ILF/CIPHER Thematic Roundtable on Paediatric ARVs

Wednesday, 18 March 2015, 13:00 – 17:00 CET
Geneva, Switzerland
International AIDS Society (IAS)

- World’s leading independent association of professionals working in HIV
- Governed by a group of international experts and run from a secretariat based in Geneva, Switzerland
- Custodian of the world’s premier gathering on HIV and AIDS, the International AIDS Conference
- Organizer of the IAS Pathogenesis, Treatment and Prevention Conference

IAS 2015
vancouver, canada
8th IAS Conference on HIV Pathogenesis, Treatment & Prevention 19-22 July 2015
International AIDS Society (IAS)

- Advocates for the implementation of effective evidence-based policies and programmes that promote and protect human rights in the field of HIV
- Promotes research and capacity building in low- and middle-income countries
- Promotes the priorities of its members through strategic communications, advocacy, and global convening; these priorities are:
  - Towards an HIV Cure
  - Paediatric HIV (CIPHER)
  - HIV Co-Infections
  - Key Populations
- Benefiting from overarching tools:
  - Journal of the International AIDS Society (JIAS)
  - Industry Liaison Forum (ILF)
CIPHER (Paediatric HIV)

Goal
Optimizing clinical management and delivery of services to infants, children and adolescents affected by HIV in resource-limited settings, through advocacy and research promotion.

Activities
• Research Grant Programme
• Global Cohort Collaboration
• Online Paediatric HIV Cohort Database
• JIAS Special Issues
• Advocacy
Paediatric HIV Cohort Database

- Online, searchable database
- Platform for cohort collaboration
- Source of information for stakeholders: researchers, funders, policy makers, industry

2014:
- 30 cohorts/networks signed up
- representing ~250,000 infants, children and adolescents in 59 countries

2015:
- Analysis tools: Summary tables, epidemiology function
Global Cohort Collaboration

Largest paediatric HIV cohort collaboration to date:

**Cohorts:**
IeDEA, EPPICC, MSF, BAIPAI, Optimal Models/ICAP, PHACS, IMPAACT

- 250,000+ infants, children and adolescents!

**First projects**
1. Time on first-line ARVs in children
2. Adolescent epidemiology
Industry remains negatively perceived and excluded from key discussions: this impacts the response to the epidemics; the Industry Liaison Forum promotes the meaningful contribution of industry to the global response

- Mechanism to constructively engage industry and other stakeholders on issues in line with IAS Priorities
ILF Advisory Group

ILF Industry Advisory Group members
- Gold Corporate Partners
- Silver Corporate Partners
- Bronze Corporate Partners

ILF Non-Industry Advisory Group members
- IAS Governing Council
- Regulatory / normative agencies
- Procurement / implementing organizations
- Governmental / intergovernmental organizations
- Experts in IAS Priorities or other issues
- Civil society
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

Meeting Report

IAS-ILF / CIPHER THEMATIC ROUNDTABLE ON PAEDIATRIC HIV

Removing barriers and seizing opportunities in paediatric HIV

19 July 2014
AIDS 2014, Melbourne, Australia

Meeting reports available online www.iasociety.org/ilf
ILF/CIPHER Thematic Roundtable 1

- Research and development
- Development of normative guidelines and guidance
- Regulatory approval and commercial production
- Reliable forecasting and funding to stabilize the market
- Post-marketing surveillance

- Developing child-friendly formulations
- Recruiting children under 12 in clinical trials
- Consulting industry during the revision process
  - Most appropriate formulations
  - Most appropriate FDC ratios
- Harmonizing regulatory processes
  - Different age bands
  - Different weight bands
  - Clinical data for generic production/formulations
- Disseminating accurate forecasts to plan production
- Focusing on a limited range of products for procurement to ensure market stability
- Disseminating accurate post-marketing surveillance data to inform countries and policy makers

Need to include paediatric HIV cohorts in follow up efforts
• FDC ratios and weight bands

• Pharmaco-vigilance and post-marketing surveillance

• New-born prophylaxis and treatment as major policy developments
  o Few drugs, little data, big market
  o Very hard to find new-borns to study

• Finding paediatric data to inform development

• EMA and FDA clarified processes:
  o For generic versions of an originator product, must follow existing dosing
  o For a novel product, no pre-requisite, so can submit using, e.g., WHO weight bands
  o Willing to consider more PK modelling/simulations

• Industry interested in focused meetings specific drugs to catalyse development

• Templates: general + drug-specific elements

• Set up of sentinel sites in RLS

• New-born trial “hot spots” do exist

• CIPHER Cohort Collaboration as a potential vehicle for prospective research

• Industry partners with queries for the CIPHER Database and Cohort Collaboration

Need to keep industry regularly informed of processes in place
#### Agenda for today’s roundtable

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>13:00 – 13:20</td>
<td>Welcome and roundtable introduction</td>
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<tr>
<td></td>
<td>Owen Ryan (International AIDS Society, Switzerland) / Executive Director</td>
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<td>Marissa Vicari (International AIDS Society, Switzerland) / Manager, CIPHER</td>
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<td>Sébastien Morin (International AIDS Society, Switzerland) / Research Officer, ILF</td>
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<td>13:20 – 13:40</td>
<td>Overview presentation I: Report from PADO2 and lead up to the next WHO guidelines</td>
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<td>Martina Penazzato (WHO, Switzerland) / CIPHER Executive Committee</td>
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<td>13:40 – 14:00</td>
<td>Overview presentation II: Innovative regulatory thinking to advance paediatric product development</td>
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<td>John Gordon (WHO)</td>
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<td>14:00 – 14:20</td>
<td>Overview presentation III: Supply and global volumes of paediatric ARVs</td>
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<td>Wesley Kreft (PFSCM, The Netherlands)</td>
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<td>14:20 – 14:30</td>
<td>Overview presentation IV: Paediatric HIV Treatment Initiative (PHTI)</td>
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<td>Fernando Pascual (MPP, Spain)</td>
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<td>14:30 – 15:00</td>
<td>Coffee break</td>
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<td>15:00 – 16:45</td>
<td>Roundtable discussion: Aligning, coordinating and accelerating actions to provide better ARVs for children</td>
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<td>Development of paediatric formulations</td>
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<td>Alignment of regulatory requirements</td>
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<td>Supply and global volume forecasts – Production planning and capacity</td>
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<td>Leading up to 2015 WHO Guidelines – Opportunities and challenges from the manufacturer’s perspective</td>
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<td>Facilitator: Nandita Sugandhi (CHAI, USA)</td>
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<td>16:45 – 17:00</td>
<td>Closing</td>
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