



Today's agenda

16:00 CET

5 minutes

Welcome and introduction

Sébastien Morin (IAS)

16:05 CET

25 minutes

PADO 3 priorities

Martina Penazzato (WHO)

Philippa Easterbrook (WHO)

16:30 CET

10 minutes

PAWG plans

Martina Penazzato (WHO)

16:40 CET

15 minutes

Q&A (from the chat)

Facilitated by Sébastien Morin (IAS)

16:55 CET

5 minutes

Closing remarks

Sébastien Morin (IAS)

Paediatric ARV Working Group PAWG

Updates
28 February 2017



World Health
Organization



PAWG Role and Mission

- To be the a reference group to provide overall technical advice (clinical/PK/programmatic) to drug and formulation development
- To have a formal role in advising manufacturers on the development of their PIPs/PSPs
- To contribute to the PK work required for informing ratio and dosing for FDCs

- Broader set of skills
- Greater responsiveness
- Greater accountability
- More transparency
- Ensure continuity and sustainability

Inclusion of pregnancy!

PAWG Membership

1. Elaine Abrams (ICAP, Columbia University, USA)
2. David Burger (Radboud University Nijmegen Medical Centre, Netherlands)
3. Yodit Belew (US FDA, USA)
4. Jessica Burry (MSF Access Campaign, Switzerland); Edmund Capparelli (University of California, San Diego, USA)
5. Diana Clarke (Boston Medical Center, USA)
6. Timothy R. Cressey (PHPT, IRD/Harvard T.H Chan School of Public Health & Chang Mai University, Thailand);
7. Paolo Denti (University of Cape Town, South Africa)
8. Carlo Giaquinto (University of Padova, Italy)
9. Diana Gibb (MRC Clinical Trials Unit, United Kingdom)
10. Rohan Hazra (National Institute of Child Health and Human Development, USA)
11. Andrea Ecker (European Medicines Agency, United Kingdom)
12. Marc Lallemand (Drugs for Neglected Diseases Initiative, Switzerland)
13. Janice Lee (Drugs for Neglected Diseases Initiative, Switzerland)
14. Linda Lewis (CHAI, USA)
15. Chewe Luo (UNICEF, USA)
16. Helen Mcilleron (University of Cape Town, South Africa)
17. Mark H. Mirochnick (Boston Medical Center, USA)
18. Lynne Mofenson (Elizabeth Glaser Pediatric AIDS Foundation, USA)
19. Victor Musiime (JCRC, Uganda)
20. Atieno Ojoo (UNICEF, Denmark)
21. Jorge Pinto (Federal University of Minas Gerais, Belo Horizonte, Brazil)
22. Natella Rakhmanina (Elizabeth Glaser Paediatric AIDS Foundation, USA)
23. Pablo Rojo-Conejo (Hospital de 12 de Octubre, Madrid, Spain)
24. Saint Raymond Agnes (European Medicines Agency, United Kingdom)
25. George Siberry (OGAC, Department of State, USA)
26. Nandita Sugandhi (Clinton Health Access Initiative, USA)
27. Anna Turkova (MRC Clinical Trials Unit, United Kingdom)
28. Marissa Vicari (International AIDS Society, Switzerland)

Three co-chairs will be appointed and more members will be added from the African region and to better include specific expertise on pregnancy, paediatric hepatitis, paediatric TB and formulation development

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
- Kick off “research toolkit” development (face2face meeting and/or call to be organized)

Research toolkit for drug development

Expected outcomes:

This project will result into a WHO/UNITAID branded research toolkit to support drug and formulation development for children. This toolkit will have a modular structure and each module will address a specific topic.

