CERTARA®

Optimizing Drug Development Decisions

Drug Development and Regulatory Strategy | Modeling and Simulation | Regulatory and Medical Writing

Impacting the Probability of Regulatory and Commercial Success in Drug Development

With a global footprint, more than 1,200 clients, and a continuously-evolving portfolio, Certara is passionate about its mission—bringing new, safer therapies to patients.

Optimizing Drug Development Decisions

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

- Making informed and quantitative go/no go portfolio decisions
- Pressure test and optimize drug development strategies
- Selecting first-in-human, final dose, and dosing regimen
- Comparing drug candidates for safety and efficacy
- 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
- Facilitating regulatory communications
- Determining and implementing the optimal regulatory filing strategy

Integrating proven capabilities in modeling and simulation with regulatory strategy and communications to optimize outcomes

Certara is a clinical services organization that leverages technology-enabled solutions to inform and optimize the most crucial drug development decisions. The company has amassed the most scientifically-advanced modeling and simulation approaches and regulatory communications capabilities and aligned them with proven drug development strategies to increase R&D productivity and the probability of commercial success for our clients.

Certara has integrated its modeling & simulation expertise with the industry's largest global regulatory and medical writing team to provide outsourced capabilities from early R&D through to lifecycle management. Today, Certara is the largest and most comprehensive company of its kind, forming close partnerships with its clients to integrate the many benefits of modeling, simulation and regulatory science into drug development programs. Certara has helped sponsors bring more than 80 drugs to market over the past several years, including 18 FDA-approved novel drugs in 2015. The company has a global footprint, with clients located in 60 countries, and staff located on four continents.

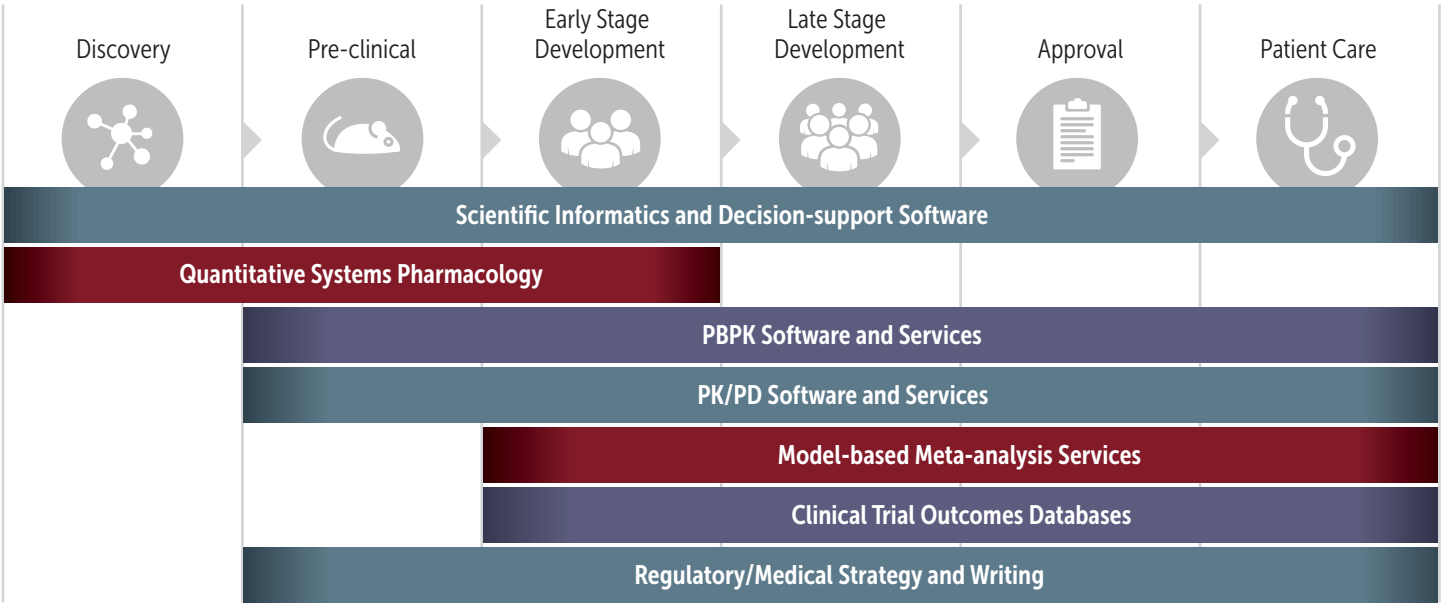
Solutions that span the drug development life cycle

Certara provides a wide range of technologies, services, and solutions to quantitatively inform key drug development decisions from early discovery through patient care. Hundreds of biopharmaceutical companies, key academic institutions, and the world's leading regulatory agencies rely on Certara's solutions to meet their drug development and regulatory objectives. We can provide a comprehensive analysis of a drug's development and clinical pharmacology strategy to identify gaps and to outline opportunities to optimize efficiency and outcomes. The company's hundreds of scientists, regulatory writers and technology experts work with sponsors either as key advisors or as fully-outsourced partners to pressure test and optimize drug development strategies, leveraging our unique portfolio of capabilities.

