

ScanBalt Clinical Research Network

- Network building between pre-clinical study centres and clinical facilities
- ITC solutions for conducting clinical trials



Participants:

Estonian Genome Project Foundation

Paul Stradins Clinical University Hospital

Sahlgrenska University Hospital

Pipeline Biotech

Tartu Biotechnology Park Ltd.

Curonia Research Ltd.

Moby Solutions Ltd.

Title: ScanBalt Clinical Research Network		
Nordic Innovation Centre project number: 04096		
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Abstract: <p>The idea of the ScanBalt Clinical Research Network is to take advantage of existing knowledge and experience of the universities, hospitals and companies in the meta-region and to link flexibly pre-clinical study centres and clinical facilities in the modern ITC infrastructure in order to create a dynamic and comprehensive platform for high quality academic and commercial research projects.</p> <p>There is a growing demand for highly specific clinical trials. The Nordic-Baltic countries and regions are too small on their own to be able to supply large enough trial groups. Through cooperation the Nordic-Baltic region can position itself on the clinical research testing map to the benefit for researchers, entrepreneurs and society as a whole. The idea of the project is to take advantage of the existing knowledge and experience of the universities, hospitals and companies in the Nordic and Baltic areas to create a dynamic and comprehensive platform for high quality pre-clinical and clinical research. ScanBalt Clinical Research Network is envisaged to link flexibly pre-clinical animal study centres and clinical facilities in the 21st century ICT infrastructure in the Baltic Sea area.</p> <p>As a result of the project completed mapping of the competencies and resources in the field of pre-clinical research, clinical trials, and mobile ICT solutions for conducting clinical trials was carried out. Based on this a database for the purpose of competencies and partner search was created. The project results support the understanding, that the patient recruitment network in the region is very needed to be competitive in clinical research. However, the scope of the continued activities should be more focused and the goal should be establishing a financially feasible and working network that could be used for patient recruitment in the overall ScanBalt region, as this was identified to be the hardest problem arising from the relative smallness of the region's countries in the world scale.</p>		
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ScanBalt Clinical Research Network

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Project summary

ScanBalt Clinical Research Network was a pilot project, which overall aim was to give added value to the vision of ScanBalt BioRegion: to be a globally competitive meta-region. Specific objectives of the project were:

1. to map the resources and competencies of clinical research in the region;
2. to create a virtual meeting point and database;
3. to identify the personalities of continued activities in the network.

To achieve abovementioned goals, at first three work groups were formed: pre-clinical, clinical, and ICT solutions for conducting clinical trials. The aim of the preclinical and clinical subproject was to set up the organizational and IT infrastructure enabling the coordinated high quality and flexible clinical research. The aim of ICT work group was to map the existing technologies, which have the most suitable solutions for building a comprehensive platform for patient follow-up. Also a steering committee and work group leaders were selected. They met three times during the project in order to share information about the development of the process, to discuss the necessary improvements in database development, and to confirm the future activities needed.

In order to increase the level of contacts needed to enlarge the size of database, the project partners recruited so called affiliated partners to trigger cooperation and to inform the potentially interested persons/institutions about the project and its aims using their local network. Hence, partner search through partners took place. In addition other projects and existing databases were used to increase the number of entries in the database. Leaflets with a short overview of the project aims and benefits, and instructions to join the database were disseminated at several international conferences and events in Sweden, in Estonia and in Belgium. Two workshops during the project were carried out to bring interested parties together to introduce them the project, its results, and to collect feedback regarding the project's benefit and suggestions for database improvement.

From technical barriers of the project communication problems (language barriers) were often the obstructive factors in the process of finding suitable cooperation partners for database enlargement. This was especially so in Estonia, Latvia, Russia, Poland, as well as in Germany and Finland as the web pages include information only in the local language.

