



Minimize the Exposure of Children to Experimental Therapies

Scientific capabilities innovation

Certara is a leading drug development and drug safety consultancy trusted by thousands of biopharmaceutical companies worldwide. Offering a broad range of scientific consulting services and software solutions, from early drug discovery, to clinical development through product commercialization, Certara is the most comprehensive single-source solutions provider in the market. By coupling industry-leading technology with a unique focus on model-based drug development and expert advisement, Certara is uniquely qualified to guide and enable organizations to make better predictions and decisions, improve drug development efficiencies and achieve faster time to market.

Clinical trial challenges in children

It is well understood that the challenges and complexities of conducting clinical studies in children are well recognized.¹ Population modeling and simulation offers powerful methods for leveraging prior knowledge to support dosing, trial design and regulatory submissions in pediatric patients. As the advantages and benefits of pharmacometric analysis for improved drug development and regulatory decision-making have become increasingly well documented, the FDA has challenged the industry to more rigorously apply modeling and simulation to double the success rate of pediatric trials.²

Leverage our knowledge of drug safety and efficacy in pediatric indications

The Food and Drug Administration (FDA) and European Medicines Agency (EMA) are requiring more evidence of pediatric safety and efficacy, adding new pressures to developing pediatric drugs. You need a drug development partner with extensive expertise in pediatric therapies.

Certara is uniquely qualified to provide both insight and technology resources to help you not only meet regulatory requirements but help you minimize the exposure of children to experimental therapies. Certara's consultancies have unparalleled extensive experience helping to maximize knowledge of drug safety and efficacy in pediatric indications.

Understand our experience in pediatric drug development

Certara has conducted more than 50 projects in pediatrics, including drugs with indications for pain, hematological diseases, and rare genetic disorders. Certara's methods leverage prior information from pre-clinical studies, adult trials, literature data, and pediatric studies of related indications or drug actions. Building that knowledge into models of patient physiology, drug actions, and trial

Benefits of Partnering with Certara

- Improved regulatory interactions with faster approvals and increased chance of success
- Optimized study designs with blood draw schedules and inclusion/exclusion criteria that are appropriate for pediatric patients
- Quantitative model of the relationship between the dosing regimen and the safety/efficacy profile across age groups
- Visibility into subpopulation and maturational effects
- Potentially reduce or eliminate the need for certain pediatric studies

Example Methods for Pediatrics

- Predicting drug exposure and response across age strata based on adult, pre-clinical and literature data
- Scaling dose from adults to pediatrics, notably predicting clearance in children
- Modeling maturational changes in pharmacokinetics (PK) and pharmacodynamics (PD) based on organ development and disease process in children
- Anticipating potential drug-drug interactions specific to pediatrics
- Extrapolating PK and PD to scenarios where studies would be difficult or impossible to perform
- Ensuring scientifically based, minimum sufficient sample sizes and trial power

characteristics enables you and your team to explore “what if” scenarios for dosing, *in silico* patient responses, drug-drug interactions and whole trial outcomes.

With the increased certainty these methods provide, our consultants have helped sponsors ensure informative pediatric trials and gain approvals based on as few as 18-24 pediatric patients, spread across multiple age cohorts—with minimal blood draws and other invasive procedures.

Simcyp Consultancy leverages the Simcyp Pediatric Simulator, which includes a full physiologically-based pharmacokinetic (PBPK) model together with extensive libraries on demographics, developmental physiology and the ontogeny of drug elimination pathways. It allows population variability in PK to be simulated over any age range and potential drug-drug interactions to be quantified.

Reduce your risk in pediatric drug development

Certara’s expertise in quantitative pharmacology and pharmacometrics reduces risk in pediatric drug development. We bring experience in small molecules and biologics in neonates, infants, children and adolescents to help you build a confident risk-benefit profile to support approval.

Certara is your partner in regulatory consultations for study design, submissions and meetings with FDA/EMA.

Expertise in regulatory writing

Synchrogenix, a Certara company, partners with pharmaceutical and biotech companies to develop submission documents for global regulatory agencies. Focusing on this crucial aspect of the drug development process has allowed Synchrogenix’s experts to hone a unique methodology and build a team of regulatory writers who are thought leaders in the field.

