Industry Liaison Forum

Strategic Plan 2006 - 2008
1. Introduction

The Industry Liaison Forum (ILF) is an initiative of the International AIDS Society (IAS). ILF promotes scientific, intellectual and financial commitment from research-based pharmaceutical and diagnostic companies to research in resource-limited settings. ILF identifies the scientific, operational and political challenges that impede HIV research in low and middle-income countries and proposes ways to address those challenges through ethical, efficient and sustainable clinical study methodologies.

The ILF is an integral component of the core purpose and vision of the IAS, as reflected in Stronger Together - Strategic Framework: 2005-2009. The IAS strategic framework directs the ILF to expand the opportunities for policy dialogue with the pharmaceutical industry and research community. Within this broader goal, the strategic framework identifies two objectives:

- Utilize the existing framework to strengthen ongoing policy dialogue with the pharmaceutical industry and academia to accelerate research in the developing world and;
- Develop additional processes to facilitate dialogue with industry on non-research related issues, in line with identified IAS priority areas.

ILF is building on its achievements by strengthening relationships with other IAS initiatives that promote similar goals. These include an open-access electronic journal (eJIAS), IAS conference awards for developing world investigators, collaboration with the HIV Research Trust to fund training for health care workers and partnering with the University of Toronto Centre for Global Health Research on a short course for AIDS programme managers (see Section 6: Linkages with Other IAS Initiatives).

The IAS is also exploring the potential to build on the success of the ILF by developing an initiative with an expanded scope of activities and stakeholder group committed to accelerating research in resource limited settings. The ILF will continue to be an important initiative of the IAS, and will provide ongoing input to the IAS staff and consultants.

2. ILF Mission

Accelerate scientifically promising, ethical HIV research in resource-constrained settings with a particular focus on the role and responsibilities of industry as sponsors and supporters of research.

3. Objectives

3.1 create opportunities for researchers from within and outside industry to coordinate with partner agencies including the WHO, UNAIDS, international and national research networks to advance HIV research in resource-constrained settings.

3.2 contribute to building consensus on best practice models and guidance for the conduct of HIV research in resource-constrained settings that safeguard the rights of research participants on contentious issues related to such areas of research as post-trial treatment and care, prevention
technologies and the involvement of local communities in trial design and conduct.

3.3 expand the stakeholders involved with ILF, including the greater involvement of researchers and organizations from resource-limited settings;

3.4 Broaden contribution from independent sponsors, policy and research agencies such as the US National Institutes of Health (NIH), US Food and Drug Agency (FDA), World Health Organisation (WHO), UNAIDS, UK Medical Research Council and the Bill and Melinda Gates Foundation.

4. ILF Structure and Governance

4.1 Chairs
Joep Lange, Academic Medical Centre and IATEC, the Netherlands
Michel Kazatchkine, Ambassador for HIV/AIDS, France
Elly Katabira, Makerere University, Uganda

4.2 Advisory Group
Pedro Cahn, Fundación Huesped, Argentina
Ernest Ekong, Military Reference Hospital, Nigeria
Helene Gayle, IAS and the Bill and Melinda Gates Foundation
Scott Hammer, Columbia University, USA
Souleymane Mboup, University Cheikh Anta Diop, Senegal
Craig McClure, IAS
Randy Tressler, Pfizer, USA
Praphan Phanupak, HIV-NAT, Thailand
David Reddy, Hoffmann La Roche, Switzerland
Paul Stoffels, Tibotec, Belgium

4.3 Secretariat
Rodney Kort, Initiatives Manager, IAS
Yasmin Halima, Coordinator, IAS Industry Liaison Forum.
Jacqueline van Tongeren, Support Manager, IAS Industry Liaison Forum

5. ILF Stakeholders
Participants in the ILF are individuals and organizations committed to research in the developing world, including dedicated scientists and business leaders from industry as well as independent investigators from resource-rich and resource-constrained settings.

