DEVELOPMENT SCIENCES: Innovation & Technology

TITLE

Predicting an Immune Response in Patients (Collaboration with Industry Consortium)

SUMMARY

An industry wide consortium* focused on building a mathematical model (QSP model) of immune response to a drug, that integrates bioinformatics and in vitro screening assays with mechanistic knowledge to predict likelihood of unwanted immune response in patients/populations with a given HLA type/composition
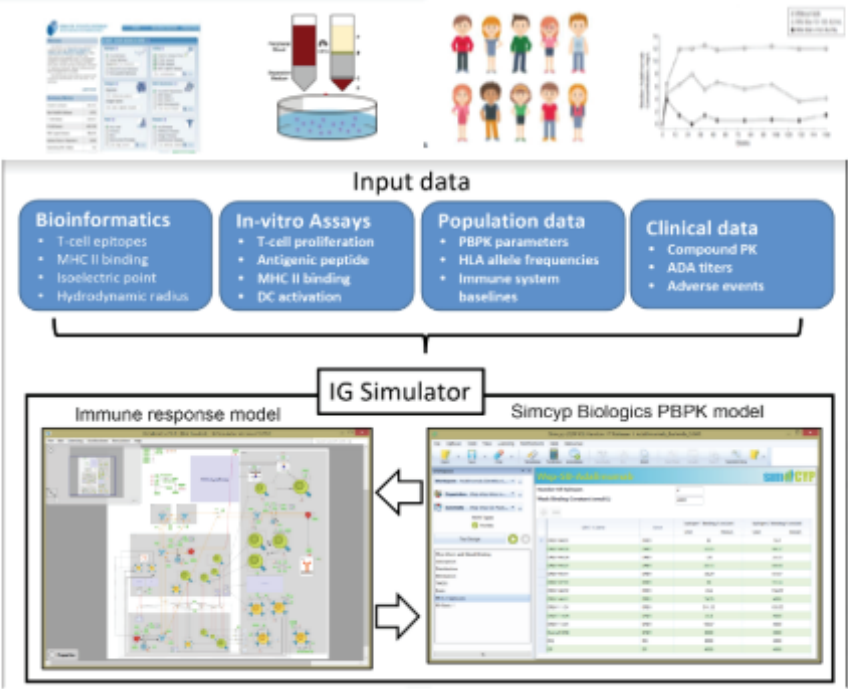
*Companies include: Certara, BMS, Pfizer, Astellas, Astra-Zeneca, Abbvie, Roche/Genentech
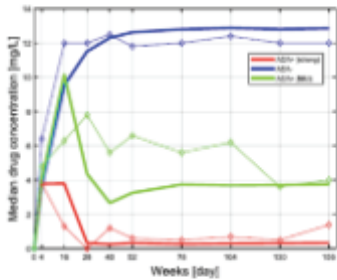
IMPACT

- Influence molecule design to minimize immunogenicity risk

- Identify molecules/patients with high risk of immunogenicity

- Risk mitigation strategy for immunogenic molecules

How it's done: The Mechanics Behind the Model

1. **Mathematical model built** from literature, in vitro, and clinical data to simulate anti-drug antibodies

2. **Model tested** with clinical study data sets from different companies participating.

Input data

Bioinformatics	In-vitro Assays	Population data	Clinical data
• T-cell epitopes	• T-cell proliferation	• PBPK parameters	• Compound PK
• MHC II binding	• Antigenic peptide	• HLA allele frequencies	• ADA titers
• Isoelectric point	• MHC II binding	• Immune system baselines	• Adverse events
• Hydrodynamic radius	• DC activation		

IG Simulator

Immune response model   Simcyp Biologics PBPK model

Predicted IG risk
Predicted IG profiles
Virtual Trials

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