CERTARA

Certara Rescue Story Vol. 2

How Certara MIDD Experts Overcame Client Regulatory Challenges

Certara's Model-Informed Drug Development (MIDD) approach leverages an integrated, quantitative systems methodology to accelerate regulatory approval and commercial success while minimizing time and costs. With a global team of 700+ experts in clinical pharmacology, pharmacometrics, regulatory strategy, and market access, we provide the expertise and dedication needed to help you achieve your goals.

From setback to breakthrough: How Certara rescued a critical drug development program

Florian Chassereau
Director, Clinical Pharmacologist, Certara

In late 2023, a U.S. client turned to Certara after the FDA raised concerns about their dose selection strategy. Our Optimus gap analysis and dose optimization recommendations led to FDA and EMA updated plan approvals, allowing the study to be filed just 2.5 weeks after the final FDA meeting.

Voice of the customer

"Dear Certara team, On behalf of the team, I wanted to extend our thanks to you all for your significant contributions and partnership this year on our program. You all worked under very compressed timelines and dug in with us to tackle all the HA interactions and IND preparations. I'm thrilled to share that the study was successfully filed yesterday, only 2.5 weeks after our last FDA meeting! We could not have done without you as part of the team."

Vice President, Head of Regulatory Affairs
Oncology Therapeutics Company

Rescue in action: Certara's expertise overcomes drug development roadblocks

Optimizing ADC dose escalation: A model-informed solution for identification of an efficacious dose

Arne van Schanke, PhD
Director, Early Development
Certara

A client developing antibody-drug conjugates faced overly conservative starting doses, stretching out FIH study design. Certara's experts leveraged allometric PK predictions and PK/PD modeling to refine dose selection based on exposure rather than preclinical toxic doses. This approach streamlined development, maintained safety, and accelerated patient access to potential benefits.

Pivoting from a planned FIH trial in healthy volunteers to a phase 1 study in oncology patients

Nathalie Rioux, PhD
VP, Head of DMPK-Drug Development Science
Certara

After a pre-IND meeting, a client needed urgent support to shift their first-in-human study to patients instead of healthy volunteers. Certara's DMPK team reviewed data gaps, provided de-risking strategies, and guided additional in vitro DDI studies. With our expertise, the client's IND submission proceeded smoothly, enabling a timely Phase 1 trial launch.

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.
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