- Synchrogenix’s sole focus is regulatory writing
- Over 28 years of regulatory writing and document support experience
- 60 in-house writers and editors
- Flexible and scalable solution
- Complete outsourcing capability

Pre-clinical/Phase 1:

- SOPs-GCP
- Clinical development plan
- IND/CTA/IMPD
- Meeting requests
- Agency responses
- Target product profile
- Briefing documents
- PIPs/PSPs

Phase 1-3:

- Study reports/narratives
- Investigator’s brochures
- Protocols
- Clinical trials registration and results posting
- Labeling
- DSUR
- Annual reports
- NDA/MAA/BLA/ANDA/ IDE

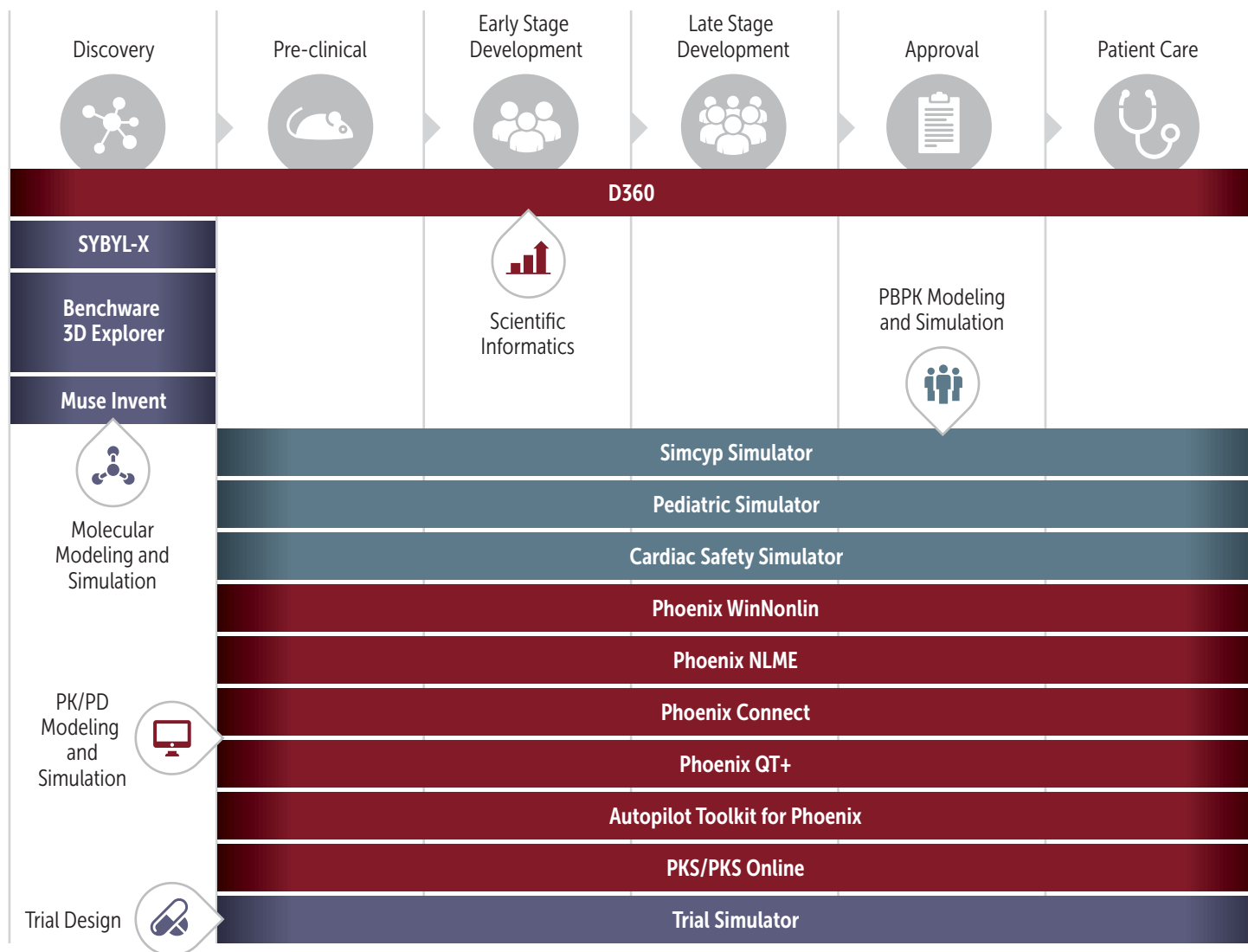
Post-marketing:

- Life cycle management
- Line extensions
- Safety reports
 - Annual safety
 - PSUR/PADER/P
- BRER
- Document maintenance

A name you can trust

Whatever your drug development challenges, Certara has the experience, the technology and the resources to provide you with the right solution. Our wide ranging capabilities enable Certara to address all your needs with a comprehensive, single-source solution that can help you make precise, proactive and breakthrough decisions. There's simply no substitute for that kind of experience, commitment and leadership.

Certara Software Services



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About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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