



**INTERNATIONAL AIDS SOCIETY
INDUSTRY LIAISON FORUM**

Evaluation Report

January 2008

Contents

Executive Summary	3
1. Background	5
2. The Evaluation	6
2.1 Objectives	6
2.2 Methodology	6
2.2.1 Online survey	6
2.2.2 Telephone interview	7
2.2.3 Data analysis	7
2.3 Other evaluation work	8
3. Evaluation Findings	8
3.1 Key ILF activities	8
3.1.1 Satellites	8
3.1.2 Forums	9
3.1.3 Discussion paper, CROI 2007 forum	9
3.1.4 Discussion papers, Advisory Group	10
3.2 ILF Impact	10
3.2.1 Achievement of objectives	10
3.2.2 Value of ILF	11
3.2.3 Wider influence of ILF	12
3.3 Looking to the future	13
3.3.1 Future areas of work	13
3.3.2 Strengthening the ILF	13
4. Discussion and Conclusions	14

Appendices

1. Data collection instruments
2. Industry representatives' feedback
3. Satellite evaluation report
4. Topics/issues for future ILF work

Author

The evaluation was undertaken by Diana McConachy, Evaluation Coordinator, International AIDS Society (IAS). Interviews were conducted by Rodney Kort, independent consultant and former Senior Manager, IAS Initiatives.

Executive Summary

Background

The Industry Liaison Forum (ILF) is an initiative of the International AIDS Society (IAS). The ILF comprises three Co-Chairs and a 19-person Advisory Group of senior scientists and business leaders from industry, and independent investigators. An additional 30 to 40 stakeholders from civil society, donor agencies, trial sponsors and UN agencies participate in ILF-sponsored meetings to address specific scientific and operational issues related to conducting research in the developing world.

In late 2005, a two-year strategic plan was developed for the ILF. Aligned to the IAS Strategic Framework 2005 – 2009, the plan articulated the following ILF mission:

To accelerate scientifically promising, ethical research in resource-constrained settings, with a particular focus on the role and responsibilities of industry as sponsors and supporters of research.¹

The Evaluation

In late 2007, the ILF was two-thirds of the way through its 2006 - 2008 Strategic Plan. An evaluation was undertaken to assess the impact of the initiative and to help guide future planning. The evaluation primarily focussed on activities undertaken in 2006 and 2007, and was framed by three objectives:

- To review the role and impact of the ILF;
- To investigate specific ILF activities and processes
 - illuminating outcomes and successes, and
 - identifying challenges and areas of difficulty;
- To identify emergent issues to guide future planning and decision-making.

A range of methods was used to collect qualitative and quantitative data to address these objectives. The two main data collection instruments were an anonymous online survey and a confidential telephone interview. Thirty-four people completed an online survey (a 40% response rate). Ten individuals representing a range of ILF stakeholder perspectives participated in an interview (a 59% response rate); seven of whom also completed a survey.

Findings

The evaluation demonstrated the important role played by the ILF in providing a means for industry representatives, as well as other key stakeholders, to come together to discuss scientific and operational questions relevant to clinical research. In 2006 and 2007 the ILF prepared three key discussion papers and implemented a variety of strategies to bring people together, including Advisory Group meetings, satellites and forums.

The vast majority of satellite participants (93%) rated the satellite(s) they had attended 'good' or 'excellent'; 76% of forum participants similarly rated the forum(s) they had attended. The value of the discussion paper produced for one of these forums was highlighted as a means of presenting key issues and guiding discussion. Discussion papers produced for the Advisory Group meeting held at the Conference on Retroviruses and Opportunistic Infections (CROI) 2007 also rated highly.

¹ Industry Liaison Forum Strategic Plan: 2006 – 2008. International AIDS Society; Geneva, 2006.

Results were mixed regarding the achievement of four key ILF objectives, suggesting that although progress has been made, there is more work to be done. A large proportion of survey respondents felt the ILF had successfully addressed the scientific and operational challenges to pre-exposure prophylaxis (PrEP); however, respondents were less definitive about the ILF's success in:

- Creating opportunities for researchers within and outside industry to work together and with other relevant stakeholders;
- Helping to build consensus on best practice models and guidance for the conduct of HIV research in resource-constrained settings;
- Informing discussion about clinical research issues in their organization.

