

ACCELERATE

INNOVATION FOR CHILDREN AND ADOLESCENTS WITH CANCER

2017 conference: WRAP up and 2017 objectives



Objectives 2017 - 2020

Three objectives over the next three years:

1. Development of Pediatric Strategy Forums
2. Implementation of the « break the 18y dogma » program
3. Setting up new business models and ways to invest in pediatric oncology research and drug development

These objectives were defined with all participants to the 2017 ACCELERATE conference and agreed upon in the last session of the meeting, and then approved by the ACCELERATE steering committee on March the 16th, 2017 .



Paediatric Strategy Forums

(as of 2017)

- **Objective** - provide a unique opportunity for interaction between all stakeholders (regulators, pharmaceutical companies, clinical and researcher academics and patient representatives) on topics requiring open discussion in drug development in children and adolescents with malignancy
- **Paediatric Strategy Forum** - scientific meeting to **share** information and advance learning which will inform a paediatric drug development strategy and subsequent decisions
- **Paediatric Strategy Forum** - introduce innovative treatments into the standard care of very rare children with cancer

Reference : Pearson et al. Eur J Cancer, 62:124, 2016

Pediatric Strategy Forums

- To be further developed and repeated
- Collaboration between Accelerate (lead Andy Pearson and Gilles Vassal) and EMA (lead Koen Norga and EMA representative)
- Address strategy by disease and by biological pathways
- Principle : transparency and reporting
- To be defined:
 - How to select topics?
 - How to follow output?
 - How to move further on the concept of prioritisation?
- Agreement (conference 2017) on next 2 topics:
 - Pediatric B-cell malignancies (late 2017)
 - Checkpoint inhibitors (early 2018)

« Break the 18y dogma » program

- Lead by Nathalie Gaspar (Gustave Roussy) and Chris Copland (Unite2cure)
- Create a new small dedicated workgroup
- Implementation plan will include (but be not limited to):
 - contact Accelerate members and ask which next trial could be a demonstration and success. Need to identify 2 to 3 cases for success
 - consider preparing tool kits (protocol templates) to share
 - consider qualification of the paper by EMA
 - share with other specialties, ie cystic fibrosis
 - Share with ethic committees and IRBs
- Set up a strategy for awareness and communication

New business models and ways to invest in pediatric oncology research and drug development

- Led by Patricia Blanc (Unite2cure) and Raphael Rousseau (Genentech-Roche)
- Create a new working group
- Interaction with the US
- To address :
 - first in child and repurposing,
 - cooperation with academia and principle of intend to file,
 - Venture Capitals and Charities,
 - precompetitive public private partnerships,
 - derisking models,.....

Decisions on the 3 working groups (2014 – 2017)

- **WG1 (improving development strategy)**
 - Work achieved and delivered with 3 outputs :
 - 1) mechanism-of-action based development strategy
 - 2) proof of concept of pediatric strategy forums
 - 3) the 18 year dogma
 - Implementation in the 2017 – 2020 Work program (Pediatric strategy forums and « Break the 18 year dogma » programs)
- **WG2 (new incentives)**
 - Work accomplished, recommendations made on better incentives within the Paediatric Medicine Regulation, to be published soon
 - Continuation in the in the 2017 – 2020 Work program with a new working group on “new business models and ways to invest”
- **WG3 (long term follow up)**
 - Work accomplished highlighting the needs, white paper to be published
 - For the time being, long term follow up of children receiving new oncology medicines will be performed within in the ongoing academic long-term follow up programs, including the SIOPE survivorship passport.

Next



Conference

March 2018

Watch the ACCELERATE website
for information on pediatric strategy forums

www.accelerate-platform.eu