



Preliminary Programme

Day 1: Thursday 4 February
 3pm-7:15pm CET / 9am-1:15pm ET / 6am-10:15am PT / 1am-4:15am AEDT

1. Welcome

3pm – 3:10pm **Welcome and introduction to the Conference**
Gilles Vassal, ACCELERATE Chair

2. Access to medicines outside clinical trial in the paediatric precision oncology landscape and capturing data

3:10pm – 3:50pm *Panel discussion (Panelists TBC)*

3:50pm – 4:00pm **Break**

3. Disparities in accessing paediatric clinical trials

4:00pm – 4:10pm **Economic and racial disparities in the US**
Speaker TBC

4:10pm – 4:20pm **Reducing inequalities in access to clinical trials in Europe**
Pam Kearns, SIOP Europe President, University of Birmingham

4:20pm – 4:40pm *Panel discussion (Additional panelists TBC)*

4:40 – 4:50pm **Break**

4. Recent developments in the regulatory environment in EU and US

4:50pm – 5:00pm **Perspectives for the European Regulatory Environment**
Fabio D’Atri, European Commission

5:00pm – 5:10pm **Implementation of the Race for Children ACT**
Greg Reaman, Food and Drug Administration

5:10pm – 5:30pm Panel discussion

5:30pm – 5:45pm **Break**

5. Parallel Breakout sessions (5:45pm – 7:15pm)

BO 1. How to facilitate repurposing of medicines that failed in adult cancer development

The development of many anticancer drugs in adults has been terminated for various reasons. Some of these drugs may target molecularly relevant alterations in paediatric malignancies. There are major hurdles for the paediatric development of these shelved-drugs. What are the hurdles and the solutions to this problem?

BO 2. Agnostic evaluation of compounds in rare sub-groups

What are the lessons learnt for recently approved medicines for agnostic indication? Can we propose the optimal, efficient, future approach agreed by stakeholders for the agnostic evaluation of innovative drugs for children and adolescents?

BO 3. RACE for children act – early impressions and what are the best metrics to measure its success

RACE for children act has been enacted in August 2020. What are the first impressions and experiences?

BO 4. Incentives for drug development including first child development and small biotech companies

Major therapeutic advances have mostly failed to materialise for diseases that are unique to children or where adult development cannot address the needs of children. What is best way to incentivise ‘First-in-Child’ development and marketed authorisation of medicines for the treatment of children with life-threatening and debilitating rare diseases, such as paediatric cancers?

BO 5. How to prioritise developments in specific areas of pressing unmet pediatric needs?

A future revision of the EU paediatric Regulation may consider having specific rewards/incentives to direct the development of medicines in specific areas where there is a pressing need for children. How should these areas or products which would be eligible to such system be identified?

7:15pm

End Day 1

Day 2: Friday 5 February
3pm-7pm CET / 9am-1pm ET / 6am-10am PT / 1am-4am AEDT

6. Welcome

3pm – 3:05pm **Welcome and introduction to the second day**
Gilles Vassal, ACCELERATE Chair

7. ACCELERATE at 360°

3:05pm – 3:25pm **The ACCELERATE Paediatric Strategy forum initiative and further development**
Andy Pearson, ACCELERATE

3:25pm – 3:40pm **The International Cooperation initiative**
Greg Reaman, Food and Drug Administration
Nicole Scobie, Zoe4Life
Teresa de Rojas, ACCELERATE

3:40pm – 3:55pm **Long-term Follow-up (LTFU) platform project**
Danielle Horton Taylor, PanCare
Mark Kieran, Bristol-Myers Squibb

3:55pm – 4:05pm ***Break***

4:05pm – 4:20pm **The Fit for Filing project**
Pamela Kearns, University of Birmingham
Elly Barry, Pfizer

4:20pm – 4:35pm **The Fostering Age Inclusive Research (FAIR) Trials project**
Nathalie Gaspar, Gustave Roussy
Chris Copland, University of York

4:35pm – 4:50pm **Real World Evidence**
Lynley Marshall, The Royal Marsden NHS Foundation Trust

4:50pm – 5:05pm ***Break***

8. Breakout sessions follow-up of Day 1

5:05pm – 6:35pm **Reporting of the main outcomes and open discussion**

9. Wrap-up and 2021 Annual Workplan

6:35pm – 6:50pm **Lessons learnt during Conference and definition of 2021 priorities**

6:55pm – 7pm ***Conclusions and end of Conference***