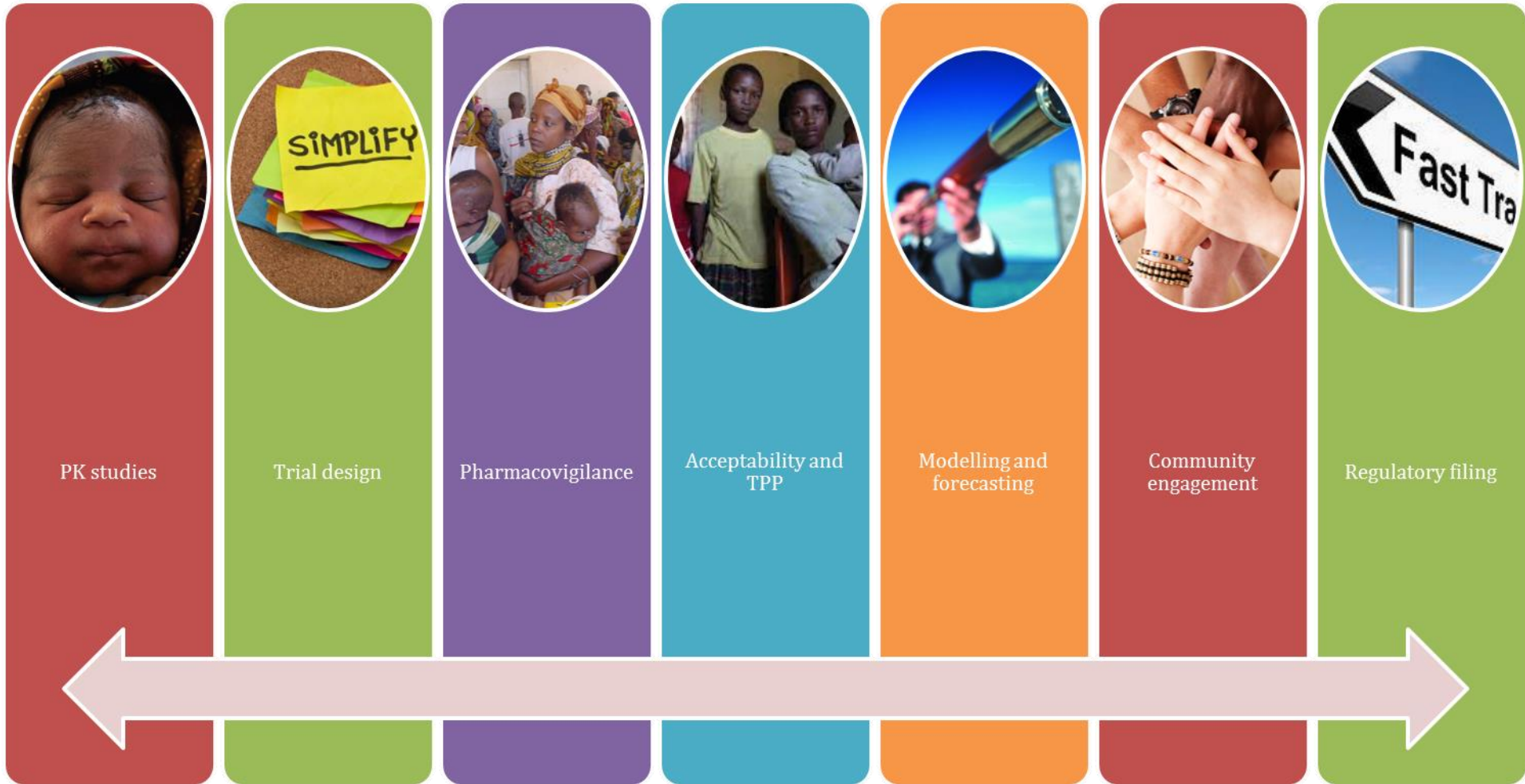
Proposed collaborators:

Technical experts from PENTA, CHAPAS and IMPAACT research networks, as well as relevant members of the Paediatric ARV Working Group; representatives from WHO Prequalification programme, EMA and US FDA.

Tentative timeline:

The project is expected to run over a period of 12 months time: final expected completion by February 2018

Potential structure



Publications

Completed:

- Drug optimization – JIAS 2015
- EFV triple modeling – Clinical Pharmacology 2016
- Research innovations – CID 2017

Under development:

- PADO3 outcomes
- Optimal use of ARVs in Neonates

To be potentially developed:

- Adolescents
- WHO Generic tools

THANK YOU!!!!

