

2020 CureSearch Pediatric Early Development Symposium

Developing iPSPs and PIPs in an Evolving Regulatory Landscape

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
- Invite greater pediatric oncology stakeholders to participate and contribute

Provide pediatric drug development resources to stakeholders

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

- Explore providing in collaboration with a like-minded partner, a Continuing Medical Education (CME) training
- Create a group of academic and industry mentors and facilitate one-on-one mentoring for researchers

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

Drive collaborative discussion around optimal clinical trial designs

- Create working group to address 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 pediatric oncology biorepositories to list on CureSearch Drug Development Resource page

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

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
- Invite academic institutions and industry leaders to participate

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



CURESEARCH
FOR CHILDREN'S CANCER

Updated December 2020