

Pioneering the Field of Quantitative Systems Pharmacology

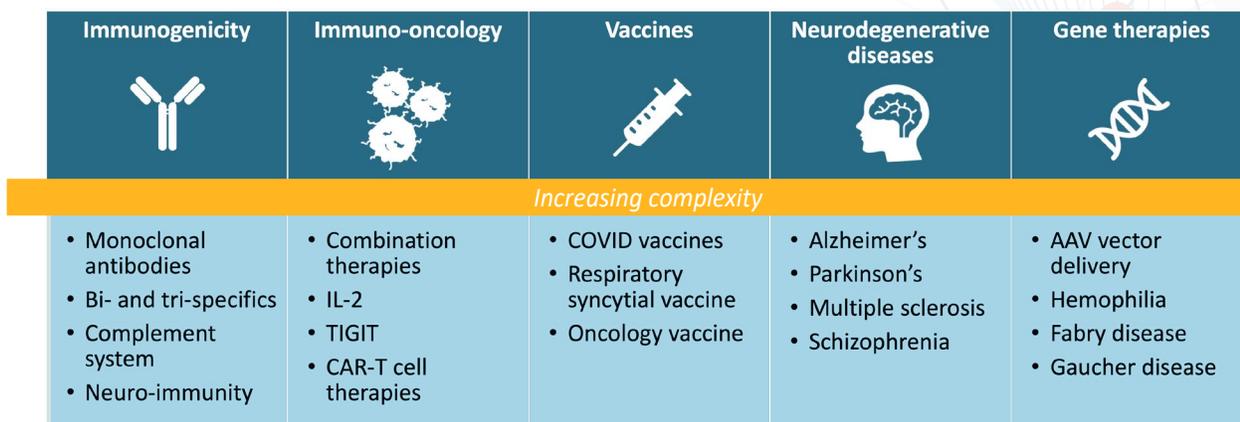
Translating R&D Concepts Into Confident Decisions

WHAT IS QSP?

An emerging discipline, Quantitative Systems Pharmacology (QSP) has already demonstrated its vast potential to improve biopharmaceutical R&D and inform decision-making across drug development. QSP combines computational modeling and experimental data to examine the relationships between a drug, the biological system, and the disease process. With the ability to leverage big data (biological and pharmacological), it enables the understanding of disease pathophysiology and identification and testing of therapeutic strategies in virtual trials with virtual patients.

QSP improves confidence in both the compound and the target.

Platform approach to QSP



TACKLING COMPLEX R&D CHALLENGES USING QSP

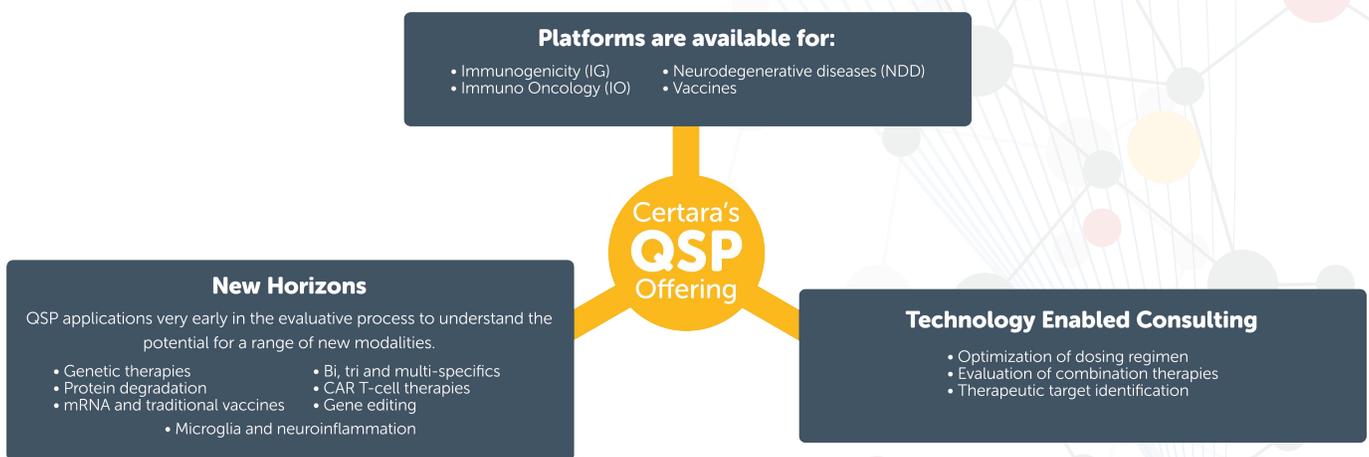
QSP helps answer questions about novel compounds and modalities, combination therapy, initial dosing for first-of-its kind therapies, and other vexing development situations:

- In a given biological pathway, what are the best target and modality for pharmacological intervention to treat a disease?
- How can we improve the therapeutic effectiveness of an existing drug through combination therapy?
- Can we predict human response (dose) to a novel mechanism based on preclinical data?
- How can we better understand the underlying pathophysiology to identify druggable pathways?
- Can we predict the effect of a drug in a special population?
- How can QSP support translation, product differentiation and utility of biomarkers?
- Can we individualize dosing regimen based on patient characteristics?
- How can we optimize clinical trials by accounting for pharmacodynamics interactions with co-medications and genotypes?

Certara's Quantitative Systems Pharmacology (QSP) Software

Regulatory-Ready Software Platforms For Reproducible Model Development

Certara is a world leader in bio-simulation and covers the whole R&D spectrum from early discovery to late-stage clinical development and regulatory filing. The Simcyp division develops industry-standard physiologically-based pharmacokinetics (PBPK) models and simulation tools. These large-scale mechanistic PBPK models are used by major large Pharma and regulators for clinical development decision making and regulatory submissions. In a growing number of applications Simcyp PBPK simulations have been accepted as evidence for drug labels.



WORLD CLASS EXPERTISE

Certara's quantitative systems pharmacology (QSP) team's skills range from applied mathematics, bio-engineering, computational science, and control theory, through biochemistry, cellular and molecular biology to PKPD and QSP modelling. The group has a dedicated FTE for literature searching and data extraction, and direct access to the PBPK expertise and IT/software development expertise and infrastructure at Simcyp. The leadership team is formed by world-renowned discipline leaders combining decades of pharma experience with cutting-edge scientific expertise in QSP.

For a free consultation, contact: Kevin.Romer@Certara.com

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions, and regulatory agencies across 62 countries.

For more information visit <https://www.certara.com/software/quantitative-systems-pharmacology/>