Welcome
Improving new drug development for children and adolescents with cancer

The value of working together
Working together: a journey......

Where to go?

2011
London

2013
Paris
Improving

2015
Vienna
Prioritising

2016
Brussels
Accelerating

2017

2018
7TH ACCELERATE PAEDIATRIC ONCOLOGY CONFERENCE
14-15 FEBRUARY 2019 | BRUSSELS, BELGIUM

In partnership with:
Improving new drug development for children and adolescents with cancer

A global endeavour
In 2018 ACCELERATE became an international platform.
A truly International Conference
is supported by:
Steering Committee

Administrative support by SIOPE and ITCC

Projet Management Team

Pediatric Strategy Forums

Annual Conference
Terms of reference
ACCELERATE-ing Pediatric Oncology Drug Discovery and Development
www.accelerate-platform.eu
The oncology paradox in 2018

Many drugs in adults
Adult disease – based pediatric developments

• Waived or delayed pediatric developments
• Poor access to pediatric patients

Rare patients

• Poor access to innovation
New oncology drug development for children: the goal

Many drugs in adults
MOA* – based development

Specific pediatric drugs

*Mechanism of action
Better Medicines for Children From Concept to Reality

PROGRESS REPORT ON THE PAEDIATRIC REGULATION (EC) N°1901/2006

COM (2013) 443 FINAL
No blame! No shame!
Generate data and find solutions
1. Pediatric development should be based on drug mechanism of action instead of adult indication

2. Prioritisation should be set up to choose compounds to be evaluated or not in children
   • Based on MOA, needs, feasibility
   • Using stronger biological and preclinical data

3. Reduce delays in starting pediatric development

4. Break the 18 years dogma

5. New incentives and rewards
1. Mechanism of action based developments
Prioritisation

Based on MOA, needs and feasibility

Using stronger biological and preclinical data
Break the 18 years dogma

Fostering Age Inclusive Research

WG5
Fostering Age Inclusive Research
(FAIR trials)

Nathalie Gaspar

Chris Copland
New incentives and rewards

New models for development

WG4
Setting Up New Business Models and Ways to Invest in Paediatric Oncology Research and Drug Development

Delphine Heenen
Sam Blackman
1. Pediatric development should be based on drug mechanism of action instead of adult indication

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   • Based on MOA, needs, feasibility
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3. Reduce delays in starting pediatric development

4. Break the 18 years dogma

5. New incentives and rewards
Further Development of Paediatric Strategy Forums

Breakout 1
Co-chairs: Andy Pearson, ACCELERATE
Darshan Wariabharaj, Janssen Research & Development

How to implement Mechanism of Action and Biology-driven Developments of Oncology Drugs for Children and Adolescents in the new Regulatory Environment?
Co-chairs: Peter Adamson, Children Hospital of Philadelphia
Patricia Blanc, Imagine for Margo

Breakout 2
How to strengthen International Cooperation?
Co-chairs: Greg Reaman, Food and Drug Administration
Nicole Scobie, Zoë4life

Breakout 3
Readdressing the Needs for long-term Follow up
Co-chairs: Mark Kieran, Bristol-Myers Squibb
Danielle Horton Taylor, Unite2Cure

Breakout 4
Designing and conducting Investigator-initiated Clinical Trials of new Drugs to meet the regulatory Requirements for Approval by Health Authorities
Co-chairs: Pam Kearns, University of Birmingham
Elly Barrv. Pfizer
### SESSION 7 - Wrap-up and 2019 Action Plan

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>15h00</td>
<td>Defining the 2019 ACCELERATE Action Plan</td>
<td>All participants</td>
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<td>16h15</td>
<td>Conclusions</td>
<td>Gilles Vassal, ACCELERATE Chair</td>
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<td>16h30</td>
<td>End of Conference</td>
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**2019 WORKPLAN**
New oncology drug development for children: an international collaboration

SCIENCE

NEEDS

Many drugs in adults
MOA* – based development and prioritisation

PRIORITISATION

Specific pediatric drugs

Work together (all stakeholders)
In a favorable regulatory environment
Thank you

Andy
Pearson
The ACCELERATE Conference Team

Andrea Demadonna
Elena Botanina
Carole Lecinse
Jerome Ducroq
Jackie Mellese
Marta Kania
Thanks to
Thanks to you

Happy Valentine's Day!

International Childhood Cancer Day