



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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European Medicines Agency  
Human Medicines Research and Development Support Division  
Paediatric Medicines Office

Prof Gilles Vassal  
Chair of Accelerate and President of Innovative Therapies for Children with Cancer in Europe (ITCC)  
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Dr Nathalie Gaspar and Chris Copland (Nathalie.GASPAR@gustaveroussy.fr and  
chriscoplandatnyork@gmail.com)  
Co-Chairs of the Accelerate Working Group – Fostering Age Inclusive Research (FAIR)

Dear Dr Gaspar, Professor Vassal and Mr Copland

RE: Foster Age-Inclusive Research

The EMA and its Paediatric Committee (PDCO) follow closely and with great interest the Accelerate's FAIR (Foster Age-Inclusive Research) initiative, aiming to facilitate timely access of novel therapies for children with cancer. In this respect the EMA and PDCO took also note of the FDA's Draft Guidance for Industry on 'Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials' (published in June 2018).

The PDCO reviews Paediatric Investigation Plans (PIPs) for medicines for treatment of children with cancer, as mandated by the EU Paediatric Regulation. With the goal of fostering timely studies in the paediatric population, we generally request early initiation of studies in adolescents, either by inclusion of adolescents in adult trials or by conduct of an adolescent trial in parallel to the adult program, whenever this is scientifically justified. Of course, PIPs are evaluated on a case-by-case basis and thus this strategy is not universally applicable.

Of note, this principle has already been applied and used by the PDCO on a regular basis in discussions during the evaluation of PIPs for paediatric oncology.

Furthermore, the EMA values collaboration and interaction with other medicine regulatory bodies and commits to enhance established frameworks for collaboration with the U.S. FDA's Oncology Centre of Excellence Pediatric Oncology Program, as agreed in the "EMA-EC action plan on paediatrics" published in October 2018, to strengthen collaboration globally on this matter.

We sincerely appreciate your efforts and hope we can all continue to work together to improve the development of medicines for children with cancer.

Kind regards

On behalf of the Paediatric Committee

Dr Dirk Mentzer

Chairman of the Paediatric Committee at the EMA

cc EMA: Dr Enrica Alteri, Dr Ralph Bax