Findings also showed that whilst opportunities for input into the ILF agenda have increased over time, wider consultation could be undertaken. A variety of topics and issues were identified for future consideration, including capacity-building in resource limited settings, first and second line therapies, research on women and microbicides.

In terms of strengthening the ILF, two key themes emerged. The first related to broadening representation in meetings, with a particular focus on government representation and increased engagement with researchers from developing countries. The second related to the ILF becoming more action-oriented and outcomes focussed.

Conclusions

The evaluation demonstrated strong support for the ILF as a vehicle for bringing together key stakeholders to address specific scientific and operational issues related to conducting research in the developing world. Findings also revealed solid support for ILF activities, especially the satellites and discussion papers, and work undertaken around pre-exposure prophylaxis. The evaluation also highlighted two key action issues:

- The need to establish more tangible objectives/outcomes for the ILF;
- The need to develop mechanisms to increase involvement of both government representatives and developing world investigators in the ILF.

1. Background

The Industry Liaison Forum (ILF) is an initiative of the International AIDS Society (IAS). Established in 2002, the ILF comprises three Co-Chairs and a 19-person Advisory Group of senior scientists and business leaders from industry and independent investigators from resource-rich and resource-limited settings. An additional 30 to 40 stakeholders from civil society, donor agencies, trial sponsors and UN agencies participate in ILF-sponsored meetings to address specific scientific and operational issues related to conducting research in the developing world.

In late 2005, a two-year strategic plan was developed for the ILF. Aligned to the IAS Strategic Framework 2005 – 2009, the plan articulated the following ILF mission:

To accelerate scientifically promising, ethical research in resource-constrained settings with a particular focus on the role and responsibilities of industry as sponsors and supporters of research.²

The plan identified four objectives to achieve this mission:

- 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.
- 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.
- Expand the stakeholders involved with ILF, including the greater involvement of researchers and organizations from resource limited settings.
- Broaden contribution from independent sponsors, policy and research agencies such as the US National Institute of Health (NIH), US Food and Drug Administration (FDA), UNAIDS, UK Medical Research Council and the Bill & Melinda Gates Foundation.

The plan also identified two priority areas for ILF work, 2006 – 2008:

- Pre-exposure prophylactic (PrEP) research; and
- Scientific, operational and ethical challenges that are relevant not only to PrEP research, but also to other areas of clinical investigation.

Four ILF approaches to PrEP issues were delineated in the plan:

- Address scientific and operational challenges to PrEP including biological, pharmacokinetic and ethical issues and costs in scientific forums;
- Identify issues related to pharmacovigilance, surveillance systems and the scaling of diagnostic resources to strengthen capacity for research in scientific forums;
- Develop consensus guidance on sponsor responsibilities for treatment, care and prevention in the conduct of trials; and coordinate guidelines developed with other related initiatives;
- Identify priority area(s) for developing PrEP research guidelines in the developing world at a multi-agency planning workshop; and coordinate guidelines with other related initiatives.

To date, key ILF activities have included the convening of Advisory Group and stakeholder meetings and the preparation of related discussion papers and reports; the organization of satellites at international conferences, and contributions to consultations on PrEP and non-PrEP related issues.

² Industry Liaison Forum Strategic Plan: 2006 – 2008. International AIDS Society; Geneva, 2006.

2. The Evaluation

2.1 Objectives

In late 2007, the ILF was two-thirds of the way through its 2006 - 2008 Strategic Plan. An evaluation was undertaken to assess the impact of the initiative and to help guide future planning. The evaluation primarily focussed on activities undertaken in 2006 and 2007, and was framed by three objectives:

- To review the role and impact of the ILF;
- To investigate specific ILF activities and processes
 - illuminating outcomes and successes, and
 - identifying challenges and areas of difficulty;
- To identify emergent issues to guide future planning and decision-making.

Evaluation findings are presented in this report.

2.2 Methodology

A range of methods was used to collect qualitative and quantitative data to address the evaluation objectives. These included:

- Review of the ILF Strategic Plan, reports, and minutes;
- Consultation with the ILF Co-chairs, members of the Advisory Group and relevant IAS staff;
- Review of monitoring information about membership, meetings and outputs;
- Interviews with and surveys of key informants including ILF participants, advisory group members and satellite participants.

The two main data collection instruments were an online survey and a telephone interview. These were developed in consultation with the IAS Senior Manager, Policy and Initiatives, the ILF Senior Consultant, and the ILF Advisory Group.

