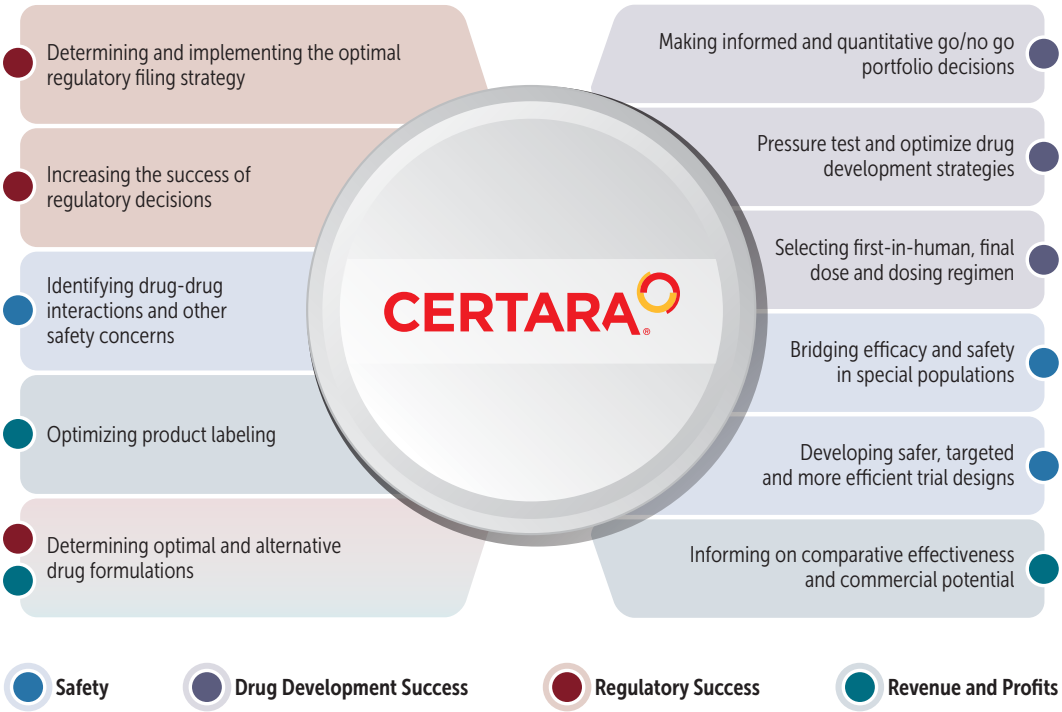
CERTARA

Certara Optimize: Changing the Game in Drug Development

Committed to scientific and regulatory advancement, Certara has organized its capabilities to create impactful healthcare solutions.

Certara Optimize™ is a strategic and programmatic approach to drug development that leverages our expertise in drug development, clinical pharmacology, the use of quantitative analysis methods, and regulatory science to optimize decision-making. As an outsourced part of your R&D team, we will support specific products, programs, or entire portfolios, advise on licensing and due diligence activities, work alongside a drug development team, or serve as a fully outsourced partner.

As game changers and innovative thinkers, we are dedicated to helping our clients develop new therapies and target new unmet medical needs, expand the benefits of existing therapies to other populations, communicate scientific information in the language of regulatory success, balance risk profiles, differentiate drugs from a competitive landscape and unlock millions of dollars in R&D savings.



The Certara team incorporates contemporary thinking in regulatory science, quantitative clinical pharmacology and value-focused decision-making toward achieving R&D and commercial objectives.

