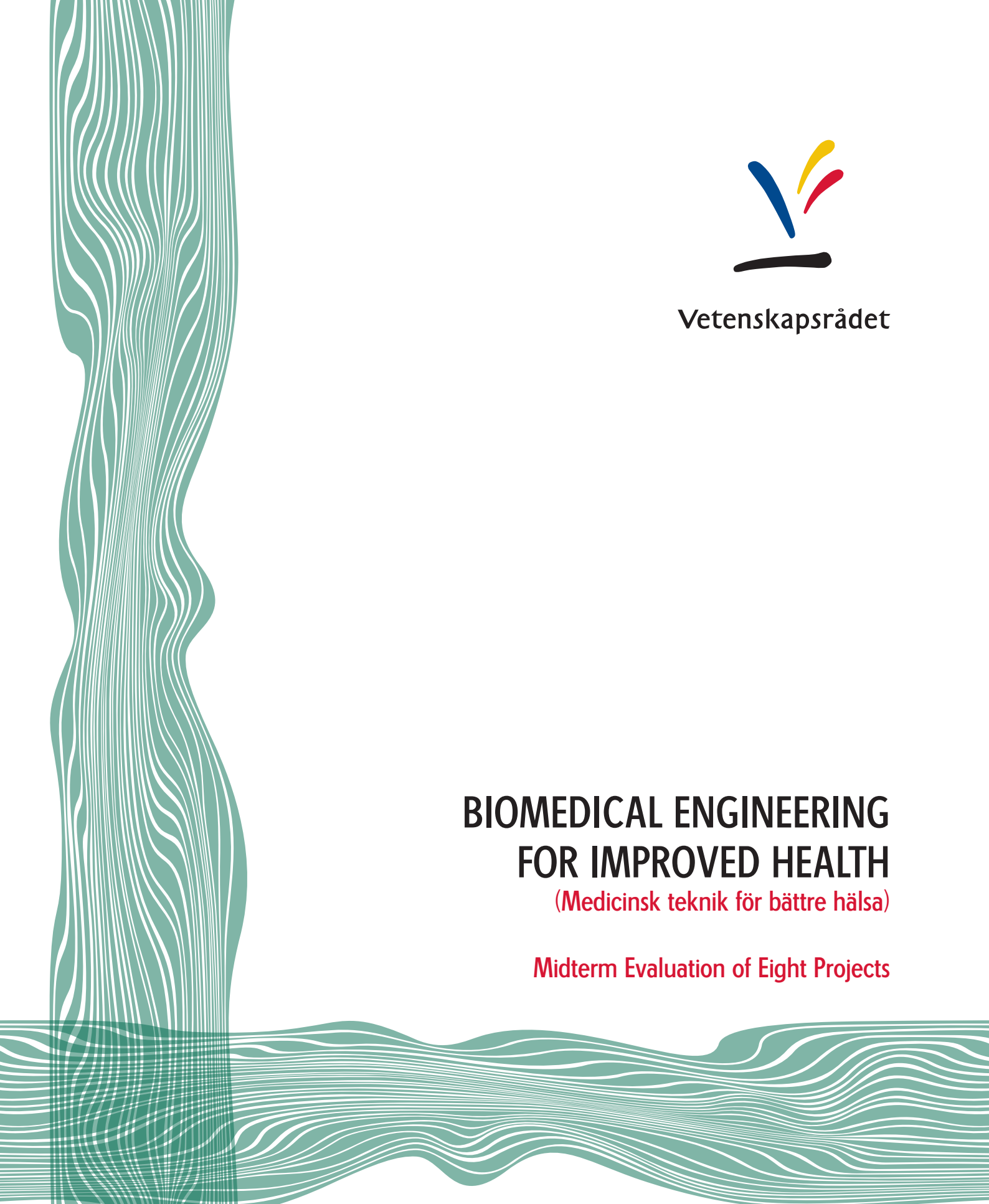

Vetenskapsrådet

BIOMEDICAL ENGINEERING FOR IMPROVED HEALTH

(Medicinsk teknik för bättre hälsa)

Midterm Evaluation of Eight Projects

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BIOMEDICAL ENGINEERING FOR IMPROVED HEALTH

(Medicinsk teknik för bättre hälsa)

Midterm Evaluation of Eight Projects

Joint Panel Report

Stockholm, 25–27 October 2009

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INTRODUCTION

1 Background to the joint programme

The Swedish Foundation for Strategic Research (SSF), the Swedish Agency for Innovation Systems (VINNOVA) and the Swedish Research Council (VR) in 2005 jointly initiated a comprehensive evaluation of Swedish research in Biomedical Engineering and related fields. The results were published in May 2006 under the title, *International evaluation of Swedish research in Biomedical Engineering*, Report 8:2006, Swedish Research Council (http://www.vr.se/download/18.176bc5ab10c4b8a9a5080001182/Medicinsk+Teknik+8+2006.pdf).

In parallel with carrying out the area evaluation, the panel was charged with the task to recommend topics and forms of support for a joint Call for Proposals planned to take place in the autumn of 2006. The panel proposed six areas to be addressed by the new Call, of which the Swedish funding bodies chose to keep five priority areas. Further, the panel recommended two modes of support, one called "Group Grants" (GG) directed towards projects that involve collaboration between at least two groups with complementary scientific directions within biomedical engineering and medicine/life sciences, respectively, the other one named "Young Faculty Grants" (YFG), intended to assist young researchers in building a platform of their own to establish new bold and independent research avenues in biomedical engineering.

A call in line with the panel's recommendation was made in June under the title *Biomedical Engineering for Improved Health* (MTBH). In late September 2006, 116 applications had been submitted, 82 of which were for GG and 34 for YFG. A new panel with eight members, chaired by Professor Richard Kitney, Imperial College, London (who had also been a member of the BME area evaluation panel), spent two days in Sweden to prioritise projects for funding. The funding bodies followed the panel's recommendation, announcing the new grant holders in late January 2007.

The strategic objective of the programme was to *stimulate novel and groundbreaking research addressing qualified medical needs with high prospective user value and with a high potential for innovation*. Means for the programme, SEK 81 million, were set aside for a five-year period from January 2007. The grants were initially approved for three years with a view to prolongation with up to two years, based upon the results of a Midterm Evaluation. Eight proposals were funded, five Group Grants and three Young Faculty Grants (for abstracts, see Appendix A).

2 Projects granted 2007–2009

Initial grants to the eight MTBH projects 2007–2009 were as follows (amounts in SEK thousand):

Grant holder	Project title Group Grants	Granted 2007–2009	Applied for 2010–2011
Paul Gatenholm	Biosynthetic Blood Vessels. From laboratory to patient care	9 641	7 290
Thomas Laurell	Integration of new biomarkers for prostate cancer diagnostics on high sensitivity nanotextured microchips	6 241	5 656
Bo Nilsson	Creation of an extrapancreatic insulin-producing organ for implantation in type 1 diabetic patients.	8 169	6 204
Göran Stemme	Rapid Pathogen Analyzer	7 743	7 858
Karin Wårdell	Neuro-engineering for navigation, intervention and implementation in neurosurgery	7 681	8 072

Grant holder	Project title Young Faculty Grants	Granted 2007–2009	Applied for 2010–2011
Anders Eklund	Towards non-invasive measurement of the cerebrospinal fluid system dynamics using MRI	3 526	4 000
T Christian Gasser	Integrated biomechanically based diagnoses of abdominal aortic aneurysms	4 250	3 000
Madeleine Ramstedt	Creation of safe antibacterial surfaces on biomaterials	1 805	0
	Total Group Grants + Young Faculty Grants	**49 056**	**42 080**

3 Midterm evaluation panel

The panel comprised five experts:

- Professor Richard Kitney (Chairman), Imperial College, Dept of Bioengineering, London, UK. http://www.bg.ic.ac.uk/staff/rikitney/
- Professor Alicia El Haj, Keele University, Institute for Science & Technology in Medicine, Stoke-on-Trent, UK. http://www.keele.ac.uk/research/istm/alicia.htm
- Ass Professor Claudine Gehin, Lyon Institute of Nanotechnology, Dept of Biomedical Sensors, Villeurbanne, FR. http://leom.ec-lyon.fr/personnel/personnel_detail.php?Nom=gehin
- Professor Roger D Kamm, Massachusetts Institute of Technology (MIT), Dept of Mechanical and Biological Engineering, Cambridge, MA, USA. http://meche.mit.edu/people/faculty/index.html?id=47
- Professor Jean-Philippe Thiran, Swiss Federal Institute of Technology (EPFL), Signal Processing Laboratory, Lausanne, CH. http://lts5www.epfl.ch/~thiran

4 Evaluation process

The funding bodies in the spring of 2009 decided to apply a procedure with a combination of distance reviews of progress reports for years 1-3 from the grant holders and a panel conducting hearings with the eight project groups. An international panel with five members was appointed, again chaired by Richard Kitney but with four new members this time – three genuinely new ones and one who had served as a distance reviewer in the original BME area evaluation. The distance evaluators, on their part, included some of the members from the 2006 prioritisation panel but also other experts.

