
# PENTA-ID

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# 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

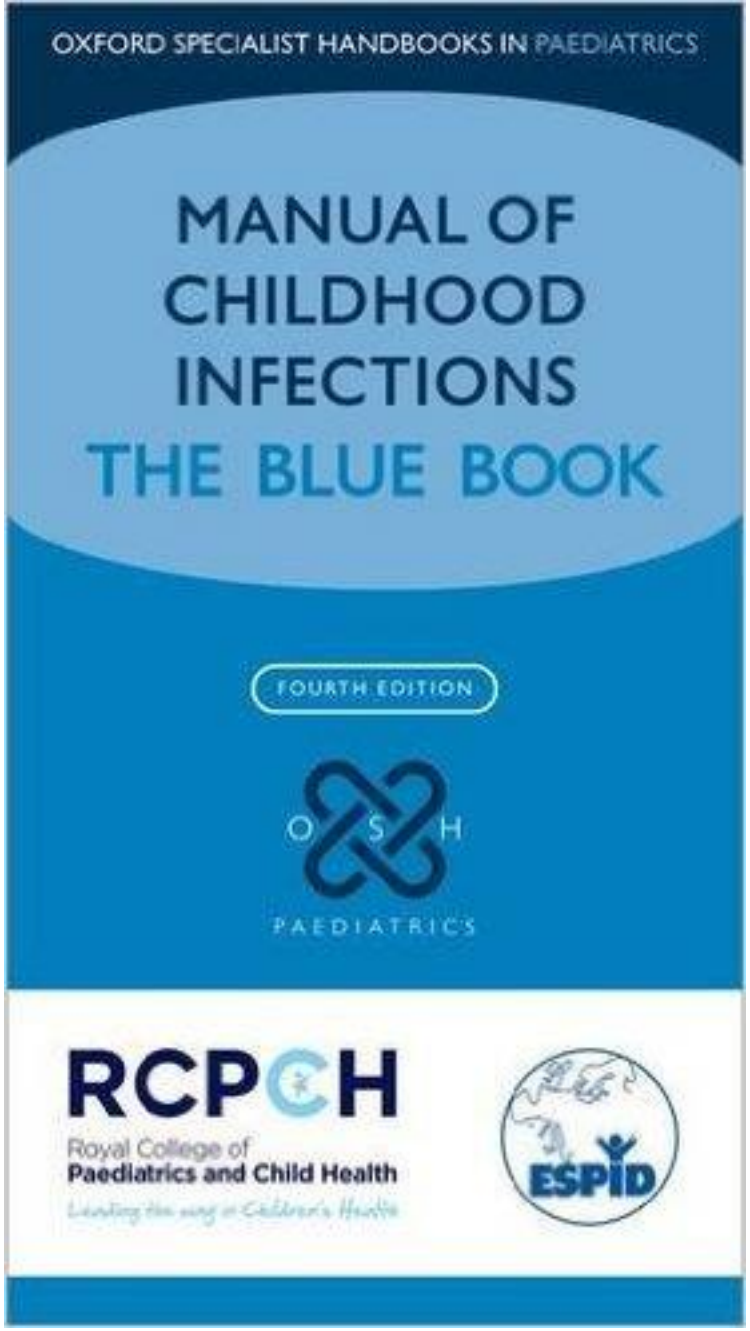
**2016 EDITION –**

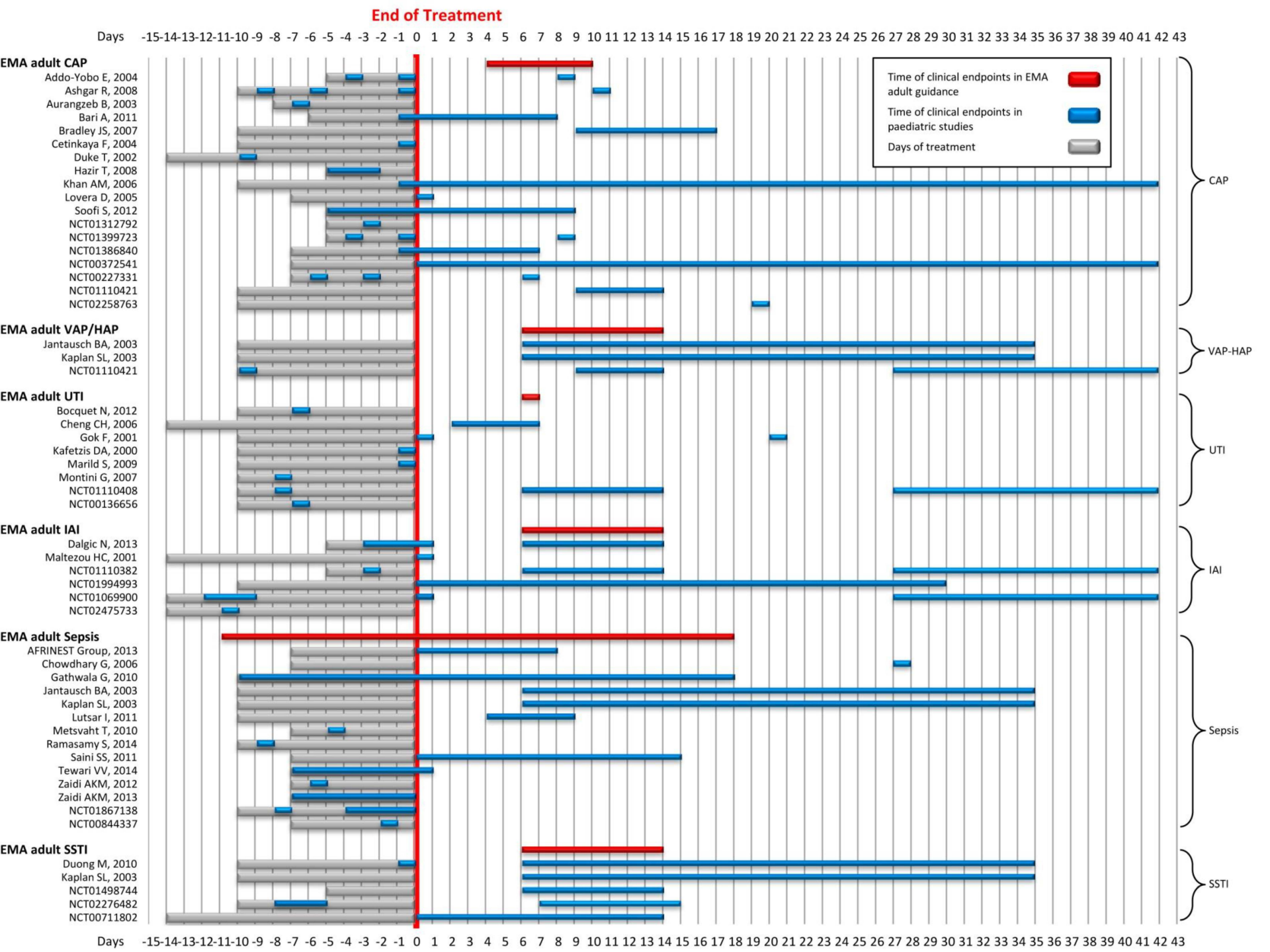
**IMPLEMENTATION**

EVIDENCE BASED GUIDANCE OF ALL COMMON INFECTION SYNDROMES

100 CHAPTERS

120 ANTIMICROBIAL DOSES FOR NEONATES AND CHILDREN – RAG RATED




End of Treatment
Days -15 -14 -13 -12 -11 -10 -9 -8 -7 -6 -5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43
Time of clinical endpoints in EMA adult guidance
Time of clinical endpoints in paediatric studies
Days of treatment
EMA adult CAP
Addo-Yobo E, 2004
Ashgar R, 2008
Aurangzeb B, 2003
Bari A, 2011
Bradley JS, 2007
Cetinkaya F, 2004
Duke T, 2002
Hazir T, 2008
Khan AM, 2006
Lovera D, 2005
Soofi S, 2012
NCT01312792
NCT01399723
NCT01386840
NCT00372541
NCT00227331
NCT01110421
NCT02258763
CAP
EMA adult VAP/HAP
Jantausch BA, 2003
Kaplan SL, 2003
NCT01110421
VAP-HAP
EMA adult UTI
Bocquet N, 2012
Cheng CH, 2006
Gok F, 2001
Kafetzis DA, 2000
Marild S, 2009
Montini G, 2007
NCT01110408
NCT00136656
UTI
EMA adult IAI
Dalgic N, 2013
Maltezou HC, 2001
NCT01110382
NCT01994993
NCT01069900
NCT02475733
IAI
EMA adult Sepsis
AFRINEST Group, 2013
Chowdhary G, 2006
Gathwala G, 2010
Jantausch BA, 2003
Kaplan SL, 2003
Lutsar I, 2011
Metsvaht T, 2010
Ramasamy S, 2014
Saini SS, 2011
Tewari VV, 2014
Zaidi AKM, 2012
Zaidi AKM, 2013
NCT01867138
NCT00844337
Sepsis
EMA adult SSTI
Duong M, 2010
Kaplan SL, 2003
NCT01498744
NCT02276482
NCT00711802
SSTI
Days -15 -14 -13 -12 -11 -10 -9 -8 -7 -6 -5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43

## 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