

# IAS-ILF/CIPHER

## Thematic Roundtable on Paediatric HIV

*Removing barriers and seizing opportunities in paediatric HIV*

19 July 2014, Melbourne, Australia

Outcomes and follow up





Meeting Report

## IAS-ILF Industry Roundtable on Paediatric ARVs

Paediatric antiretrovirals:  
The barriers to and solutions for improved access to optimal  
drugs in resource-limited settings



27 November 2013  
Geneva, Switzerland



## IAS-ILF Industry Roundtable on Paediatric HIV

November 2013, Geneva, Switzerland

Bring industry and other stakeholders together  
to discuss gaps

Provide a platform where industry can interact  
with the processes in place (going beyond  
perceptions of conflicts of interest)

**Need to include paediatric HIV cohorts in  
follow up efforts**

*Meeting report available online*  
[www.iasociety.org/ilf.aspx](http://www.iasociety.org/ilf.aspx)

## IAS-ILF/CIPHER Thematic Roundtable on Paediatric HIV

July 2014, Melbourne, Australia

Bring industry along with **paediatric HIV cohorts** and other stakeholders together to discuss gaps

Can collaboration between cohorts and industry provide opportunities for progress in paediatric HIV?

Participation from the largest **paediatric HIV cohorts** (through CIPHER), ARV manufacturers (both originators and generics) as well as other key stakeholders.

### Welcome and roundtable introduction

Co-Chairs: Lynne Mofenson (US National Institutes of Health, USA)  
Shaffiq Essajee (CHAI, USA)

### Challenges along the paediatric ARV pipeline:

#### Summary of the IAS-ILF Industry Roundtable on Paediatric ARVs

Shaffiq Essajee (CHAI, USA)

### CIPHER and Paediatric HIV cohorts collaboration

Marissa Vicari (IAS, Switzerland)  
Annette Sohn (TREAT Asia / amfAR, Thailand)

### Knowledge gaps and WHO guidelines

Martina Penazzato (WHO, Switzerland)

### Roundtable discussion

#### Removing barriers and seizing opportunities in paediatric HIV

What can cohorts do for industry? What can industry do for cohorts?

Can collaboration between cohorts and industry tackle some of these challenges?

- Developing child-friendly formulations
- Recruiting children under 12 years in clinical trials
- Gathering information on most appropriate:
  - Formulations
  - FDC ratios
  - Age bands
  - Weight bands
- Providing clinical data (e.g., PK data)
- Providing accurate post-marketing surveillance data
- Informing paediatric HIV cure research by looking for Mississippi-baby-like patients

Facilitator: Shaffiq Essajee (CHAI, USA)

### Summary and action points

Co-Chairs: Lynne Mofenson (US National Institutes of Health, USA)  
Shaffiq Essajee (CHAI, USA)

Dinner reception for additional informal exchanges between participants

- Assisting industry in developing child-friendly formulations
- Recruiting children under 12 in clinical trials
- Informing industry on most appropriate:
  - Formulations
  - FDC ratios
  - Age bands
  - Weight bands
- Providing clinical data (e.g., PK) for generic production or formulations
- Providing accurate post-marketing surveillance data

New-born prophylaxis and treatment

Next steps on harmonizing around age/weight bands

FDC ratios – how can we come up with rational ratios?

Post marketing surveillance and pharmacovigilance collaborations

### Challenges/opportunities

- New-born prophylaxis and treatment poised to become a major policy development in new guidelines
  - Few drugs, little data, big market
  - Very hard to find new-borns to study
- Challenges around defining FDC ratios and optimal weight bands
  - Differences in approval processes
  - Historical issues on FDC ratios
  - Some specific potential problems
- Challenges with pharmaco-vigilance and post marketing surveillance
- Industry often struggles to find paediatric data to better inform development



- New-born trial “hot spots” do exist!
- Cipher *network* could be a vehicle for prospective research by identifying them
- This needs to happen urgently



- Regulators clarified approval processes:
  - For generic versions of an originator product, must follow existing dosing
  - For a novel product, no pre-requisite, so can submit using, e.g., WHO weight bands
- Both EMA and FDA are willing to consider more PK modelling/simulations
- Industry expressed desire to convene focused meetings (potentially hosted by CIPHER) on *specific* drugs to catalyse development



- Templates: general + drug-specific elements
- Set up of sentinel sites in RLS



- Industry partners already coming up with queries for the database and cohort collaboration!