Delivering Comprehensive Services

With more than 130 scientists with PhDs and MDs available for client engagements, Certara has experience in all major therapeutic areas, with special expertise in oncology, immunology, CNS, and infectious, metabolic, respiratory, and rare diseases. Our team can integrate prior knowledge about a class of drug, mechanism of action, target exposure, binding and expression, commercial performance, etc. with clinical data to quantitatively inform key drug development decisions. Our modeling and simulation approaches are used for both small molecules and biologics, for adult and vulnerable populations (pediatrics, geriatrics, renally- and hepatically-impaired), and to address major areas of unmet medical and global health care needs.

End-to-end Solutions to Improve R&D Productivity



Certara's solutions, the most comprehensive in the industry, span the drug development cycle, providing measurable value for internal decision-making and in gaining regulatory approval.

Strategic Pharmacometrics Consulting

Modeling and simulation has the proven ability to influence every phase of the drug development process. It carries quantitative data, knowledge and wisdom from one phase to the next, and from one indication to another, and it can combine information from both proprietary and published sources. Certara integrates that information to inform key drug development decisions by performing quantitative analyses, such as population PK, exposure-response, and disease state (eg, tumor size) modeling to predict clinical outcomes. As the largest and most experienced consulting company in this field, we incorporate best practices into all drug development programs, to develop a clinical program that maximizes R&D efficiencies. In addition, the company uses knowledge derived from events that occurred in earlier modeling studies to design future studies that move faster, more predictably, and reliably. Certara's Model-based Meta-analysis (MBMA) expertise, which uses the company's proprietary curated databases, allows sponsors to compare the effectiveness of an investigational drug to other emerging competitor drugs, scale from biomarker to endpoint, or scale to other indications to inform trial design aspects and dose/regimen. These modeling and simulation approaches provide answers to fill key development gaps and allow for a better understanding of benefit: risk.

PBPK and QSP Leadership

Certara has led the industry in advancing the use of PBPK in drug development by modeling and predicting pharmacokinetic behavior in virtual patient populations. The company has developed the Simcyp Simulator, which is the result of more than 12 years of collaboration with a consortium that includes 33 leading pharma companies, academic institutions, and major regulatory bodies. In addition to managing the consortia membership, the Certara PBPK consulting team works directly with sponsors by leveraging all of these capabilities, including its biologics and pediatric simulators to inform R&D, achieve label claims, and expedite regulatory submittals. PBPK can be used to inform, recommend and expedite smaller studies and increasingly, to obviate the need for certain trials, evaluate special populations, and identify knowledge gaps.

Certara now provides QSP to its clients. QSP is a relatively new discipline that has enormous potential to improve pharma R&D productivity, by focusing on target exposure, binding and expression. QSP can be used from the early stages of discovery onwards, helping identify biological pathways and determinants of disease. QSP may also be able to take advantage of the enormous amounts of data we now have access to including those arising from the genomics and proteomics arena.

