CERTARA

Certara supports efficient infectious disease drug development and commercialization.

If you're involved in an infectious disease drug program, then you're well aware of the challenges of this therapeutic area including the high risk and expense of R&D, the difficulty of conducting clinical trials in sensitive populations (children, patients with renal and/or hepatic impairment, and pregnant women), the frequent use of combination therapies which increases the risk of drug-drug interactions (DDIs), and the difficulty in obtaining a return on investment.

At Certara, we have a unique set of disciplines and technologies to address these challenges. We are the industry leader in applying a quantitative decision-making framework across the drug development life cycle, bridging from safety and efficacy to effectiveness.

Infectious Disease Statistics

5.7M

Lower respiratory infections, diarrheal diseases, and tuberculosis rank amongst WHO's top 10 leading causes of global deaths

$103B

The estimated global infectious disease market by 2022, the majority led by anti-virals and vaccines

Trends in Infectious Disease

Global Influenza pandemic, antimicrobial resistance, Ebola and other high threat pathogens, vaccine hesitancy, Dengue, and HIV dominate WHO's Top 10 List of Health Threats

Helping our clients achieve regulatory and commercial success for infectious disease programs

Antibiotics

Population PK modeling[1], QTc (cardiac safety) modeling and analysis[2], PK/PD modeling and related dataset construction[3] supported the early decision-making and regulatory submission of Pretomanid, the third new drug for tuberculosis in almost 50 years.

Antivirals

An integrated clinical pharmacology strategy was applied to optimize clinical trial design, identify safe and effective dosing, and facilitate regulatory approval for the use of Tamiflu in infants.[4-6]

Global Health

Clinical pharmacology, pharmacometrics expertise, and support of translational medicine, regulatory science, and strategy led to the development of moxidectin for the oral treatment of the neglected tropical disease onchocerciasis.[7-9]

Medical countermeasures

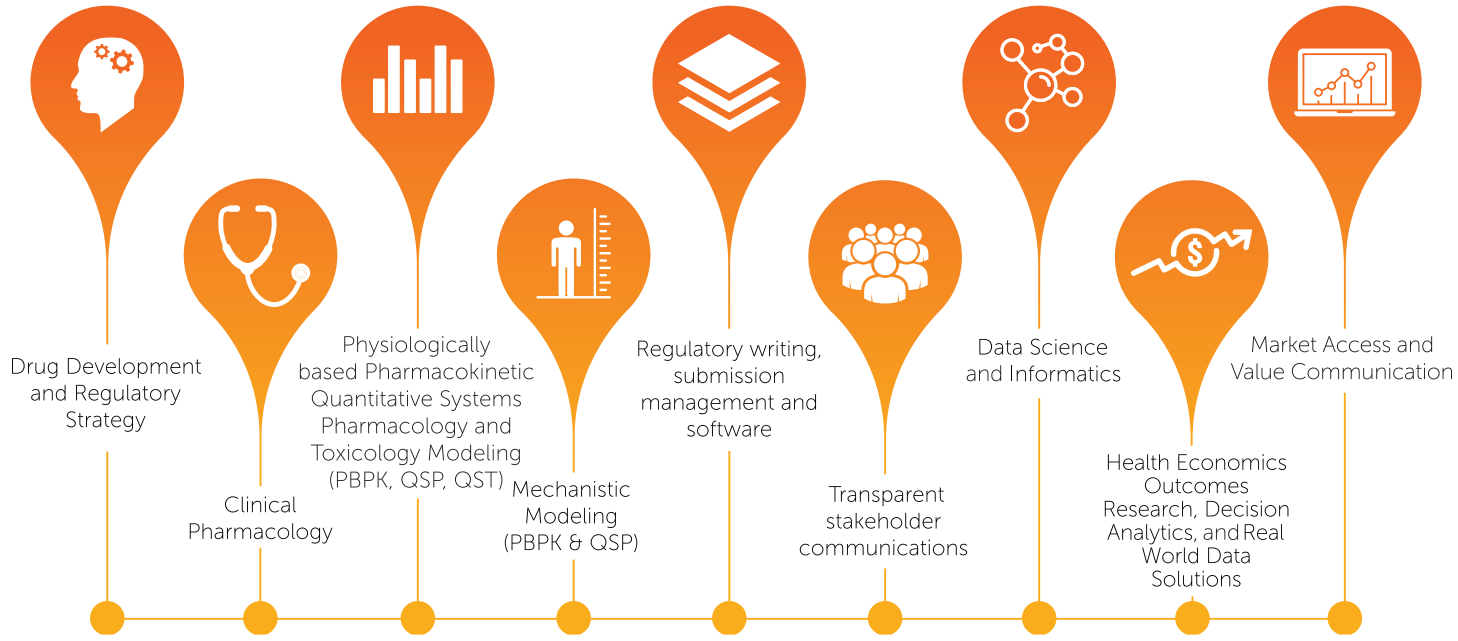
PK/PD dose optimization for bioterrorism studies, where human efficacy studies aren't ethical, aided in the approvals of the Botulism Toxin Heptavalent[10] and Tecovirimat[11], the small molecule therapeutic for smallpox prevention.

