

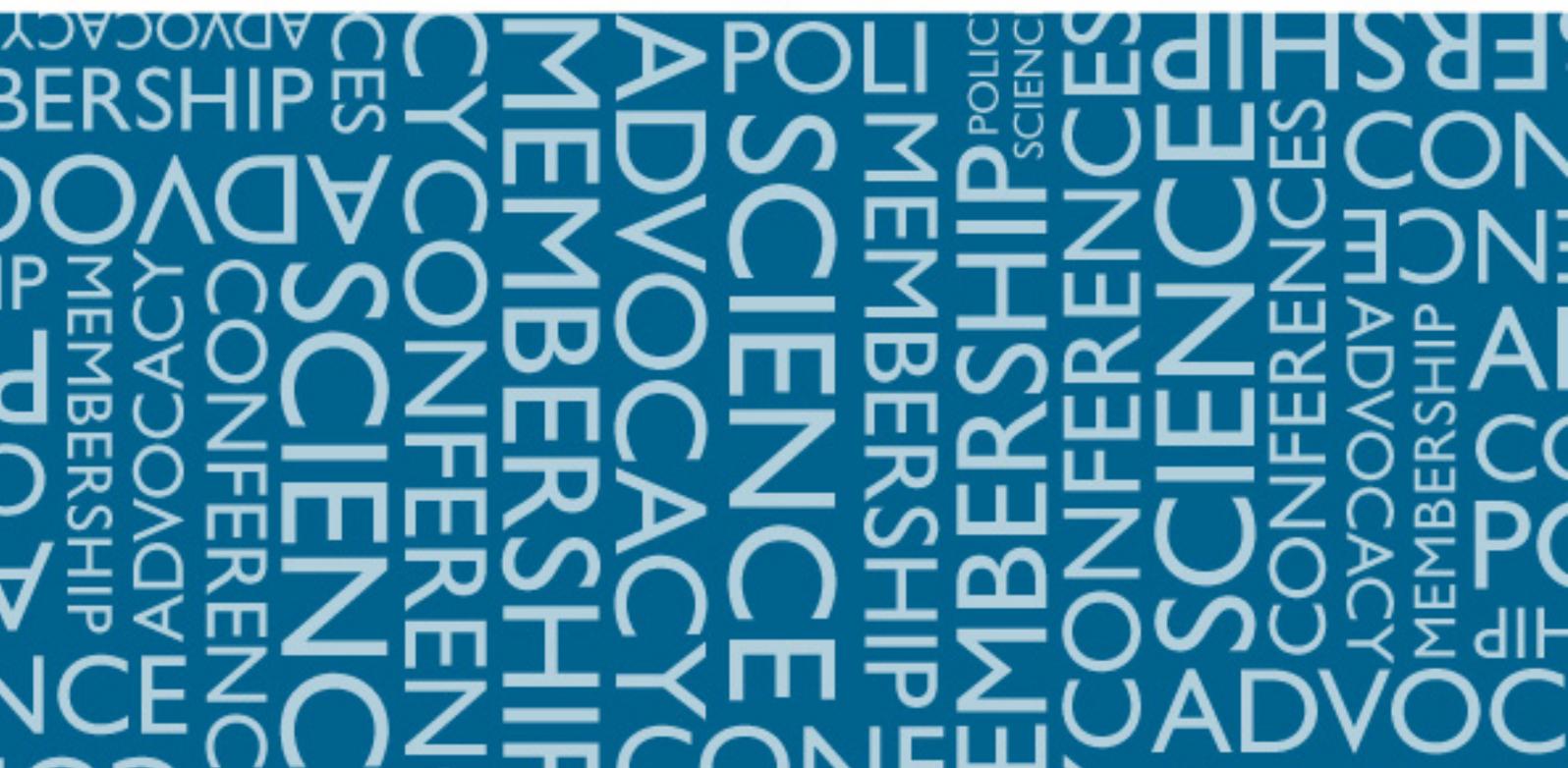
ILF/CIPHER THEMATIC ROUNDTABLE ON PAEDIATRIC ARVs

Aligning, coordinating and accelerating actions to provide better ARVs for children