2.2.1 Online survey

An anonymous online survey was sent all ILF Advisory Group members and participants who had some involvement in the ILF in the previous three years (n=92)³. The survey sought feedback about key ILF activities, the impact of the ILF, and the issues that should be addressed by the ILF in the future (Appendix 1a). Of the 84 surveys received, 34 (40%) were completed and returned.

Survey respondents

The largest proportion of respondents identified as 'independent investigator' or 'other' (see Table 1). Respondents who placed themselves in the 'other' category included 'research institution', 'care provider', IAS and 'university'.

³ Names were provided by the ILF Coordinator. Of the 92 emails sent out, 8 (9%) bounced back. In most cases this was because the individual no longer worked for the organization.

Table 1: Survey respondents' main affiliation

<i>Affiliation</i>	<i>f</i>	<i>%</i>
Independent investigator	9	26.5
Civil Society	6	17.6
Industry	6	17.6
Sponsor	2	5.9
Donor	1	2.9
UN agency	1	2.9
Other	9	26.5
<i>Total</i>	<i>34</i>	<i>100</i>

Although survey respondents' length of involvement with the ILF varied, half had been involved for more than three years (average 3.1 years) (see Table 2). Twelve respondents (35%) were members of the ILF Advisory Group.

Table 2: Survey respondents' time with ILF

<i>Years</i>	<i>f</i>	<i>%</i>
One year	2	5.9
Two years	10	29.4
Three years	5	14.7
More than three years	17	50
<i>Total</i>	<i>34</i>	<i>100</i>

2.2.2 Telephone interview

To supplement the survey data, 17 individuals who represented a range of ILF stakeholder perspectives, especially the Advisory Group and industry, were invited to participate in a short, confidential telephone interview which sought information about their organization's contribution to the ILF, benefits gained from this involvement, and suggestions for strengthening the ILF (Appendix 1b). Ten interviews (59%) were conducted. Seven interviewees also completed a survey.

Interviewees

Six interviewees were members of the ILF Advisory Group and three represented industry. Most interviewees had been involved with the ILF for at least two or three years, with several indicating their involvement began when the ILF started to focus on pre-exposure prophylaxis (PrEP) issues. Several indicated their involvement began around six years ago, when the ILF was first launched to look at industry responsibilities for post-trial care. A few interviewees noted they were not involved in the ILF as representatives of their organization, but participated as individuals.

2.2.3 Data analysis

Responses to open-ended questions were transcribed and analysed for content and key themes. Frequencies and cross-tabulations were tallied for closed questions. Total numbers vary in some instances because non-responses were excluded from valid data. The information collected was

triangulated and cross-checked to illuminate similarities and differences in the perspectives offered and to highlight key issues⁴.

2.3 Other evaluation work

As an adjunct to the evaluation of the ILF, the ILF satellite, *Are we prepared for PrEP? The Challenges of Implementing Proven Biomedical Prevention Technologies*, held at the 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Sydney, July 2007, was evaluated in depth. Satellite participants were invited to complete a short questionnaire at the end of the satellite which sought feedback about their reasons for attending, coverage of satellite objectives, and any benefits gained. Approximately 80 people attended the satellite and 34 questionnaires were returned (approximately 43% of attendees). Findings are reported separately (see Appendix 3).

3. Evaluation Findings⁵

3.1 Key ILF activities

A major part of ILF work in 2006 and 2007 was the organization of satellites and forums, and the production of discussion papers. Feedback about these activities was sought in the online survey.

3.1.1 Satellites

Two ILF satellites were held at international AIDS conferences in 2006 and 2007:

- *What if pre-exposure prophylaxis (PrEP) works?* XVI International AIDS Conference (AIDS 2006), Toronto, Canada, August 2006; attended by approximately 300 people;
- *Are we prepared for PrEP? The Challenges of Implementing Proven Biomedical Prevention Technologies*, 4th IAS Conference on HIV Pathogenesis, Prevention and Treatment (IAS 2007), Sydney, Australia, July 2007; attended by approximately 80 people.

Survey respondents were asked if they had attended either satellite and, if so, their main reasons for attending (from a five-item list). They were also asked to give an overall assessment of the quality of the satellite(s) using a four-point scale (excellent/good/fair/poor).

