CERTARA

Thinking Beyond Borders: d3 Medicine Joins Certara

A purpose-driven organization, d3 Medicine (d3), now part of Certara, shares a commitment for putting the patient first and thinking differently: to accelerate drug development and optimize the use of new medicines.

By changing the game in drug development, we can help our clients develop new therapies, unlock millions of dollars in savings, expand indications to meet unmet medical needs, and differentiate products from a competitive perspective. With a laser-like focus on results, our strategic and programmatic approach to drug development maximizes the most advanced quantitative methods and innovative thinking in the market.

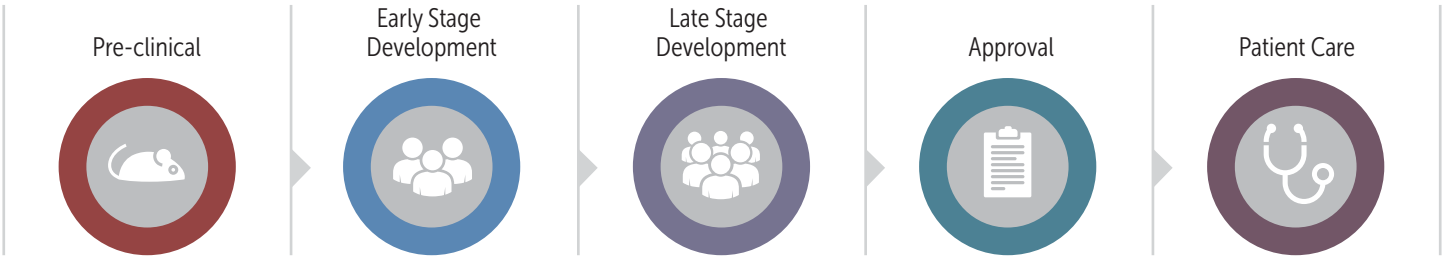
Spotlight on the Clinical Pharmacology Roadmap

As clinical pharmacology comprises more than 50 percent of a drug label, the need to understand how to optimize safety and efficacy in drug development is critical. We understand the impact of clinical pharmacology on a drug development program and devise strategies to harness that knowledge toward a more successful program in consideration of:

