



Today's agenda

15:00 CET

5 minutes

IAS – Welcome and introduction

Sébastien Morin (IAS)

15:05 CET

15 minutes

WHO – Guidelines uptake and PADO priorities

Martina Penazzato (WHO)

15:20 CET

10 minutes

PHTI – Update on PHTI projects

Fernando Pascual (MPP)

15:30 CET

10 minutes

IATT – Update on IATT formulary + uptake

Nandita Sugandhi (CHAI)

15:40 CET

10 minutes

PAPWG – Update on PAPWG + expansion to adult ARVs

Wesley Kreft (PFSCM)

15:50 CET

10 minutes

**CTA – Updates on fast-tracking development and
introduction of paediatric formulations**

George Siberry (PEPFAR)

16:00 CET

25 minutes

Q&A (from the chat)

All participants (moderated by Sébastien Morin, IAS)

16:25 CET

5 minutes

IAS – Closing remarks

Sébastien Morin (IAS)

Review of guidelines and PADO 3 outcomes

Geneva
December 6-7th 2016



World Health
Organization

Rationale for prioritisation

LPVr 4-in-1: first line for under 3 years to address the lack of optimal formulations

EFV triple: first line 3-10 years to provide an FDC to maximise adherence and simplify procurement

ATVr and DRVr: use in 2nd and 3rd line formulations and overcome issue with separate administration of RTV

NVP/AZT mg: better dosage form to facilitate dosing for PnP

RAL better formulation: use in infants and young children to enable rapid introduction of INI for use in 1st line regimen

DTG single or FDCs: identified as key drug to introduce INI in first line with potential for harmonisation across the full age spectrum

TAF: key drug for future use in 1st line to minimise toxicity with potential for harmonization across the full age spectrum

Objectives

- **Review medium- and long-term priorities** for the development of new paediatric ARV drugs and formulations for paediatric HIV treatment and prevention.
- **Identify research gaps** to be addressed and inform optimal use of ARVs in infants, children and adolescents to enable future development and uptake of priority products.
- Identify synergies and promote alignment with drug and formulations development for other anti-infective agents to be used in paediatric **hepatitis and tuberculosis**.

Participants

- Research networks and PAWG members
- Regulators (FDA, EMA, PQ)
- PHTI partners (UNITAID, DNDi, CHAI, MPP)
- Implementers (PEPFAR, EGPAF, ICAP)
- TB community (Researchers and TB alliance)
- Hep community (Researchers)
- Civil society (ICW and YP+)

Day 1: Tuesday, 6 December 2016

08:30-08:45	Registration	
Co-chairs: George Siberry and Atieno Ojoo		
08:45-09:15	Welcome and Introductions	Meg Doherty
	Overview of meeting objectives and agenda	
Session 1: PADO three years later		
09:15-09:45	PADO: how far have we gone and how can we maximize the impact of the priority list?	Martina Penazzato
09:45-10:00	ARV Pipeline for infants, children and adolescents	Polly Clayden
10:00-10:15	PHTI: the progress and the challenges of development	Fernando Pascual
10:15-10:45	Discussion & Clarifications	All
10:45-11:05	<i>Break</i>	
11:05-11:20	Introduction of new products: the example of LPVr pellets and ABC/3TC	Nandita Sugandhi
11:20-11:35	Innovative delivery for children and key principles for product selection: target product profile	Atieno Ojoo
11:40- 12:30	Discussion & Clarifications	All
12:30-13:30	<i>Lunch</i>	
Session 2: Focusing on babies		
13:30-14:00	Treating and preventing HIV in newborns and infants	Elaine Abrams
14:00-14:30	PK in infants and young children: informing drug and formulations development	Tim Cressey
14:30-15:30	Discussion & Clarifications	All
15:30-15:45	<i>Break</i>	
Session 3: Optimizing sequencing		
15:45-16:00	Program perspective on the use of second and third line drugs: New Horizon program	Carolyn Bolton-Moore
16:00-16:20	HIVDR a growing concern: how to plan for a smart long-term ARVs sequencing	Daniel Kuritzkes
16:20-16:40	Innovative strategies for simplification and better ARV sequencing	Di Gibb
16:40-18:00	Discussion & Clarifications	All

Day 2: Wednesday, 7 December 2016

Co-chairs: Elaine Abrams and Carlo Giaquinto

08:30-8:45	Community perspective	Jacque Wambui Julian Kerbogossian
08:45-10:45	Working Group Activity <ul style="list-style-type: none">- Newborns- Alternative strategies and optimal sequencing- Cross-cutting issues	All
10:45-11:00	<i>Break</i>	
Session 4: From HIV to Hepatitis treatment		
11:00-11:20	Overview of current knowledge on hepatitis B and C in children and treatment approaches	Giuseppe Indolfi
11:20-11:30	Global estimates of burden of HCV, and treating children with hepatitis: a reality check from the field	Manal El-Sayed
11:30-11:45	Paediatric Investigation Plans for chronic hepatitis C	Andrea Ecker and Carlo Giaquinto
11:45-12:30	Discussion & Prioritization	All
13:00-14:00	<i>Lunch</i>	
Session 5: From HIV to TB treatment and prevention		
14:00-14:30	Overview of current issues in TB medicines for children	Tony Garcia Prats
14:30-14:45	Accelerating pediatric TB drug development	Cherise Scott
14:45-15:40	Facilitated discussion: Identifying synergies and alignment between TB and HIV	James Seddon and All
15:40-16:00	<i>Break</i>	
Session 6: Where do we go from here?		
16:00-16:20	Group work report back	Rapporteurs
16:40-17:15	Discussion	All
17:15-17:25	Setting priorities for Products and Formulations development: mid and long term horizon	George Siberry
17:25-17:35	Research questions for treatment optimization	Devasena Gnanashanmugam
17:35-18:00	Discussion and Group endorsement	All
18:00-18:10	Next steps and closing remarks	Meg Doherty and Martina Penazzato



Next steps: PADO3 dissemination

- ILF webinar with industry (January TBD)
- Meeting report by end of January/early February 2017
- WHO Think Thank meeting @CROI 2017
- Update of EOI for paed ARVs
- Peer review paper (Supplement)
- AMDS meeting
- Webinar for regulators
- Webinar for programme managers

Next steps: PAWG activities

- Q1 meeting @CROI to discuss vision and workplan
- Review dosing and ratios for new formulations
- Review of existing PIPs/PSPs relevant to PADO priorities
- Joint call with TB working group to explore weight-band dosing (?)
- Kick off “research toolkit” development (face2face meeting and/or call to be organized)