Twenty-three respondents (58%) had attended *What if PrEP works?* and 11 respondents (27%) had attended *Are we prepared for PrEP?* Six respondents had not attended either satellite. The reasons most frequently cited by the 28 respondents for their attendance were the topic/content of the satellite (43%) and the applicability of the satellite to their own area of work (30%).

⁴ Parlett, M. & Hamilton, D. (1976). Evaluation as Illumination: a new approach to the study of innovatory programs. In Glass, G (Ed.) *Evaluation Studies: Review Annual*. Sage: Beverley Hills, CA

⁵ As the primary purpose of the ILF is to promote commitment from research-based pharmaceutical and diagnostic companies to research in resource-limited settings, the IAS requested that the evaluative feedback provided by industry representatives be analyzed and reported separately. The views of eight industry representatives are presented in Appendix 2. Due to the small number, this data could not be compared statistically with the larger data set.

The vast majority of respondents (93%) rated the satellite(s) ‘good’ or ‘excellent’. Four respondents commented on their rating, noting that the satellite (and speakers) had been well prepared, or the satellite had been educative, providing an opportunity for stakeholders (especially industry) to discuss the issue from different perspectives. One respondent suggested that some speakers may not have been the leaders in the field.

3.1.2 Forums

Two forums organized by the ILF were run at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2006 and 2007:

- *Scientific and Investment Considerations for PrEP Research*, Denver, 2006;
- *Defining Industry Responsibilities in PrEP Research and Implementation*, Los Angeles, 2007.

Survey respondents were asked if they had attended either forum and, if so, their main reasons for attending, as well as their overall assessment of the quality of the forum(s).

Fourteen respondents (20%) had attended *Scientific and Investment Considerations for PrEP Research* and 19 respondents (46%) had attended *Defining Industry Responsibilities in PrEP Research and Implementation*. Eight respondents had not attended either forum. The reasons most frequently cited by the 25 respondents for their attendance were the topic/content of the forum (49%) and the forum’s applicability to the respondent’s own area of work (23%). Although the majority of these respondents (76%) rated the quality of the forum(s) ‘good’ or ‘excellent’, approximately one quarter gave a rating of ‘fair’.

Three respondents commented on their ratings:

Obviously, not everyone agrees, but it is an unequalled experience as far as making sure all the opinions are heard.

I thought the session on defining industry responsibilities went way beyond the scope of what it should have covered...this group is not one to promulgate guidelines or to define ethical standards but that is what the session was focusing on.

It is not exactly clear what the ILF hopes to achieve by these Forums.

3.1.3 Discussion paper for participants at forum, CROI 2007

The ILF produced a discussion paper for the forum, *Building Consensus on Industry Responsibilities Related to PrEP Research and Implementation*, held at CROI, 2007. Survey respondents who had read the paper (58%, n=19) were asked to indicate their level of agreement with the following statements:

- The paper captured the key issues relating to PrEP research and implementation;
- The paper helped guide discussion at the meeting;
- The paper proved to be a useful resource after the meeting.

Although there was strong overall agreement with the statements, especially the first two, almost one quarter of respondents had not found the paper be a useful resource after the meeting (Table 3).

Table 3: Rating of discussion paper

<i>Statement</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>%</i>
Paper captured key issues (n=18)	0	11	17	72	100
Paper helped guide discussion (n=19)	0	11	47	42	100
Paper was a useful resource afterwards (n=17)	0	23	24	53	100

3.1.4 Discussion papers for Advisory Group members' meeting, CROI 2007

The ILF produced two discussion papers for the Advisory Group meeting held in conjunction with CROI in Los Angeles, 2007:

- *Accelerating Access: Reducing Delays in Regulatory Approval*
- *Ensuring Drug Safety: Pharmacovigilance in Developing Countries*

Survey respondents who had indicated they were members of the ILF Advisory Group (n=12) were asked to rate each paper's coverage of the topic area on a four-point scale (excellent/good/fair/poor). Nine committee members responded, all rating the papers 'good' or 'excellent', with at least one third rating the papers 'excellent'.

3.2 ILF Impact

To build up a picture of the impact of the ILF, particularly over the past two years, feedback was sought about the ILF's success in achieving key objectives, the value of the ILF to the organizations involved, the contribution of these organizations to the ILF, and the ILF's broader influence.