Vaccines

M&S approaches were used to predict the timing of influenza vaccine-induced immunity, support vaccine recommendations that better protect maternal-child health, and inform the development new vaccines and their use in pregnant women.[12]

Our proven approach for increasing the reliability and predictability of R&D and payer issues

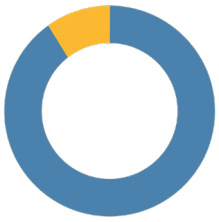
Certara's Capabilities for Anti-Infective Drug Development



Supporting the Development and Approval of Hundreds of New Drugs

Our work covers virtually all therapeutic areas, including oncology, immunology, rare disease, CNS, metabolic and infectious disease, and complex biologics. We can help address the development and patient access challenges associated with special populations, such as pediatrics, geriatrics, co-morbidity and global health. We have unmatched expertise working under unique regulatory programs, such as breakthrough, orphan and priority review, in concert with all major regulatory and global health authorities.

Certara's multidisciplinary teams work with both large pharma and emerging biotech – across all geographies



90+%
of all novel drugs approved by FDA over the past 4 years were supported by Certara software and/or services

200+
global regulatory and health authority submissions in the past 4 years

1,650
active customers in 60 countries

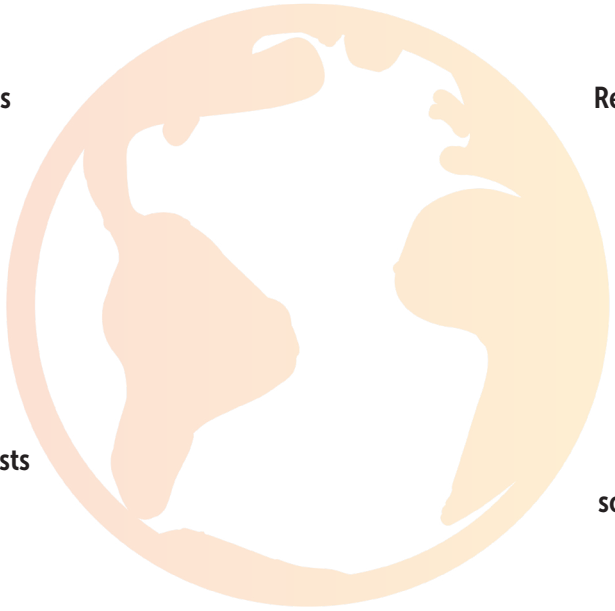
Applying our Multidisciplinary Talent to Accelerate Change

As innovators and disruptive thinkers, we are dedicated to helping our clients develop new therapies and target new unmet medical needs. This requires a diverse team of scientists, mathematicians, software developers, writers and many others coming together to deliver on a promise of improving health worldwide. Today, we employ 850 talented individuals across four continents, each working to deliver medicines that matter.

