2016, the ILF highlighted the perspective of the HIV biomedical industry and catalysed multi-stakeholder dialogue and engagement across the HIV response. Its contribution aligned with the IAS HIV Programmes and Advocacy Department Operational Strategy, which focuses on influencing policy, inspiring research, and instigating action to remove structural barriers.

“There is a broad spectrum of representation across all sectors, with equal voice from all participants. This promotes open, unbiased dialogue leading to objective action.”


“The ILF serves a very important purpose to bring together members of the public and private sectors in the HIV fight to a common table where issues of collective interest can be advanced. This is a critical role for the IAS as a “non-partisan” organization.”


“The ILF is uniquely situated to offer constructive comments to improve regulatory systems, as long as it is done in such a way that advances the process.”

– Elliot Cowan, Partners in Diagnostics – ILF Advisory Group member since 2014

“Very happy with our partnership and looking forward to an exciting year ahead.”

– John Bannister, Omega Diagnostics – ILF Advisory Group member since 2014

Policy: Influence global and national HIV policy and bridge gaps between the HIV response and the broader integrated health landscape.

Research: Inspire HIV research targeting scientific gaps that link research to strategic programme priorities.

Structural barriers: Instigate action to remove structural barriers and address human rights violations that inhibit access to and uptake of comprehensive HIV services for selected populations and communities.

Catalyses multi-stakeholder dialogue and engagement

Influences policy, inspires research, and instigates action to remove structural barriers

Involves a strong advisory group composed of industry and non-industry representatives

Focuses on issues in paediatric HIV and regulatory affairs

Highlights the perspective of the biomedical industry

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POLICY

Advocating for improvements of the WHO Prequalification Programme of In Vitro Diagnostics

The WHO created its Prequalification of In Vitro Diagnostics Programme (PQDx) to ensure “access to safe, appropriate and affordable [in vitro diagnostic medical devices] of good quality in an equitable manner”, especially in resource-limited settings with limited domestic regulatory frameworks. To support improvement of this important programme, the ILF performed a broad consultation of the diagnostic industry on successes and challenges of WHO PQDx. The insights, gathered from 13 companies and other independent experts, were shared with WHO PQDx as an opportunity to promote dialogue and receive feedback. Following future discussions to clarify diverging perspectives, the ILF will bring public attention to unsolved challenges, if any, in an effort to advocate for policy improvements.

Supporting an enabling environment for global hepatitis targets

Welcoming the World Health Assembly’s approval of the WHO Global Health Sector Strategies on HIV, Viral Hepatitis and Sexually Transmitted Infections, the ILF released an opinion piece discussing some of the essential elements to overcome the HIV/HCV co-infection epidemic, in particular for people who inject drugs. The text discusses the importance of accompanying targets with predictable and focused funding for testing, prevention and treatment, as well as placing most-at-risk populations (people who inject drugs, in this case) at the centre of the response. The blog post also highlights that access to care remains an issue despite advances in science with curative medicines now able to cure nearly all people living with hepatitis C (including people co-infected with HIV), and the emergence of promising policies. The blog post is available here.

Promoting evidence-based scale up of early infant diagnosis and point-of-care diagnosis

In line with the UNAIDS 90-90-90 targets, by 2020, 90% of all people living with HIV should know their HIV status, 90% of all people with diagnosed HIV infection should receive sustained antiretroviral therapy, and 90% of all people receiving antiretroviral therapy should achieve viral suppression. Early infant diagnosis (EID) and the use of point-of-care (POC) diagnostics are integral parts of a strategy to achieve the first 90 target (testing). However, challenges persist around evaluation of EID devices and quality assurance for POC diagnostic technologies. The ILF provided a platform to discuss challenges and progress in these areas. The two key take-home messages from this interactive discussion were: (1) the need for rapid implementation of the available POC EID platforms; and (2) the importance of considering quality assurance for POC diagnostics as an investment, not a cost. The report is available here.

RESEARCH

Developing a global accelerator for paediatric formulations

In 2016, the ILF became a partner of the Global Pediatric Antiretroviral Commitment-to-Action (CTA). In this context, it ensured that various industry perspectives (from both originators and generic manufacturers) were included in the development of a global accelerator for paediatric formulations. This global accelerator is a new collaborative framework to fast track development of paediatric ARV formulations. It includes a set of recommendations for regulatory agencies and industry, as well as an innovative financing mechanism. Key milestones in this area include a series of expert meetings (reports available here and here), which led to the development of an action plan in three stages. This plan is being reviewed for endorsement by CTA partners. Once validated, the plan will be shared with the broader group of stakeholders and stages 1 (which includes recommendations and efforts to better define the paediatric ARV market) and 2 (which is a proof of concept) should start in parallel.

