CERTARA

Changing the Game in Oncology Drug Development and Patient Access

We can help maximize your understanding of your anti-cancer drug's safety and efficacy profile to support regulatory and commercial success. Certara's strategic and technology-enabled services provide support across the drug development continuum from pre-clinical first-in-human studies and clinical drug development for small molecule and complex biologics, to regulatory submissions, health economics/outcomes research and market access value communication.

Cancer Stats

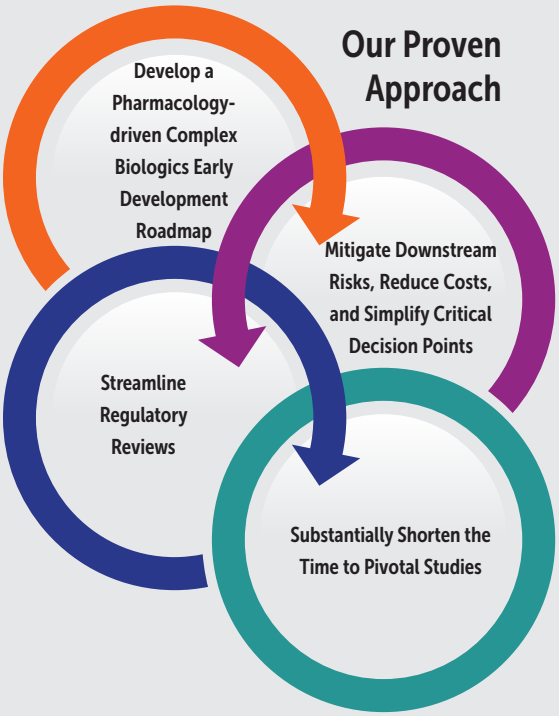
9.6M
The global number of deaths in 2018 due to cancer as estimated by The Institute of Health Metrics and Evaluation (IMHE)

$200B
The estimated global market for oncology therapeutics by 2022

17M
The global number of cancer diagnoses in 2018

27.5M
The global number of cancer diagnoses estimated by 2040

Our Proven Approach



Strategic Considerations for Successful Development of Complex Oncology Therapeutics in Early Development

- Development and evolution of the Target Product Profile (TPP)
- Risk assessment and mitigation planning
- Translational exposure-response (E-R) and exposure-safety analyses (E-S)
- Defining PK/PD relationships and application of quantitative modeling and simulation
- First-in-human (FIH) starting dose calculation methodology
- Phase I and II integrative dose selection strategy
- Clinical pharmacology data collection and analysis plans
- Evaluate appropriate data collection and timings
- Determine analyses requiring cross-functional data integration
- Address key pharmacology-related critical questions

Certara's Capabilities for Oncology Drug Development

- Early Drug Development Strategy and Model-informed Precision Dosing
- Strategic and Translational Clinical Pharmacology
- PBPK Mechanistic Modeling and Virtual Twin Technology
- Rare and Orphan Oncology Drug Development
- QSP, Immuno-oncology and Immunogenicity Consulting
- Strategic Regulatory Support/Medical Writing and IND/NDA Submissions
- Data Science and Informatics/ Clinical Trial Optimization
- Health Economics/ Outcomes Research and Evidence Synthesis
- Market Access Value Communication

Certara's Technology-Enabled Services for Oncology Drug Development

End-to-end Model-informed Drug Development Decision-making

Drug Performance Assessment

Disease Characterization

Quantitative Systems Pharmacology and Toxicology Consulting

Regulatory Strategy, Communications, and Submissions, Competitive Positioning, Market Access, Health Economics Outcomes Research and Real World Evidence

Regulatory and Payer Success

Clinical Trial Optimization

Drug Development and Clinical Pharmacology Strategy, Pharmacometrics, Clinical Trial Design , QSP Immunogenicity and Immuno-oncology Consulting, PBPK Modeling and Simulation for Complex Biologics

Science and Technology Decision-support Platform

90+%
of all novel FDA drug approvals were supported by Certara for the 4th Consecutive Year

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

Certara's Simcyp Simulator - Getting Real Answers from Virtual Populations

Leverage Physiologically-based Pharmacokinetic (PBPK) Modeling to Inform Critical Oncology Drug Development Decisions

Simulate mAb PK in humans using a mechanistic minimal Simcyp PBPK model which can account for the levels of both endogenous IgG and exogenous therapeutic mAbs in each compartment and sub-compartment.

Simcyp's antibody drug conjugate (ADC) model enables mechanism-driven studies of ADCs and drug-drug interactions (DDIs).

Use PBPK to evaluate the PK of oncology drugs for dose selection in clinical trials and to predict the potential clinical relevance of PK DDIs.

Simcyp's virtual PBPK cancer population is a useful platform for investigating tumor disposition, impact on treatment regimens, and for conducting virtual DDI trials to assess the potential for safety concerns.

Simcyp Simulator's solid cancer models combine knowledge of the tumor composition with the drug's physiochemical properties to simulate the distribution of small molecule drugs or biologics .

Simcyp Simulator can be used to support pediatric oncology dosing.

Certara's Simcyp Simulator has been used to inform label claims on novel oncology drugs used to treat indications including:

- Non-Small Cell Lung Cancer
- Advanced Ovarian Cancer
- Metastatic Breast Cancer
- Thyroid Cancer
- Acute Myeloid Leukemia
- Basal Cell Carcinoma
- Multiple Myeloma
- Chronic Lymphocytic Leukemia
- Chronic Myeloid Leukemia
- Acute Lymphoblastic Leukemia
- Mantle Cell Lymphoma
- Peripheral T-cell Lymphoma
- Prostate Cancer
- Solid Tumors

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