The charge of the 2009 panel was to assess progress in the eight projects as of 31 August 2009, scientifically and otherwise, and to give recommendations for funding for 2010-2011 of those projects that applied for a grant for the final term of two years. In addition, the panel was asked to share some general observations at overall programme level. The amount available for the remaining period of the programme is SEK 32 million.

The grant holders were asked to submit their midterm reports according to guidelines (Appendix B) jointly produced by the three funding bodies. Deadline for the reports was 31 August 2009. The midterm reports were peer-reviewed by in total 9 international experts (Appendix C) outside the circles of the panel. Guidelines to the distance evaluators and forms to fill out for the evaluations reports (Appendix D) were jointly produced by the three funding bodies. The original proposals granted were also available as was a brief description of the two types of grants as background material. Each midterm report was assessed by at least three experts, resulting in 25 distance evaluation reports. The latter were submitted by 5 October 2009 and immediately made available to the panel members.

The panel meeting was held in Stockholm on 25-27 October 2009 (Appendix E). During the panel visit one-hour hearing sessions were performed with representatives for each grant, 3-5 persons per group grant and 1-3 per young faculty grant (Appendix F). Each session started with a 30 min presentation by the group according to the following structure:

- Overall description of the project.
- Results achieved so far (also noting progress made after submission of Midterm Report).
- Work plan for years 4 and 5.
- Expected overall results as compared to the objectives stated in the original proposal.

The second half of each hearing was devoted to questions from the panel and discussion.

Between the sessions the panel held internal discussions. After the final hearing session the panel members drafted their report. The draft was mutually undersigned. The chairman later provided a slightly edited version, in which he had corrected some linguistic errors and standardised the structural format.

5 Evaluation secretariat

The evaluation process was planned and conducted by a secretariat consisting of Lena-Kajsa Sidén, SSF, Margareta Eliasson, VR, and Pontus von Bahr, VINNOVA. Sten Söderberg, VR, assisted in the drafting of the guidelines for the grant holders' midterm reports and of the assessment form used by the distance evaluators.

Appendices (attached at the end of the complete Evaluation report)

A Abstracts from the eight evaluated projects (from the original proposals autumn 2006)
B Guidelines for grant holders' midterm reports
C Distance evaluators
D Distance evaluators' assessment form
E Panel itinerary
F Hearing participants

INTERNATIONAL PANEL'S GENERAL OBSERVATIONS

Overall, the panel was impressed with the high quality of the work presented at the mid-term review. The presentations reflected the high calibre of Swedish science in the biomedical engineering sector and demonstrated the level of internationally competitive and leading research in these fields. The research showed good collaborative bridges which had been built between the engineering and clinical disciplines as a result of the programme grants. In many cases potential products were planned for development which could have direct impact on clinical practice within 5-10 years. The training environment created through the funding was excellent, with a substantive number of younger PhD and postdoctoral researchers gaining experience in multidisciplinary environments. More specifically, the panel noted the added value which the project funding has brought to the groups within the programme. In some cases the investigators were able to establish new collaborations both nationally (to strengthen Swedish internal connectivity) and externally - to improve the international research profile of Sweden. The funding to the groups was used to form a platform for additional successful applications to other sources of funding, which included internal Swedish funding bodies and external organisations (e.g. planned submissions to the EU Framework Programme). The funding also contributed to the infrastructure base at Swedish Universities, which will benefit ongoing and future research.

It was clear that in many of the cases there are significant opportunities to commercialise the ideas presented at the review. Although still under development by many of the groups, the panel encouraged the applicants to form clear exploitation plans which would be implemented through the additionally funded, remaining two years of their project. This could potentially benefit the generation of new industrial developments in the area within Sweden in the form of SMEs - or provide additional income through licensing opportunities in internationally and nationally based companies. The panel noted that partnerships with industry were an essential part of the implementation of new technologies into a healthcare sector and stressed the importance of clarifying the plans for implementation during the next two years of funding. Agencies, like Vinnova, could, perhaps, play an active role in providing professional guidance in commercialising research of the projects.

In general, the dissemination of the research which has taken place over the last three years had been good. There is clear evidence of active participation in the international conferences occurring in the field. However, the publication record in high quality journals needs attention, with papers slow in getting to press. Although many papers appeared to be planned, were in preparation or recently submitted, there were relatively few publications coming out of the total programme at this stage. The panel felt that this could disadvantage the PIs in building their research efforts and did not reflect the rapid pace of the field.

In the case of the Young Faculty Grants, the calibre of the new investigators was generally high. The successful applicants were clearly examples of the excellent quality of the next generation of Swedish researchers. There were examples of how the PIs had leveraged the programme funding to gain further support and there were good examples of new partnerships which had emanated from the grants. There was clear evidence in some cases of how the grants awarded under the programme would contribute to the career development of the applicants.

The panel would like to see further evidence of support for the younger academics, in terms of mentorship within the University environments, as well as better integration into academic departments and their strategy. We would suggest that clear evidence of mentoring and career guidance should be demonstrated in the plans for future Calls.

We continue to be disappointed that young faculty are not provided with full salary support from their home institution. This is a serious constraint on their ability to develop their research careers and to become full participants in their field internationally - is out of line with practice in leading international universities.

Professor Richard I Kitney
Chairman of the Review Panel
On behalf of the Panel
November 2009

INTERNATIONAL PANEL'S EVALUATION OF INDIVIDUAL PROJECTS

Group Grant: Paul Gatenholm et al

Project: Biosynthetic Blood Vessels. From laboratory to patient care

Summary of Project

This is a large, multi-faceted project on the development of a new type of small-calibre blood vessel. The approach is novel, using bacterial cellulose as the substrate material. Methods have been developed for fabricating the vessels, mechanical testing, and in vivo testing in various animal models. While much progress has been made, challenges still remain in that the vessels suffer from poor mechanical properties with a tendency for delamination, and also are prone to thrombosis.

Scientific Quality

In general, the scientific quality is good. Production methods for the bacterial cellulose vessels are effective and work has progressed well. Extensive tests in animals have been carefully conceived and have yielded valuable results, feeding back to further engineering studies. Mechanical testing has proven to be a challenge and this need is only partially addressed by the existing collaboration with Prof. Lally in Dublin. In other respects, such as the micro-structural characterisation of the graft material and on issues relating to biocompatibility, progress is strong with encouraging results. Cellular studies, both with smooth muscle cell incorporation and endothelial adhesion, have also progressed, but are no longer a major focus of the project. As one measure of scientific quality the work is being published in good journals, but at a moderate pace. Many publications are under review and the rate of publication appears to be accelerating.

Organisation and Execution, Collaboration, Leadership etc

This is a strong team with leadership under Prof. Gatenholm. The work is being performed in several laboratories; however, this means that effective coordination requires special effort. Strong engineering, immunology and clinical (surgical) expertise is in place and the team appears to be functioning efficiently. Since an early collaborator left the project, there has been a need for a microbiologist, this may now be being addressed by the addition of a new faculty member at Chalmers. The panel were impressed by the involvement and commitment of the vascular surgeons involved in the project.

Impact on Research, Healthcare and Industry

This is a highly competitive field with other groups around the world working toward both tissue engineered (cellular) and de-cellularised vessels. The present approach is, in some respects, lagging, but if it can be made to work, it would have significant impact. This is a true high risk, high potential impact study. Demand for a successful small-diameter graft would be enormous. Connections with the start-up company, Arterion, are a strong asset should the team resolve current issues.

Relevance and Transfer of Knowledge to Users

Users in this case include the tissue engineering research community and the vascular surgeons. As mentioned above, dissemination of these results to the research community via archival publications has been somewhat slow. The end-users, the surgeons, have been less targeted for publication and presentations, but there have been a number of abstracts at vascular surgical meetings.

Quality of the Project Plan

Several issues need to be addressed if the project is ultimately to succeed. Among these are (i) the mechanical compliance of the graft needs to be further reduced (it currently exceeds venous compliance, and arterial compliance is even lower), (ii) the de-lamination problem needs to be solved, and (iii) the graft needs to be capable of long term, thrombus-free implantation. While the research team presented some potential solutions to these problems, each by itself, could lead to ultimate failure.

Conclusions and Recommendations

Overall, this is a strong project and an effective team. The team should be commended on good progress, and in particular, the rapid advance to animal testing. Two areas of weakness were identified, however, in microbiology and in mechanical testing. The former appears to have been addressed, but there remain significant mechanical issues that may require focused effort by someone who works more closely with the rest of the team. Despite these few concerns, the panel was favourably impressed with the progress of the project to date.

The panel recommends that the project be funded for a further two years.

Group Grant: Thomas Laurell et al

Project: Integration of new biomarkers for prostate cancer diagnostics on high sensitivity nanotextured microchips

Summary of Project

The project addresses Prostate cancer (PCa), which is the most common cancer in men and a major cause of death. While measuring PSA (prostate specific antigen) in plasma is a good indication of prostate disease, assay specificity is a problem. Only 25% of men with slightly elevated PSA do have a carcinoma when biopsied. The aim of the project is to move beyond PSA based diagnostics for the differentiation of PCa to an integrated diagnostic strategy that also incorporates disease prognosis, treatment strategy and therapeutic response. The project aims to develop a new generation of integrated diagnostic tools. This involves the development of a unique nano-textured protein chip surface, with ultra hydrophobic properties which is, nevertheless, biocompatible.

