



European network of paediatric research  
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Enpr-EMA newsletter 2021

Dear friends and colleagues,

The COVID-19 pandemic has continued to challenge global health systems in 2021. However, despite the difficult circumstances, all of us have worked hard to deliver better medicines and improve the conduct of clinical trials for paediatric patients.

We have made great achievements in our core work – as exemplified by the outputs and progress of our working groups, most recently by the publication of the [guide on informed consent and assent for paediatric clinical trials in Europe](#) in Archives of Diseases in Childhood. This guide will serve as an important reference to everyone involved in paediatric clinical trials in Europe.

This year we met only virtually, at 3 remote meetings of the member networks and the Coordinating Group. We had the opportunity to discuss the review of the Paediatric and Orphan Regulations by the European Commission and upcoming changes in the context of the Clinical Trials Regulation, while also progressing various initiatives in our working groups and exchanging the latest COVID-19-related developments in relation to the paediatric population.

For more information on Enpr-EMA's work and achievements in 2021 as well as the other topics discussed, see the [report of the annual meeting of the members and Coordinating Group](#).

Please be reminded to provide your thoughts during the [open public consultation on the revision of the EU general pharmaceuticals legislation](#) by 21 December 2021.

Finally, we would like to remind you of the available information and training resources in relation to the Clinical Trial Regulation (EU) No. 536/2014 and the Clinical Trials Information System (CTIS) coming into application on 31 January 2022: [Clinical Trials Regulation](#); [Clinical Trials Information System: training and support](#); [Sponsor Handbook](#) and [Training Module 19 - SMEs and Academia](#).

We would like to thank you all for your support and your hard work for medicines for children. We wish you a relaxing holiday season and a moment of rest after a challenging year. We look forward to continuing our work together, and we hope to be able to come together in person again next year.

Our best wishes for 2022,

**Pirkko Lepola** (Chair)

**Gunter Egger** (Co-chair)



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