Conducting Pediatric Clinical Trials

with Heart

Pediatric drug development requires special care in recruitment to address ethical, scientific, and logistical challenges. We understand the compassionate, specialized clinical and regulatory expertise required when working with vulnerable pediatric populations and their families. We have experience working with international pediatric networks, opinion leaders, patient advocacy groups, and regulatory bodies, with many of our executives actively involved in the industry, and can capitalize on relationships with global partners invested in this patient population.

Addressing the Growing Need for Medications for Children

Pediatric development plans are a requirement for all new medicines, indications, dosing forms, regimens, and routes of administration, and pediatric clinical research is on the rise. Additionally, all applications for marketing authorization for new medicines must include the results of studies in children as described in an agreed-upon pediatric plan, unless the medicine is exempt because of a deferral or waiver.

Understanding the Diversity of Pediatric Clinical Trials

At Synteract, we are at the forefront of working with sponsors in pediatric drug development with broad experience in ~100 studies across 6 continents, in 62+ countries.

Over the course of our history, we have performed:

95+ PEDIATRIC CLINICAL TRIALS  17 INDICATIONS  1,395 SITES  24,100 PATIENTS

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We can assist with all aspects of pediatric drug development, including medical and regulatory strategy; trial design; creation, submission, follow-up and updates of PPSs and PIPs, and more. Our clinical experts will guide you through evolving global regulations and data requirements each step of the way.

95+ Total Studies

A - Respiratory: 16%
B - Endocrinology: 14%
C - Gastroenterology: 10%
D - Infectious Disease: 10%
E - Hematology: 9%
F - Dermatology: 7%
G - Metabolic: 7%
H - Dental: 5%
I - Neurology: 4%
J - Nutrition: 3%
K - Oncology: 3%
L - Cardiology: 2%
M - Ophthalmology: 2%
N - Psychiatry: 1%
O - Cosmetic: 1%
Pediatric Drug Development: Regulatory Updates to Know

All applications for marketing authorization for new medicines must include the results of studies in children as described in the pediatric plan, unless the medicine is exempt because of a deferral or waiver. Pediatric legislation internationally has led to better medicines for children, but gaps still exist that regulatory agencies want to close.

How will pediatric drug development requirements impact sponsors?

In August 2017, the United States passed the FDA Reauthorization Act and with it the Research to Accelerate Cures and Equity for Children Act (RACE). RACE will eliminate exemptions and improve opportunities for cancer drugs development for children by:
- Requiring companies to do PREA studies in children when the molecular target of their drug is relevant to children’s cancer
- Ending exemption of PREA obligations for cancer drugs with orphan designations if the molecular target of the drug is relevant to children’s cancer

In August 2018, the FDA will publish a list of molecular targets substantially relevant to growth and progression of pediatric cancer. It will also publish a list of molecular targets substantially relevant to children’s cancer drugs development for children by:
- Requiring companies to do PREA studies in children when the molecular target of their drug is relevant to children’s cancer
- Ending exemption of PREA obligations for cancer drugs with orphan designations if the molecular target of the drug is relevant to children’s cancer

In the EU, the Commission report on 10 years EU Pediatric Regulation (October 26, 2017) showed encouraging impact of the Pediatric Regulation overall, though the regulation appears most effective when adult and pediatric needs overlap.

Global Progress Continues

Fewer advances have been made in diseases that are unique to children. While some instances of over- or under-compensating drug developers with financial rewards exist, overall benefits seem to outweigh costs.

Therefore, the European Commission does not currently recommend re-opening the leg-