Scientific Quality

The scientific quality of the project is high. They have produced a series of parallel technological paths which are designed to produce different assays for the assessment of prostate cancer using PSA based techniques. The group have established that single method assays are not reliable predictors of prostate cancer. A lot of the project is based on assay implementation via lab on a chip technology using multiplex PCa micro-array technology. The group have also worked on novel hydrophilic and hydrophobic structures.

Organisation and Execution, Collaboration, Leadership etc

The organisation of this project is outstanding. These people are real professionals. What is impressive is the way in which they have brought together engineers and clinicians in what is now a well integrated team with a great deal of mutual respect. These are people that are clearly highly respected in their respective fields. Both individually and collectively they have wide knowledge of the international scene in the area of the project and the associated fields. Individual members of the team have joint appointments in leading international centres (eg the Sloan Kettering Cancer Center in New York). The group have also formed links with other international groups – some of which are technology providers, for example a group in Korea.

Impact on Research, Healthcare and Industry

By the end of the project a great deal of high quality research will have been completed. It is rather early to tell what will be the clinical impact (although it is likely to be significant). The project has had the effect of creating strong activity in the area of the research. This is likely to be of importance in enhancing the Swedish research base.

Relevance and Transfer of Knowledge to Users

The project is highly relevant, prostate cancer affects a significant percentage of the male population. Because of the clinical involvement in the project, the clinical application of the technology is bound to happen. The group are already considering patent protection and mentioned that there are a number of spinout companies planned. In addition, Beckman Coulter Inc of California has expressed significant interest in the project. The group reported that they have a series of papers submitted to major international journals.

Quality of the Project Plan

The project group presented a clear project plan for the next stages of the work. The plan is clearly detailed and there seems little doubt that the team will adhere to the plan.

Conclusions and Recommendations

The view of the panel is that this is a high quality project. The project team have used the funds from the grant alongside other funding to create an impressive array of work which is resulting in innovative and high quality technology. The group made a point of stressing that the execution of the project would not have been possible without the grant. This is a clear case of effective seed funding.

The panel recommends that the project be funded for a further two years.

Group Grant: Bo Nilsson et al

Project: Creation of an extrapancreatic insulin-producing organ for implantation in type-1 diabetic patients

Summary of Project

The project set out to design a strategy for islet transplantation for the treatment of diabetes. The proposition is a 3D approach which promotes rapid vascularisation and enables long term survival of implanted islets, without immunological attack. The 3D protocol aims at providing a polymer based biomaterial with heparin binding and VEGF release strategies to induce endothelial cell attachment and tubule formation. The project team are also investigating the use of a co-culture of islets and MSCs which will benefit treatment by improving immunological tolerance and angiogenic properties of the graft.

Scientific Quality

The Uppsala group is world leading in the efforts to develop islet cell implantation for the treatment of diabetes – they have an extensive international funding base. The project has facilitated collaboration between an excellent polymer group and the clinical immunology group where islet transplantation is ongoing. The quality of the overall programme is high. There are, however, concerns about the direction the MTBH programme is taking in terms of material selection and plans.

Organisation and Execution, Collaboration, Leadership etc

The project is supported by a network of grants. The programme has been successful in establishing collaboration between the materials group and the clinical immunology group. This collaboration has led to a successful JDRF grant between the two departments. Although large animal trials are being

planned, there is some question as to whether they are appropriate for testing the technology and the cellular innovations being developed e.g. MSC/islet autologous therapies. The external reviewers expressed concern about the leadership (and drive) in the project. There was also some concern that without a clear two year projected plan the project will not meet the objectives originally proposed.

Impact on Research, Healthcare and Industry

The project has great potential in healthcare in Sweden and the treatment of diabetes worldwide. The project has clear links to healthcare providers and operates a GMP facility - with the ability to rapidly transfer products to the clinic. There is an excellent and well established route to the clinic for new treatments. The relationship with industry is less clear, although various strategies for commercialisation were outlined. The heparin coating of cells and materials is patented by a partner company, who are keen to exploit this development.

Relevance and Transfer of Knowledge to Users

The project is very relevant to healthcare end-users. The participants in the project are hospital-based, so a knowledge transfer route is already in place. Publications are in progress and a number of papers are in preparation or submitted. Emphasis should be placed on getting publications out into the academic community in the near future.

Quality of the Project Plan

There was some question as to the value and novelty of the materials being developed for the islet implantation, with a potential failure due to immunogenicity. Heparinasation of the surface is proposed, but it is not clear how successful this will be in achieving immuno-suppression and rapid vascularisation - as required for islet survival. There are complex components to the project, these need to be integrated through to animal trials. It is not clear that this will be achieved within the remaining two years.

Conclusions and Recommendations

The panel felt that the project had achieved some of the objectives of the original proposal, but was in danger of not meeting the full objectives if the next two years of the project are not better ordered and structured. The PIs need to put forward a clear plan of what the project will achieve within the next two years, to ensure that they define a clear set of deliverables. It is also important to determine what MBTH will add and deliver - in terms of a product (rather than a diffuse group of multiple elements). The justification for the use of MSC co-cultures and choice of interrogation, using appropriate animal models, should be clarified. The PIs should define a clear strategy for the next two years.

The panel recommends that the project be funded for a further two years.

Group Grant: Göran Stemme et al

Project: Rapid Pathogen Analyzer

Summary of Project

This project aims at developing an integrated, highly sensitive diagnostic technology allowing quantitative identification of pathogens in air/aerosol, from the breath of an individual or in environmental air, to define carriers of pathogens before clinical outbreak. The entire chain of techniques needed to incorporate the diagnostic test will be integrated in a portable device, with functions ranging from automated airborne sample collection to electronic readout signal.

Scientific Quality

The first phase of the project has involved proof-of-concept work for the various system components that will be integrated into the final system: the micro-sensor system based on micro-fluidics and a micro machined liquid-air interface has been developed. Work on the transportation of the virus to sensor site and on-chip bioassay, with mass amplification, is in progress. A multiphysics simulator for particle capture has also been developed. The midterm report is well documented and illustrates the experimental set-up and device achievements to date. The project is recognised as being high risk and, potentially, high return. The group has experienced some difficulty with detection in uncontrolled laboratory conditions, due to lack of sensitivity and specificity, low S:N, requirements for enrichment or amplification, and slow response time. Some technical specifications for expected analytical specifications might be set up as benchmarks.

Organisation and Execution, Collaboration, Leadership etc

The team is organised and productive in relation to the research plan - with the necessary expertise and resources. The original research plan has been implemented without change. Progress has been made in respect to both hardware and bio-ware. This project is very multi-disciplinary - with well balanced competences in engineering, MEMS, virology, immunology and clinical medicine. The leadership is exemplary and the main applicant demonstrates convincing director's control over the project and its participants. The panel was impressed at the level of commitment and enthusiasm of all the participants.

Impact on Research, Healthcare and Industry

The research has the potential for very high impact, with many possible applications in other areas (animal, military, food), as well as direct additional applications (e.g. room filtration). However, large uncertainties remain with respect to the sensitivity and selectivity of the sensing system. Concerning IPR and exploitation plan, this is currently a weak point as no exploitation plan is proposed - but the project team have at least one PCT submitted. The field of the project is highly competitive internationally and the partners are strongly encouraged to patent innovative subparts of their work in order to anticipate potential IP (intellectual property) transfer to industry. The project has excellent prospects for creating renewal and sustainable growth in Sweden.

Relevance and Transfer of Knowledge to Users

The group has made a significant effort in disseminating their project to society through public TV (at the National and European levels); but not really toward the scientific community - only 5 conference papers have been published. There was no evidence of full papers being prepared for peer reviewed journals – this needs to be rectified.

Quality of the Project Plan

Proof of concept for most of the system components has been performed, the aim for years 4 and 5 is to design and build an integrated device. The proposed plan is well structured and convincing, and the deliverables are well-defined.

Conclusions and Recommendations

The project is going well, with the researchers from engineering working closely with clinical researchers to develop a sensing device for air-borne pathogens. The problem is particularly challenging, due to the low concentration of pathogens that need to be detected. The ability to resolve sensitivity and selectivity is a real issue for the success of the project. A number of realistic approaches are proposed to overcome these problems.

The two weak points which the group must address are the publication issue - with a special effort toward publishing fully papers in peer review journals; and to address the IP policy (ie to patent components/processes/concepts of the system in order facilitate a smooth transfer to industry).

The panel recommends that the project be funded for a further two years.

Group Grant: Karin Wårdell et al

Project: Neuroengineering for navigation, intervention and implementation in neurosurgery

Summary of Project

The project, led by Dr Karin Wårdell, is divided in three subprojects, which address the following topics:

- The development of patient-specific FEM-models for the electric field surrounding DBS electrodes,
- The development of high precision optical intracerebral navigation; to explore the extent to which optical signals processed to record the microcirculation and the tissue's reflectivity can be used for high precision intracerebral navigation,
- To develop an optical touch pointer for guided brain tumour resection, that will be integrated into a handheld suction tube.

