



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Summary of 2018 Annual Workshop

EnprEMA Meeting June 8th 2018



Overview

Good attendance – all stakeholders

- New topics
 - HTA
 - Involvement of CTFG
- Concerns
 - Voices of parents
 - Adolescents
- Ongoing topics
 - Existing WGs

HTA

- Involvement of EUnetHTA is a interesting development
- Needs follow-up

International Collaboration between networks and Regulatory Agencies

Proposal

- WG that includes:
- Regulatory Agencies
- One network per Regulatory Agency

Principles for identifying standards of care

Proposal

- WG that identifies principles for identifying standards of care and promoting standardisation of care during clinical trials

Engaging Parents, family members and carers

Proposal

- WG that promotes the voice of parents, family members and carers
- Share best practice for involvement and engagement
- Recruit family groups to EnprEMA
- Ensure trials and PIPs have been designed with parent views

Research Nurses

Proposal

- WG that meets the needs of research nurses
- Share best practice for involvement and engagement
- Recruit research nurse networks to EnprEMA
- Ensure trials and PIPs have been designed with nurse views

Adolescents

Proposal

- WG that meets the needs of adolescents
- Share best practice for involvement and engagement
- Ensure trials and PIPs have been designed to account for adolescents
- Promote appropriate inclusion of adolescents in trials

Paediatric Pulmonary Artery Hypertension

Proposal

- WG to build on the work of a multistakeholder meeting in 2017

GCP Training

Further work

Ethics

Further work

Young People's Advisory Groups

Further work

Trial preparedness

Further work

Interactions between networks, industry and regulators

Further work