18 March 2015

Geneva, Switzerland

Evaluation report

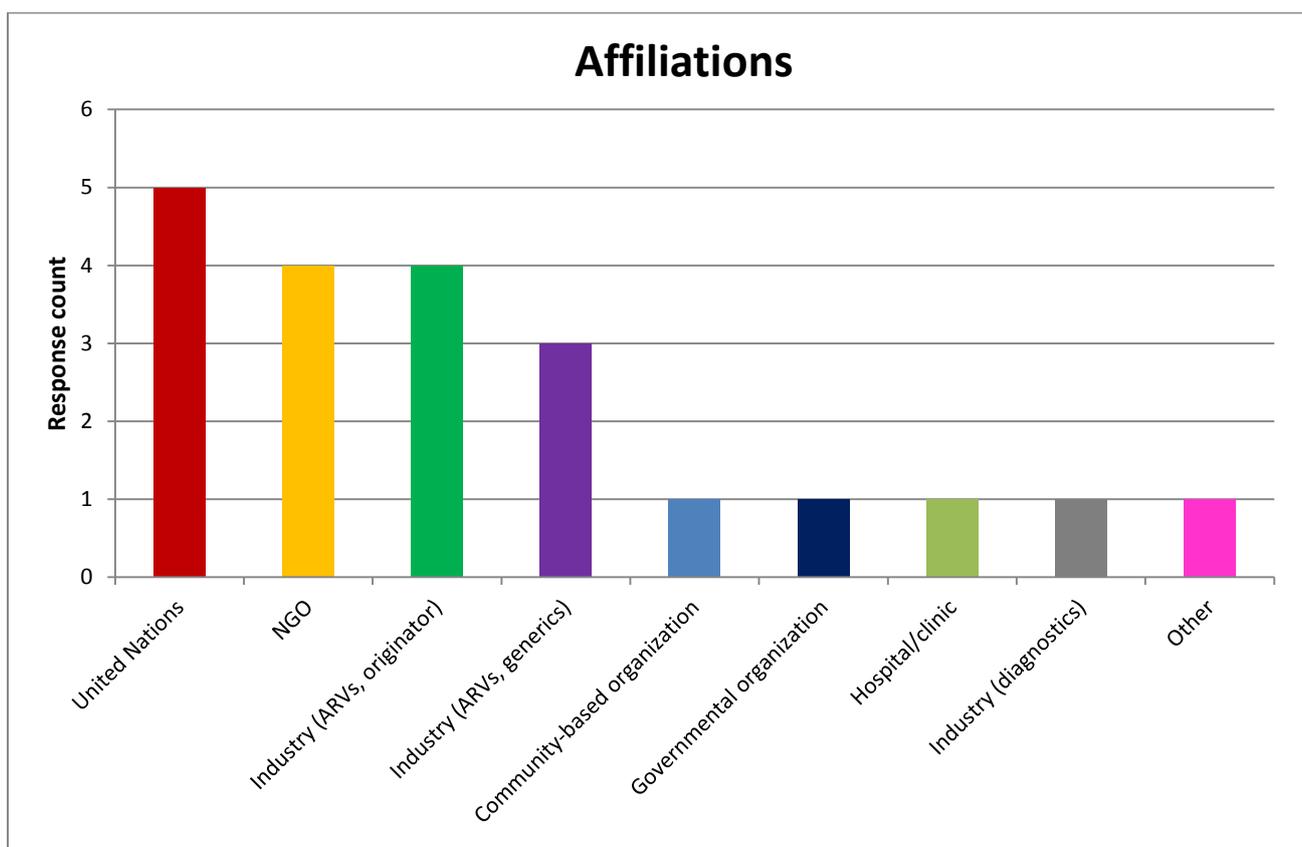


Introduction

The International AIDS Society's (IAS's) Industry Liaison Forum ([ILF](#)) and Collaborative Initiative for Paediatric HIV Education and Research ([CIPHER](#)) held roundtables on paediatric HIV in Geneva, Switzerland, in November 2013 (see [meeting report](#)) and in Melbourne, Australia, in July 2014 (see [meeting report](#)). Following these successes, a roundtable on paediatric ARVs was organized on 18 March 2015 (see agenda in Appendix A). This meeting was an occasion to report on the recent progresses in the paediatric ARV space and to address some of the identified challenges in that field. The information presented is a summary of results from the online survey of participants (see Appendix B), providing feedback and criticisms to better conduct future events.

