CERTARA

Changing the Game in Drug Development and Patient Access

At Certara, we are innovators, dedicated to helping our clients develop new therapies and target unmet medical needs, expand existing therapies to other subpopulations, communicate scientific information in the language of regulatory success and market access, balance risk-benefit profiles, differentiate therapies from the competitive landscape, and unlock millions of dollars in R&D savings.

Company Stats

800+
Employees including
280+
PhD, PharmD, & MD consultants

Certara software is used by major regulatory agencies and considered a "gold standard" by the US FDA

110+
Global submissions to regulators and health authorities in the last 3 years from
250+
Regulatory science consultants

90%
of all novel drugs approved by the US FDA in the past 3 years were supported by Certara software or services

1,700
companies, academic institutions, global non-profits, and leading regulatory agencies in
60
countries partner with Certara

Impactful Science—From Bench to Market

Leveraging Model-informed Drug Development, Regulatory Science and Real World Value Assessments to Optimize R&D and Commercial Decisions

M&S quantitative solutions enable a well pressure-tested **development, regulatory, and patient access strategy**

MIDD, market access, HEOR, and real-world evidence information must be presented, written and packaged through the **most effective and compelling submissions**

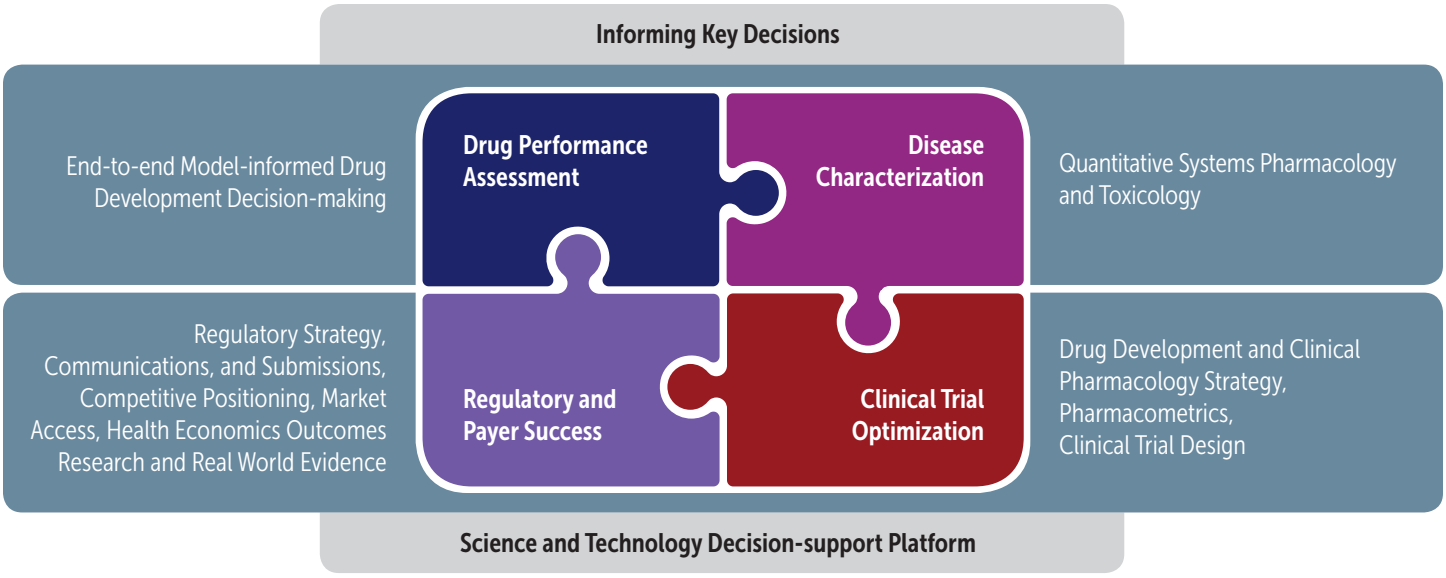
Integrating **real-world value assessments with MIDD and regulatory strategy** throughout the development cycle will optimize market value

A modern, state-of-the-art drug development strategy uses **quantitative methods to demonstrate safety, efficacy, quality, and comparator effectiveness** to regulators and payers

