

The CureSearch Pediatric Early Development Symposium was held virtually on October 1-2, 2020. This inaugural event convened representatives from all areas of pediatric oncology: pharmaceutical and biotechnology companies, clinical research organizations, academic leaders, parents and patient advocates, venture capitalists, regulators, and like-minded partners. Attendees and speakers participated from across the United States, Canada, the United Kingdom, the Netherlands, Italy, Germany, Switzerland and France.

The two-day meeting featured interactive sessions exploring key, timely topics in iPSP and PSP development: The Evolution of Cooperative and Collaborative Groups; Formulation Consideration for Pediatrics; Advancing Promising Agents Into The Clinic: What Is An “Acceptable” Preclinical Data Package?; Clinical Development Considerations: Lessons Learned from PIPs and PSPs; Nuts and Bolts of Writing and Negotiating Successful PIPs and PSPs; Global P(a)ediatric Development: How To Engage Internally and Enable External Alignment; and PIP/PSP Development and Implementation.

The recurring themes through the Symposium were the urgent need for **early and frequent collaboration**, and expanded opportunity for **CureSearch to drive this collaboration as a connector and resource** for academic and industry leaders.

2020 Pediatric Early Development Symposium Action Plan

Based on robust panel discussions and audience participation, CureSearch has identified three key opportunities below. Over the next 12 months, working collaboratively with global stakeholder and volunteer leaders, CureSearch will execute on the following strategies:

Strategy

Promote global collaboration across all roles in pediatric drug development

Develop a comprehensive list of current industry leaders who trained as pediatric oncologists and are interested in collaboration to advance pediatric drug development

- Consult with CureSearch Industry and Scientific Advisory Councils to begin creation of a global roster
- CureSearch has expanded the participants in our working groups, mentorship meeting planning and invitations to contribute to and present at meetings based on this list. CureSearch will continue to build connections with pediatric oncology champions in industry and integrate them into CureSearch activities.

Design and launch a virtual open-forum for Industry and Academic leaders to ask questions, request assistance, connect, and collaborate

- Identify core members to actively engage on platform
- CureSearch has explored several platforms and discussed implementation options with stakeholders including industry and academic leaders and Young Investigators. In 2022, CureSearch will explore sponsorship opportunities and aims to open this forum in association with the 2022 PEDS meeting.

Provide pediatric drug development resources to stakeholders

Bridge the educational gap for academic leaders on the drug development process

- CME credits have been explored but are not implementable in a single year. CureSearch will continue to explore opportunities for deployment of educational information.
- Create a group of academic and industry mentors and facilitate the development of a mentorship meeting.

Create a Pediatric Oncology Drug Development Resource page on curesearch.org to include:

- Global regulatory processes and links to regulation
- Global patient advocacy groups and consortiums
- Case Studies, White Papers & Studies

Address areas of unmet need in clinical development for children with cancer

Drive collaborative discussion around optimal clinical trial designs

- Create a venue of discussion for engaging with consortia globally
- Collaborate with like-minded partners to explore increasing industry-sponsored master protocols

Discuss the current state of research-only biopsies from children

- Host the 2021 CureSearch Virtual Summit Series
- Create comprehensive list of biorepositories housing pediatric cancer biospecimens to list on the CureSearch Drug Development Resource page that will be expanded in 2022.

Create a working group to explore the unique issues related to regulatory submissions for cellular and immunotherapies for pediatric cancer

- Identify Chair and members
- Establish the preclinical data needs for regulatory filings

Actions