Attendance

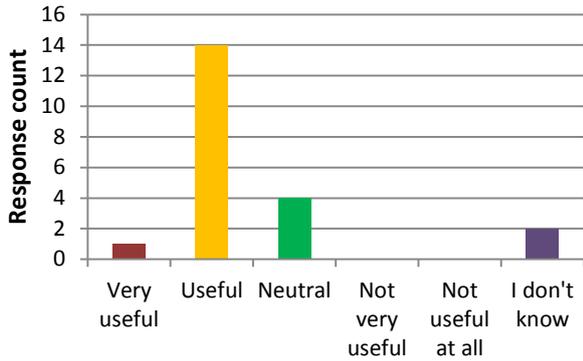
A total of 51 people attended the meeting and 21 people (41%) responded to the survey; most (17/21 people: 81%) attended the meeting in person. From the four people attending through WebEx, three (75%) rated their experience as fair (this was due to problems encountered with connecting the sound system to the computer used for WebEx). The most represented organizations were from the United Nations, followed by non-governmental organizations, ARV originators (industry) and ARV generic manufacturers (industry).



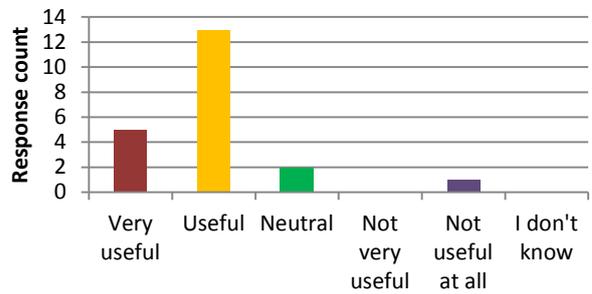
Feedback from participants

Participants were asked to rate the usefulness of different parts of the meeting.

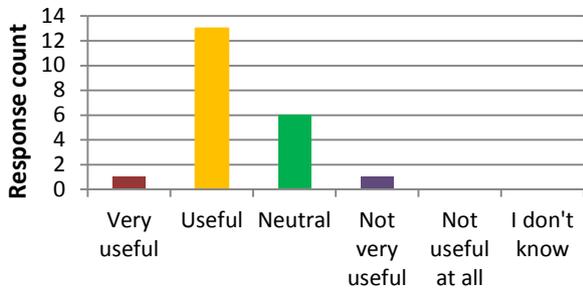
Welcome and roundtable introduction



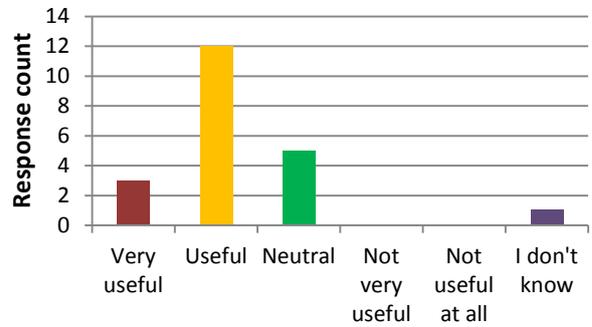
Overview presentation I: Report from PADO2 and lead up to the next WHO guidelines



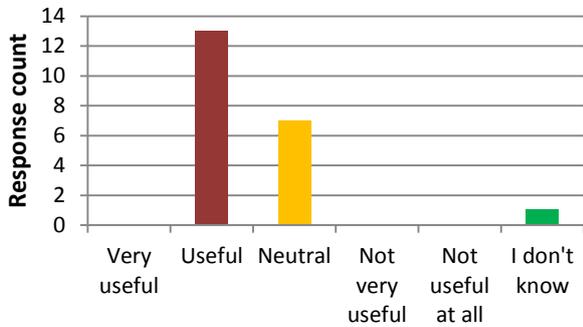
Overview presentation II: Innovative regulatory thinking to enhance paediatric product development



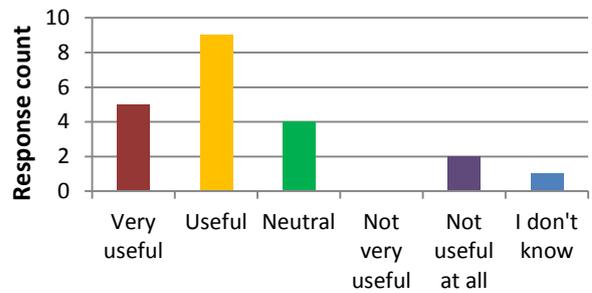
Overview presentation III: Supply and global volumes of paediatric ARVs



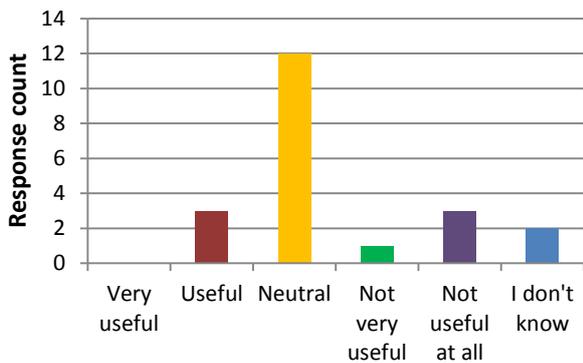
Overview presentation IV: Paediatric HIV Treatment Initiative (PHTI)



