



Accelerating Pediatric Drug Development with Biosimulation and Regulatory Science

Pediatric drug development is a complex and challenging process, which has only been exacerbated by an ever-changing regulatory landscape. With an increased demand to develop a scientific-based approach that's acceptable to global regulatory authorities, it's crucial to reassess your pediatric drug discovery and development strategies to achieve regulatory and commercial success.

Certara applies a strategic and programmatic approach to pediatric drug development, underpinned by clinical pharmacology, regulatory expertise, and quantitative approaches. Our multidisciplinary team of experts can help you achieve regulatory success, strengthen the feasibility of studies, and reinforce safety for pediatric practices.

ADVANCE YOUR PEDIATRIC PROGRAM WITH CERTARA

With experience working on over 100 pediatric programs, Certara's expertise in pediatric drug development is unparalleled. Our multidisciplinary team includes drug development and regulatory strategists with significant experience designing and stewarding complex pediatric programs.

Set your program up for success

Certara's quantitative methods leverage existing data to develop and iterate clinical trial design while exploring alternative dosing scenarios, in silico patient responses, drug-drug interactions, and whole trial outcomes.

Empower drug performance predictions

Our consultants also use the Simcyp™ Pediatric PBPK Simulator—the industry's most sophisticated physiologically-based pharmacokinetic (PBPK) technology—for modeling drug performance and assessing drug-drug interactions in neonates, infants, and children.

Strengthen regulatory engagement and submissions

Our regulatory expertise in pediatric practices, programs, and development spans more than 15 therapeutic areas, including oncology, infectious diseases, and cardiovascular disorders. Core competencies include consulting, writing, preparing and managing documents—including pediatric investigational plans (PIPs) and pediatric study plans (PSPs).

Discover how Certara can accelerate your pediatric drug development program.

[Learn more at certara.com/services/practice-areas/pediatric-practice/](https://www.certara.com/services/practice-areas/pediatric-practice/)

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 62 countries.

For more information, visit www.certara.com.