Scientific Quality

Overall the project is of good scientific quality. The project's first two tasks have the potential to address some important questions relating to the mechanism of DBS and light-tissue interaction. The third task is more applied, aiming to integrate existing techniques into a useful device. The long-term objective of the first sub-project should be clarified, in terms of scientific and clinical outcome. The second sub-project has high clinical potential and is recognised as being innovative. The third sub-project has real potential, but validation work and usability testing remain to be done.

Organisation, Execution, Collaboration, Leadership etc

Good integration of clinical and engineering expertise, with good commitment from the partners and effective leadership from the PI.

Impact on Research, Healthcare and Industry

The project is at mid-term. The impact is still moderate, but the project remains promising, with the potential for having a significant effect on the clinical practice in functional neurosurgery. An EU project application has been submitted, which is recognised as a good effort for leveraging this grant and to promote international visibility and collaborations. On the other hand, industrialisation and exploitation of the results have to be considered seriously and as early as possible. Proper IP protection is a crucial first step. Exploitation plans for each of the sub-projects of the project (especially subprojects 2 and 3) have to be clarified (eg, spin-off company, licensing to big players, such as Elekta – but, potentially, also to Medtronic, Boston Scientific, St-Jude Medical etc).

Relevance and Transfer of Knowledge to Users

Overall, the outcome of this project could result in patient benefit, by improving existing technologies and medical procedures. The relevance of the first sub-project (patient specific modelling of the electric field around DBS electrodes) should be clarified, and (long-term) scientific objectives should be more clearly defined.

Quality of the Project Plan

The project plan is in line with the initial proposal. The new sub-tasks that have been added are considered to be relevant.

Conclusions and Recommendations

The project is of good scientific quality and progressing well, with an effective leadership and involvement from the PI and good commitment from the partners. The project is promising, with a clear potential of having a significant impact on the clinical practice in functional neurosurgery. A few points could be improved, such as the long-term objective of the first sub-project and the industrialisation and exploitation of the results - which have to be considered seriously, and as early as possible.

The panel recommends that the project be funded for a further two years.

Young Faculty Grant: Anders Eklund

Project: Towards non-invasive measurement of the cerebrospinal fluid system dynamics using magnetic resonance imaging

Summary of Project

Intracranial pressure (ICP) is an important factor in several common neurological conditions, including traumatic brain injury, hydrocephalus, intracerebral haemorrhage and headaches. Information relating to intracranial pressure can be used for monitoring progress of disease and to evaluate treatment. However, currently, the measurement of the intracranial pressure in a patient requires an invasive procedure. The primary objective of the project is to develop non-invasive methods for measuring intracranial cerebrospinal fluid (CSF) dynamic parameters such as intracranial pressure. The approach is to investigate the cardiac cycle dynamics measured with Magnetic Resonance Imaging (MRI) and to develop new computer modelling and advanced signal-processing techniques for the analysis of the resulting data.

Scientific Quality

The scientific quality of the work was considered to be high. The project comprises the development of techniques, instrumentation etc for the non-invasive measurement of cerebrospinal fluid dynamics using MRI, principally in relation to hydrocephalus. Although this is also a problem in children, the project team is focussing on hydrocephalus in the elderly – where the problem manifests itself in a number of ways, including severe gait problems. The placement of a CSF shunt is a very common, and generally successful, neurosurgical operation (with about 70,000 operations pa in Western Europe). The project team has investigated both the slow and fast dynamics associated with pulsing due to arterial blood flow. The work to date has comprised three components: the study of CSF dynamics, the development of mathematical models, and MR studies.

Organisation and Execution, Collaboration, Leadership etc

The project is well organised. Three disciplines are involved: biomedical engineering, neurology and radiology. In terms of the execution of the project one of the key factors in relation to its success to date has been significant and sustained clinical input (both the neurologist and radiologist involved were present at the review meeting). This has meant that it has been possible to carry out a significant amount of experimental work on humans.

Impact on Research, Healthcare and Industry

The impact of the research was primarily covered by the neurologist, who stated that the techniques developed in the project and the results were changing the way in which clinicians viewed hydrocephalus. Although the shunts which are currently used have been successful, the work of the project has led to new insights, in terms of CSF dynamics, which is now leading to new shunt designs. The group have links with a spinout company from the University of Umeå which is exploiting the infusion device for CSF developed in the project.

Relevance and Transfer of Knowledge to Users

Because of the close clinical involvement in the project, clinical relevance is assured. The group also showed evidence of attending a significant number of presentations at international conferences, as well as being involved in conference organisation and the international society for Hydrocephalus. When asked about other groups working in the field, the response was that no-one was taking their integrated approach to the problem and, hence, they are keen to transfer the knowledge gained from the project.

Quality of the Project Plan

The group showed clear evidence of a project plan for the next two years, which should result in some very good conclusions.

Conclusions and Recommendations

The conclusions of the panel were that this was a well executed project which is likely to have significant clinical impact in relation to an important clinical problem. Hydrocephalus is an important problem in the elderly, but one which is addressable by surgical intervention. By understanding the problem in much more detail, as a result of the work of the project, it should be possible to have significant clinical impact.

The panel recommends that the project be funded for a further two years.

Young Faculty Grant: T Christian Gasser

Project: Integrated biomechanically based diagnoses of abdominal aortic aneurysms

Summary of Project

The project aims to develop a computational algorithm that can be used to predict the risk of AAA rupture. The majority of the work is directed toward computational modelling; but, with a link to the clinic via the collaborating surgeons - Dr. Roy and his colleagues. Since current methods for predicting susceptibility to rupture are very poor, many individuals undergo high risk surgery unnecessarily. Conversely, many who need treatment go untreated. There are many steps in developing an effective computational model, especially given the considerable amount of work done previously by other groups. Hence, much of the report and presentation was directed toward a discussion of different computational approaches.

Scientific Quality

The PI has an excellent background, having worked with some of the leaders in the field of arterial wall modelling. Consequently, the research leading to the FEM of the arterial wall and thrombus is elegant and was clearly presented. Similarly, the extensions to this model to incorporate the internal blood flow are carefully conceived and represent a natural extension of the wall modelling. Combined with geometry data obtained from CT scanning, these form the basis for predicting internal wall stresses and surface shear stresses, two parameters postulated to correlate with the likelihood of wall rupture. New work in the project seeks to add the capabilities of coupling the fluid flow and wall motion, incorporating the thrombus into the models with realistic mechanical properties. In the longer term the aim is to develop a model for vessel wall remodelling that would, presumably, have predictive capabilities. All of the work is of high quality, and although the number of publications is low, the panel felt that the work being done would ultimately appear in print and be widely accepted.

Organisation and Execution, Collaboration, Leadership etc

This is a small project by comparison to some of the others in the programme - involving just the modeller and his surgical colleagues. The team appear to have a good working relationship, with excellent complementarity of expertise. In addition to the formal collaboration, the PI has contacts with other groups around the world who can help. For example, with the fluid dynamic modelling (Hussein at U Houston) and with the wall remodelling (Humphrey at Texas A&M). While not funded, these collaborations are real, with the exchange of students. Overall, the project is functioning smoothly under the leadership of the PI.

Impact on Research, Healthcare and Industry

Although the PI has formed a new company, the ultimate goal being to make the predictive algorithm a commercial product, it will be some time before the work reaches this stage of development. Similarly, since there are several other groups working on the same problem (and given the complexity of the models), it may be some time before the PI can establish himself as a "leader" in the research community. That is not to say that his work will not have impact, but the impact is somewhat diminished by working in such a crowded field. Ultimately, the results of the project are likely to play an important role in surgical planning, but this may take some years.

Relevance and Transfer of Knowledge to Users

The problem being addressed is highly relevant and of considerable interest to both the bioengineering and medical communities. Dissemination of these new results appears to be progressing at a reasonable pace; however, as mentioned above, it may be some time before these methods become widely adopted in the clinic. Still, the PI is publishing and presenting to the right audiences and his work will most certainly have impact.

Quality of the Project Plan

While the project plan has been carefully thought through, it has many parts and may be overly ambitious. It would be useful for the PI to formulate his own hypotheses regarding the critical mechanisms associated with rupture, and focus his efforts on those, adding only the essential components to his model. For example, the role of vortices in wall rupture was not well motivated, and the emphasis on this might be deleted in order to focus on other, more likely mechanisms. In other respects, the plan is reasonable, especially with regard to the proposed continuation of interactions with Dr. Roy and his surgical colleagues.

Conclusions and Recommendations

The panel felt that this has already been a highly productive project, well matched to the expertise of the PI. While productivity as measured by publications has been low, this will most certainly improve in the coming year. Much of the originally proposed work has already been completed, however, so this is a good time for the PI to step back and assess the current status of the project, and make a carefully reasoned decision regarding his plan for the next two years. He will need to distinguish himself from the rest of the field, and the way to do this is by focusing on what he feels are the most critical issues, rather than merely continuing to add new functionalities to the model, some of which may not be necessary.

The panel recommends that the project be funded for a further two years.