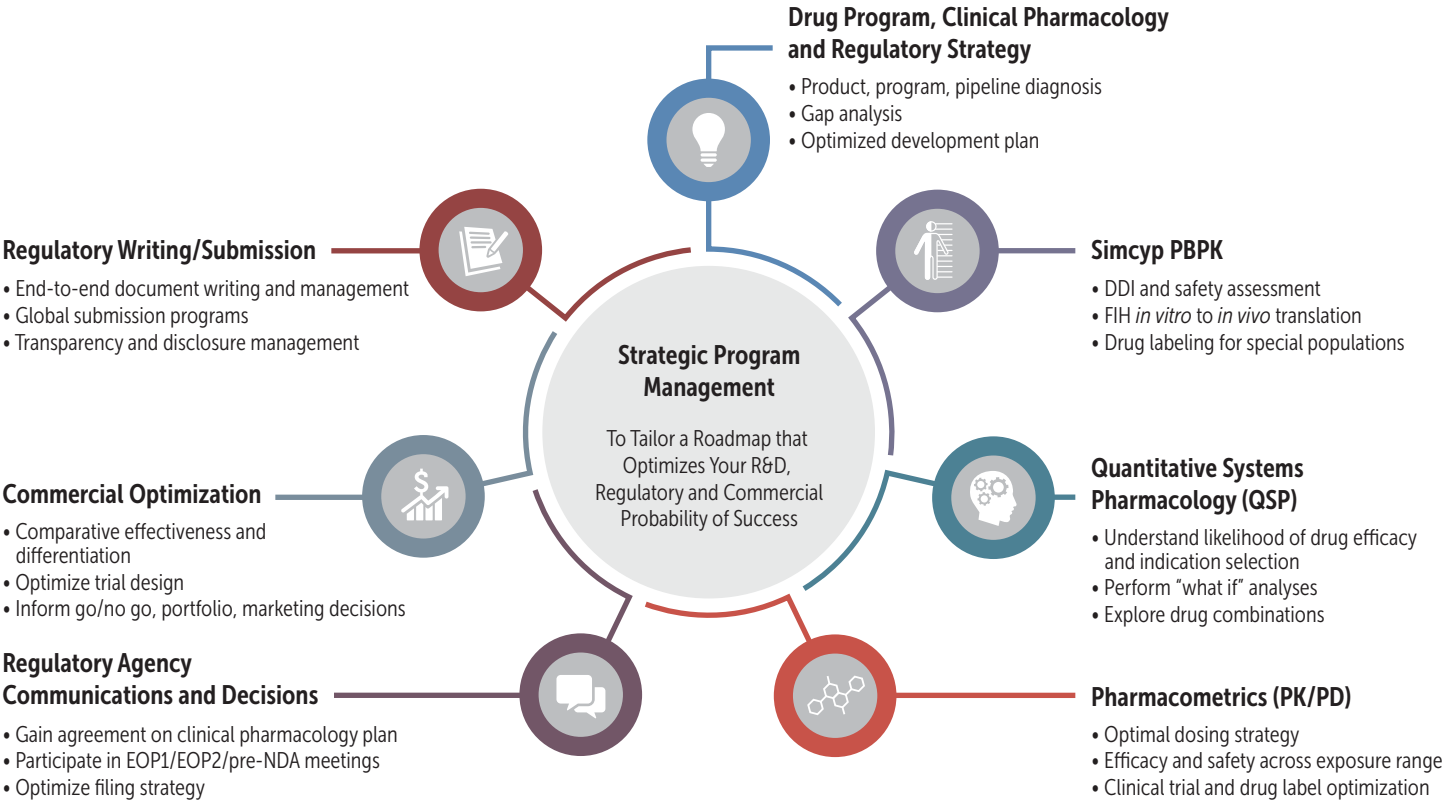
Thinking Without Borders™

By leveraging its world-leading pharmacometrics portfolio with proven drug development, clinical pharmacology and regulatory science experience, Certara is uniquely qualified to advise and optimize on the myriad of crucial decisions that determine success in today's drug development programs. As a partner and member of your team, we will develop a robust plan for each compound that is pressure-tested and executable, anchored by model-informed drug development (MIDD), focused on regulatory approval, commercialization and optimal use of medicines, and delivered with certainty, efficiency, and cost-effectiveness.

Certara has helped sponsors bring more than 80 drugs to market over the past several years and advised on hundreds of programs from early clinical development stages through proof of concept. Those drug programs, for companies including both large pharma and emerging biotech, cover a range of therapeutic areas, including oncology, immunology, rare disease, CNS, metabolic and infectious disease. They address the needs of special populations, such as pediatrics, geriatrics, co-morbidity and global health challenges. They have been developed in accordance with the leading global regulatory agencies, such as FDA, EMA, and PMDA. And they have been executed under unique regulatory programs as breakthrough drugs, orphan designation and priority review.

The Certara Optimize Approach

- Our work typically begins with a comprehensive analysis and pressure-testing of the drug development, regulatory, and clinical pharmacology strategy;
- We then evaluate and provide a gap analysis (of a pipeline, specific drug, program, TA, or others), which is harmonized with the overall clinical development plan, to identify key gaps and program risks and outline a strategy to mitigate identified risks;
- Ongoing stewardship of clinical pharmacology and pharmacometrics program to ensure our deliverables are fit-for-purpose and meet strategic objectives, are aligned with regulatory authority requirements and expectations, and are updated and adjusted based on program evolution;
- As a member of your development team, we drive that strategic program by leveraging the wide range of Certara's capabilities to answer key technical and regulatory challenges and:
  - Optimize cost and time of development
  - Provide a decision support system that consistently delivers reliable, reproducible and predictable decisions, now expected by regulators and payers
  - Inform and optimize label claims
  - Understand all dimensions and levers of efficacy and safety translation
  - Avoid ethical pitfalls
  - Maximize commercial success via the interplay of model-based meta-analysis, PK/PD analysis and health economics and outcomes research modeling
- Through our Synchrogenix regulatory writing capability, uniquely versed in the language of quantitative science, create regulatory dossier, clinical, non-clinical, CMC and safety plan documents, regulatory agency communications and all required submission documents;
- We are always available to guide and/or participate in key regulatory meetings.

