



June 19, 2020

- Professor Gilles Vassal, ACCELERATE Chair and Innovative Therapies for Children with Cancer in Europe (ITCC) President
- Dr. Nathalie Gaspar, ACCELERATE Fostering Age Inclusive Research (FAIR) Working Group Co-Chair
- Chris Copland, ACCELERATE Fostering Age Inclusive Research (FAIR) Working Group Co-Chair

RE: Fostering Age-Inclusive Research (FAIR) Trials Initiative

Dear Professor Vassal, Dr. Gaspar, and Mr. Copland,

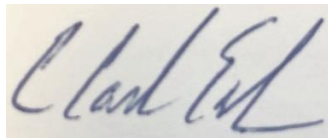
The Biotechnology Innovation Organization (BIO), European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio – the EuropaBio Association of Bioindustries, the Pharmaceutical Research Manufacturers of America (PhRMA), and our members recognise and value the efforts led by the ACCELERATE'S FAIR Initiative. With the goal of facilitating timely access to novel therapies for children with cancer, we see the FAIR Initiative as an important step to encourage researchers, regulators, ethics committees, and health technology assessment bodies to support and consider the systematic inclusion of adolescents (i.e., individuals from 12 to below 18 years of age), in oncology studies based on the benefit-risk profile of a product, when scientifically, ethically justified and feasible.

Together the Biotechnology Innovation Organization (BIO), European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio – the EuropaBio Association of Bioindustries, Pharmaceutical Research Manufacturers of America (PhRMA), representing the world's leading biotechnology and biopharmaceutical companies and related organisations, we want to bring innovative treatments to all patients that need them and encourage researchers, regulators, ethics committees, and health technology assessment bodies to recognise the use of flexible and practical innovative approaches so that new medicines can reach patients as soon as possible. We encourage an open dialogue between authoritative bodies and

companies on timely development strategies for paediatric populations (e.g. inclusion of adolescents in adult studies, or conducting adolescent studies concurrent to adult studies, where scientifically and ethically justified and feasible).

We do appreciate the efforts led by the FAIR Initiative and hope to continue to partner with ACCELERATE to speed up the delivery of innovative therapies to children and adolescents.

Yours sincerely,



E. Cartier Esham, Ph.D.
Executive Vice President, Emerging Companies
Senior Vice President, Science and Regulatory
Biotechnology Innovation Organization (BIO)



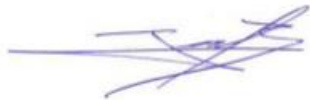
Magda Chlebus
Executive Director
Science policy & Regulatory Affairs
EFPIA



Alexander Natz
EUROPE Secretary General

Signature: 
Print Name: Richard Moseicki

Chief Medical Officer and Executive Vice
President, Science and Regulatory
Advocacy
PhRMA



Bernard Grimm
Healthcare Director
EuropaBio