However, the principal problem that the project partners faced during the project was the clash of interests. Especially large clinical research organisations (CROs) saw the project as a competitor in their field and are at the moment not really ready to cooperate. Nevertheless, several participants had the experience, that smaller CROs are very much interested in the ScanBalt Clinical Research Network. Although hospitals readily gave the data, the majority of hospitals were in an opinion, that before the patient recruitment network has not achieved financial sustainability, they are not willing to participate in it actively. Hence, hospitals are ready to network, if somebody else funds it. It also appeared that companies are not interested in mapping, if these do not generate any revenue and profits to them. They are not very keen in looking far ahead. Hence, as a result of the project it was concluded that the discrepancy of interests between different potential partners and participants in ScanBalt Clinical Research Network (all kinds of hospitals, CROs, university research groups and private companies that offer pre-clinical, clinical or ICT services for conducting clinical trials) is so big that it is not reasonable to try to create a big universal network that would have data of all the possible patients.

Despite some setbacks all project aims were achieved. In the field of ICT solutions the project concentrated on the latter phases of drug development mapping existing technologies, which have the most suitable solutions for patient follow-up. However, innovative medicine calls for involvement for new technologies already in the development process. ICT solutions are important

tools for drug discovery, because they can significantly reduce drug-discovery costs and time-to-market. Some phases of pre-clinical drug development where IT is more and more important are following:

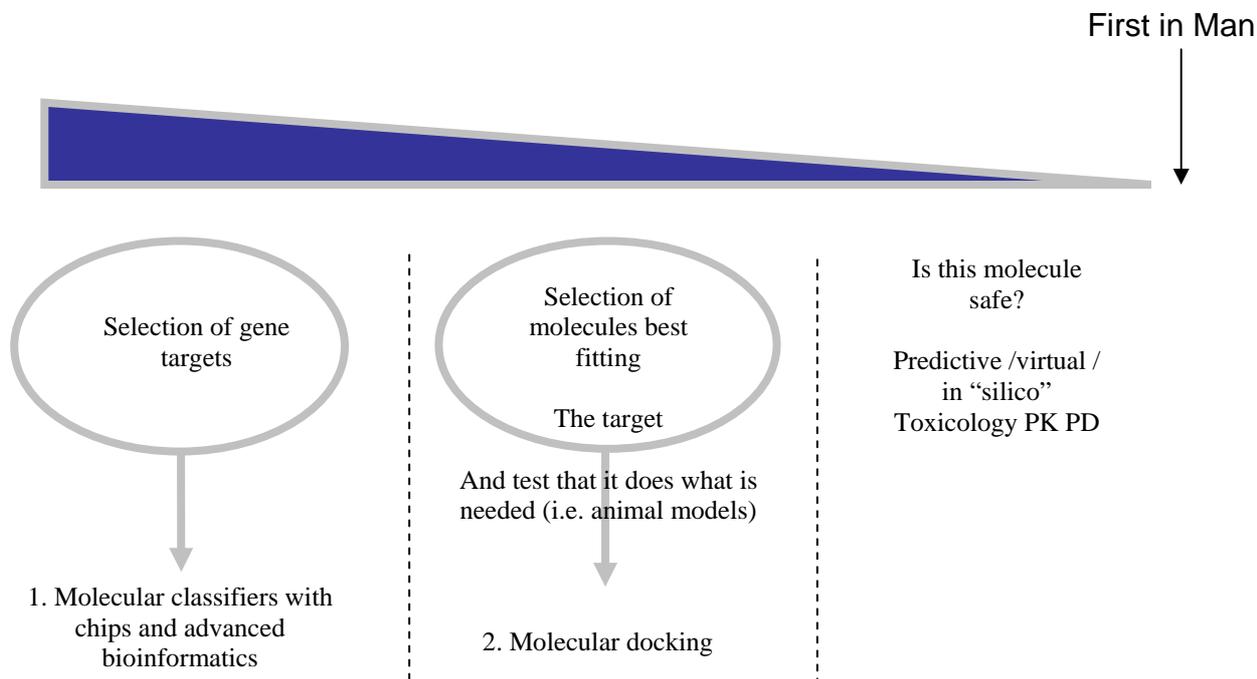


Figure 1. The importance of ITC solution during the phases of pre-clinical drug development (Berta Villegas, ScanBalt Clinical Research Network – ScanBalt Forum 2005, Oslo)

With an aim to boost cooperation and to reduce drug-discovery costs also a database for the purpose of easy access to competencies, partner search and cooperation regarding clinical research in the region was created as a result of this project. During the project 205 entries of companies, universities, and other organizations were collected in the fields of pre-clinical and clinical research as well as information and communication technologies providers. There are database entries from ten different countries: Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Norway, Poland, Russia, Sweden, USA, and Singapore. Also core persons and institutions necessary for future activities were contacted.