Regulatory and Medical Writing

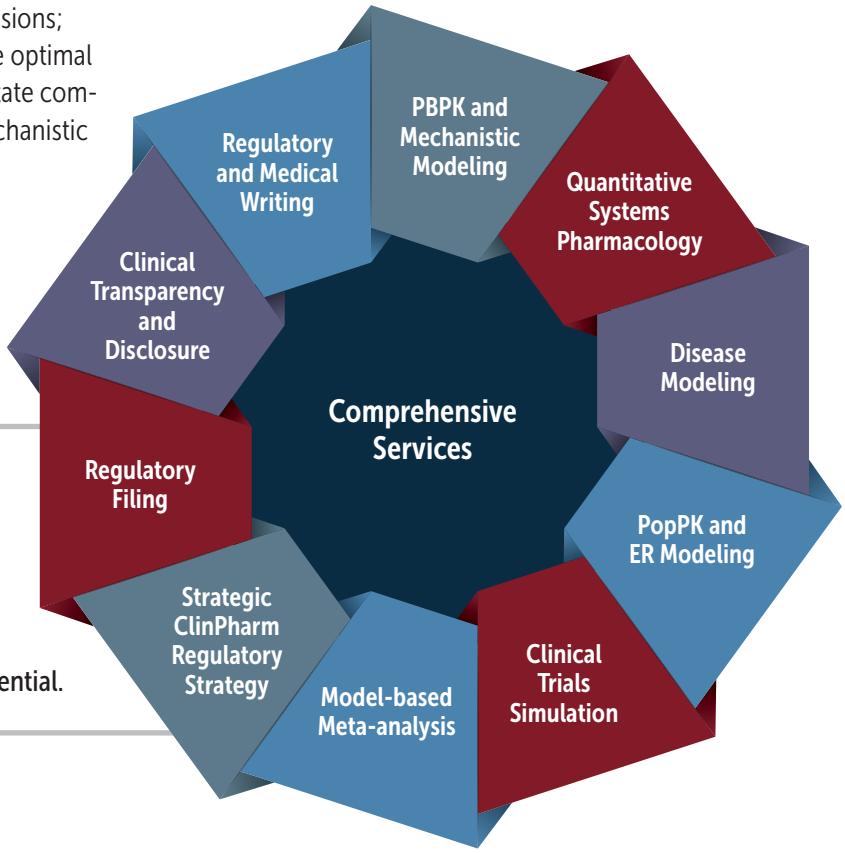
Through its Synchrogenix division, Certara's team of more than 100 regulatory writers has developed a rigorous, proven, quality-controlled set of processes to ensure the highest quality regulatory and medical documentation. With in-house experts in all functional areas, the team is highly skilled in managing the transition from pre-clinical to clinical trials and developing the requisite documentation for initial and global filings. Its service offerings include non-clinical, clinical, chemistry, manufacturing, and controls (CMC), and drug safety writing; submission management for all common technical document (CTD) modules; transparency and disclosure reporting; regulatory and medical communications; and post-marketing safety writing. Further, Certara has the only artificial intelligence-enabled (AI) regulatory writing technology designed specifically to support the clinical and drug development markets. That technology analyzes previously written documents in order to construct an automated process for developing new documents and redacting information to meet clinical trials transparency and disclosure requirements based on pre-defined process rules.

Providing Gold Standard Modeling and Simulation Software

Certara's software has wide-ranging appeal and is used by pharmacologists, toxicologists, biostatisticians, pharmacometricians, pre-clinical scientists, chemists, and geneticists. Certara software is used to inform key safety and efficacy decisions; identify, optimize and validate drug targets; determine optimal dosing; design clinical trials; triage compounds; facilitate comparisons with competitor compounds; and assess mechanistic drug performance.

