

# **Global Research in Pediatrics**

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# Background

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- ❑ BPCA 2002 (US)
- ❑ The European regulation on Medicinal Products for Paediatrics 2007 (EC)



- ❑ Increasing Paediatric drug trials



- ❑ *Problem: insufficient infrastructure*
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# Problems in infrastructure

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“..... insufficient capacity for paediatric medicines research, the scarcity of human and economic resources. ...

.....complexity of conducting clinical trials in paediatric population...”

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# EC initiative

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- The 7<sup>th</sup> framework programme

- RFA: Network of excellence for medicines research in paediatrics



- GRiP

- Kalle Hoppu, Carlo Giaquinto
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# GRiP

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- To enhance the availability of medicines in Europe and in the USA



- Deliverable
    - Paediatric clinical pharmacology training programme
    - Integrated electronic infrastructure
    - Standardization of research tools
    - etc
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# GRiP: specific objectives

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- ☐ **Paediatr clin pharmacol training**
  - ☐ Electronic infrastructure integration
  - ☐ Research tool harmonization
  - ☐ New trial methodologies
  - ☐ Paediatric drug formulation
  - ☐ Neonatal trials
  - ☐ Globalization
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# Training programme (WP1)

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## □ For whom?

- MDs, pharmacists, health care professionals, regulatory authorities, industry, etc

## □ By who?

- Kalle Hoppu, Evelyn Jacq-Aigrain, John van den Anker, Shinya Ito
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# Training programme (WP1)

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- ❑ To develop curriculum
  - ❑ To establish training “programmes”
  - ❑ To develop “Virtual Learning Environment”
  - ❑ To organize “exchange programmes”
  - ❑ To establish a “governance structure” including certification processes
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# GRiP: WP leaders

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- ❑ **Training:** Kalle Hoppu
  - ❑ **Epi:** Miriam Sturkenboom
  - ❑ **Tool:** Martin Offringa, Steven Hirshfeld
  - ❑ **New meth:** Paolo Baiardi, Martin Offringa
  - ❑ **Formulation:** Ian Wong
  - ❑ **Neonatol:** Evelyn Jacq-Aigrain
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