Representatives of the world’s leading biotechnology and biopharmaceutical trade associations have made a joint statement calling for clinical trials to be made more inclusive for young people with cancer. In an open letter released this June, they call on researchers to systematically include adolescents in oncology studies based on the benefit-risk profile of a product, when scientifically, ethically justified and feasible.

‘We want to bring innovative treatments to all patients that need them,’ the letter states, ‘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.’

The letter is addressed to leading members of the ACCELERATE Platform on Innovation for Children and Adolescents with Cancer and gives specific endorsement to the ACCELERATE FAIR Trials initiative, which advocates reducing the age of trial entry to 12 years of age in adult early phase studies, where scientifically, ethically justified and feasible.

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

Signatories represent the following associations:
BIO (Biotechnology Innovation Organization)
EFPIA (European Federation of Pharmaceutical Industries and Associations)
EUCOPE (European Confederation of Pharmaceutical Entrepreneurs)
EuropaBio (European Association for BioIndustries)
PhRMA (Pharmaceutical Research and Manufacturers of America)
Professor Gilles Vassal, Chair of the ACCELERATE FORUM states, ‘We need a better and stronger partnership between the scientists, the clinicians, the pharmaceutical companies, the regulators and patient advocates because we need to significantly improve the way we develop drugs.’

Dr Nathalie Gaspar and parent representative, Chris Copland, joint chairs of the ACCELERATE FAIR Trials initiative added, ‘We are very pleased with the readiness shown by the Pharmaceutical and Biotech sector, as well as the regulators (FDA in the USA and EMA in Europe), to speed up oncology research for young people by supporting joint adolescent and adult early phase trials.’

Professor Pamela Kearns, (University of Birmingham, Cancer Research UK Clinical Trials Unit in the United Kingdom) and SIOP Europe President, says: ‘It is my hope that age limits won’t be the barrier in the future. It’s about the biology of the drug and the needs of the patient, that’s where the future of clinical trials needs to be.’

Paediatric oncologists and parents are available for press/broadcast interviews to provide further details on this issue. Please contact: Carole.Lecinse@gustaveroussy.fr

Further information:

- **ACCELERATE**
- FAIR Trials Initiative call to action video
- FAIR Trials Resources (FAIR Investigations/Sponsor Toolkit; FAIR for AYA ‘Stamp of Approval’; E-learning tools)
- Detailed information catering to various stakeholders (paediatric & medical oncologists; patient & parent advocates; industry and regulators)

**ACCELERATE**

ACCELERATE offers a unique and innovative promise in providing answers to some of the most vexing challenges in childhood cancer thanks to the international cooperation between academic paediatric oncologists and haematologists, researchers, representatives from biopharma companies, regulatory networks and patient advocates which are all equal members of
ACCELERATE. In contrast to many conventional medical/scientific platforms, ACCELERATE features a deliberate problem-solving structure in which alternatives to specific treatments are posed and a consensus treatment plan emerges from deliberations by the full range of stakeholders.

'Fostering Age Inclusive Research' (FAIR) Trials Initiative Group
Research into teenage and young adults’ cancer has made slower progress than for any other age group. One reason is that many clinical trials exclude patients under 18, without medical justification. To confront this problem, 'Fostering Age Inclusive Research' (FAIR) Trials Initiative Group was established in 2017 by the ACCELERATE platform. Made up of 15 experts from Academia, Industry and Patients/Parents advocacy, the group aims to raise awareness and promote changes. You can find out about the group's work and what you can do to help here.

www.accelerate-platform.org/fair-trials | contact@accelerate-platform.org | T: +32 2 880 62 85
Twitter: @ACCELERATE_cure | #FAIRtrials / #ACCELERATEcure

NOTE TO EDITORS

- In Europe and North America respectively, more than 46,000 and 29,000 adolescents and young people (aged 15 to 24) are diagnosed with cancer every year [1]
- In Europe and North America respectively, more than 6,000 and 3,000 adolescents and young people (aged 15 to 24) die of cancer each year [1]
- Several cancers in adolescents and young adults have dismal prognosis (metastatic form and some histological types) with few chances of cure and improvement over the years [2]
- 80% are disease-free after 5 years from diagnosis, thanks to currently available multidisciplinary treatments and good histology cancer incidence in adolescents and young adults [3]
• Two-thirds of survivors experience long-term side effects of treatment, which are severe and impact on the daily life of half of those affected.

• Beyond 5 years from diagnosis, disease-free survivors of a cancer occurring at adolescence and young adulthood have higher mortality rates than their non-affected peers.


