



ACCELERATE

INNOVATION FOR CHILDREN AND ADOLESCENTS WITH CANCER

ACCELERATE PLATFORM (CDDF-ITCC-SIOPE MULTI-STAKEHOLDER PLATFORM)

5th ACCELERATE Paediatric Oncology Conference

Brussels, Belgium
2–3 March 2017

PROGRAMME



PROGRAMME

Day 1 Thursday 2nd March 2017

13:30 **Introduction**
Gilles Vassal (ITCC/Gustave Roussy, FR)

SESSION 1 : LEARNING FROM SUCCESS AND FAILURE IN PEDIATRIC ONCOLOGY DRUG DEVELOPMENT


Chairs: Anne Goeres (Unite2Cure, LU) & Ralf Herold (European Medicines Agency, UK)

13:50 **Successful practice changing development plans: Rituximab in Burkitt lymphoma**
Véronique Minard (Gustave Roussy, FR)

14:05 **Unfeasible development plans : Vemurafenib in melanoma in adolescents**
Stephen Simko (Genentech/Roche, USA)

14:20 **Feasibility of Mechanism of Action driven development plans: Dabrafenib in B-RAF mutated pediatric malignancies**
Mark Russo (Novartis, USA)

14:35 **Delays in implementing pediatric oncology developments: Inotuzumab in leukemias**
Peter Adamson (Children's Oncology Group /The Children's Hospital of Philadelphia, USA)

14:50  **Round table discussion : How to build on lessons learnt ?**
Participants: Cesare Spadoni (aPODD Foundation, UK) & Jaroslav Sterba (University Hospital Brno, Czech Republic)

16:00  Coffee break

SESSION 2 : WHERE ARE WE AFTER 10 YEARS?

Chairs: Martin Schrappe (SIOPE, DE) & Lida Pacaud (Novartis, CH)


16:30 **The 10 year EMA report on the EU regulation with a focus on oncology**
Koen Norga (EMA / Antwerp University Hospital, BE)

16:45 **Preparing the 10year report: state of play, public consultation and economic impact**
Florian Schmidt (European Commission - DG Santé, BE)

17:00 **Impact of the US regulations (BPCA, PREA) on pediatric oncology development**
Martha Donoghue (FDA, US)

17:15 **Raising awareness and the EU political agenda**
Delphine Heenen (Unite2Cure, BE)

17:30 **Raising awareness in the US**
Susan Weiner (CCCA - Children's Cause for Cancer Advocacy, USA)

17:45  **Round table discussion: what are the changes needed?**
Participants: Pamela Kearns (Cancer Research UK / University of Birmingham, UK)

18:45 End of day 1

19:45  Networking dinner - The Twelve Restaurant, Thon Hotel EU

Day 2 Friday 3rd March 2017

SESSION 3 : ONGOING INITIATIVES TO IMPROVE THE EFFICIENCY OF PEDIATRIC DRUG DEVELOPMENT

Chair: Chris Copland (Unite2Cure, UK), Franca Ligas (European Medicines Agency, UK)

08:30 **Scrutinizing class waived oncology drugs: could it be done differently?**

Andy Pearson (ITCC, UK)

08:45 **The IML2 ITCC-P4 pediatric preclinical proof of concept platform**

Louis Stancato (Lilly, USA)

09:00 **Getting rid of the 18-year dogma**

Nathalie Gaspar (Gustave Roussy, FR)

09:15 **Pediatric Strategy Forum : a new concept proposed by ACCELERATE**

Andy Pearson (ITCC, UK)

09:30 **Developing new therapies for children with neuromuscular diseases**

Emma Heslop (Newcastle University, UK)

09:45 **Complementary questions to speakers**

10:00  Coffee break

10.30-12.00  **Round table discussion: identify barriers and propose solutions**

Moderator: Gilles Vassal (ITCC/Gustave Roussy, FR)

Participants: Peter Adamson (Children's Oncology Group / The Children's Hospital of Philadelphia, USA), Samuel Blackman (Silverback Therapeutics, USA), Vickie Buenger (Coalition Against Childhood Cancer, USA), Ralf Herold (European Medicines Agency, UK), Michelle Rashford (BMS, USA), Nicole Scobie (Childhood Cancer International, CH)

