

BioSim – a new tool in drug development

Thematic area: Life Sciences, Genomics and Biotechnology for Health.

Instrument: Network of Excellence

Co-ordinated by: The Technical University of Denmark.

Total budget: 18m€

Duration of project: 5 years from December 2004.

Number of partners: 44

Subject of case study: Simcyp, Sheffield.

Project website: <http://biosim.fysik.dtu.dk:8080/biosim/>

The Challenge

Pharmaceutical R&D is lengthy, costly and the success rate in delivering new drugs is often perceived to be low. The biology of disease can be highly complex. An increased understanding of the underlying pathways in pathobiology and a more rational approach to the design, selection and testing of drugs should be possible in consequence of the increasing use of computational models to provide a dynamic and quantitative description of the relevant physiological, pharmacokinetic and pharmacological processes.

The Project

BioSim is intended to strengthen the area of biosimulation, by application of biological modelling as a tool to support the pharmaceutical sector in discovering and developing safe and effective drugs efficiently and, perhaps, more quickly and cheaply. The network takes a broad view of the opportunities to develop *in silico* simulation models for cellular, physiological and pharmacological processes involved in drug efficacy, metabolism and safety.

There is significant European academic strength in computer assisted modelling but the efforts are often fragmented because of the diversity within the broad field. Industry has an increasing need to recruit modellers but is not currently well served by universities because of a lack of training programmes. The BioSim Network of Excellence represents a new forum for collaboration across the disciplines and between academia and industry. By seeking to capitalise systematically on the rapidly growing volume of biological information and drawing on expertise from complex systems theory, BioSim provides a new resource for hypothesis generation and testing.

The Consortium

BioSim comprises 44 members drawn from universities, four Member State regulatory agencies, large companies and nine SMEs, and is collaborating with the European Federation of Pharmaceutical Sciences.

The view from Simcyp

European added value for BioSim

The UK is strong in the fundamental academic disciplines of biology and mathematics and has recognised the importance of biomathematics as a key interface in the life sciences and engineering. But there has been a decline in UK academic capabilities in some of the traditional areas most relevant to the work of pharmaceutical companies, in particular in pharmacology, clinical pharmacology and toxicology. This academic weakness has grown

despite national recognition of the economic importance of the pharmaceutical sector and the efforts of companies to articulate their needs for training and for a supportive research environment. Therefore, BioSim and other efforts at the EU level are valuable in stimulating awareness of the importance of rebuilding the academic sector expertise in education, research and training to underpin private sector drug discovery and development – perhaps particularly in safety assessment capability.

In addition to these long-term objectives for the field, Simcyp hopes to benefit from participation in BioSim in several ways.

1. By hosting and exchanging postdoctoral researchers to build company research efforts.
2. By access to European databases of physiological, demographic and other information with which to construct virtual populations, develop predictive algorithms and employ in meta analysis of data sets.
3. Participation by regulatory authorities is an important attraction for the industry partners in BioSim because of the collective opportunity to develop the future environment for the science-based registration of new drugs. Too often regulatory agencies are only involved in the later stages of drug innovation – their strong presence in BioSim is a stimulus to build engagement during the formative stages of pharmaceutical R&D.

Involving larger pharmaceutical companies

One initial problem in building the consortium was that some larger pharmaceutical companies have been reluctant to get involved in FP6, deterred by perceptions of excessive documentation requirements and management complexities within a large Network of Excellence. Yet, it is essential for industry experience and perspectives to be captured within the network if the academic expertise is to be applied realistically and in order to capitalise on the training and mobility opportunities offered by the network. In this context, Simcyp as SME partner is a particularly valuable asset to the consortium, not just because of the specific technical expertise it contributes but also because of its many pre-existing links with large pharmaceutical companies: there is an expectation that Simcyp can provide a vital interface for the Network of Excellence.

Judging value

In its second year of operation Simcyp is already creating good links to the partners within its specific Work Package. Building on the early deliverables arising from collaboration and transfer of expertise, the Network of Excellence will be judged successful by Simcyp if it results in new training programmes for data analysis and modelling. Improving these skills would help the EU to compete on a global basis in understanding all the elements that constitute the “big picture” of drug development and, thereby, facilitating company R&D efforts in innovation.

Tips for success

Although this Network of Excellence is still at an early stage, other lessons can be drawn from the current experience:

- *Communication* Good communication and management procedures are essential in a large Network of Excellence. Therefore, excellence in scientific leadership must be

augmented by the professional management competencies that are needed for strong coordination and a collective awareness of the longer timelines that may be necessary for a larger network to enable all partners to benefit, for example, in arranging consortium meetings to consolidate the networking and attain critical mass.

- *Industry engagement* There is little doubt that a Network of Excellence can be successful in bringing together leading centres of academic expertise. But if that expertise is also to be employed successfully in support of EU innovation and competitiveness then it is very important to ensure that the network is “industry friendly” so that the network understands how the private sector works and what it needs from the public sector. For example, the future use of the Network of Excellence as an instrument to engage with industry requires early commitment to (i) clarifying Intellectual Property issues and (ii) involving industry as host for consortium-funded postgraduate and postdoctoral students.
- *European coherence* The BioSim Network of Excellence is an important initiative but it is not the only EU-funded activity in this area. For example, the Innomed PredTox Integrated Project and the COST programme on physiologically based pharmacokinetic modelling are also exploring relevant topics. There is scope for better strategic integration between these multiple activities, particularly with a view to establishing a permanent role for the Network of Excellence, if it can successfully draw on applied as well as basic science.