PDCO perspective & proposals

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Principles of interactions between PDCO and Enpr-EMA

- Collaboration in guideline development and in development of paediatric inventories on therapeutic needs
- Contribution to PIP process for therapeutically meaningful drug developments
- Creating of networks' contact points to facilitate experts' identification and procedural participation within strict timelines
- Create regulatory/disease-specific training sessions for networks - EMA - PDCO members
- Communication of feasibility evaluations and protocol assessment of PIP studies

Experience so far

Face to face meetings between research networks and PDCO

- PRINTO
- RIPPS, France
- FinPedMed and NordicPedMed, Finland
- NIHR CRN Children, UK

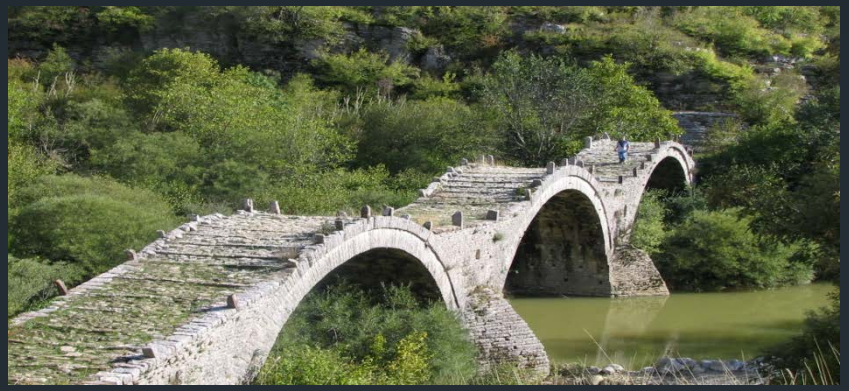
Experience so far

- Common aims :
  - ✓ Improve the methodology, design and feasibility of paediatric clinical studies
  - ✓ Develop standardized (innovative?) methods and tools for monitoring and evaluating the efficiency, effectiveness, and safety of therapeutic interventions for children
  - ✓ Increase availability of high quality licensed paediatric medicines

- Bridges to build :
  - ✓ Research questions vs. licensing demands
  - ✓ Trial design expertise vs. trial conduction experience
  - ✓ Meeting regulatory requirements vs. technical support to industry
  - ✓ Business sustainability vs. prediction of scientific and regulatory landscape
  - ✓ Drug development pipeline vs. true paediatric therapeutic needs vs. global trials
  - ✓ Meaningful early interactions vs. successful Marketing authorization applications

Building a bridge

or how can the networks assist…



- Increased cooperation between the European network, PDCO and global regulatory networks.
- Horizon scanning activities on emerging innovation and proactive communication.
- Evaluation of trial methodology based on real life information : feasibility evaluation ⟺ licensing assessment outcomes = agreement on clinically meaningful measures.
- Documentation of paediatric clinical needs and exploration of alternative regulatory pathways.
- Promotion of safety monitoring including off label use of medicines + registries/ PASS/ PAES.
- Integration of real-world data into a paediatric medicine’s lifespan.
- Bring companies together for basic science research to be used openly.