As a result of the mapping process it turned out that the public private partnerships (PPP) in form of joint collaboration in the the field of clinical research is very needed. There exists also a growing need for the exploitation of cross-disciplinary innovation potential to make clinical studies easier, faster, safer and of higher quality, thus stimulating the competitiveness of academic research as well as the capacity of the industry to develop new drugs faster. From the point of view of the ScanBalt Clinical Research Network project partners as well as participants, efficient patient recruitment network and new ICT solutions could be the best ways to address public health challenges in the Nordic-Baltic region, because uncoordinated action reduce the capacity to enrol patients in clinical studies, increasing the costs of clinical research, and hampering scientific productivity. Considering the smallness of the Nordic-Baltic region it has to centralize the resources to pool competence and increase effectiveness in order to be competitive in the world context.

However, it was agreed that the scope of the continued activities should be more focused as otherwise it would start competing with big clinical research organizations and this is not needed, as it would be difficult to achieve a competitive advantage or some unique point, that would justify the networks existence. Therefore, it was proposed, that the network could specify itself on some

specific disease area and enable deeper research and cooperation possibilities. The goal should be establishing a financially feasible and working network, that could be used for patient recruitment in the overall ScanBalt region.

To conclude, as a result of the pilot project the initial mapping of spearhead competencies, potential partners and participants in ScanBalt Clinical Research Network was carried out. The database that was compiled based on this data is beneficial to researchers, CROs, hospitals (especially clinical trial units), and private companies, that offer pre-clinical, clinical or ICT services for conducting clinical trials. Having regard to future activities knowledge of existing problems, obstacles and needs in the drug development are of value.

Based on this gained knowledge it was concluded that the future vision of the project based on this pilot is to set up a working patient recruitment network in the ScanBalt region starting from the network based one disease area, the most probably diabetes. The new organisation will be based on the interconnection of networks of academic infrastructures (trial units and clinical research centres) for clinical research as well as of hospitals interconnection with industrial partners. This network could provide substantial support through services facilitating transnational trials. Based on the results of this project it will be possible to extend the network stepwise to other disease areas after the „base” network has achieved its viability.

Next step from ScanBalt is to concentrate on the technical project with preparing a detailed plan to this end, to pinpoint acting partners for the first disease specific network as well as to prepare a preliminary financial plan for the first step.

Appendix 1. An example page from the database

The screenshot shows the ScanBalt Clinical Research Network Mapping interface. At the top, there is a navigation bar with 'The BioRegion Incubator Projects Activities Organisation Members' and a search bar. The main header includes 'NETWORK OF NETWORKS' and the ScanBalt logo. The sidebar on the left lists various network categories such as 'Educational mobility', 'Economic Barriers for borderless Cooperation', and 'ScanBalt Clinical Research network'. The main content area shows search results for 'Preclinical' in 'Finland'. Two results are displayed: DelSiTech and Novamass Analytical. Each result includes contact information and a list of competences.

Home » Projects » ScanBalt Clinical Research network » Clinical Research database

THE SCANBALT CLINICAL RESEARCH NETWORK MAPPING

Area:

Country:

Free text:

In the free text field you can search for words in all of the fields. It can either be part of a company name or scientific keywords.

Area	Preclinical
clinic/company/lab	DelSiTech
Address	Tykistökatu 4 D
Postal code	20520
City	Turku
Phone number	
Country	Finland
Website	http://www.delsitech.com/
Contact person	Harry Jalonen
Contact e-mail	harry.jalonen@delsitech.com
Preclinical competences	in Vivo delivery system
Other preclinical competences	
Clinical competences	
Other clinical competences	
ICT competences	
Other ICT competences	
Unique strengths	silica-based implant, subcutaneous and intra-muscular injectable technology for controlled release of small molecular drugs and biopharmaceuticals: proteins, polysaccharides (heparin) and viruses.
Collaboration interests	
ongoing collaborations	
Additional information	
Area	Preclinical
clinic/company/lab	Novamass Analytical
Address	P.O.Box 3000/Chemistry
Postal code	90014
City	Oulu
Phone number	
Country	Finland
Website	http://www.novamass.net/
Contact person	Jouko Uusitalo
Contact e-mail	info@novamass.net
Preclinical competences	
Other preclinical competences	CRO
Clinical competences	
Other clinical competences	