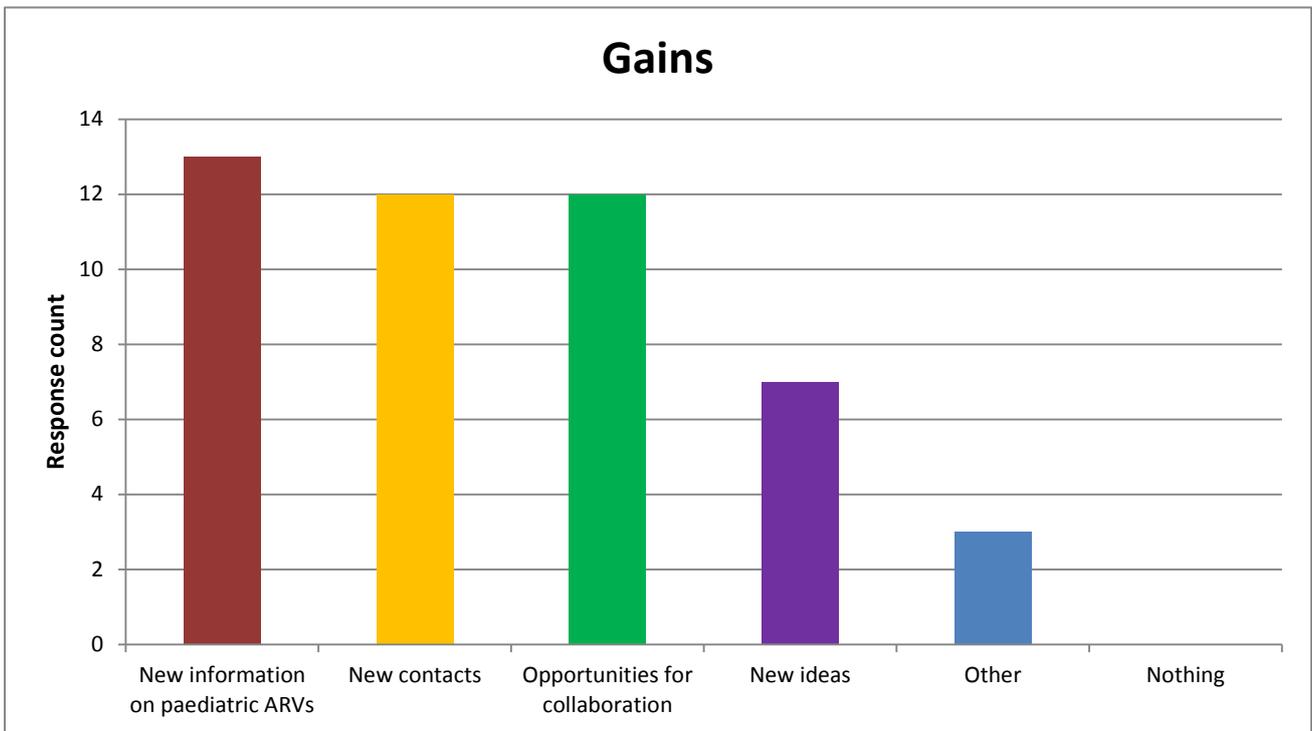
Roundtable discussion: Aligning, coordinating and accelerating actions to provide better ARVs for children



