SJD Sant Joan de Déu Fundació de Recerca

Patient Engagement in Research Area

Begonya Nafria

Patient Engagement in Research Coordinator at Barcelona Children's Hospital

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Challenges to be addressed in Paediatric Clinical Trials In Europe

Patient Experience Data:

- Developed with (young) patients/caregivers.
- Ensure the validation of the PED tools. Use existing frameworks (e.g. PFMD)
- Use friendly tools for reporting PED.
- Make compatible the data collection process with the daily life of patients (*allow them to be kids and teenagers*).
- Diversity and accessiblity.

Challenges to be addressed in Paediatric Clinical Trials In Europe

Patient involvement in the conception and design of PED:

1. Involve the patients/parents before finalize the clinical trial protocol (PIP stage).
2. Meaningful involvement of children and young people with experts in PPI field:
   - **eYPAGnet** and **conect4children**
3. Training of stakeholders. Prioritization of young patients.

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Regulatory requirements

Require in all clinical trials approved in Europe:

1. Involvement of patients/caregives in the study protocol design (EU-ACT)
2. Inclusion of PED tools co-designed with patients/caregivers
   - Consider disease & SHD diversity
3. Assess PED and their value as secondary endpoints.
4. Consider the role of PED on safety of medicines

Thank you so much!

begonya.nafria@sjd.es