

2022 CureSearch Pediatric Early Development Symposium (PEDS) Leveraging Big Data to Advance Pediatric Clinical Trials

The CureSearch Pediatric Early Development Symposium (PEDS) was held virtually on October 12-14, 2022. This third annual 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 participated in a three-day meeting addressing the following topics:

- The current landscape of clinical trial innovation
- The promise and practicalities of decentralized trials
- Real-world evidence and external controls
- Innovations in working with Big Data
- Operationalizing the ideal clinical trial

The recurring themes throughout the Symposium were that pediatric drug development **must be treated as a global enterprise; that more collaboration is necessary between investigators (academics) and organizations, including industry, to generate data that move regulatory requirements forward in relevant targets; and that there must be a concerted effort to improve data collection through quality standards and simplification.**

Based on robust panel discussions and participant insight, CureSearch has identified several key impact areas for follow-up initiatives. Working collaboratively with global stakeholder and volunteer leaders, CureSearch will execute the following strategies:

I. Strategy: Increase the visibility of decentralized trials in the pediatric oncology space, and create viable clinical opportunities for their execution.

Action: Serving an educational role, CureSearch will increase access to pediatric clinical trials by collaborating with CRO connections to identify barriers to decentralized trials within the pediatric oncology space, and engaging young investigators in the field. It is anticipated that a publication will result from the 2022 PEDS work, highlighting barriers in the field.

II. Strategy: Consider how real-world evidence might be used in the place of randomized clinical trials for pediatric oncology drug development and novel indications.

Action: Supporting the community's use of RWE — CureSearch will facilitate interactions between key stakeholders through multiple avenues, including connecting with patient advocates to improve clinical trial access, and releasing responsive RFAs with co-funding partners.

III. Strategy: Make Big Data practical, approachable, and available to the pediatric cancer research community, including academics and pharmaceutical researchers.

Action: The CureSearch Summit in April 2023 will address the mechanisms by which pediatric oncology might serve as a model for implementing machine learning and artificial intelligence.