ICT competences	
Other ICT competences	
Unique strengths	studies on in vitro ADME (drug metabolism, CYP related drug-drug interactions and permeation) as well as provide tailor-made problem solving based on LC/MS and NMR techniques
Collaboration interests	
ongoing collaborations	
Additional information	
Area	Preclinical
clinic/company/lab	Pharmatest Services
Address	Itäinen Pitkätatu 4C, 2nd floor
Postal code	FIN-20520
City	Turku
Phone number	
Country	Finland
Website	http://www.pharma-test.net/
Contact person	Jussi Halleen
Contact e-mail	jussi.halleen@pharma-test.net
Preclinical competences	
Other preclinical competences	CRO
Clinical competences	
Other clinical competences	
ICT competences	
Other ICT competences	
Unique strengths	Services for the testing of drug compounds (especially oncology, functional foods, osteoporosis and osteoarthritis).
Collaboration interests	
ongoing collaborations	
Additional information	
Area	Preclinical
clinic/company/lab	Safety City
Address	Itäinen Pitkätatu 4 B
Postal code	FIN-20520
City	Turku
Phone number	
Country	Finland
Website	www.safetycity.fi
Contact person	Tero Karhi
Contact e-mail	tero.karhi@safetycity.fi
Preclinical competences	
Other preclinical competences	CRO
Clinical competences	
Other clinical competences	
ICT competences	
Other ICT competences	
Unique strengths	Services include toxicology, pharmacology, hematology, histology and histopathology
Collaboration interests	
ongoing collaborations	
Additional information	

Appendix 2:

The vision, mission and strategy for financially sustainable network

The vision of the follow-up proof of concept project to the ScanBalt Clinical Research Network pilot project is to set up a working patient recruitment network in the ScanBalt region embracing one disease area - diabetes. The new organization will be based on the interconnection network of academic clinical research infrastructures, hospitals, patients and industry.

This diabetes network has to provide effective and efficient infrastructure for prompt recruitment of patients and for clinical trial management: legally and organizationally sound tool for electronic selection of patients from different clinical databases and research sites, efficient system for obtaining approvals by ethics committees and obtaining informed consent from participants, appropriate management IT tool for conducting and monitoring clinical trials and securing the quality of the data generated.

The transnational pattern of the planned thematic network will most probably be a challenge. Careful mapping of legal systems and inner regulations of the partnering networks/databases will be crucial to address the cross-border nature of the network. Effective contractual system between partners will be a necessary output of the legal exercise. Another pillar for the sustainable clinical research infrastructure will be well balanced basic rules and financial conditions of the partnering. The pricing conditions for users of the network have to be enough to maintain and develop the system yet affordable and competitive for partners in academic endeavor. Additionally appropriate IT infrastructure for conducting clinical trials has to be selected, adjusted and, if necessary, developed.

To achieve above, a capable and motivated lead partner as well as active local partners are needed. It will be an advantage to make the network operational by the opening of the funding possibilities under FP7, including the planned Innovation Medicine Initiative Technology Platform.

The Estonian Genome Project Foundation in cooperation with Tartu Biotechnology Park and Sahlgrenska University Hospital has started to select partners as well to design general outline for this proof of principle project. It will be important to engage an industrial pharma partner in early phase of the planning of the project. So, in parallel preliminary talks with a leading diabetes company Novo Nordisk have been initiated. The draft project plan and application is scheduled to be completed by October, 2006.

The proof of concept project, if successful, can be stepwise extended to other therapeutic areas as well as to wider European regions.



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Nordic Innovation Centre

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The Nordic Innovation Centre initiates and finances activities that enhance innovation collaboration and develop and maintain a smoothly functioning market in the Nordic region.

The Centre works primarily with small and medium-sized companies (SMEs) in the Nordic countries. Other important partners are those most closely involved with innovation and market surveillance, such as industrial organisations and interest groups, research institutions and public authorities.

The Nordic Innovation Centre is an institution under the Nordic Council of Ministers. Its secretariat is in Oslo.

For more information: www.nordicinnovation.net