How Model-informed drug development rescue projects from a risky situation

Certara's Model-Informed Drug Development (MIDD) accelerates regulatory approval and commercial success through a quantitative systems approach. Our global team of 700+ experts in pharmacology and regulatory strategy supports you in minimizing time and costs to achieve your goals.

Urgent support for preparing NDA query responses to PMDA

Mayumi Hasegawa PhD
VP, Certara Drug Development Solutions

Certara provided essential clinical pharmacology and pharmacometrics expertise to a Japanese client facing urgent PMDA NDA queries. By collaborating closely with the client, we conducted detailed simulation analyses and created precise query responses. Our support effectively addressed regulatory challenges, facilitating the client's path toward approval and highlighting the importance of expert guidance during critical times.

Support for justification of restart of the clinical trial

Paul Martin PhD
Sr. Director, Certara
Drug Development Solutions

A US client required assistance to justify being taken off clinical hold for a drug being developed in oncology. Certara's clinical pharmacology team was assigned as a member of the project team. We performed modeling analyses to understand exposure-response for efficacy, safety, QTc, and biomarkers, as well as the translation of doses in mouse TGI studies to the clinic. The analyses contributed to the briefing book, justifying the restart of the trial. The trial has now resumed in the clinic.

Overcoming a tight schedule for a NICE submission, CADTH pharmaceutical reviews, and INFARMED query responses

Shuai Fu PhD
Associate Principal Scientist, Certara
Drug Development Solutions

A French client required urgent assistance with indirect treatment comparisons for their NICE submission and support for CADTH and INFARMED queries for their MAA submission. Certara provided comprehensive collaboration across functions, ensuring high-quality results under tight deadlines. This built trust and led to over eight years of successful support for two generations of drug approvals.

Answering questions about risks to potential investors for the joint development

Kevin Hershberger, PhD
Vice President, Certara
Drug Development Solutions

For a Chinese drug discovery client, Certara formed a multidisciplinary team to support them in addressing investor concerns. We independently reviewed the development data package, identifying strengths, risks, and recommendations for mitigating risks. This approach facilitated a clinic-enabling program, leading to a successful co-development collaboration between the client and a major pharmaceutical company shortly afterwards.

Partner with Certara to move your program forward faster to acheive your goals.

Learn more

About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries.
Visit certara.com |