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, QTc (cardiac safety) modeling and analysis, PK/PD modeling and related dataset construction 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.

**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.

**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 and Tecovirimat, 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.
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


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

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