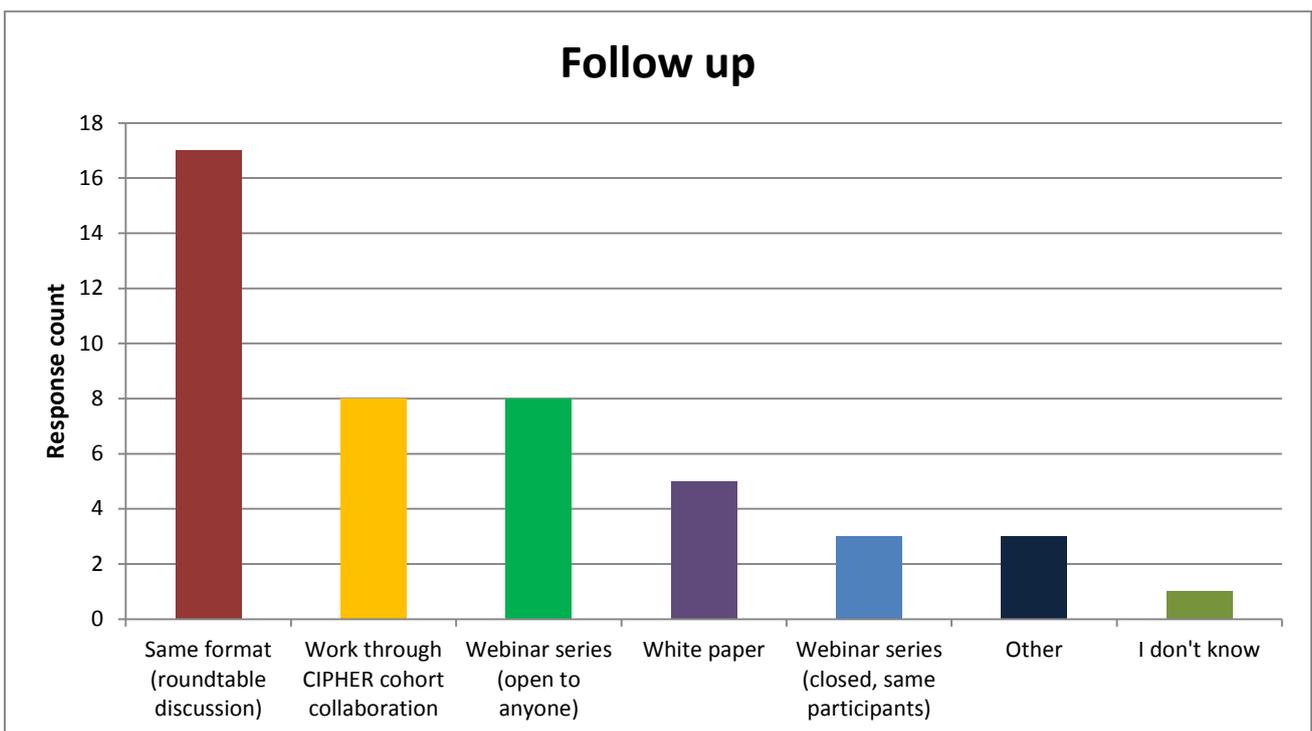
Closing



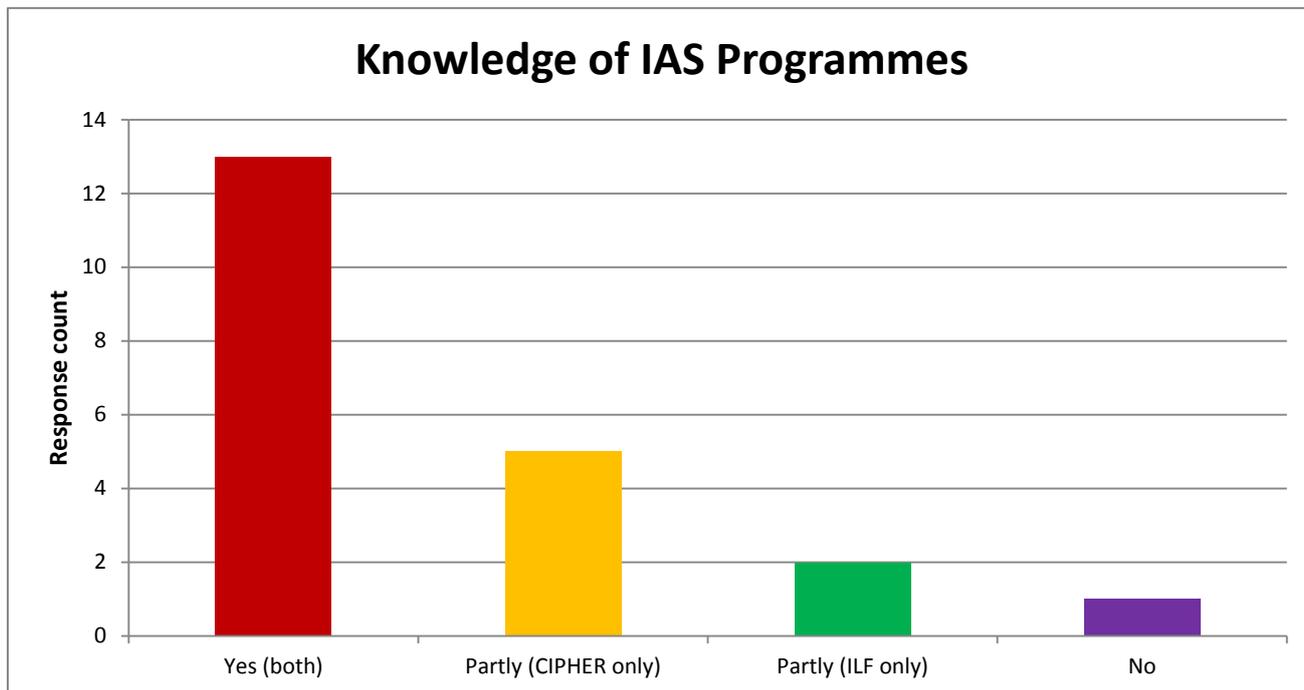
Participants were asked what they gained from this meeting. The most common gains were in new information regarding paediatric ARVs, new contacts and opportunities for collaboration. Of the respondents who said that they gained new contacts, 83% (10/12) said that they were planning to follow up with these new contacts.