Certara's Capabilities

- Drug Development and Regulatory Strategy
- Clinical Pharmacology
- Strategic MIDD and Pharmaco-metrics
- Mechanistic Modeling (PBPK and QSP)
- Strategic Regulatory Writing and Submissions
- Stakeholder Communications and Engagement
- Data Science and Informatics
- Health Economics/ Outcomes Research
- Market Access Value Communication

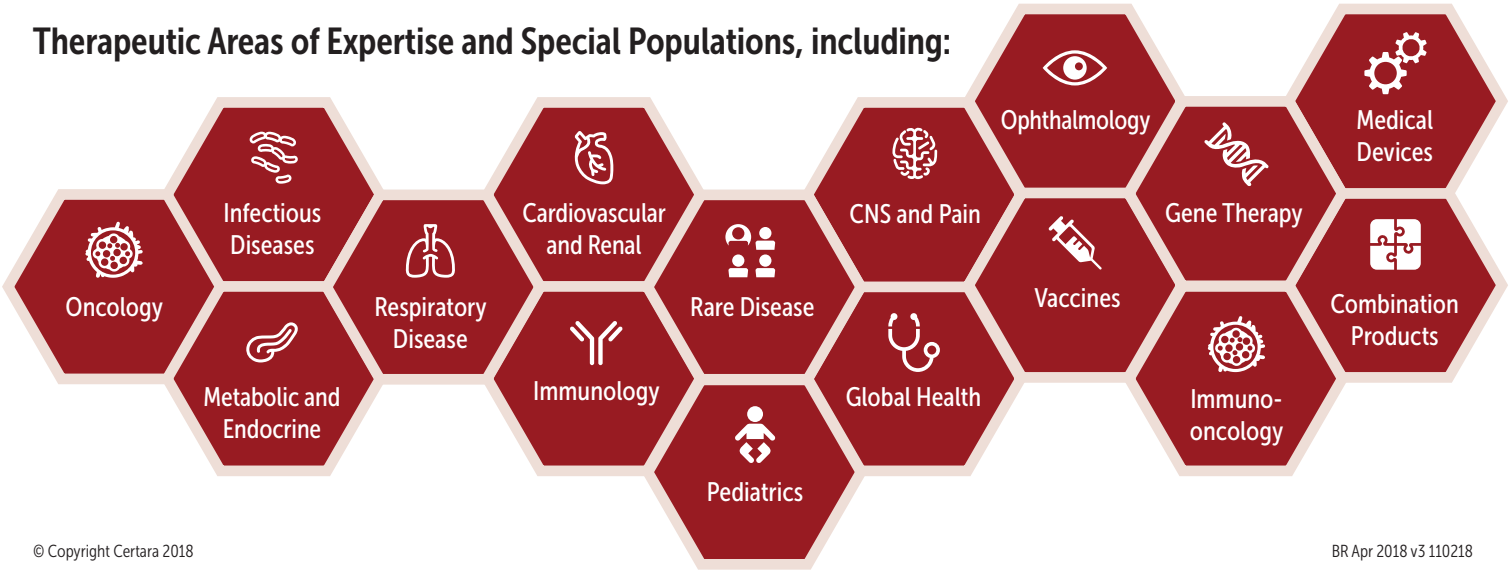
www.certara.com



Key decisions analyzed and informed by Certara's work include:

- Making informed and quantitative **go/no go portfolio** decisions
- Pressure testing and **optimizing** drug development and market access decisions
- Selecting **first-in-human**, final dose, and dosing regimen
- Comparing drug candidates for **safety**, **efficacy**, and **commercial viability**
- Developing safer, targeted, and **more efficient trial designs**
- Informing on **comparative effectiveness** and commercial potential
- Determining optimal and alternative **drug formulations**
- Identifying **drug-drug interactions** and other safety concerns
- Optimizing **product labeling**
- Analyze real world outcomes for **drug value assessment**
- Facilitating **regulatory and health authority** communications
- Determining and implementing the **optimal regulatory filing strategy**

Therapeutic Areas of Expertise and Special Populations, including:



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