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Experience with Enpr-EMA
An SME





Learning Objectives

- Personal experience from SME
 - Contacts
 - Website
 - Responses
 - Interactions
 - Ideas for improvement



Proveca



- Founders responsible for gaining first PUMA – Buccolam
- Developing off-patent Medicines for children
- Licensing in EU through PUMA
- Most products require some degree of clinical work
- Require specialist advice and input to clinical trial design prior to submitting a PIP





KOL/Clinician Identification



- Usual approach via network, publications, conferences
- Germany, NL, France and UK
- Good response from Germany, no response from NL or France
- Clinicians in UK identified through MCRN
- Helpful advice, willing to meet



Enpr-EMA



- Introduced to Enpr-EMA through UK contact
- Contacted KOLs in NL
- Rapid response
- Confidentiality Agreement set up through central contact
- Helpful advice from 2 clinicians





Enpr-EMA Mission Statement



- Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.
- This will be achieved by:
 - **Fostering high quality ethical research on the safety and effectiveness of medicines for children.**
 - **Establishing a European paediatric research network of national and European specialty networks, investigators and centres with expertise in performing trials in the paediatric population**
 - Efficient inter-network and stakeholder collaboration in order to build up the necessary competences at Community level and to avoid unnecessary duplication of studies.
 - To inform parents, carers, children and young people about clinical trials and encourage their participation.
 - Raising awareness among health care professionals of the need for clinical trials in all ages of children and supporting their involvement in such studies.
 - Assisting and entering into discussions with ethics committees on issues relevant to research and clinical trials in children.





Available networks from Website



[ECFS-CTN](#) (European Cystic Fibrosis Society - Clinical Trials Network)

[EUNETHYDIS](#) (European Network for Hyperkinetic Disorders)

[EPOC](#) (European Paediatric Oncology off-patent medicines Consortium)

[FINPEDMED](#) (Finnish Investigators Network for Pediatric Medicines)

[GNN](#) (German Neonatal Network)

[ITCC](#) (Innovative Therapies for Children with Cancer)

[I-BFM-SG](#) (International BFM Study Group)

[FIMP-MCRN](#) (Italian Paediatric Federation- Medicines for Children Research Network)

[MCRN](#) (Medicines for Children Research Network – The Netherlands)

[MICYRN](#) (Mother Infant Child Youth Research Network, Canada)

[NIHR-MCRN](#) (National Institute for Health Research - Medicines for Children Research Network – UK)

[Newcastle-CCLG](#) (Newcastle Children's Cancer and Leukaemia Pharmacology Studies Group)

[PENTA](#) (Paediatric European Network for the Treatment of AIDS)

[PRINTO](#) (Pediatric Rheumatology International Trials Organisation)

[Scotmcn](#) (Scottish Medicines for Children Network)

[UKPVG](#) (United Kingdom Paediatric Vaccines Group)

[EBMT](#) (European Group for Blood and Marrow Transplantation)

[CICPed](#) (Paediatric Network of Clinical Investigation Centres, France)





Relevant networks



- **FINPEDMED** (Finnish Investigators Network for Pediatric Medicines)
- **FIMP-MCRN** (Italian Paediatric Federation-Medicines for Children Research Network)
- **MCRN** (Medicines for Children Research Network-The Netherlands)
- **NIHR-MCRN** (National Institute for Health Research-Medicines for Children Research Network – UK)
- **CICPed** (Paediatric Network of Clinical Investigation Centres, France)





Personal Experience

- Concept of Enpr-EMA ideal for SME
- Finding appropriate information and contacts through website is difficult
- Resource intensive and limited success
- Infrequent responses despite several emails
- Contact through introductions most fruitful
- Follow-up has had limited success so far



Learning Outcomes



- A single point of contact to help get started would be invaluable
- Help to identify appropriate first contacts
- Response to emails often requires several attempts; expect silence
- Partnership approach from the outset would work well for SME

Questions

