

10 October 2018

Patient/Parents Enpr-EMA WG

Vision:

Promote paed therapeutic development by connecting regulatory work and paed R&D with young patient and parents' networks with the goal to avoid fragmentation and duplication of efforts and resources.

Mission:

Providing EnprEMA network with the patient perspective and act as a consulting body for topics such as patient involvement, data sharing, and multistakeholder collaboration.

Area of interest:

Paed Data from Collection/Usage/Governance to Sharing and FAIR

Problem: Data silos, inefficient use of patient data and lack of interoperability is crippling the R&D for children.

The goal of this WG is to map, measure and propose possible solutions for Data Sharing in the Paed Research Networks

Action Plan:

- Assessment of the current situation in data collection/ usage/ governance/ sharing and compliance with the FAIR principles
- Assessment of the patient/parent and patient community inclusion in governance and data access in EnprEMA network.
- Develop a data sharing strategic guidance to facilitate data sharing in paediatric study development and implementation and inclusion of patients and their communities in the decision-making processes.
- Promote and disseminate the findings and the importance of Data Sharing and FAIR principles in all stakeholders
- Involve patient representatives from YPAG WG and Youth Patient groups and Patient Organizations

Structure

The WG is developing a first core group of 5-10 Patient Rep/Regulators operating as a Steering Committee

The first core group including Patient Rep/Regulators from the EMA Committees and WG which have experience in Regulatory activities and Medicines development in the Paediatric population.

Participants list to the core group:

Dimitrios Athanasiou
Marco Greco
Julian Isla Gomez
Virginie Hivert
Viviana Giannuzzi, TBI
Mariette Driessens, TBI

End of 2019 in a second phase it will invite 15 experts from all stakeholder groups will be added (Academia, HCP, CROs, Industry etc.)

WG Topic	Assessment and evaluation of Paed Data Collection/Usage /Governance/Sharing in Enpr-EMA networks
Objectives	<ol style="list-style-type: none"> 1. Mapping and interaction with EnprEMA network and other relevant stakeholders. 2. Assess the current situation on Collection/Usage/Governance/Sharing and compliance with the FAIR principles in Enpr-Ema network. 3. Assessment of the patient/parent and patient community inclusion in governance and data access in EnprEMA network. 4. Gather examples of good as well as suboptimal practice on data sharing in the paediatric population. 5. Collect and analyse the feedback 6. Promote and identify the pain points 7. Promote dialogue to consolidate proposals among different parties 8. Develop a data sharing strategic guidance to facilitate data sharing in paediatric study development and FAIR implementation

Action points:

- Enrich the Core Team with more expertise and resources
- Create an EnprEMA network Map and establish interaction with EnprEMA network and other relevant stakeholders.
- Draft a survey to measure the current situation on data and patient involvement in the decision making and access.
- Collect and analyse the feedback
- Identify the pain points and friction points
- Deliver a report of the findings for publishing on EMA website.
- Promote dialogue a dialogue between the various stakeholders in a EnprEMA and other stakeholder
- Develop a data sharing strategic guidance to facilitate data sharing in paediatric study development and FAIR implementation

2019 activities and steps:

1. Working Group Establishment mid 2019
2. Set up the Core Team
3. Agreement on Mission and Vision of the WG
4. Identification and prioritization of common topics of interest
5. Selection of the main topic and setting up of the objectives
6. Development of the actions plan
7. Identifications of further interested parties could support a respective WG as co-members
8. Enrich the Core Team with more expertise and resources
9. Develop a detailed action plan

2020 activities and steps:

1. Mapping exercise and connection establishment with EnprEMA network and other relevant stakeholders.
2. Draft a survey to measure the current situation on data and patient involvement in the decision making and access.
3. Collect and analyse the feedback
4. Identify the pain points and friction points
5. Deliver a report of the findings for publishing on EMA website.
6. Promote dialogue to consolidate proposals among different parties
7. Organize a joined event
8. Develop a data sharing strategic guidance to facilitate data sharing in paediatric study development and FAIR implementation