3.2.1 Achievement of objectives

Survey respondents were asked to assess the ILF's success in achieving four key objectives:

- Creating opportunities for researchers within and outside industry to work together and with other relevant stakeholders;
- Helping to build consensus on best practice models and guidance for the conduct of HIV research in resource-constrained settings;
- Addressing scientific and operational challenges to pre-exposure prophylaxis (PrEP);
- Informing discussion in participant's organization about clinical research issues.

Results were mixed (see Table 4). The ILF was deemed to have been most successful in addressing scientific and operational challenges to pre-exposure prophylaxis (PrEP) (rated 'successful' or 'very successful' by 83% of respondents), and moderately successful in helping to build consensus and creating opportunities for stakeholders to work together (rated 'successful' or 'very successful' by 60% and 59% respectively). The ILF was deemed to have been least successful in informing discussion about clinical research issues in respondents' organizations.

Table 4: Rating of achievement of key ILF objectives

Objective	Not very successful	Somewhat successful	Successful	Very successful	%
Creating opportunities to work together (n=31)	6	36	26	32	100
Helping to build consensus (n=30)	13	27	40	20	100
Addressing challenges to PrEP (n=30)	0	17	40	43	100
Informing discussion about clinical research issues (n=31)	19	26	26	29	100

The reasons for the disparity in ratings cannot be definitively reported because only three respondents provided additional written comments, noting the following:

I believe that ILF has been under-utilized as a mechanism for enhanced advocacy with pharmaceutical industry for intensified research in developing countries. I believe that the forum could be used more effectively to achieve this goal.

We have not had a chance to really discuss critical issues about ART resistance, risk, community, etc.

I think that the publications that came out from the ILF meetings should have a broader distribution not only to the stakeholder involved in the forum but to other organizations and in various languages (Spanish, French, Portuguese, etc.)

3.2.2 Value of ILF

The value of the ILF was investigated with both survey respondents and telephone interviewees. Survey respondents were asked what their organization gained through its involvement with the ILF. Twenty people (59%) responded, 15 noting benefits. The opportunity to discuss and work on key research issues with different stakeholder groups (n=8) and the opportunity to network (n=6) were the main benefits identified, exemplified by the following comments:

Useful information about PrEP and industry related links. Networking too and creating a good opportunity for industry and researchers to work together.

A place at the discussion table about an important topic, and feedback on the results of the meetings of the ILF

State of the art discussions on issues relevant to HIV prevention and the role of public and private organizations

A further five respondents noted their organization had gained very little, they did not represent an organization, or they had minimal involvement with the ILF. It should be noted that reasons for non-response (n=14, 41%) were not sought.

Telephone interviewees were asked a similar question. Almost all interviewees stressed the unique nature of the ILF, being one of the few venues where a range of industry players as well as other stakeholders can discuss scientific and operational questions relevant to clinical research. Although this included barriers to clinical research, some interviewees also noted benefits beyond clinical

research issues, such as discussing regulatory hurdles to drug access. The diversity of stakeholders was stressed by several interviewees as an ILF strength which had contributed to the quality of discussion.

The types of important knowledge and information some interviewees had gained through their involvement with the ILF included the appropriate design and conduct of biomedical prevention research trials (e.g., PrEP) as well as a better understanding of the issues/pressures on industry in conducting or supporting clinical research in the developing world. Some interviewees noted that the recent ILF focus on PrEP had limited the benefit of the ILF to some stakeholders, such as companies without a PrEP compound in clinical trials

Telephone interviewees were also asked what their organization was able to contribute to the ILF. A key theme in terms of contribution was the expertise and, in some cases, unique perspective individuals and organizations brought to the ILF. All interviewees who were either working or had worked in resource-limited settings felt they brought that experience and perspective to ILF discussions, including a knowledge of the research infrastructure in the developing world, differences between developed and developing world patient and clinical trial populations and opportunities for developed/developing world research collaborations. Several individuals from developed world organizations indicated they contributed a commitment to bringing drug products (across product lines) and expertise in programme implementation in the developing world to the ILF table.

