

**Paediatric Strategy Forum for  
Medicinal product development for mature B-cell malignancies in children  
Co-organised by ACCELERATE and EMA -  
13 - 14 November 2017**

The second multi-stakeholder Paediatric Strategy Forum, jointly organised by ACCELERATE and the European Medicines Agency (EMA), focussed on mature B-cell malignancies in children and adolescents. Paediatric Strategy Forums have been created 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 with cancer. The goal of this meeting was to share information, in a pre-competitive setting, to inform paediatric drug development strategies and subsequent decisions and to facilitate the developments of innovative medicines for the treatment of children with mature B-cell malignancies, and ultimately to introduce these medicines into the standard-of-care of children.

This Paediatric Strategy Forum successfully gathered 73 participants including patient representatives from Unite2Cure, European and North American experts in mature B-cell malignancies in children, drug development experts, representatives from pharmaceutical companies and from EU national competent authorities and EMA (including Paediatric Committee [PDCO]), Committee for Medicinal Products for Human Use [CHMP], Committee for Orphan Medicinal Products [COMP] and Scientific Advice Working Party [SAWP] members) and the US Food and Drug Administration (FDA). A comprehensive overview of the epidemiology and biology of mature B-cell malignancies was presented, and the therapeutic needs of paediatric patients with mature B-cell malignancies discussed. Fourteen pharmaceutical companies described the pharmacology and clinical information of twenty medicines currently being developed, mainly in adults, for the treatment of B-cell malignancies. .

As a conclusion, it was proposed to form an international working group to develop a clinical trials strategy to investigate in timely manner, medicinal products for the treatment of relapsed mature B-cell malignancies in children. Additionally, it is planned to draft a scientific paper on the topics discussed at the Forum.