Participants were also asked what they believed would be the best method for the ILF and CIPHER to follow up on the roundtable. The majority said that they would keep the same format.



Participants were also asked to rate their knowledge of the ILF and CIPHER. Most respondents were aware of both.



Participants were asked what could be done to improve future roundtables. Many suggested extending the future event to an entire day rather than only having a few hours designated for discussion. Others suggested having more active participation from industry (in particular from the generic manufacturers). Selected quotations are provided here:

“Ideally [an] entire day should be dedicated to the topic.”

“Someone from the industry should also present their view of the market. This perspective was missing.”

“[Ensure participation] of key regulatory bodies and research networks”

“Perhaps for future meetings, request ahead of time that the industry stakeholders also prepare short presentations regarding priorities, challenges, needed collaboration or support, etc. Another method might be to break off into smaller groups prior to the greater group discussion. Ask representatives from various organizations (including industry) to then moderate each group’s discussion regarding specified questions. Each group leader (again including industry) could then begin the conversation by responding for their group.”

“[Provide] advance notification to participants of subjects under discussion with background reading to allow for reading and research to enhance the subsequent discussions.”

“Make it more action-oriented (e.g., capture/summarize next steps/action items and gain agreement whilst everyone still in room).”

Participants were also asked to suggest ways in which industry could be engaged more to contribute to the paediatric HIV space. Selected quotations are listed here:

“Invite [industry] to put up subjects for discussion and/or to lead a session.”

“Work with countries to harmonize product registration.”

“Need continued collaboration with paediatric treatment networks in order to move new drugs into paediatric age groups (e.g., dose selection, PK data, safety) needed in all age groups but most innovator companies in [the USA and Europe] don’t have easy access to enough patients to thoroughly evaluate paediatric issues.”

“Distinction must be made between the different players in industry: the innovators who also look more at clinical practices such as adherence and outcomes, and [generic] producers who look at optimization of supply chain. Interests are substantially different and discussion of topics should be adapted accordingly.”

“[Provide] as much clarity as possible on future demand for existing products and products of choice for [the] future.”

“Drawing industry into the CIPHER Cohort Collaboration is an excellent start. Reduce the number of parallel systems and direct resources towards existing activities. Collaboration across sectors is key.”