6. Sustainability and Success

6.1 Funding
IAS-ILF receives sponsorship from industry in the form of unrestricted educational grants. Sponsorship covers the operational costs of ILF including staffing, event planning, design, printing and distribution of reports and other materials, and support for investigators from the developing world to attend ILF meetings and events.
6.2 ILF profile and communication

Achievements and the evolving research agenda of ILF is disseminated through the IAS website, newsletter, conference events, reports and related programmes such as IAS educational and policy initiatives.

7. ILF Priorities 2006-2008

The priorities for ILF are based on emerging issues of contention and concern as identified by industry participants engaged with ILF. Pre-exposure prophylactic (PREP) research was identified as a priority for ILF in an agenda-setting meeting involving key ILF participants and expert contributors in November 2004. The rationale for PREP recognises the urgent need for biomedical prevention technologies that reinforce existing prevention approaches in resource-limited settings. A parallel interest in PREP concerns the scientific, operational and ethical challenges that are not unique to PREP but shared across other areas of clinical investigation. These include the standards for treatment and care during and post-study, standards for providing prevention interventions during studies, involvement of communities in study design and conduct, compensating trial subjects for harm and the design of appropriate models of animal and human research. Above all, it is acknowledged that the ethical baseline for prevention research will be set higher than the parameters for treatment research. As such, a stringent framework that encapsulates responsibilities of industry supporters of prevention research will also adequately address ethical challenges and liabilities pertinent to other areas of treatment study.

Within PREP, three areas of support were identified explicitly for ILF:
1. Delivering a high-level learning environment conducive to the critical analysis of data from current studies and exploring potential for future PREP agents.
2. Defining clear responsibilities applicable to industry and non-industry sponsors
3. Strengthening the network of relationships between independent investigators, industry, government and private sponsors.

Below are the approaches to addressing the three priority areas over the next two years:

<table>
<thead>
<tr>
<th>PRIORITY 1 (ILF)</th>
<th>OUTCOME</th>
<th>TIMELINE</th>
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<tbody>
<tr>
<td>Address scientific and operational challenges to PREP including biological, pharmacokinetic, ethical issues and costs.</td>
<td>Scientific Forums</td>
<td>Feb 06 - Jul 06</td>
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<th>PRIORITY 2 (ILF)</th>
<th>OUTCOME</th>
<th>TIMELINE</th>
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<tr>
<td>Identify issues related to pharmacovigilance, surveillance systems and the scaling of diagnostic resources to strengthen capacity for research.</td>
<td>Scientific Forums</td>
<td>Jul 06 - Feb 07</td>
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<th>PRIORITY 3 (ILF)</th>
<th>OUTCOME</th>
<th>TIMELINE</th>
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<tr>
<td>Develop consensus guidance on sponsor ILF</td>
<td>ILF</td>
<td>Aug 06 – Dec</td>
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responsibilities for treatment, care and prevention in the conduct of clinical trials.

Coordinate guidelines with other related initiatives including UNAIDS.

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<tr>
<th>PRIORITY 4 (ILF-Expanded Initiative)</th>
<th>OUTCOME</th>
<th>TIMELINE</th>
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<tr>
<td>Identify priority area(s) for developing PREP research guidelines in the developing world</td>
<td>Multi-agency Planning Workshop</td>
<td>Nov 06</td>
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<tr>
<td>Coordinate guidelines with other related initiatives including UNAIDS.</td>
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8. Linkages with Other IAS Initiatives

The ILF is well-placed to benefit from links with other IAS initiatives that share the same objectives. As such, ILF is committed to broadening its role within the IAS and strengthening relationships with a range of projects that would support ILF in its goal to strengthen research capacity in the developing world.

In particular, ILF aims to:

8.1 Support investigator participation and development

Scholarships and bursaries made available for young, developing country researchers through IAS should be strategically linked to promote attendance and participation in scientific debates including discussions at the ILF.

8.2 Research education and training

Targeted activities such as eJIAS and the Short Course on Evidence-based AIDS Programmes (organised in collaboration with the University of Toronto) support the development of senior research and policy staff from developing countries and should be linked to the ILF.