

c4c Multi-Stakeholder Meeting on Paediatric Inflammatory Bowel Disease (IBD)

14-15 April 2021

4PM – 7:30PM CET (both days)

Virtual event

Conect4children is pleased to inform that the c4c International Multi-Stakeholder Meeting (MSM) on Paediatric Inflammatory Bowel Disease (IBD) will take place VIRTUALLY on 14-15 April 2021. The meeting has been organized with the participation of the European Medicines Agency (EMA) and the Food and Drug Administration (FDA).

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) **on topics requiring open discussion on development of medicines in the best interests of children and adolescents. The goal of these meetings is to share information, in a pre-competitive setting, to facilitate the development of innovative medicines and ultimately their introduction into the standard-of-care of children and adolescents.**

Rationale

The incidence of paediatric onset Inflammatory Bowel Diseases (IBD), ie Crohn's disease (CD) and ulcerative colitis (UC) has risen dramatically in recent decades, with a marked increased incidence in regions where the disease used to be rare: 10% of IBD patients are first diagnosed in childhood or teenage, 1.5% of all IBD patients are younger than 17 years.

Over the last 2 years, recommendations have been published by both FDA and EMA to guide the development of medicinal products for the treatment of children and adolescents with IBD. Several paediatric development plans, including for recently approved new molecular entities, have been granted and are ongoing.

From an industry perspective, there is an explosion of development in the IBD space and paediatric developments are delayed, facing major issues in enrolling patients. From an academia and parents perspective, children and adolescents with IBD still have little or no access to innovative treatments in clinical trials in a timely fashion. In addition, the involvement of patients and parents is sub-optimal.

Over the recent years, several important assets have been developed that would support innovative and more efficient development pathways. PIBDNet, an international network has been created with more than 150 experts from 25 countries. IMPROVE CARE NOW has created a collaborative community (clinicians, researchers, parents and patients) to improve care for PIBD patients. A European funded project (PIBD-SETquality) has developed a treatment algorithm for PIBD on high and low risk predictors

for early complicated or relapsing disease, along with a safety registry and a prospective real world data cohort.

Objectives

The goal of the meeting is **to propose a strategy in order to facilitate prioritisation and to improve the timely development of therapeutic innovations for children and adolescents with IBD**, addressing properly paediatric unmet needs through science, introducing innovative development pathways and increasing accessibility for all patients. The overarching goal is to set up cooperation of academia and industry, with support of advocacy and regulators within a new and facilitating regulatory environment.

The meeting will provide the opportunity to share and discuss all recent advances and progresses in the field of paediatric IBD, to review and discuss molecules with an ongoing paediatric development plan and to define new development pathways introducing alternative innovative trial designs and pharmacological evaluation, concrete use of extrapolation, use of real world data and earlier initiation of paediatric studies.

Outputs

The output of the meeting will be a common understanding of the needs, issues and available assets by ALL stakeholders and a proposed strategy based on a stronger cooperation between academia and industry, that will include patients advocates and facilitated interactions with regulatory agencies.

No regulation decisions will be made during the meeting which will share publicly available information. However, the conclusions of the meeting will pave the way for future development plans and concrete actions.

Who can participate?

International academic experts in paediatric inflammatory bowel disease, representatives from Pharmaceutical companies developing assets in inflammatory bowel diseases, representatives from regulators (EMA and FDA) and patients advocates.

The meeting will be **on invitation only**. Interested participants can apply by filling the **Expression of Interest form** available on the next page before 9 March 2021. Invited participants will be contacted in due time

Expression of Interest

I AM A CLINICIAN >

I AM A PATIENT/ADVOCATE >

I AM A REGULATOR >

I AM A INDUSTRY REPRESENTATIVE >