

Neonatology

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at the European Medicines Agency



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Meetings

Identify areas of shared concern

Potential topics included:

- Navigation of EMA website
- Pre-clinical models
- End-points
- Designs
- When to study neonates



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Meetings

Identify areas of shared concern

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- When to study neonates

Not easy to
agree a
common
topic to work
on



Subsequent events

- FDA set up a Neonatal Scientific Advisory Panel (as a result of increased emphasis on neonates after FDASIA)
- FDA is considering a stakeholders meeting to examine areas of shared concern
 - Similar potential list to the list drawn up by the WG
- Pause to maximise value of efforts by working with FDA

Next steps

- Develop more interest from the clinical community
- For example, meeting at European Society for Paediatric Research hosted by the Clinical Pharmacology Section (Karel Allegaert)



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Neonatal Medicines Research in Europe: opportunities and influences

Objectives of meeting:

- To brief participants about the global and European context for research about medicines in neonates, with particular reference to industry studies
- To explore the opportunities for forming a European neonatal medicines research network
- To discuss concerns shared with regulators (EMA and FDA)



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Neonatal Medicines Research in Europe: opportunities and influences

Outcomes of meeting:

- Improved awareness of the opportunities for neonatal medicines research
- Action plan / recommendations for a European neonatal medicines research network
- Feedback to the groups in discussion with EMA / FDA



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