The Certara Quantitative Systems Toxicology & Safety (QSTS) Pharma Consortium: Overview and Invitation to Join

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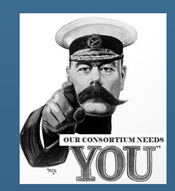
You have all seen the impact of Simcyp® on drug development in your company. Now we want to replicate this success in the area of drug safety. Please encourage your toxicology & safety pharmacology colleagues to contact us about our QSTS Consortium initiative!



Background & Objective

Safety issues occurring preclinically, during clinical development or post-marketing, make a significant contribution to attrition of candidate drugs, delays to drug project progression and registration, product labelling, physician prescribing preference, patient compliance, and withdrawal from sale.

Our long-term vision is to transfer safety pharmacology, toxicology and patient safety to the in silico world, bit by bit.

To get there we aim to provide a multi-organ modelling & simulation toolbox for safety pharmacology, toxicology and patient safety, to a quality standard acceptable to regulatory agencies, with the ability to link these platforms together.

In order to achieve this we intend to convene a consortium similar to the Simcyp consortium: a multi-year project with clear milestones and deliverables leading to a suite of in silico tools to support drug discovery, development and regulatory submission.

We will start the consortium-agreed activities from January 2020.

The Certara QSTS Consortium Format

The format would essentially be the same as the Simcyp consortium, which started with 3-4 pharma companies and grew from there.

This would be backed-up with collaborations with key academic groups, small-medium enterprises and subject matter experts.

Voting on 'wish list' items would be as per the Simcyp consortium.

Proposed short-term deliverables

Our priority organ systems are the 'Big Three' in terms of impact and attrition due to safety, namely cardiovascular, CNS and liver.

We would opt to go for some 'low-hanging fruit' in the first year:

These may not be everyone's burning priorities in toxicology and safety pharmacology, but our reasons are as follows:

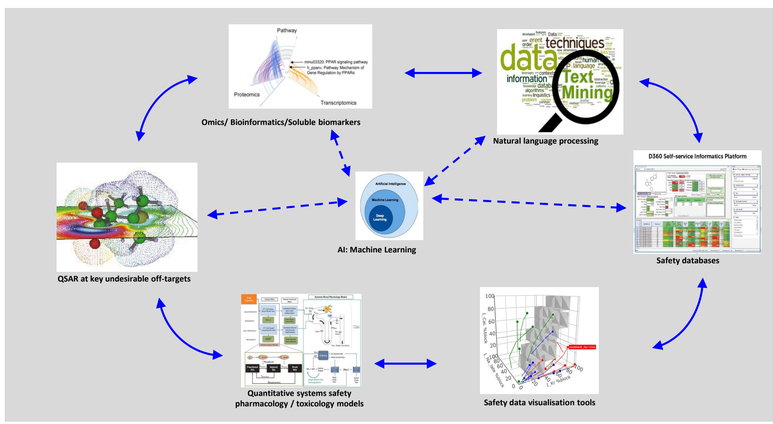
1. We need to hit the ground running with an immediate pre-filled list, rather than respond to a wish list from a face-to-face consortium meeting in January 2020, from a standing start;

2. The areas selected are the most tractable/achievable; achieving success with these will raise confidence about use of an in silico approach in toxicology and safety pharmacology;

3. In the first year we have to all get used to working with each other, and the data format requirements etc., and going about it this way will help optimise how we go on to tackle the more challenging areas of safety later on.

The ultimate QSTS in silico toolbox

This is the in silico toolbox we ultimately aim to achieve; however our initial focus will play to our strengths, namely quantitative systems safety modelling.



Contacts

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Meet the QSTS Team

Will Redfern PhD joined Certara in April 2019 as Vice President, QSTS. Experienced safety pharmacologist, having worked at AstraZeneca for over 20 years, and before that, Syntex and Quintiles. Former president of the Safety Pharmacology Society.

Mark Holbrook PhD joined Certara in 2018 and is Senior Advisor to the QSTS Team. Experienced safety pharmacologist, having worked at Celltech, AstraZeneca, Pfizer and Covance.

Ciarán Fisher PhD is a Principal Scientist in QSTS. Joined Certara in 2015 and has worked on distribution models and reverse translation approaches within the Simcyp Simulator and as part of the EUToxRisk (H2020) and TransQST (IMI) projects.

Jeremy Craven PhD is a Senior Research Scientist in QSTS. Before moving to Certara in 2018, Jeremy worked for 25 years at the University of Sheffield in the Department of Molecular Biology and Biotechnology, working primarily in the areas of structural biology and molecular and cellular modelling.

Sebastian Polak PhD is a Senior Principal Scientist. Joined SimCyp in 2007 and led the development of a cardiac safety modelling and simulation system (CSS – Cardiac Safety Simulator). Also Professor in Biopharmacy at the Jagiellonian University Medical College, Kraków, Poland.

Mitra Abbasi PhD is a Research Scientist and has been working for Certara UK Limited's Simcyp Division since June 2015. She has been involved in multiple Simcyp projects. She has developed safety pharmacology algorithms for Simcyp's Cardiac Safety Simulator (Simcyp-CSS).

Sofia Ferreira PhD is a Research Associate. She Joined Certara in 2017 and her role involves research, data collection and mechanistic modelling for projects related with QSTS. She is part of the TransQST and EUToxRisk projects developing PBTK/TD models to evaluate the safety of medicines and other chemicals.

Vipul Gupta PhD is a Research Associate. He joined Certara in 2018. In his current role, he is constructing a large-scale kinetic model of liver metabolism coupled with PBPK to evaluate drug toxicity as a part of the TransQST IMI-2 consortium.

Dennis Reddyhoff PhD is a Research Associate. He joined Certara in 2017 initially as part of Translational Science in DMPK before moving to QSTS and is contributing to the TransQST and EUToxRisk projects.

Zofia Tylutki PhD is a Research Scientist. She joined the company in August 2018, contributing to the TransQST, eTRANSAFE and EUToxRisk projects. Zofia works part-time at Certara (based in Kraków), and 2 days per week at the Jagiellonian University.

The CERTARA QSTS Team 2019

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