3.2.3 Wider influence of ILF

Feedback was sought from the ILF Senior Consultant about other impact the ILF may have had in 2006 and 2007. The following examples were provided to illustrate the ILF's broader influence:

- ILF represented at/contributed to major meetings/events addressing PrEP research including:
 - HIV Collaborative Forum scientific meeting on prevention technologies, Washington DC, September 2006;
 - UCLA Think Tank on PrEP Policy, UCLA, Los Angeles 10-12 May 2006;
 - Family Health International (FHI) meeting, Furthering the PrEP Scientific Agenda, Washington DC, 9 January 2007.
- ILF invited as advisor with drug regulators on pre-qualification and access to antiretrovirals for patients in developing countries, World Health Organization (WHO) technical regulatory package, 27-28 November 2006.
- ILF and PrEP referenced in the NAM HIV and AIDS Treatment Directory 2006 (on aidsmap.com).
- ILF included in AIDS Vaccine Advocacy Coalition (AVAC) 'PREP Watch' online resource for those interested in PrEP research.
- ILF invited to deliver training on microbicides and PrEP to European and US activist groups (e.g., European Community Advisory Board, April 2006; AIDS Treatment Activist Coalition (ATAC) March and July 2007).
- ILF PrEP documents circulated, e.g., at the FHI meeting (above) and the Forum for Collaborative Research: Biomedical Interventions for HIV Prevention Working Group Meeting, Washington DC, 18-19 Sept 2006.
- ILF post-trial-care criteria used as the basis for Hoffmann la Roche's corporate social responsibility and trial guidance document (reported by D. Reddy, ILF Satellite, 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rio de Janeiro, July 2005).

- Work of IAS-ILF referenced by Gilead at various meetings (e.g., European Community Advisory Board meeting on PrEP, Brussels, June 2007).
- ILF work described by R. Ridzon, Bill & Melinda Gates Foundation (ILF participant), at Microbicides meeting, 3rd South African AIDS Conference, Durban, South Africa, 5–8 June 2007.
- Role/work of IAS and IAS-ILF in PrEP implementation referred to by L. Paxton, CDC (an ILF participant), in presentation to Botswana Ministry of Health., May 2007.

3.3 Looking to the future

Feedback about future ILF directions was sought from the survey respondents. Feedback about strengthening the ILF was sought from the survey respondents and the telephone interviewees.

3.3.1 Future areas of work

Survey respondents were asked which issues or topics in clinical research they considered the ILF should address in the future. Twenty people (59%) responded, identifying a wide range of topics and issues (see Appendix 3). The most commonly noted topics were research on women (n=3) and microbicides (n=3). The most frequently identified issues related to building capacity in resource limited settings (n=2) and first and second line therapies (n=2).

3.3.2 Strengthening the ILF

Survey respondents were asked if they had any additional comments about the ILF; for example, the process for developing the ILF programme, or strategies for engaging researchers from developing countries. Eight people (24%) provided additional feedback; another two stated they had no comments.

Five respondents noted the importance of engaging researchers from developing countries, proposing the following types of strategies:

- Identify the best candidates and financially support their participation at meetings;
- Hold some meetings in low income settings;
- Use a targeted approach to identify researchers with specific interests through the IAS membership and conference delegate databases.

Other feedback received related to the need for increased consultation with industry representatives to identify topics of mutual interest, strengthened links between ILF and IAS programmes, and clarification of the role of the ILF in relation to other groups that focus on the same or similar topics to avoid fragmentation or duplication of effort.

Telephone interviewees were asked whether they (or their organization) had adequate opportunities to contribute to the development of the ILF programme/agenda. ‘Yes and no’ was the most frequent response to this question. While most interviewees indicated that opportunities for input or influence on the ILF agenda had increased in recent years, most also indicated there was room for improvement in this area; this was particularly true of interviewees from resource-limited settings. Concerns were raised by two interviewees that the ILF agenda appeared to be driven by the topical interest of a few individuals, rather than by a consensus-setting process in which the entire Advisory Group was involved. It should be noted that interviewees who were not on the Advisory Group were satisfied with having influence on, but not a direct say, in setting the agenda.

Telephone interviewees were also asked how the ILF could be strengthened. The two most common suggestions offered were to broaden representation in ILF meetings (with a particular focus on government representation) and to establish more tangible outcomes/action from ILF discussions. Several interviewees noted the role developing world governments can play in facilitating clinical research (including government regulatory agencies). In addition to including government in relevant ILF events, several interviewees suggested expanding ILF stakeholders to include additional civil society/community representation (especially civil society organizations from the developing world), and representation from industry representatives working in the developing world.

