

# 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 (IHME)



**\$200B**

The estimated global market for oncology therapeutics by 2022



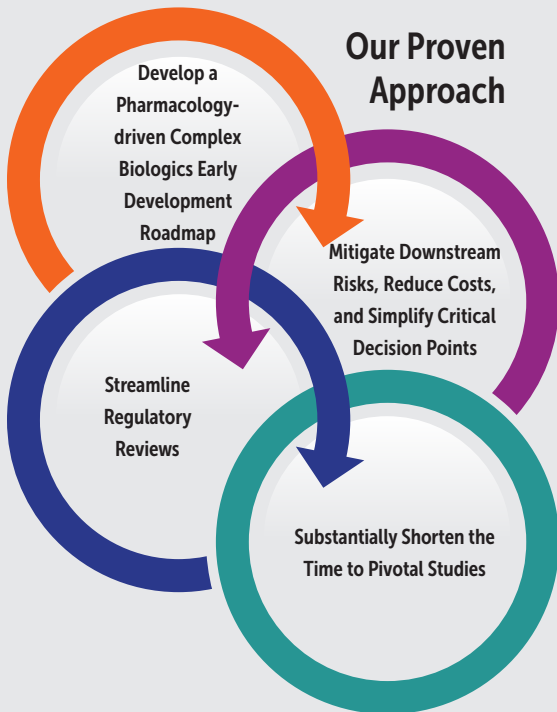
**17M**

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, Immunology and Immunogenicity Consulting



Strategic Regulatory Support/Medical Writing and IND/NDA Submissions



Data Science and Informatics/Clinical Trial Optimization

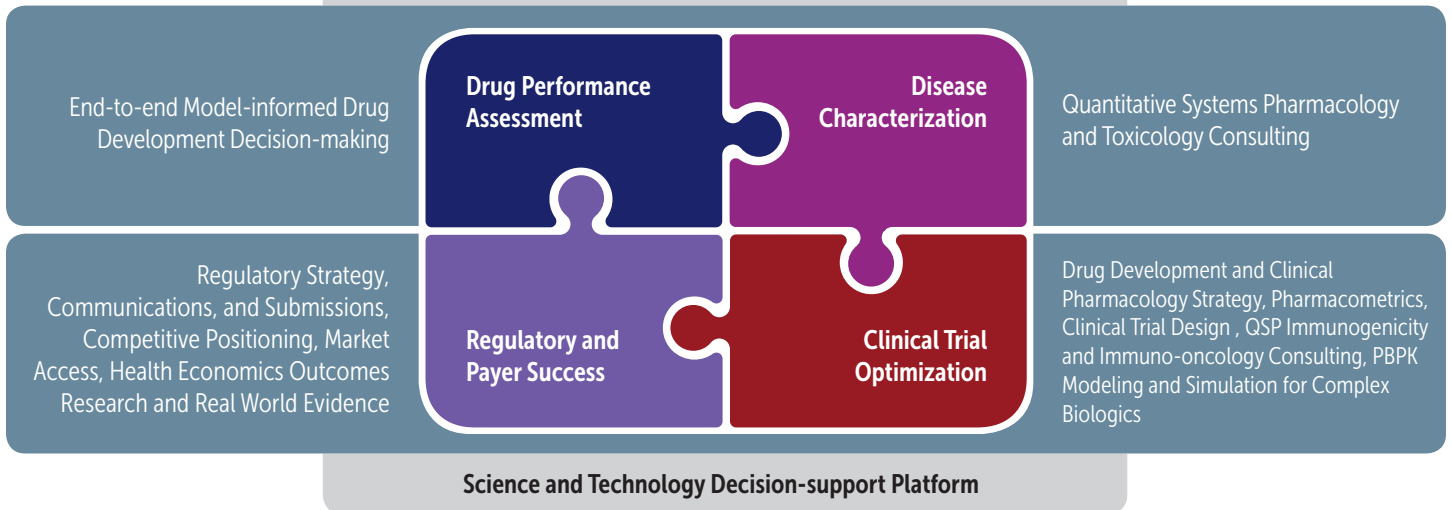


Health Economics/Outcomes Research and Evidence Synthesis



Market Access Value Communication

## Certara's Technology-Enabled Services for Oncology Drug Development



**90+%**

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



## 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 physicochemical 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:**