12:00  Lunch

SESSION 4 : ACCELERATING

Chairs: Nicole Scobie (Childhood Cancer International, CH) & Samuel Blackman (Silverback Therapeutics, USA)

13:00 **Setting up the base line : Timing for approval of oncology PIPs**

Gilles Vassal (ITCC/Gustave Roussy, FR)

13:15 **The iMATRIX**

Hubert Caron (Roche, NL)

13:30 **The Pediatric MATCH trial**

Peter Adamson (Children's Oncology Group / The Children's Hospital of Philadelphia, USA)

13:45 **The ITCC strategy**

Birgit Georger (Gustave Roussy, France)


14:00  **Round table discussion: how to accelerate innovation for children and adolescents with cancer?**

Participants: Patricia Blanc (Unite2Cure, Imagine for Margo, FR), Martha Donoghue (FDA, USA)

14:45  Coffee break

SESSION 5 : INVESTING IN PEDIATRIC ONCOLOGY DRUG DEVELOPMENT

Chairs: Jeffrey Skolnik (Inovio Pharmaceuticals, USA) & Patricia Blanc (Unite2Cure, Imagine for Margo, FR)

- PROGRAMME
- 15:15 **Proposals for change from Accelerate**
Pamela Kearns (Cancer Research UK / University of Birmingham, UK)
 - 15:30 **New perspectives in pediatric oncology drug development**
Raphaël Rousseau (Genentech/Roche, USA)
 - 15:45 **CureSearch Catapult - Building a Sustainable Funding Model to Propel Promising Research into the Clinic**
Laura Thrall (CureSearch for Children's Cancer) - via phone conference
 - 16:00  **Round table discussion: think out of the box - how to fund and invest in pediatric oncology drug development?**
Participants: Anne Goeres (Unite2Cure, LU) & Delphine Heenen (Unite2Cure, BE)
 - 17:00 **Conclusion - Defining next steps forward together**
Gilles Vassal (ITCC/Gustave Roussy, FR)
 - 17:45 End of the conference

Event Outline

The conference is part of a unique multi-stakeholder joint initiative, the ACCELERATE multi-stakeholder Platform. Co-organised by CDDF, ITCC and SIOPE, this platform provides a transparent forum enabling patients and parents' organisations, academic paediatric oncologists and haematologists, pharmaceutical companies and EU regulatory network representatives to collaborate and jointly address specific obstacles to a faster and more effective treatments for children and adolescents with cancer, including the needed changes to the Paediatric Medicines Regulation.

Innovative therapies could target several paediatric malignancies and, thus, save many young lives. However today less than 1 in 10 children in relapse with a terminal cancer has access to these types of medicines, and investment in paediatric oncology drug development is insufficient.

Paediatric drug development is currently regulated in Europe via the EU Paediatric Regulation (EC No 1901/2006). 2017 is the year of the 10th year report by the European Commission on this Regulation: 10 years of learning, 10 years of success and failure, 10 years of interaction between stakeholders; a huge experience to build upon in order to accelerate innovation for children and adolescents with cancer.

The annual conference is a unique occasion for high-level experts to reflect upon and discuss concrete proposals to accelerate new oncology drug development for children and adolescents.

Programme Committee

- Gilles Vassal (ACCELERATE platform chair/Gustave Roussy, France)
- Patricia Blanc (Imagine for Margo, France & Unite2Cure)
- Silvia Chioato (Pfizer, Italy)
- Ralf Herold (European Medicines Agency, UK)
- Peter Lack (Childhood Cancer International, Switzerland & Unite2Cure)
- Koenraad Norga (Antwerp University Hospital, Belgium & vice-chair PDCO, EMA)
- Andrew Pearson (The Institute of Cancer Research, UK & ITCC)
- Raphael Rousseau (Roche Genentech, USA)
- Stefan Schwoch (Eli Lilly, UK)
- Nicole Scobie (Childhood Cancer International, Switzerland & Unite2Cure)
- Jeffrey Skolnik (Inovio Pharmaceuticals, USA)
- Heinz Zwierzina (Innsbruck University - CDDF, Austria)

Venue

Thon Hotel EU
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Conference Secretariat

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