Certara continues to build a strong team, so we can make a world of a difference

275
Scientific Consultants

250
Regulatory Scientists



100
Market Access Specialists

50
technology & software developers

References

1. Salinger DH, Subramoney V, Everitt D, Nedelman JR. Population pharmacokinetics of pretomanid. Antimicrob Agents Chemother. 2019. doi: AAC.00907-19 [pii].
2. Li H, Salinger DH, Everitt D, et al. Long-term effects on QT prolongation of pretomanid, alone and in combinations, in patients with tuberculosis. Antimicrob Agents Chemother. 2019. doi: AAC.00445-19 [pii].
3. Salinger DH, Nedelman JR, Mendel C, Spigelman M, Hermann DJ. Daily dosing for bedaquiline in patients with tuberculosis. Antimicrob Agents Chemother. 2019. doi: AAC.00463-19 [pii].
4. Kamal MA, Van Wart SA, Rayner CR, et al. Population pharmacokinetics of oseltamivir: Pediatrics through geriatrics. Antimicrob Agents Chemother. 2013;57(8):3470-3477.
5. Kamal MA, Acosta EP, Kimberlin DW, et al. The posology of oseltamivir in infants with influenza infection using a population pharmacokinetic approach. Clin Pharmacol Ther. 2014;96(3):380-389.
6. Rath BA, Brzostek J, Guillen S, et al. Safety, virology and pharmacokinetics of oseltamivir in infants with laboratory-confirmed influenza: A phase I/II, prospective, open-label, multicentre clinical trial. Antivir Ther. 2015;20(8):815-825.
7. Jamsen K, Kirkpatrick C, Opoku NO, Attah SK, Awadzi K (Deceased), Kuesel AC, Olliaro P, Olipoh G, Ryg-Cornejo V, Tan B, Sullivan M, Fleckenstein L, Rayner CR. Determining the Optimal Dose of Moxidectin for Onchocerciasis via Pharmacokinetic-Pharmacodynamic (PK-PD) Modelling of Data from Healthy Volunteers and Patients with Onchocerciasis. Presented at the American Society of Tropical Medicine & Hygiene Annual Meeting. November 5-9, 2017, Baltimore, MD. http://www.abstractsonline.com/pp8/#!/4395/presentation/2116
8. Milton P, Walker M, Kuesel AC, Opoku NO, Attah SK, Kanza E, Bakajika D, Howard H, Halleux CM, Rayner CR, Smith D, Pearce G, Sullivan M, and Basáñez MG. The potential for six-monthly mass administration of moxidectin to accelerate onchocerciasis elimination. Presented at the American Society of Tropical Medicine & Hygiene Annual Meeting. November 5-9, 2017, Baltimore, MD. https://www.certara.com/wp-content/uploads/Resources/Posters/Milton_ASTMH_2017_Poster_MGB_Final_TDR_1.pdf
9. PR Newswire. News release: U.S. FDA Approves Moxidectin For The Treatment Of River Blindness. June 13, 2018. https://www.prnewswire.com/news-releases/us-fda-approves-moxidectin-for-the-treatment-of-river-blindness-300666114.html
10. Hall C, Douglas D, Atnikov K, Menard AL, Marier JF, Beliveau M. Exposure-Response Modeling and Simulation to Support Human Dosing for Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine) or BAT. Presented at the 50th Annual Interagency Botulinum Research Coordinating Committee (IBRCC) Meeting. January 2019, Annapolis, MD.
11. Leeds JM, Fenneteau F, Gosselin NH, et al. Pharmacokinetic and pharmacodynamic modeling to determine the dose of ST-246 to protect against smallpox in humans. Antimicrob Agents Chemother. 2013;57(3):1136-1143. https://www.ncbi.nlm.nih.gov/pubmed/23254433; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3591874/. doi: 10.1128/AAC.00959-12.
12. Dodds M. Optimizing the Timing of Material Influenza Vaccination. Presented at the American Society of Clinical Pharmacology and Therapeutics Annual Meeting. March 15–18, 2017, Washington, DC.

About Certara

Certara optimizes R&D productivity, commercial value and patient outcomes through its unique portfolio of model-informed drug development, regulatory science, and market access solutions. In fact, 90+% of all novel drugs approved by the US FDA in the past four years were supported by Certara software or services. Its clients include 1,600 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 60 countries.

For more information, visit www.certara.com or email marketing@certara.com

Brochure v5 09262019