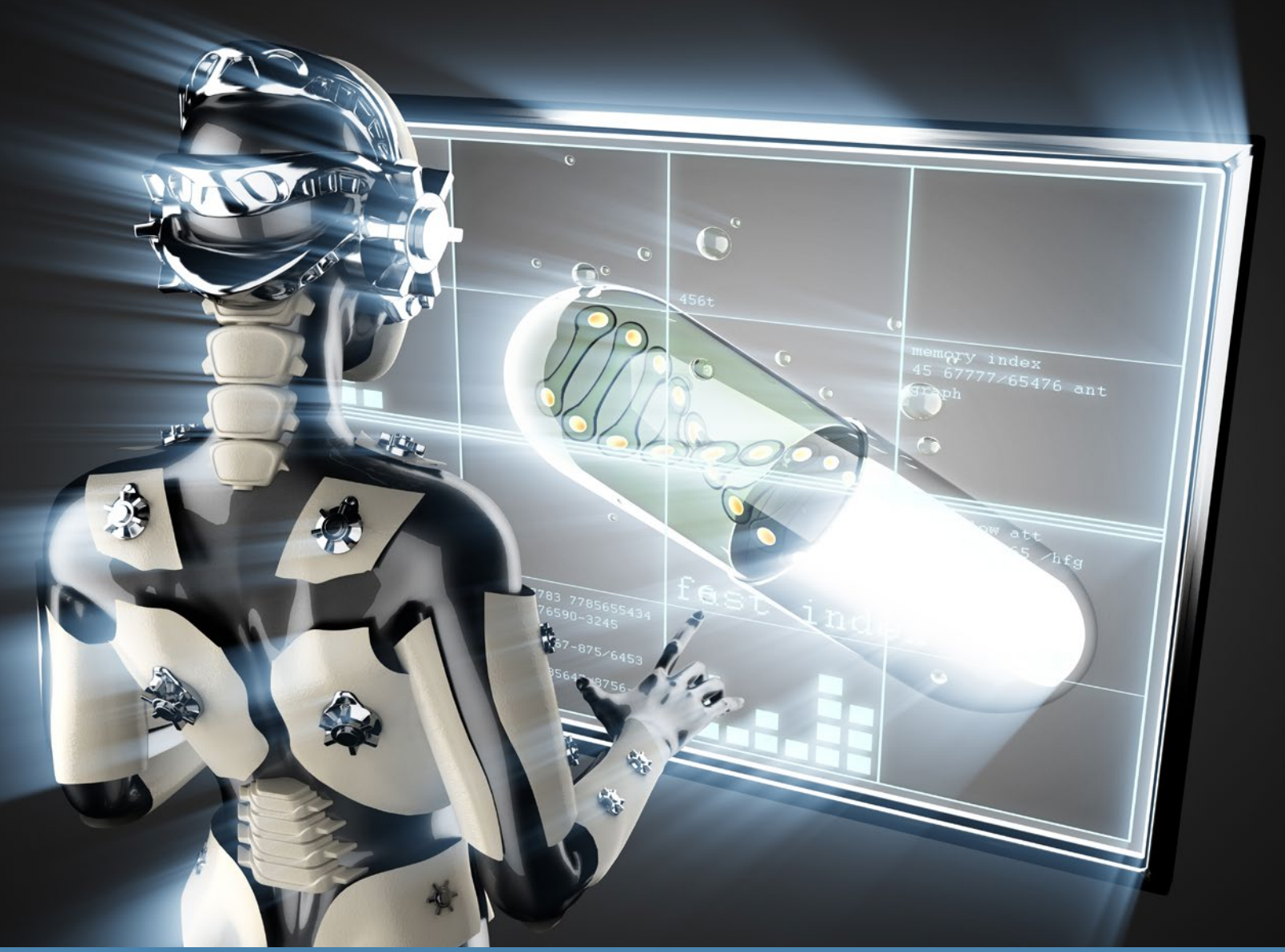
Certara's award-winning software portfolio includes:

- Phoenix platform, which includes WinNonlin, the industry gold standard for PK/PD and non-compartmental analysis, Phoenix NLME for population PK modeling, Phoenix Connect for data import/export and reporting, Phoenix IVIVC toolkit, and Phoenix Knowledgebase Server, a 21 CFR compliant database and repository;
- Simcyp Simulator, the leading PBPK technology for both small molecules and biologics incorporates numerous databases containing human physiological, genetic and epidemiological information to predict behavior in virtual populations. Simcyp also provides pediatric, cardiac and Simcyp *in vitro* analysis simulators;
- D360 informatics platform, which facilitates scientific data access, analysis, and collaboration across researchers within an organization and amongst development partners;
- Certara's Clinical Trials Outcomes Databases and KEEP Platform, which provide analysis-ready data on the safety and efficacy of drugs on the market or in development for more than 30 key therapeutic areas. These tools are used to leverage key development insights to inform go/no go, portfolio, marketing, comparative analysis, and clinical trial decisions.



Unique Portfolio of Quantitative and Regulatory Advisory Services– Flawlessly Delivered by Certara

Certara's services have enabled sponsors to reduce cost, risk and uncertainty in R&D decision-making, while increasing time-to-market and commercial potential.



Focused on Regulatory Success

The world's leading regulatory agencies regard modeling and simulation as one of the most important approaches for increasing R&D efficiency and effectiveness of the drug development process. Certara is leading the charge, partnering with our clients to prepare for, and achieve successful regulatory interactions, while working alongside those same regulatory agencies to advance the integration of these evolving scientific capabilities into the regulatory review process. The company's scientific and regulatory communications experts have supported multinational clients, both large pharma and emerging biotech on regular and accelerated approvals, new drugs and biologics, generics and line extensions, breakthrough and first-in-class products, and single, multiple and global filings.

Certara addresses these exciting opportunities through drug development and clinical pharmacology strategy, strategic regulatory writing, in-depth knowledge of modeling and simulation and traditional clinical operations, and an awareness of the global health authority's positions. By combining the power of advanced quantitative solutions and superior regulatory writing and submission strategy, Certara is reshaping the pharmaceutical industry's approach to drug development.

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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