

c4c Multi-Stakeholder Meeting discussed Medical Devices in Paediatric Type I Diabetes: what are patients needs and how to improve development and accessibility of devices?

21 February 2023
Hybrid event (Berlin & Zoom)

Summary

The third International conect4children Multi-Stakeholder Meeting on Medical Devices in Paediatric Type I Diabetes took place on 21 February 2023 in Berlin and virtually with the participation of more than 120 attendees from 23 countries (Europe and US) representing young patients and advocates, clinicians, academics and researchers, pharmaceutical companies and regulators (EMA, FDA)/Notified Bodies*/policymakers.

The concept of a Multi-Stakeholder Meetings is to facilitate dialogue and provide an opportunity for constructive interactions among all relevant stakeholders on topics requiring open discussion on development of medicines and medical devices in the best interests of children and adolescents. No regulation decisions are made during the meeting and only publicly available information are shared. The value of such meetings has been demonstrated in paediatric oncology by [ACCELERATE](#) in the recent years.

The overarching objective of the meeting was to propose a strategy to improve the timely development and access of medical devices for children with type I diabetes, properly addressing paediatric unmet needs, introducing innovative development pathways in the regulatory environment and increasing accessibility for all patients.

The first session set the scene with an overview of current treatment/care and needs and the interventions by young patients, parents and advocates to highlight the unmet needs of young patients.

During the second session, the focus moved to the understanding the regulatory environment for evaluation and authorization of medical devices. Presentations and discussion focused on the European and US regulatory landscape and some insights from the Coordinating Research and Evidence of Medical Devices (CORE-MD) project.

The first part of the afternoon was dedicated to presentation of medical devices already available on in the pipeline by the representatives of five companies: diabeloop, Insulet, Tandem Care, Medtronic, Ypsomed.

The last session gathered a multi-stakeholder panel with the goal to address three important questions which emerged from the previous discussions:

- How to generate clinical evidence for children with type I diabetes?
- What proposals to ensure the evaluation of paediatric medical devices in a timely fashion?
- What proposals to facilitate access for all patients?

Following the meeting conclusions, a joint article will be submitted to a peer reviewed journal in the specialty.

This successful meeting showed the potential value of multi-stakeholder discussion and working together in paediatric fields other than oncology.

**Notified Bodies are responsible for assessing medical devices (MDs) and diagnostics (IVDs).*