Expectations to the European Paediatric Network from a research-based pharmaceutical company

Dr. Ramesh Padavala
Head Paediatrics
Novartis Pharmaceuticals AG

11th March 2011
London

Agenda

- What is the need?
- Challenges
- What is expected from Networks
- Summary

What is the need?

- A collaborative framework to work on Paediatric medicines to implement the vision of “Better medicines for children” and the regulatory requirements (The Paediatric regulation : Regulation (EC) No 1901/2006)

without:

- subjecting children to unnecessary trials,
- or delaying the authorisation of medicines for use in adults.

Challenges

- Rarity of the diseases in children
- Extremely small sample sizes
- Age specific dosage forms and formulations
- Ethical considerations
- Optimal integration of paediatric trials in the Global Clinical Development Plan
- Diverse regulatory requirements from different regions e.g. US / Europe

What is expected from the networks

Linking Paediatric Patient Care and Medicines Development

- Scientific/medical specialists information in the disease areas
- Specialists input to the paediatric investigation plan
- Aligning study protocols with patient needs and paediatric practice
- Informing the paediatric patient and care givers
  - Child appropriate assent process
  - Consent and assent forms
  - Patient information sheets

What is expected from the networks

Optimizing Trial design and conduct

- Child-appropriate study designs
- Assessing the feasibility of the paediatric trials
- Accessibility of multiple sites
- Addressing children's needs when participating in clinical trials

What is expected from the networks

Strategies for enhancing patient recruitment

- Locate existing sites and resources
- Enhance communication between networks and sponsors
- Identify existing structural and organisational recruitment hurdles and constraints
- Collaborate on finding solutions to identified hurdles
- Develop training for trial sites and sponsor staff

Summary

- There is a need for optimal collaboration between the Paediatric research networks and the pharmaceutical industry to achieve the goal of “ Better Medicines for Children”
- Specifically, this collaboration should support
  - *optimizing PIPs and study protocols*
  - *fast patient recruitment and trial execution*
  - *high quality of trial conduct and data*
  - *Providing optimal care for children participating in clinical trials*

Thank you