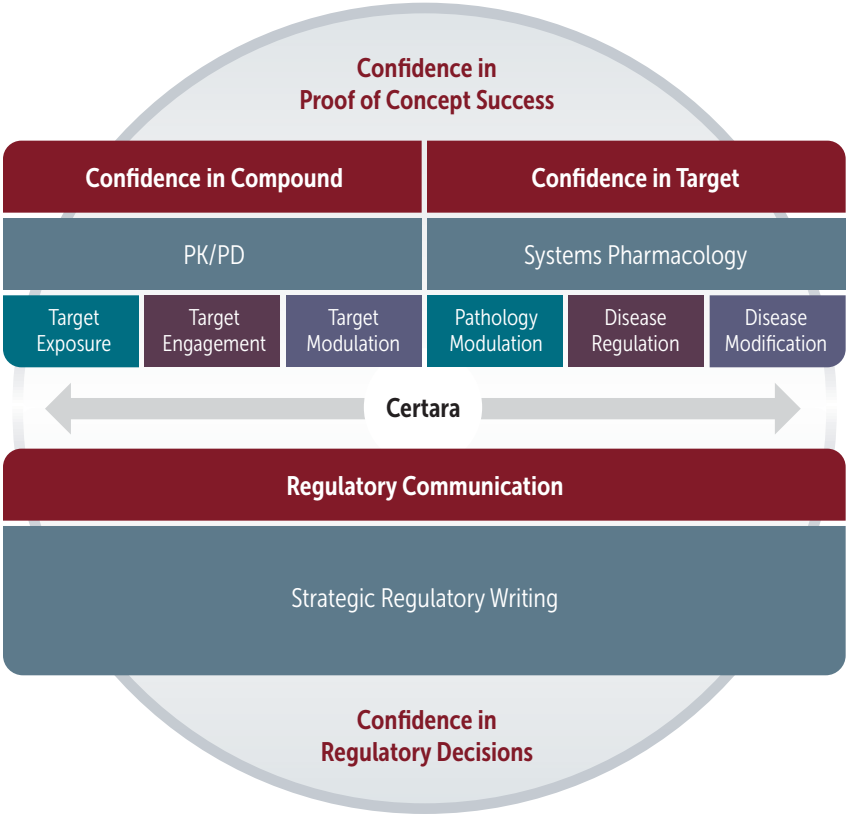


Certara applies a programmatic discipline to each engagement, providing the data and regulatory science backbone with regard to safety, efficacy, risk/benefit, and comparative effectiveness.

Delivering Confidence, Creating Value

While Certara Optimize is employed across the development life cycle, it is of unquestionable value when applied to improving the confidence in two key areas: the proof of concept and regulatory success. By leveraging the largest and most advanced portfolio of quantitative and regulatory science technologies, Certara's team can improve confidence and probability of success:

- **Simcyp PBPK** – The global leader in PBPK technology informs key management decisions relating to clinical trial design, the need for specific clinical trials, first-in-human dosing, formulation design, dosing in special populations, and drug-drug interactions (DDIs).
- **Quantitative Systems Pharmacology** – By focusing on target exposure, binding and expression, QSP is used to identify biological pathways and determinants of disease.
- **Pharmacometrics Modeling** – Certara has the largest and most experienced group of modelers using population PK, exposure-response and disease-state modeling to predict clinical outcomes.
- **Model-based Meta-analysis** – Using Certara's proprietary curated databases, these models compare the effectiveness of drugs against competitor products, scale from biomarker to endpoint, or scale to other indications.
- **Synchrogenix Regulatory Writing** – With more than 100 staff writers, this team employs a rigorous, proven, and quality-driven process of regulatory documentation and communications support across from discovery through to life-cycle management.



Certara's team of more than 250 PhD, PharmD, and MD scientists and regulatory writers work to uncover and ameliorate technical issues that could impact the probability of success for a compound, recommend a specific strategic roadmap to achieve milestones and articulate the most compelling data-rich communications and submittal package.

Understanding Regulatory Thinking

Over the past few years, all major regulatory bodies have promoted the use of model-informed drug development technologies, along with an emphasis on clinical pharmacology science to inform key decisions. MIDD has the ability to inform every phase of the drug development process, from evaluating the viability of a compound emerging from the discovery phase to informing key label claims without the need for clinical trials. MIDD has been highlighted in more than a dozen regulatory guidance documents, including the 2017 PDUFA and GDUFA, FDA clinical pharmacology labeling guidance, ICH E11, EMA First-in-Human, and multiple others.

Certara has an outstanding relationship with global regulators, as a partner in technology development, as a user of these technologies for regulatory review and approval, in creating and executing educational programs and publications, and in representing our client's drug programs. Our commitment to advancing this science anchors Certara Optimize and the partnership with our clients.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.

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