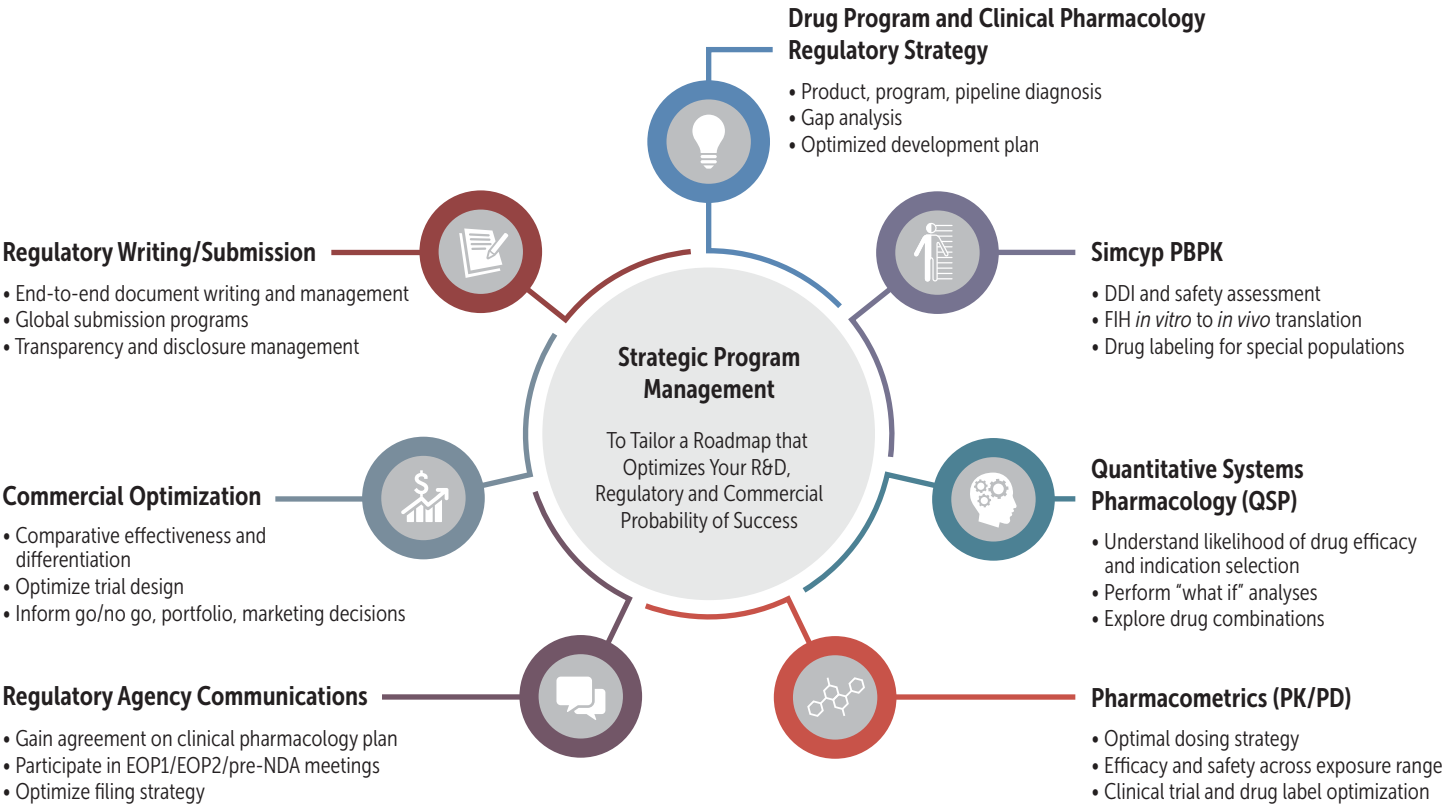
- the rigors and latest thinking on the part of the regulators;
- speed, efficiency, and optimization of the development process;
- the competitive landscape and a 'pharmacology-to-payer' perspective

We begin with an assessment, diagnosis and gap analysis. Next, we develop and implement a roadmap that translates model-informed drug development (MIDD) into the decision-making process and leverages all data to align with that optimized clinical strategy. And by layering in our expertise from having sat on both sides of the table at critical regulatory meetings, we are confident in our recommendations and know how to best leverage MIDD throughout a program.

We can support specific products, programs or entire portfolios, participate in licensing and due diligence activities, work alongside a drug development team, or serve as that fully outsourced partner.



Early engagement is key to assuring that you are designing studies, collecting data, and anticipating the needs of regulators. Early engagement will enable go, no-go decisions, ramp up the drug development cycle, and allow for the minimization or even elimination of clinical studies. While ideal in early stage, the benefits of our programmatic approach and quantitative methodology can be achieved throughout the development cycle.



Rising Value of Model-informed Drug Development (MIDD)

The impact of MIDD is undeniable, as at least one of these quantitative technologies is used in the approval of more than 90 percent of all novel drug approvals. Further, MIDD is actively encouraged by global regulators. 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 label claims without the need for clinical trials.

Certara has an industry-leading portfolio of MIDD technologies and strategies, including Simcyp PBPK, QSP, PK/PD, exposure-response, QT prolongation, disease modeling, and model-based meta-analysis.

In other words, we are revolutionizing the drug development paradigm by applying quantitative science and smart regulatory strategy to inform the most crucial drug development decisions.

Our Team's Approach

Our staff is comprised of experienced drug developers, clinical pharmacologists, quantitative scientists, and regulatory specialists. Our team can advise on all aspects of drug development strategy and, together with the client, derive a more robust plan that has been pressure tested from multiple angles. We incorporate contemporary thinking in regulatory science, quantitative clinical pharmacology and value-focused decision-making. Patient health is always at the forefront of our work.

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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