Prof Mike Sharland
St George’s University, London
PENTA-ID

- In 20 years PENTA has completed 11 trials, more than 1500 enrolled
- Two trials currently open, 1 in follow up.
- 106 sites (40 recruiting), including labs
- 2012 – PENTA-ID recognised by EnprEMA as the Level 1 Paediatric Clinical Trials Network in Europe to conduct clinical trials in paediatric Antimicrobials, including antibiotics/virals/fungals.
- Observational – ARPEC/GARPEC
- PK – NeoGent/NAPPA
- Interventional – NeoMero, NeoVanc, CAP-IT.
- Pediatric partner of COMBACTE
- Educational programme
2016 EDITION – IMPLEMENTATION

EVIDENCE BASED GUIDANCE OF ALL COMMON INFECTION SYNDROMES

100 CHAPTERS

120 ANTIMICROBIAL DOSES FOR NEONATES AND CHILDREN – RAG RATED
2. Guidelines
2.1. New EU Guidelines Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections
Action: Concept Paper to be released for consultation 1Q 2016
First draft of Addendum to be released for consultation 1Q 2017
Comments:

Work plan for the CHMP Infectious Diseases Working Party (IDWP) for 2016

EnprEMA Working Group on Pediatric Antibiotic Clinical Trial Design May 2016
Discussion

• PK - filling the gaps – collaboration/pooling
• Optimal study design for new antibiotics – phase 1/2a
• How close to adult regulatory guidance
• Sample size to determine pk/safety – can this be standardised
• Potential to pool CIS in pediatric studies
• Recruitment in UDR/MDR populations
• Strategic trials combining new antibiotics – can we learn from HIV?
• How should global strategic trials be influenced by regulatory guidance.
• Pharmacovigilance