Young Faculty Grant: Madeleine Ramstedt

Project: Creation of safe antibacterial surfaces on biomaterials

Summary of Project

This project aims at reducing bacterial growth and subsequent infection of medical devices and biomaterials. The specific aim is to create antibacterial surfaces that allow mammalian cells to grow and differentiate normally in close proximity to the surface. The novelty lies in using thin layers of polymer brushes which can be modified as originally proposed by the addition of silver ions or salts. The level of funding is low and the project has partially been conducted at Cambridge University from 2007-2008 (Cambridge provided 50% of her salary). Dr Ramstedt has been back at the University of Umeå, full time, since early this year.

Scientific Quality

This is an important problem, and the focus of many efforts around the world. The first results obtained, however, show that the original approach for making a film containing silver which was both antibacterial and not cytotoxic to mammalian cells didn't work. The silver can be harmful to some mammalian cells, making it unsuitable as an antibacterial agent in medical devices: if the concentration of silver is reduced, the silver ions lose their cytotoxicity as well as their antibacterial effect. After two years, and based on a literature review, the applicant decided to change the active ingredient in the films to Gallium (Ga) ions using a similar approach. The problem raised by one of the expert external reviewers is that Gallium would suffer the same deficiencies as silver.

Organisation and Execution, Collaboration, Leadership etc

This project involves a high degree of interdisciplinarity, as it requires chemical synthesis to make the polymers used in the coatings, a good understanding of inorganic chemistry, and expertise in both mammalian and bacterial cell culture. This has contributed to a slow initial progress, considering the amount of work to do across a spectrum of different fields, some of which the applicant lacks the needed resources and expertise. Nevertheless, the PI is motivated and has managed to leverage numerous informal collaborations existing both at the beginning (connection with the Clinical Bacteriology group at Umeå) of the project as well as new collaborations in Umeå to progress with the work. She also managed to obtain funding from other sources to pursue this work further.

Impact on Research, Healthcare and Industry

The project would have a significant impact on healthcare, if successful, but currently it is very far removed from achieving its aim. The first choice concerning the silver appears to not be a judicious choice although the field of silver bioactive surfaces against infection was well-known. Similar problems may arise with Gallium. The project seems to lack collaboration with users and/or industry, no industrial or translational partner is evident.

Relevance and Transfer of Knowledge to Users

The researcher is ensuring that results are being presented at a range of different meetings attended by other researchers, but should also link up with potential end-users of the technology. Publications are starting to appear in scientific journals.

Quality of the Project Plan

The project plan was an ambitious one, of very high risk, at a low funding level. The re-focus onto modified antimicrobial chemistry using gallium may also prove unsuccessful as Gallium could suffer the same deficiencies as silver. This issue has to be addressed - eg by establishing an alternative strategy. The project plan for the next years has to be better structured, detailed and convincing.

Conclusions and Recommendations

This project suffers from several weaknesses in its goal of pursuing quality research in the biomaterials area. The PIs revised scientific approach still failed to convince the panel that she will have an impact on the field or that she will generate commercial opportunities or scientific impact in the field of antimicrobial surfaces. The initial proposal underestimated the challenge of this undertaking. She has identified the flaws in her initial strategy and has now put together a better team for the second half of the project.

It is important to point out that Dr Ramstedt did not apply for an extension to the grant for years 4–5. After the start of the original MTBH project, Ramstedt received a supplementary grant from the Swedish Research Council (from a source separate from the MTBH programme). She intends to use this to fund the project during years 4 and 5. She, therefore, chose not to apply for any further support from the MTBH programme.

The panel feels that the PI would benefit from better mentoring from senior academics (in this case biomaterials and medical). In working largely as an individual, and as a research worker at a very early stage in her career, the panel felt that Dr Ramstedt would benefit from the experience of colleagues who have more practical experience in the field – this is strongly recommended.

Professor Richard I Kitney
Chairman of the Review Panel
On behalf of the Panel
November 2009

APPENDICES

A Abstracts from the original applications in the autumn of 2006

1 Young Faculty Grants

Project Leader: Eklund, Anders (Assoc Prof), University of Umeå
Project title: Towards non-invasive measurement of the cerebrospinal fluid system dynamics using magnetic resonance imaging
Project homepage: http://www.hydrocephalus.se/UHRG.html

Intracranial pressure (ICP) is an important factor in several common neurological conditions, including traumatic brain injury, hydrocephalus, intracerebral hemorrhage and headaches. Information about intracranial pressure can be used for monitoring progress of disease and to evaluate treatment. Today, measurement of the intracranial pressure of a patient requires an invasive procedure, either through a burr hole in the skull or through a cannula placed in the lumbar space. The primary objective of this project is to develop non-invasive methods for measuring intracranial cerebrospinal fluid (CSF) dynamic parameters such as intracranial pressure. Our approach will be to investigate the cardiac cycle dynamics measured with Magnetic Resonance Imaging (MRI) device, and develop novel modeling and advanced signal-processing techniques for the analysis of the resulting data.

Project Leader: Gasser, T Christian (PhD), Royal Institute of Technology
Project title: Integrated biomechanically based diagnoses of abdominal aortic aneurysms
Project homepage: http://researchprojects.kth.se/index.php/kb_7905/io_10226/io.html

An Abdominal Aortic Aneurysm (AAA) is a frequently observed pathological enlargement of the infrarenal aorta, and if kept untreated, it might enlarge until rupture. According to the current clinical view, a surgical or minimal invasive treatment denoted as AAA repair is indicated when the aneurysm exceeds a certain dimension or expansion rate. However, in particular for complex shaped AAAs, this kind of rupture risk assessment seems to be questionable, and hence, it is under ongoing and controversial scientific discussion. In contrast, a detailed biomechanical analysis of the formation could provide much more reliable data for clinical decisions. In view of this proposal, structural and fluid biomechanics are applied to develop a diagnostic tool for clinical examinations. To this end diagnostic parameters are derived from patient specific hypothetical Finite Element models, which are generated from routinely taken clinical images. The feasibility of the proposed innovative project aims will be considerably strengthened by the proposed multi-disciplinary support of the involved collaborators. The diagnostic tool to be developed is novel and beside clinical benefits it will help to understand the biomechanics of AAAs, which is of basic scientific interest for a fundamental pathological understanding of this disease.

Project Leader: Ramstedt, Madeleine (PhD), University of Umeå
Project title: Creation of safe antibacterial surfaces on biomaterials
Homepage: http://www.chemistry.umu.se/forskning/group-leaders/madeleine-ramstedt/

This research is aimed at defeating bacterial growth and subsequent infection of medical devices and biomaterials. We will create long term stable polymer films that release therapeutic concentrations of silver (Ag). The possibility to design and combine different types of Ag salts, polymer functionalities and properties, create a new and unique bactericidal toolbox for constructing tailor-made polymer films. The aim is to create antibacterial surfaces that allow mammalian cells to grow and differentiate normally. The surfaces will be extensively tested using bacterial and mammalian cells. Ag coatings ranging from surface precipitates to hydrogels and metal films have been studied in literature but strong, long lasting films covalently anchored to biomaterials have not been well examined previously, nor have extensive Ag tests on mammalian cells been performed. The element of high risk is the challenge of pulling together

and covering all aspects and orientations of this multidisciplinary research. The Swedish knowledge for creating antibacterial biomaterials surfaces is expected to be greatly enhanced by the project and by national and international collaborations with well established groups. At the end, surfaces that can be safely and successfully produced and used will have been developed. The gain for hospitals and the medical society is evident as is the potential for clinical implementation and industrial innovations.

2 Group Grants

Project Leader: Gatenholm, Paul (Professor), Chalmers University of Technology
Project title: Biosynthetic Blood Vessels. From laboratory to patient care
Project homepage: http://www.chalmers.se/chem/EN/divisions/biopolymer-technology/tissue-engineering

Cardiovascular disease is the major cause of death and morbidity in developed countries. Many patients in need for reconstruction of their vascular system either in the heart, lower extremities or other locations are lacking native replacement vessels. There are no satisfactory products on the market, particularly for small diameter blood vessels. The overall goal of this program is to develop a new generation of biocompatible replacements for blood vessels. Biosynthetic Blood Vessels, BBV, will be prepared by innovative technology for production of tubes using controlled fermentation of the cellulose producing bacteria Acetobacter Xylinum. The long term goal is to fulfil a preclinical evaluation of this new biomaterial and to bring it to a clinical phase. This is a focused program in which biomaterial scientists will work together with biotechnology experts, physicists, chemists, cell biologists, molecular biologists and cardiovascular surgeons. The program consists of two main parts: biosynthesis and biomanufacturing of tubes which includes establishment of GMP production facility and a preclinical part which includes cell studies, biocompatibility evaluations and animal studies. The program particularly promotes career development for young female scientists.

The project can be seen as risky but there is a great potential for success. The project will have direct clinical implications to the benefits of patients with cardiovascular diseases.

