Certara Strategic Consulting: Drug Development and Pharmacometrics Leadership

Certara Strategic Consulting, the largest and most comprehensive model-informed drug development and strategic pharmacometrics organization, brings together the resources of Certara’s leading consulting group, Pharsight Consulting Services (PCS), with scientific powerhouse, Quantitative Solutions, and now, d3 Medicine.

Certara Strategic Consulting (CSC) delivers value by integrating advanced modeling and simulation approaches into the most crucial drug development deliverables—to inform internal decision-making and strengthen global regulatory submissions.

Leveraging our experience working on thousands of key drug development projects on behalf of hundreds of biopharmaceutical companies, CSC brings its track record of success and a broad range of expertise to each assignment.

The CSC team provides high-quality, regulatory-compliant PK/PD, exposure-response, disease modeling and other quantitative analyses and modeling for internal decision-making and regulatory submission packages. Our scientists support pre-clinical and clinical study analysis for new drug approvals, line extensions, in-licensing options, and product portfolio decisions.

Valued Partnerships are Key to Our Mission

Our team of more than 100 scientists, consultants and industry professionals can develop and implement a strategic clinical pharmacology plan for your compound, program or portfolio.

Each CSC team member works to build a comprehensive knowledge-base of drug discovery, pre-clinical, early-phase clinical, literature, and competitor data, which can be used to optimize decisions in later development, including the “go/no go” that will lead to commercial success. We use quantitative methods to assess trends for safety and efficacy across exposure ranges, and provide support for dose justification and dose modifications. These analyses are also used to inform post-approval study decisions.

Our work allows knowledge and wisdom to be carried over from one phase of the drug development process to the next. The companies that benefit most from this approach will systematically integrate the technology across all phases and tap into what has been known about a drug candidate to optimize clinical trials.

Certara Strategic Consulting, along with the other Certara divisions, offer a full range of clinical pharmacology, modeling and simulation, and regulatory advisory services, including Simcyp PBPK, QSP, and Synchrogenix regulatory writing.
We can provide you with additional resources and specific expertise to support you along the full value chain from data-management, to analysis and interpretation and subsequent integration in reporting and filings.

**Scientific and Regulatory Leadership**

Deeply committed to our mission of bringing new, safer therapies to patients, we are scientists working with our clients to advance the discipline of model-informed drug development. That commitment manifests itself across Certara. It is evident in the hundreds of peer-review papers written by our team. It can also be seen in our integration of mechanistic PBPK and QSP modeling with top down PK/PD approaches. We have incorporated models alongside trials to minimize the impact on clinical volunteers. We have led the industry by developing model-based meta-analysis and clinical outcomes databases to determine comparative effectiveness of new drug candidates and improve competitiveness. And it is evidenced in the hundreds of drug approvals that our modeling and simulation and global regulatory writing professionals have supported in recent years. Ultimately, it enables us to help our clients successfully achieve regulatory and commercial milestones, and most importantly, bring safer and more effective medicines to patients.

**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.

For more information visit www.certara.com or email sales@certara.com.