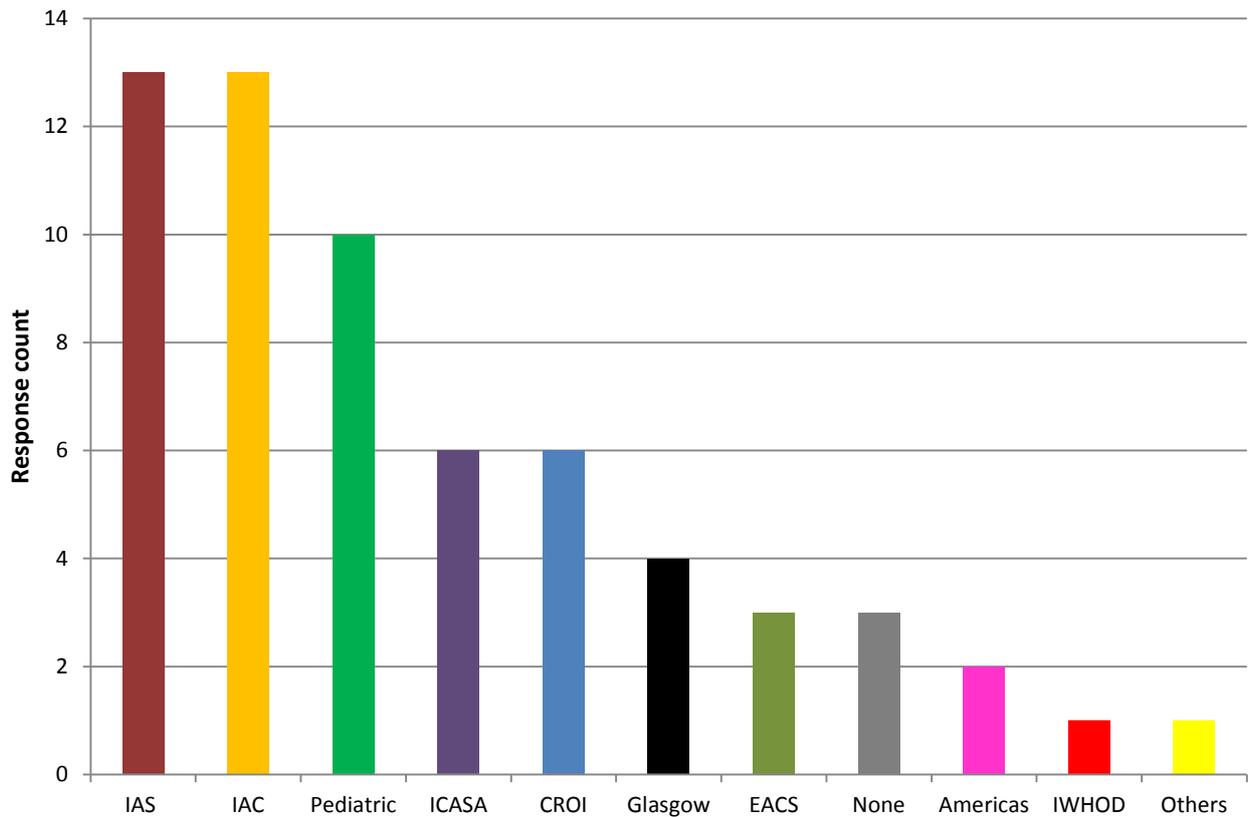
“Paediatric HIV will likely not generate profits for either originator or generic manufacturers. Need to find new ways to fund further development work, etc.”

Additional comments included the following:

“Expand invitees to include funders (broader range). Many funders won’t fund work carried out by or with pharma companies. Bring them to the table to help them understand why traditional funding model[s] for product/formulation development and clinical trials [are] not adequate for paediatric HIV - and build willingness of funders to fund projects that pharma are involved in.”

Participants were then asked which events they usually attended. The most commonly attended events were the IAS Conference on HIV Pathogenesis, Treatment and Prevention and the International AIDS Conference (13/21 people: 62%), closely followed by the International Workshop on HIV Pediatrics (10/21 people: 48%).

Commonly attended events



Legend:

IAS	IAS Conference on HIV Pathogenesis, Treatment and Prevention
IAC	International AIDS Conference
Pediatric	International Workshop on HIV Pediatrics
ICASA	International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA)
CROI	Conference on Retroviruses and Opportunistic Infections (CROI)
Glasgow	HIV Drug Therapy Glasgow
EACS	European AIDS Clinical Society Conference
Americas	HIV Drug Therapy in the Americas
IWHOD	International Workshop on HIV Observational Databases

Overall, the meeting received a positive evaluation. One respondent said that the roundtable was a “wonderful gathering and [a] very informative group discussion!” In addition, when participants were asked at the end of the roundtable if this had been useful and should be repeated, most people clearly said: “Yes!”

THEMATIC ROUNDTABLE ON PAEDIATRIC ARVs

ALIGNING, COORDINATING AND ACCELERATING ACTIONS TO PROVIDE BETTER ARVs FOR CHILDREN

Organized by the International AIDS Society's Industry Liaison Forum (ILF) and
the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER)

Wednesday, 18 March 2015, 13:00 – 17:00 CET
Room St. Moritz, Starling Hotel & Conference Center, Geneva, Switzerland