Project Leader: Laurell, Thomas (Professor), University of Lund
Project title: Integration of new biomarkers for prostate cancer diagnostics on high sensitivity nanotextured microchips
Project homepage: http://www.elmat.lth.se/forskning/nanobiotechnology_and_labonachip/research/labonachip_based_prostate_cancer_biomarker_detection/

Prostate cancer (PCa) is the most common cancer in men and a major cause of death. While measuring PSA (prostate specific antigen) in plasma is a good indication of prostate disease, assay specificity is a problem. Only 25% of men with slightly elevated PSA do have a carcinoma when biopsied. Thus, we must now move beyond PSA based diagnostics for the differentiation of PCa to an integrated diagnostic strategy that also incorporates disease prognosis, treatment strategy and therapeutic response. This project targets the development of a new generation of integrated diagnostic tools, where a unique nanotextured protein chip surface, having ultra-hydrophobic properties yet being biocompatible, offers improved detection levels and the highest non-contact spotting array density reported. Limit of detection will be lowered several decades by employing Europium-tagged nanoparticles as fluorescent probes in the bioassays, enabling pM-fM detection levels. This will enable the development of multiplex microchip assays for new PCa biomarkers linked to the Kallikrein gene locus, e.g. hK2 and hK4. Based on the scientific excellences represented in the team a strong cross-disciplinary research platform has already been formed, ranging from nanotechnologies to the clinic. The consortium will utilise their recent clinical PCa biomarker discoveries and link these to new lab-on-a-chip concepts, where multiplex analysis in microscale will provide a vastly improved accuracy in PCa diagnostics.

Project Leader: Nilsson, Bo (Professor), University of Uppsala
Project title: Creation of an extrapancreatic insulin-producing organ for implantation in type-1 diabetic patients
Project homepage: http://www.klinimm.uu.se/node150

The current procedure in clinical islet transplantations is to infuse the isolated islets into the whole blood of the portal vein of the liver but using this technique only a small fraction of the transplanted pancreatic islets successfully engraft. An important explanation to the loss of tissue is the instant blood mediated inflammatory response (IBMIR) described by us which is triggered by tissue factor and cyto/chemokines expressed by pancreatic islets in the whole blood environment. At present the IBMIR is a major obstacle to overcome before islet transplantation can become a routine treatment of Type 1 diabetic patients and if xenogeneic porcine islet transplantation is to become possible. Extrahepatic transplantation has never been shown to work in larger animals but the proposed project intends to apply recent advances in biotechnology and cell therapy. In order to avoid the IBMIR we will attempt to assemble an extrapancreatic insulin-producing organ allowing transplantation to a site outside the liver, e.g. a subcutaneous, intraadipose or intramuscular location. The composite graft will be made up of human or porcine islets, endothelial and mesenchymal stems cells, a fibrin/hyaluronan gel and a biodegradable skeleton. If creation of this extrapancreatic organ would succeed, a substantially larger islet mass would engraft and escape specific immune responses, thereby making it possible to cure patients with Type 1 diabetes mellitus with islets from only one donor.

Project Leader: Stemme, Göran (Professor), Royal Institute of Technology
Project title: Rapid Pathogen Analyzer
Project homepage: http://www.ee.kth.se/php/index.php?action=research&cmd=showproject&id=96

Infectious diseases require in most cases rapid diagnosis and urgent treatment. Thus, life threatening, acute infections would greatly benefit from a close to instantaneous diagnosis such as in certain bacterial, septic conditions where minutes and hours matter, and for many viral diseases including respiratory or gastrointestinal infections caused by i. e. influenza, calicirus or respiratory syncytical virus infections. An integrated, highly sensitive diagnostic technology allowing quantitative identification of pathogens in air/aerosol could also define carriers of pathogens before clinical outbreak, a significant problem in immunosuppressed patients. The presently proposed project has the potential to enrich and detect extremely small amounts of pathogens in air/aerosol, from breath of an individual or in the air. This would mean a most significant improvement compared to present state-of-art of identification in pathogens in these diseases. The work will be conducted as a cross disciplinary effort where groups at Karolinska Institute, Linköping University (pathogen expertise) and KTH (microsystem technology and microfluidics expertise). The challenge (and risk) of this project lies in the achievement of sufficient sensitivity and selectivity in a miniaturized system combining previous recent results in QCM based detection and fluidics technology with a selective pathogen detection. Target program area: "Implanted biosensors and integrated diagnostics"

Project Leader: Wårdell, Karin (Professor), University of Linköping
Project title: Neuroengineering for navigation, intervention and implementation in neurosurgery
Project homepage: http://www.imt.liu.se/bit/neuroengineering/

Frontline international research related to navigation and intervention in neurosurgery will be performed. Implementation in healthcare is expected to have high impact on combating neuro-degenerative disorders. Electric fields influence on neural tissue during deep brain stimulation (DBS) will be investigated on a molecular to organ level. Patient specific modelling and simulation based on MRI, tissue's characteristics and biochemistry will be compared with clinical outcome. To improve intracerebral navigation, laser Doppler perfusion monitoring and reflectance spectroscopy, MRI and brain atlases will be used in combination during stereotactic and functional neurosurgery. We will explore how well

optical signals can be obtained and separated between grey-white boundaries, sub-nuclear matter and to which extent blood vessels can be detected. Patients undergoing DBS, cell grafting, RF-lesioning and biopsies will benefit from safe and precise navigation. An optical touch pointer for intra-operatively porphyrin fluorescence guided resection of invasive brain tumours will be developed and clinically evaluated. Integration of the probe in neuronavigation systems will enhance the chance for excision radicality near "non-touch" zones. High risk elements include patient specific modelling of DBS and recordings of optical and biochemical data during surgical procedures. "Image-guided surgery" or "Systems biology including integrated modelling" is suggested as prioritised area.

B Guidelines for Midterm Report

The purpose of this report is to provide a basis for a midterm assessment of the research project. The report should contain an account of the activity up to now as well as objectives and plans for the remaining part of the foreseen five-year grant period.

In view of the upcoming decision on concluding funding, the report will be an important document primarily for the assessment of scientific quality but also of the strategic relevance of the project. These guidelines are therefore somewhat more ambitious than would be the case for a midterm evaluation where funding for the entire period had already been granted. A comparison of the position and results achieved so far with the objectives and milestones expressed in the original project plan is of high importance. The amount to be distributed among the eight MTBH projects for the remaining part of the five-year grant period, based on the results of the midterm evaluation, is SEK 32 million.

The report shall be written in English. The report, together with an accompanying letter signed by the Project Leader, is to be submitted by 31 August 2009, addressed to Vetenskapsrådet, att: Margareta Eliasson, 103 78 Stockholm. Electronic copies of the text report (Pdf) and the economic report (Excel) shall, at the same time, be sent to: margareta.eliasson@vr.se.

1 Summary

An executive summary of the report (max. 1 page).

2 Background, objectives and organization of the project

An introductory description (max. 2 pages) of the project with regard to:

2.1 Background. How did this project come about?
Short-term and long-term relevance and expected impact according to the original application. Vision for utilization of the anticipated results.

2.2 Concrete goals and objectives according to the original application.

2.3 The start-up process from project start up to the day of this report. Describe and explain
– any changes in the goals
– any delays or other changes
compared to the original application.

2.4 The basic organization of the project. Describe principles for decision-making, project leadership and management. Describe perceived important strengths and weaknesses in the organization. What should be kept and what needs to be changed? Enclose an organization chart as Appendix 1.

2.5 Participating researchers: Indicate key persons, research groups etc. Be brief about "formal" roles but describe their actual *roles* or *involvement* clearly. Indicate any unfilled positions. (The complete list of project staff is to be reported in Appendix 3, Tab B).

3 The research of the project (max. 2 pages)

3.1 Scientific achievements
Describe the research and the results achieved so far (by each group or subproject, as appropriate). Compare the results with the objectives and milestones in the original project plan. Comment on any unforeseen results achieved apart from and beyond the original objectives and goals that were not expected at the time of the original application.

3.2 Publications etc. (To be reported in Appendix 2 (not in the main text))
Attach, as Appendix 2, a list of all publications or other research products produced with funding from the project, sorted by Research Group and starting with the Project Leader.

3.3 Effects of joint funding
Indicate any effects of the fact that funding is provided jointly by three different granting bodies as compared to one single body. What is the value added of joint funding for your project? What has been achieved compared to a "traditional" project funding situation with a single/main funding agency?

4 Utilization of research results (max. 1 page)

Describe utilization of research results in the following three categories. For each category, please distinguish between (a) documented utilization of the project findings so far, (b) utilization in terms of results that are underway to be implemented or can be foreseen in the short-term future, and (c) impact and plans for utilization after the completion of the project (= grant period). Also indicate which of these research results you anticipate as the most important contribution of your project to the theme of the announcement, and which results you expect to be the most valuable contributions to the research system as a whole? To assist in structuring this description, the accompanying template could be used (voluntary)

- results of the project that are considered relevant to, and having a short-term or long-term impact on needs in industry, healthcare, education and/or other sectors of society,
- results of the project in terms of applications e.g. trials for new clinical application(s), prototypes, technical instruments, new measurement methods, innovations, spin-off companies (founded or being contemplated), etc.,
- any substantial new knowledge development that has had or may have impact within the academic system in terms of competence development, closer collaboration between the faculties of engineering and medicine in graduate education, etc., increased participation in national and international academic networking, etc.