Contextualizing advances in prevention research

As results for two trials of long-acting dapivirine vaginal ring – ASPIRE (MTN 020) and The Ring Study (IPM 027) – were announced, ILF Advisory Group members co-authored an opinion piece answering a key question that many scientists had in mind: “What’s next for women?”. Published as a blog post, this contextualises advances in HIV prevention for women and what these promising results mean for the HIV prevention toolbox. The blog post is available here.
Enhancing communication between industry and key paediatric ARV initiatives

In order to remove some of the barriers that prevent optimal communication between industry and key paediatric ARV initiatives, the ILF, in collaboration with the IAS Collaborative Initiative for Paediatric HIV Education and Research (CIPHER), held a webinar to disseminate the main outcomes of the Geneva Paediatric HIV Week in December 2016. The webinar specifically focused on ensuring that ARV manufacturers are continuously informed of the latest developments in the paediatric ARV field. The recording is available [here](#). In addition, the ILF supported WHO by ensuring liaison with ARV manufacturers for information on their development pipelines to inform the Paediatric ARV Drug Optimization 3 meeting.

**Key initiatives promoting collaboration and coordinated action for drug optimization of paediatric ARVs:**
- **IATT:** Inter-Agency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children
- **PADO:** Paediatric ARV Drug Optimization group
- **PAPWG:** Paediatric ARV Procurement Working Group
- **PAWG:** Paediatric ARV Working Group
- Programmes refer to in-country paediatric HIV programmes.

### STRUCTURAL BARRIERS

Evaluating the meaningful engagement of people living with HIV in the biomedical industry

The Greater Involvement of People Living with HIV/AIDS (GIPA) is a guiding principle to promote substantial and meaningful engagement of people living with HIV at all levels of the HIV response. It has catalysed a more nuanced understanding of how people openly living with HIV have shaped and influenced the AIDS response. More than 37 million people are living with HIV today; the majority of them are of working age. People living with HIV are in every circle of society, irrespective of their HIV status disclosure. The ILF developed a survey to explore how the biomedical industry interprets the GIPA principle and meaningfully involves people living with HIV in response to the evolving HIV environment. The findings will be reported in 2017, highlighting best practices, and discussing any gaps and remaining challenges.

### LOOKING AHEAD

The ILF 2017-2020 Strategy will build on the ILF collaboration platform to address issues in the two focus areas of paediatric HIV and regulatory affairs, in alignment with domains of the IAS HIV Programmes and Advocacy Department Operational Strategy 2017-2020 (policy, research and structural barriers).

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**ILF collaboration platform**

Maintain a multi-stakeholder platform, including a broad industry contribution to improve collaboration across sectors

**ILF focus on paediatric HIV**

Fast track the development of paediatric HIV medicines (focusing on the most-needed paediatric ARV formulations)

**ILF focus on regulatory affairs**

Improve regulatory approval processes for timely access to quality HIV diagnostics and medicines by populations most in need
The ILF thanks its advisory group members for their continued contribution throughout the year.

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Linda-Gail Bekker
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Duncan Blair
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Abbvie
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ViViD Healthcare
WHO HIV/AIDS Department
Abbott
Amsterdam Institute for Global Health and Development
Elizabeth Glaser Pediatric AIDS Foundation
MSD
Omega Diagnostics
Cepheid
Cipla
Medicines Patent Pool
ViViD Healthcare
Merck
Roche Molecular Systems
Sysmex Corporation
Fenway Institute
Janssen
U.S. Food and Drug Administration
National Empowerment Network of People Living with HIV/AIDS
University of Bonn
Gilead Sciences
European Medicines Agency
MSD
Universidade Federal do Rio de Janeiro
WHO Prequalification Programme
Female Health Company
Abbvie
Global Network of People Living with HIV
Istituto Superiore di Sanità

1 Term ended in 2016
2 Term started in 2016
3 Observer for regulatory affairs
4 IAS Governing Council member
1 The first-ever global targets on viral hepatitis, which were adopted at the 69th World Health Assembly, include:
- Reduce new cases of chronic hepatitis by 30% (2020) and 90% (2030), i.e., from 6-10 million new cases in 2015 to <1 million in 2030.
- Reduce hepatitis B and hepatitis C mortality by 10% (2020) and 90% (2030), i.e., from 1.4 million deaths in 2015 to <500,000 in 2030.

2 CTA partners include the World Health Organization, the Pediatric HIV Treatment Initiative (PHTI, which includes UNITAID, the Clinton Health Access Initiative, the Drugs for Neglected Diseases initiative, and the Medicines Patent Pool), the US President’s Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and, since 2016, the International AIDS Society through the ILF and CIPHER.