13:00 – 13:20	Welcome and roundtable introduction <i>Owen Ryan (International AIDS Society, Switzerland) / Executive Director</i> <i>Marissa Vicari (International AIDS Society, Switzerland) / Manager, CIPHER</i> <i>Sébastien Morin (International AIDS Society, Switzerland) / Research Officer, ILF</i>
13:20 – 13:40	Overview presentation I: Report from PADO2 and lead up to the next WHO guidelines <i>Martina Penazzato (WHO, Switzerland) / CIPHER Executive Committee</i>
13:40 – 14:00	Overview presentation II: Innovative regulatory thinking to advance paediatric product development <i>John Gordon (WHO)</i>
14:00 – 14:20	Overview presentation III: Supply and global volumes of paediatric ARVs <i>Wesley Kreft (PFSCM, The Netherlands)</i>
14:20 – 14:30	Overview presentation IV: Paediatric HIV Treatment Initiative (PHTI) <i>Fernando Pascual (MPP, Spain)</i>
14:30 – 15:00	Coffee break
15:00 – 16:45	Roundtable discussion: Aligning, coordinating and accelerating actions to provide better ARVs for children <ul style="list-style-type: none">• Development of paediatric formulations• Alignment of regulatory requirements• Supply and global volume forecasts – Production planning and capacity• Leading up to 2015 WHO Guidelines – Opportunities and challenges from the manufacturer's perspective <i>Facilitator: Nandita Sugandhi (CHAI, USA)</i>
16:45 – 17:00	Closing <i>Marissa Vicari (International AIDS Society, Switzerland) / Manager, CIPHER</i> <i>Sébastien Morin (International AIDS Society, Switzerland) / Research Officer, ILF</i>

Appendix B: Survey (page 1 of 2)

Thank you for participating to the recent ILF/CIPHER Thematic Roundtable on Pediatric ARVs. Your contribution was deeply appreciated.

In order for the Industry Liaison Forum and CIPHER to follow up in the most appropriate manner, please share your feedback through our online survey: [Click here](#)

1. How useful would you rate the different parts of the meeting?
(1-10 – 1: not useful, 10: very useful)
 - a. Welcome and roundtable introduction
 - b. Overview presentation I: Report from PADO2 and lead up to the next WHO guidelines
 - c. Overview presentation II: Innovative regulatory thinking to advance paediatric product development
 - d. Overview presentation III: Supply and global volumes of paediatric ARVs
 - e. Overview presentation IV: Paediatric HIV Treatment Initiative (PHTI)
 - f. Roundtable discussion: Aligning, coordinating and accelerating actions to provide better ARVs for children
 - g. Closing

2. What did you gain from attending this meeting? Please select all that apply.
 - a. New information on paediatric ARVs
 - b. New ideas
 - c. Opportunities for collaboration
 - d. New contacts
 - i. Will you follow up on these new contacts?
 - Yes
 - No
 - I don't know
 - e. Nothing

3. What in your view would be the best way for the IAS to follow up on this roundtable? Please select all that apply.
 - a. Continue with the same format (multi-stakeholder roundtable discussion)
 - b. White paper
 - c. Webinar series (closed, with same participants)
 - d. Webinar series (open to anyone)
 - e. Work through CIPHER Cohort Collaboration
 - f. I don't know
 - g. Other ideas (please explain below)

4. What improvements could be made for future roundtables (e.g., duration, location, issues to be covered or stakeholders to be invited)?

Appendix B: Survey (page 2 of 2)

5. Please suggest how you think industry can further be engaged in supporting paediatric HIV.

6. Before this meeting, were you aware of the IAS Industry Liaison Forum (ILF) and the IAS Priority on Paediatric HIV (CIPHER)?

- a. Yes (both)
- b. Partly (only the Industry Liaison Forum)
- c. Partly (only the IAS Priority on paediatric HIV)
- d. No

7. Do you have any additional comments, suggestions and/or questions?

8. What type of organization do you work for?

- a. Academia
- b. Community-based organization
- c. Governmental organization
- d. Hospital / clinic
- e. Industry – ARVs (originator)
- f. Industry – ARVs (generics)
- g. Industry – Diagnostics
- h. Industry – Prevention
- i. Industry – Other
- j. Non-governmental organization
- k. UN family organization
- l. Other

9. Which events do you generally attend?

- a. Conference on Retroviruses and Opportunistic Infections (CROI)
- b. European AIDS Clinical Society Conference (EACS)
- c. HIV Drug Therapy Glasgow
- d. HIV Drug Therapy in the Americas
- e. IAS Conference on HIV Pathogenesis, Treatment and Prevention
- f. International AIDS Conference
- g. International Congress on AIDS in Asia and the Pacific (ICAAP)
- h. International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA)
- i. International Workshop on HIV Observational Databases
- j. International Workshop on HIV Pediatrics
- k. None
- l. Others

10. How did you attend the meeting?

- In person
- Through WebEx
 - i. Please rate your experience. (*excellent, good, fair, poor*)

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