5 New collaborations emanating from the project (max. 1 page)

Describe the participants, objectives, forms, extent and the contents of the following types of cooperation:

- Scientific collaboration between different disciplines and departments (shown in joint sub-projects, publications etc.),
- International collaboration, including participation in EU projects (shown in mutual projects, regular exchange of researchers, shorter visits etc.),
- Collaboration with industry, healthcare and other sectors of society.

6 External information and other activities (max. 1 page)

What efforts have been made to disseminate information about the activities and results and of the project to different target groups? Describe other externally oriented activities within the project, e.g. conferences, seminars etc. State website address, indicate when the information on the website was last updated and how often the information on the website is updated.

7 Midterm Economic Report (To be reported in Appendix 3 (not in the main text).)

7.1 Expenses and staff for 2007-2009
To be reported in Appendix 3, Tabs A1-A2 and B, according to the accompanying template.

7.2 Present funding situation
For projects similar or related to the project being evaluated, enclose a list of presently available and pending grants to the Project Leader. In the case of Group Grants, also include grants to the Group Leaders. To be reported in Appendix 3, Tab C, according to the accompanying template.

8 Plans and proposed budget for years 4-5 and plans for further activities (max. 2 pages)

8.1 Research plan for 2010-2011
In view of what has been achieved, present your research plan for the project for the remainder of the five-year grant period. The plan should be related to the objectives of the project. Any changes in relation to the original project plan should be noted and explained.

8.1.1 Goals and objectives for 2010-2011
When expressing objectives, try to think as far as possible in terms of the so called "SMART" Criteria sometimes used in project management. The concept SMART refers to setting objectives that are Specific, Measurable, Achievable, Relevant, and Time-bound. *)

*) See VINNOVA (2008): VINNOVA´s Focus on Impact. A Joint Approach for Logic Assessment, Monitoring, Evaluation and Impact Analysis, pp. 34-35. VINNOVA ANALYSIS VA 2008:01.

8.1 2 Work plan for 2010-2011
Describe
– plans in terms of overall and joint activities,
– plans for the respective groups or subprojects relevant to your project.

8.2 Proposed budget for 2010-2011:
To be reported in Appendix 3, Tab D, according to the accompanying template.

8.3 Continued work after the first five years
Briefly describe your plans, visions and foreseen activities to continue work along the lines of this project after grant period.

9 SWOT reflections (max. 1 page)

For the continued work within a research team it may be beneficial to discuss perceived Strengths, Weaknesses, Opportunities and Threats at this stage of a project. Without having to present a formal SWOT analysis, the team is invited to reflect on these four keywords as related to the project.

Strengths and weaknesses here refer to the internal capabilities of the project, i.e. are under its control. Opportunities and threats are found in the external environment, usually outside the control of the project.

Templates accompanying these Guidelines

- Template for description of utilization of research results (voluntary).
- Templates for the Midterm economic report including project staff; present funding situation; and proposed budget for 2010-2011. To be reported in Appendix 3.

Appendices to be provided by the respondent

Appendix 1 Organization chart

Appendix 2 List of all publications or other research products produced with funding from the project, sorted by Research Group and starting with the Project Leader. To the extent feasible, use the following codes:

A Original articles in refereed scientific journals
B Original refereed scientific conference contributions
C Review articles, book chapters, etc

D Patents (granted + pending), demos, etc
E Software
F Presentations aimed at a general public, etc.
G Other "research products" that you would like to include

Appendix 3

A1 For all grants: Midterm Economic Report per 30 June 2009. Overall Project level.
A2 For Group Grants: Midterm Economic Report per 30 June 2009. Group Level.
B For all projects: Staff presently and earlier engaged in the project.
C For all projects: Present funding situation.
D For all projects: Proposed budget for the overall project, years 2010-2011.

Further information

Vetenskapsrådet: Margareta Eliasson, margareta.eliasson@vr.se, 08-54 64 41 79
Stiftelsen för Strategisk Forskning: Lena-Kajsa Sidén, LKS@stratresearch.se, 08-50 58 16 73
VINNOVA: Pontus von Bahr, pontus.vonbahr@vinnova.se, 08-473 30 91.

MTBH Midterm Report: Template ad item 4, "Description of utilization of research results" (table voluntary; otherwise describe in running text)

	Documented utilization so far	Utilization in terms of results that are underway to be implemented or that can be foreseen in the short-term future	Impact and plans for utilization after the completion of the project (=grant period)
Relevance for, or impact on, needs in industry, healthcare, education and/or other sectors of society			
Applications, e.g. trials for new clinical application(s), prototypes, technical instruments, new measurement methods, innovations, spin-off companies (founded or being contemplated), etc.			
New knowledge development that has had or may have impact on the academic system in terms of competence development, closer collaboration between the faculties of engineering and medicine in graduate education, etc., increased participation in national and international academic networking, etc.			

C Distance evaluators

- Dr Elizabeth Berry, Elizabeth Berry Ltd, Leeds, UK. www.voxelera.co.uk.
- Prof Barbara Boyan, Georgia Institute of Bioengineering and Bioscience, Atlanta, GA, USA, http://www.bme.gatech.edu/facultystaff/faculty_record.php?id=48.
- Prof Jean-Louis Coatrieux Université de Rennes 1 LTSI - INSERM Rennes, FR. http://www.hindawi.com/20469014.html.
- Ass Prof Jan D'hooge, Katholieke Universiteit Leuven, Dept of Cardiovascular Diseases, Leuven, BE. http://www.kuleuven.be/cv/u0014531.htm.
- Prof David W Grainger, University of Utah, Dept of Bioengineering, Salt Lake City, UT, USA. http://www.bioen.utah.edu/faculty/DWG/People/Bio%20Profiles/David%20Grainger/DavidGrainger.html.
- Prof Barry J Hoffer, National Institutes of Health, National Institute on Drug Abuse (NIDA), Baltimore, MD. USA http://www.drugabuse.gov/dir/cell-neuro.html.
- Prof Molly Stevens, Imperial College, Dept of Materials, London, UK. www.imperial.ac.uk/people/m.stevens.
- Prof Dr Elisabeth Verpoorte, University of Groningen, Dept of Pharmacy, Groningen, NL. http://www.rug.nl/farmacie/onderzoek/basiseenheden/farmaceutischeanalyse/verpoorte.
- Prof Dr med Anette-G Ziegler, University of Munich, Diabetes Research Institute, Munich, DE. http://www.kind.med.tu-muenchen.de/cms/front_content.php?idcatart=228.

D Distance evaluators' assessment form

Biomedical Engineering for Improved Health – Midterm Evaluation 2009

Distance Evaluation Report

Please firmly single-click with the cursor on top of the grey-shaded areas for automatic formatting when you start writing. The shading will disappear then!

A. Project Details

Project title	Name of project leader

B. Reviewer Details

Reviewer's name and affiliation
Reviewer's area(s) of expertise relevant to this project evaluation
Degree of expertise (scale 1-5; 5 highest) in relation to the project: Engineering aspects: Medical and Clinical aspects: and , respectively Overall confidence level in the assessments made in this evaluation report:

C. Assessment

Please provide written comments addressing the following criteria and place a tick (X) in the far left column next to the appropriate statement and associated mark.

1 Scientific quality

1.1 Scientific quality of the project

	1	Weak or poor scientific quality and poor development as an 'excellent' research environment. The project has low scientific interest.
	2	Only parts of the project have a good scientific quality. Parts of the project have scientific interest.
	3	The project has a good scientific quality, and a potential to develop into a very good research environment. The project is scientifically interesting.
	4	The project has a very good scientific quality and a high potential to further develop into an excellent research environment. The project has considerable scientific interest.

	5	Extremely good scientific quality and an excellent research environment. The project is of major scientific interest.

Comments:

1.2 Expertise within the project

	1	Uneven and fragmentary expertise among participants.
	2	Varying, but partly good, expertise among participants.
	3	Overall good expertise among participants.
	4	Very good expertise among participants.
	5	Exceptionally high, unique and creative expertise among participants.

2 Organization and execution, collaboration, leadership, etc

2.1 Execution of the project in view of the original plan

	1	The execution of the project has been weak.
	2	The execution of the project plan has been followed to some extent.
	3	The execution of the project is acceptable.
	4	The execution of the project is good.
	5	The execution of the project is excellent with a well implemented plan.

Comments:

2.2 Degree of multi-/interdisciplinarity and collaboration between Medicine – (Life science – Engineering)

	1	A narrow project/group with little breadth of field.
	2	The project/group represents relatively few (sub)-disciplines within a relatively limited field.
	3	The project/group has a breadth of field and high multidisciplinary ambitions.
	4	The project/group has a considerable breadth of field and effectively exploits opportunities for multidisciplinary interaction.
	5	An exceptionally strong, partially unique and creative multi-/interdisciplinary project/group with ambition and vision, which has been demonstrated in a convincing manner.

Comments

2.3 Degree of commitment within the group/project

	1	The commitment has not been convincingly demonstrated.
	2	Varying, but partly good commitment.
	3	Overall good commitment.
	4	Strong and well-documented commitment.
	5	Very strong commitment has been convincingly demonstrated.

