

# PDCO feedback

PCWP with all eligible organisations meeting 22 November 2017

Presented by:

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# Opportunities and Challenges with Patient & Healthcare Professional Organizations:

Interaction in both cases it can be viewed as an **additional burden** in the process but the **benefits** are **well received and understood**, for this reason

**PDCO appreciates the help and support that both** groups provide in the Committee

- **Provide an insight in the opportunities and challenges**
- **Feasibility challenges in performing CTs in Children**

# Parent and Patient Organizations Contribution:

There are many areas that we work together

- **general to specific cases**
- **benefit risk**
- **burden**
- but also **ethical issues** - For example the use of **PLACEBO**

We need to work together more on

- **acceptability** of CTs
- advocating the **need of paediatric CTs** with parents and patient organization
- **willingness of families and children to** participate in CTs and in the
- **medicines development process**
- **EDUCATION** is important.

**We welcome the inclusion** of young people in the processes of EMA in a safe and effective way

# Healthcare Professional Organizations Contribution:

Provides the Committee :

- **everyday experience of clinical practice**
- **much needed expertise**, especially in the
- **neonates**, rare diseases etc
- **BUT also this two-way interaction**, promotes the benefits of having medicines tested and monitored via the controlled CTs pathway VS the **uncontrolled off label use!**
- Still the **Effect Size and the Contribution** should be measured and accessed like it should be for every stakeholder. Especially for PO and HCP Org since it is a volunteer positions.
- It is the POs and HCP Organizations responsibility to send and maintain the best people in these positions

- Still the **Effect Size and the Contribution** should be measured and evaluated like it should be for every stakeholder.
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# Feasibility of Trials:

Finally in this panel it is important to highlight the **challenges faced in paediatric medicines development** in EU and we need to discuss how to tackle:

- the **low recruitment** in EU and we need to discuss how to
- **the fragmentation and discrepancies of Ethics Committees** in paediatric Trials, that affects directly the feasibility of CTs in children **and sometimes delays paediatric medicines development.**

We need to **work together to change minds and hearts** and in this effort we should work with universities, with young doctors, young academics but also the various and fragmented EU Ethics Committees.

This is a place **PCWP** have a huge role to play in moderating the discussions and reaching out.

# THANK YOU!

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