

## c4c Multi-stakeholder meeting on Paediatric Irritability

18-19 March 2024

Nice, France  
& virtual

### Call for Expression of Interest

conect4children (c4c) is pleased to announce that the fifth c4c International Multi-Stakeholder Meeting (MSM) will address **the topic of Paediatric Irritability**.

The meeting will be a **hybrid** meeting that will take place in **Nice, France, on 18 and 19 March, 2024, after the European College of Neuropsychopharmacology (ECNP) New Frontiers Meeting 2024**.

***Multi-Stakeholder Meetings** have been conceived with the aim to **facilitate dialogue and provide an opportunity for constructive interactions between relevant stakeholders** (patients/patient representatives, clinicians, academics, pharmaceutical companies and regulators from the EMA and FDA) **on topics requiring open discussion on the development of medicines in the best interests of neonates, children and/or adolescents**. The goal of these meetings is to share information, in a pre-competitive setting, to define unmet medical needs, to define how best to address those needs and facilitate the development of innovative medicines towards eventually their introduction into the standard-of-care of neonates, children and/or adolescents.*

### Rationale

Irritability, along with emotional dysregulation and aggressiveness, is a condition that occurs across multiple psychiatric diagnoses. There are very few therapeutic options. So far, only 2 drugs are approved for the treatment of irritability in the context of autism spectrum disorders in childhood. However, irritability is very frequently a clinically relevant focus of off-label treatment for several paediatric psychiatric disorders.

The Multi-stakeholder Meeting on Paediatric Irritability aims at defining a strategy for the development of interventions for the treatment of irritability in different conditions and will explore the regulatory framework to support paediatric irritability as a target for drug development programs.

### Specific objectives

- Provide an update on the science
- Clarify definitions and context
- Understand current treatments and define unmet medical needs
- Discuss relevant medicinal products
- Explore the regulatory framework and outcome measures
- Propose a strategy to accelerate development of therapeutic interventions

A large part of the meeting will be dedicated to panel discussions and interaction.

The overarching objective of the meeting is **to propose a strategy to improve the timely development of and access to relevant therapeutic interventions**, properly addressing paediatric unmet needs, introducing innovative development pathways in the regulatory environment and increasing accessibility for all patients.

### Outputs

The outputs of the meeting will be:

- an article in a peer reviewed journal
- an action plan to implement the proposed strategies

**No regulatory decisions will be made during the meeting, which will focus on publicly available information.** The views expressed by representative of Regulatory Agencies are personal and might not be understood or quoted as being made on behalf of or reflecting the position of the Regulatory Agencies or one of their committees or working parties.

**However, the findings and conclusions of the meeting are aimed at paving the way for future development plans and concrete actions.**

### Who can participate?

International academic experts in child and adolescent psychiatry, representatives from pharmaceutical companies interested in developing relevant assets or having relevant assets, representatives from regulatory agencies (EMA, FDA) and patients, parents and representatives of advocacy groups.

The meeting will be **on an invitation only** basis following expression of interest. Interested parties can apply by submitting the **Expression of Interest form** available below

**Submit your  
Expression of interest**

(if the button does not work correctly, please use the following link: <https://shorturl.at/buEX9>)

Deadline for submission: **15 Jan 2024 EOB (Brussels time)**

Invited participants will be contacted in due time.

**The c4C Multistakeholder Meeting on Paediatric Irritability Programme Committee**