



European Network of Paediatric Research at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Severe Paediatric Asthma Collaborative in Europe (SPACE)

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Background

Significant problems with performing clinical trials in children with severe asthma:

- phenotypes less well characterised
- numbers fewer than in adult asthma
- children and young people engage less well with complex clinical trial interventions than adults.

Objective

to rapidly develop the infrastructure to increase participation of children into trials of new asthma therapies

- by bringing together European Respiratory Paediatricians with direct links to major secondary and tertiary paediatric asthma services across Europe in a CRC

Planned deliverables

- To develop minimum core dataset to allow identification of eligible children across Europe
- To survey number of eligible children for trials in CRC member hubs and associated national spokes
- To develop a bid for a registry of eligible children
 - To enhance participation in trials
 - To generate new insights into responsive subgroups
- To support children within engagement group to help better understand how to improve opportunities and remove barriers to engagement in therapeutic clinical trials
- First kick-off meeting hosted by Enpr-EMA: 27th May 2016

Timelines

- Phase 1: develop core dataset for children with severe asthma (months 2-18)
- Phase 2: (months 18-23)
 - Prospective survey of children with severe asthma
 - To identify number of children eligible for agreed PIP studies
- Phase 3: develop and submit a bid for a registry of children eligible for biologic and new receptor blocker therapies (month 23-24)

Thank you for your attention

Further information

European Network of Paediatric Research at the European Medicines Agency
([Enpr-EMA](#))

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