Health Partnering Day 2016
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Health-related topics: ICT, SSH, Food Security
SC1-PM-16-2017

TITLE: *In silico* Trials for Developing and Assessing biomedical products

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Fit for Health 2.0 and HEALTH-NCP-NET 2.0 projects are funded by the European Commission

Project idea / SimOmics expertise

Project idea: *In silico* trials for developing and assessing immunotherapies for cancer, autoimmune disease and infection

Why this focus:

- **Immunomodulators** including monoclonal antibody, cell therapies, vaccines, small molecules and novel biologics have been shown key efficacy in the treatment of cancer, autoimmune diseases and infection. Over 20 billion Euros/year is being spent on R&D for immunotherapies for these diseases.
- **The 3Rs:** Small animal models are often poor in translation due to difference in epitopes and immune function between mice and humans. Non-human primates are expensive and raise ethical concerns, modelling provides an approach that reduces and refines animal usage.
- ***In silico* models:** Thus the need for approaches that capture disease *complexity*, patient *heterogeneity* and therapeutic *delivery* leading to a decrease in development costs, time to market, off target problems and better trial design.

SimOmics is an SME with key expertise in simulation modelling of immune function applying principles from critical systems engineering to provide confidence in the disease models. Simomics has worked with pharmaceutical and chemical industry to develop evidence based models for therapeutic discovery/development and chemical safety testing.

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Topic

SC1-PM-16-2017: *In silico* trials for developing and assessing biomedical products.

Title: *In silico* trials for developing and assessing immunotherapies for cancer, autoimmune disease and infection

Aims and objectives are to develop:

1. A set of exemplar *in silico* projects identified as priority areas by pharmaceutical industry where novel immunotherapeutics are key priorities and key assets are undergoing clinical trials. The three disease areas are:

- **Rheumatoid Arthritis:** (autoimmune disease)
- **Colorectal Cancer:** (tumour immunotherapy)
- **Tuberculosis:** (infection)

2. Key standards for *in silico* trials and model development

3. Platforms and processes that can be re-used in chemical safety testing

4. A framework to work with regulators (EMA/FDA) to ensure model outputs can be used as part of the therapeutic approval process

How: A collaboration of SMEs, academic and pharmaceutical/chemical testing industry with key expertise in modelling and systems biology coupled to clinical and industrial expertise.

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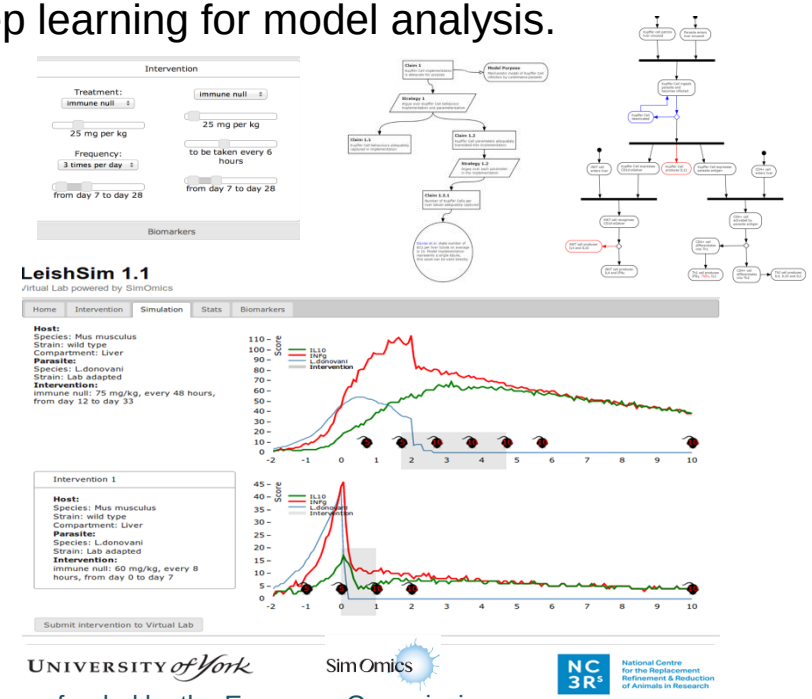
Applying SimOmics Technologies in model development

SimOmics technologies, software and expertise:

Evidence Tool: a series of tools to support the development, and deployment of computer-based simulations to support decision making in pharmaceutical development and chemical testing.

Model Processes and analysis: Multi-scale modelling, domain modelling languages, statistical analysis packages, visualisation tools, deep learning for model analysis.



What are we looking for in potential partners:

- **Expertise in DMPK modelling in these disease areas**
- **Development of libraries of virtual patients that can be re-used and post-competitive testing of biomedical products**
- **Experience in working with regulators**

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Contact details

Thank you!

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