A majority of interviewees also stressed the need for ILF to move beyond discussion to action on specific issues, with tangible outcomes set to measure progress; several interviewees expressed disappointment that more progress had not been made on key areas of clinical research (e.g., in microbicides) despite the enormous resources and expertise around the ILF table;

Several interviewees suggested IAS could strengthen the profile of ILF through its communication channels, and that clarifying the role, structure and goals of ILF vis-à-vis the IAS would be helpful. A few interviewees suggested expanding the charter of ILF to allow it to address issues beyond clinical research, such as working to remove regulatory barriers to drug access in the developing world. A few interviewees also suggested the ILF could play more of an advisory role on relevant policy issues for the IAS leadership, as it has recently in referring the pharmacovigilance issue to the IAS.

ILF Advisory Group

The online survey respondents who indicated they were members of the Advisory Group (n=12) were also asked if they had any comments about the group. Four respondents provided comments, noting the following:

Keep it going. It's an important part of IAS.

So far it has streamlined the activities of the ILF.

It is a well focussed group, but the discussion should rise beyond the board room.

There should be as many practical recommendations as possible.

4. Discussion and Conclusions

The evaluation demonstrated the important role played by the ILF in providing a means for a range of industry representatives, as well as other stakeholders, to come together to discuss scientific and operational questions relevant to clinical research. It was also evident that this was viewed as a two-way process, with people not only having the opportunity to meet with other key individuals and organizations, but also to share their different perspectives and experiences and, in particular, developing and developed world views. For some people the ILF also played an educative role, enhancing understanding of the issues faced by industry and the design and conduct of research trials.

In 2006 and 2007 the ILF used a variety of strategies to bring people together to address key issues. These strategies included the organization of Advisory Group meetings, satellites and forums, and the production of discussion papers. Not surprisingly, evaluation findings showed that the topic/content of ILF satellites and forums was the main influencing factor in a participant's decision to attend. Satellite participants rated the satellite(s) they had attended highly, several noting the value of the

satellite as a vehicle for bringing different stakeholders together to discuss important issues. Some forum participants were less satisfied with the overall quality of the forum(s) they had attended, several noting a lack of clarity of purpose.

The value of the discussion paper produced for one forum was evident. Respondents clearly appreciated the fact that the paper presented the key issues as well as guiding discussion during the forum; although the paper's value as a resource after the forum was less clear-cut. The two discussion papers produced for the Advisory Group meeting held at CROI 2007 were rated very highly by Advisory Group members.

In terms of the achievement of four key ILF objectives, results were mixed, suggesting that although progress has been made, there is more work to be done. A large proportion of respondents felt the ILF had been successful in addressing scientific and operational challenges to pre-exposure prophylaxis (PrEP). Findings were less clear-cut about the ILF's success in:

- Creating opportunities for researchers within and outside industry to work together and with other relevant stakeholders
- Helping to build consensus on best practice models and guidance for the conduct of HIV research in resource-constrained settings
- Informing discussion about clinical research issues in organizations.

Some concern was expressed that the primary focus on PrEP in the past two years may have made the ILF less relevant for some participants. A variety of topics and issues were identified for future consideration, including capacity-building in resource limited settings, first and second line therapies, research on women and microbicides. The evaluation also showed that although opportunities for input into the ILF agenda had increased over time, wider consultation could be undertaken.

In terms of strengthening the ILF, two main themes emerged. The first related to broadening representation in meetings, with a particular focus on government representation and increased engagement with researchers from developing countries. The second related to the ILF becoming more action-oriented and outcomes focussed. Although the ILF Strategic Plan 2006 – 2008 presented the ILF mission statement, four objectives, two priority areas for work and four approaches, the plan did not delineate timeframes, milestones or indicators of achievement to guide action and the achievement of outcomes.

4.1 Conclusions

The evaluation demonstrated strong support for the ILF as a vehicle for bringing key stakeholders together to address specific scientific and operational issues related to conducting research in the developing world. Evaluation findings also revealed solid support for ILF activities, especially the satellites and discussion papers, and the work that had been undertaken around pre-exposure prophylaxis.

The evaluation also highlighted two key action issues:

- The need to establish more tangible objectives/outcomes for the ILF;
- The need to develop mechanisms to increase involvement of both government representatives and developing world investigators in the ILF.