WHAT IS QSP?

A relatively new discipline, QSP has vast potential to improve biopharmaceutical R&D and inform decision-making across the drug development process. It 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) , QSP 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.

✓ New Modalities	✓ Target Selection
✓ Dose Selection & Optimization	✓ Target Engagement
✓ Combination Therapy	✓ Discovery
✓ Compound Repurposing	✓ Disease Triage
✓ Biomarker Determination	✓ Portfolio Strategy

WHAT R&D QUESTIONS ARE BEST ANSWERED USING QSP?

- In a given biological pathway, what is the best target and modality for pharmacological intervention to treat disease X?
- How can we improve the therapeutic effectiveness of an existing drug through combination therapy?
- Can we predict the effect of a drug in a special population/other indication?
- Can we individualize dosing regimen based on patient characteristics?
- Can we predict human response (dose) to a novel mechanism based on preclinical data?
- Which biomarkers do we require to answer the above questions?

CERTARA'S QSP PRACTICE: SOFTWARE PLATFORMS AND CONSULTING SERVICES

Certara's QSP practice is led by Dr. Piet van der Graaf, professor at Leiden University and the editor-in-chief of Clinical Pharmacology & Therapeutics, a peer-reviewed publication. Dr. van der Graaf and his team are routinely invited to speak at industry events and to regulatory bodies, including co-chairing the FDA's July 1, 2020 Scientific Exchange on QSP.

SPECIFIC AREAS OF EXPERTISE:

IMMUNOGENICITY (IG)

IG can be a showstopper in biologics, with 89% incidence rate and 49% of those impacting efficacy. IG management is a complex, multifactorial problem in need of a solution.

Certara facilitates a consortium of six major pharma companies and has developed a technology platform that is used to enable compound prioritization and inform go/no-go decisions.

The model can use first-in-human data to design Phase II/III trials, predict impact of disease and co-medication, extrapolate to new populations, and predict if IG can be managed via dosing regimens.

VACCINES

QSP is being used to simulate vaccine responses in virtual patients early in the development cycle and throughout all subsequent phases via virtual trials.

Certara is currently developing a QSP vaccine platform for a novel COVID-19 vaccine. That platform is derived from our unique IG Simulator and will be used to develop other vaccines.

IMMUNO-ONCOLOGY (IO)

Cancer IO drug therapy has had a huge impact in patient care, expected to reach $39B by 2024.

Certara manages a consortium with six leading pharma companies focused on developing an IO Simulator to test combination cancer therapies, evaluate different dose regimens, and select biomarkers in computer-generated, virtual patients.

The IO Simulator incorporates the pertinent biology, pharmacology, and variation between individuals to guide clinical development of IO therapies. It is being used today on a range of pivotal development programs.

NEURODEGENERATIVE DISEASES (NDD)

NDDs are complex and usually involve dysregulation in multiple biochemical pathways. Understanding the disease and potential treatments requires the combination of genetics, expression and mRNA, cell diversity, cellular networks, brain networks and science networks into one comprehensive model.