Comments

2.4 Access to relevant equipment and infrastructure

	1	The group lacks equipment of importance to the project.
	2	The group generally has satisfactory access to the infrastructure required.
	3	The group has access to acceptable infrastructure, including e.g. relevant databases, biobanks, major equipment, research facilities, and access to experimental material incl. animals and patient material.
	4	The group has very good access to required infrastructure including e.g. the above. It also has contacts and ambitions to get access to equipment and facilities not already available.
	5	The group has access to all equipment and facilities required.

Comments

2.5 Leadership, management

	1	The project does not demonstrate an acceptable leadership/management.
	2	The project has a somewhat unclear or unconvincing leadership. Leadership is insufficiently documented.
	3	The project has a good leadership structure providing a firm ground for a well functioning management of the activities. Leadership has been documented.
	4	The project demonstrates a well considered leadership providing a firm ground for a well-functioning management of activities and resources. Leadership has been reasonably well documented.
	5	The project demonstrates a strong leadership providing a firm ground for efficient management of activities and human and other resources, both scientifically and administratively. Leadership has been convincingly documented.

Comments

3 Impact on research, health care and industry

3.1 Effects on research

	1	The research appears not to have had any visible effect on the development of research within the field.
	2	The research results have had some effect on the research field. They have also led to results and development of new methods within certain sub-fields.
	3	The research results have had an effect on the research field, leading to interesting results and the development of new methods.
	4	The research results have had a major effect on the research field and led to the development of new methods with a major innovative value within several sub-fields.
	5	The research results have had a major effect on the research field and led to significant and, to some extent, pioneering development of new methods.

Comments

3.2 Medical and clinical relevance of the project

	1	The project addresses a topic of some clinical need. Its potential for clinical application (new methods of diagnosis or treatment, etc) is moderate.
	2	The project addresses a topic of moderate clinical need, with potential for clinical application
	3	The project addresses a topic of fairly high clinical need, with a high potential for clinical application
	4	The project addresses a topic of high clinical need, with a very high potential for clinical application and patient benefit
	5	The project addresses a topic of high clinical need, with excellent potential for clinical application and may result in concrete effects on health and social well-being

Comments

3.3 Commercialisation, incl. collaboration with industry, and securing IPR

	1	There appear to be a low degree of understanding for IPR issues *and/or* the project seems to lack collaboration with users and/or industry.
	2	The project group has initiated some measures towards commercialisation of the results. IPR issues are as yet less well developed.
	3	There is a plan for the commercialisation of the results of the project and a plan for how to secure IPR. However, more actions toward commercialisation could be taken.
	4	There is an acceptable plan for the commercialisation of the results and a credible plan for how to secure IPR. Some action to initialise commercialisation has been taken, including collaboration with users and/or industry.

	5	There is a well drafted plan for the commercialisation of results from the project. The group also has a well considered and credible plan for securing IPR. They have already started commercialisation activities.

Comments

3.4 Contribution of the project to renewal and growth in Sweden

	1	The project has low potential to contribute to creating renewal or sustainable growth.
	2	The project has some potential of contributing to renewal and sustainable growth.
	3	The project has good potential of contributing to renewal and sustainable growth.
	4	The project has very good prospects of contributing to renewal and sustainable growth.
	5	The project has excellent prospects of creating renewal and sustainable growth.

Comments

4 Relevance and transfer of knowledge to users

4.1 Information dissemination - transfer of knowledge

	1	The group lacks an acceptable plan for the transfer of knowledge between preclinical and clinical research, and for transfer to healthcare providers, patients, society and industry.
	2	There is a plan for the transfer of knowledge, but the plan lacks detail and implementation has not been initialised.
	3	There is an acceptable plan for the transfer of knowledge to recipients. Parts of the plan have been initialised.
	4	There is a well-developed plan for the transfer of knowledge. A major part of this plan is underway of being implemented.
	5	A plan for the transfer of knowledge has been implemented in an excellent way.

Comments

5 Quality of the project plan

5.1 Relevance of the project plan for years 4 and 5

	1	The project plan for years 4 and 5 does not focus on relevant topics either regarding scientific issues or clinical needs
	2	The project plan for years 4 and 5 shows some relevance
	3	The project plan for years 4 and 5 is regarded as reasonably relevant
	4	The project plan for years 4 and 5 is relevant
	5	The project plan for years 4 and 5 is excellent, written with enough detail, focusing on the relevant issues regarding scientific issues as well as clinical needs

Comments

5.2 Realism of the project plan for years 4 and 5

	1	The project plan for years 4 and 5 is unrealistic regarding either personal resources, infrastructure or other prerequisites
	2	The project plan for years 4 and 5 is not regarded as fully realistic
	3	The project plan for years 4 and 5 is regarded as reasonably realistic
	4	The project plan for years 4 and 5 is regarded as realistic
	5	The project plan for years 4 and 5 is credible and regarded as very realistic, written with enough detail regarding personal resources, infrastructure and other prerequisites

6 Conclusion

6.1 Overall evaluation of the project

	1	The overall quality of the project is regarded as low
	2	The overall quality of the project is regarded as limited
	3	The overall quality of the project is regarded as moderate
	4	The overall quality of the project is regarded as significant
	5	The overall quality of the project is regarded as excellent

Comments

6.2 Comment on funding years 4–5 in view of the maximum frame of SEK 31 million.

Please note that seven projects apply for concluding funding within this frame!

	1	The project should be discontinued
	2	The project could be funded for two more years but at a proportionately lower level than for years 1-3
	3	The project should be funded at about the same level as for years 1-3
	4	The project should be funded at a proportionately higher level than for years 1-3
	5	The project would deserve funding at a significantly higher level than for years 1-3

Comments

7 Optional: Any advice to the project group (via the Panel)

Comments

My earlier statement (*before* taking part of the Midterm Report), that I have no conflicts of interest in the assessment of this proposal (directly or indirectly), is still valid.
Possible comment on any other relations with main actors in the project under evaluation

Evaluator's name:	
Signature for paper (or scanned) version:	
Place and date:	
E-mail address:	
Telephone:	

E Panel itinerary

Sunday 25 October 2009

pm	Arrival at Arlanda airport and check-in at Central Hotel, Vasagatan 38, Stockholm. Take Arlanda Express Train to the City Terminal. Exit the train to the street at the left of the train's front end. Central Hotel is only 5 minutes' walk away – see the green circle marked "3" in the upper-left quadrant of the map at https://www.arlandaexpress.com/textpage.aspx?page=61
18.00	Preparatory meeting at the hotel, directly followed by
19.30	**Dinner at Restaurant Stockholm Fisk, Vasagatan 1** (diagonally across from hotel)

Monday 26 October 2009

Venue: Swedish Foundation for Strategic Research (SSF), World Trade Center, Kungsbron 1, level G7 (Main entry next to the top red ring in the upper-left quadrant of the map indicated above)

08.20	Panel gathering in hotel lobby + short walk to SSF
09.00 – 09.30	Project presentation by Stemme group
09.30 – 10.00	Questions to Stemme group
10.00 – 10.10	Panel internal discussion
10.15 – 10.45	Project presentation by Nilsson group
10.45 – 11.15	Questions to Nilsson group
11.15 – 11.25	Panel internal discussion
11.30 – 11.45	**Break**
11.45 – 12.15	Project presentation by Wårdell group
12.15 – 12.45	Questions to Wårdell group
12.45 – 12.55	Panel internal discussion
13.00 – 14.00	**Lunch at WTC Restaurant** (Kungsbron 1, directly inside entrance)
14.00 – 14.30	Project presentation by Gatenholm group
14.30 – 15.00	Questions to Gatenholm group
15.00 – 15.10	Panel internal discussion
15.15 – 15.45	Project presentation by Laurell group
15.45 – 16.15	Questions to Laurell group
16.15 – 16.25	Panel internal discussion
16.30 – 16.45	**Break**
16.45 – 19.15	Panel discussion, overall review of the projects for day 1, report drafting
20.00	**Dinner at Restaurant KB, Smålandsgatan 7**

Tuesday 27 October 2009

Venue: Swedish Foundation for Strategic Research (SSF), World Trade Center, Kungsbron 1, level G7

09.00 – 09.30	Project presentation by Gasser
09.30 – 10.00	Questions to Gasser
10.00 – 10.10	Panel internal discussion
10.15 – 10.45	Project presentation by Eklund
10.45 – 11.15	Questions to Eklund group
11.15 – 11.25	Panel internal discussion
11.30 – 11.45	Break
11.45 – 12.15	Project presentation by Ramstedt
12.15 – 12.45	Questions to Ramstedt
12.45 – 12.55	Panel internal discussion
13.00 – 14.00	Buffet lunch inside SSF's premises
14.00 – 15.00	Overall review of the projects for day 2
15.00 – 17.00	Report writing, continued
17.00 – 18.00	Panel discussion, incl. overall generic comments on the Midterm status of the programme and the Chairman's "Proforma" & Final review of the Panel's joint report. Signing of the report by the full panel.

F Project participants in Hearings on 26 and 27 October 2009

Group Grants	**PL: Paul Gatenholm, Prof, Chalmers**
26 October	Aase Bodin, Postdoc, Chalmers, Team 2 Leader
	Carl-Johan Malm, GU-Sahlgrenska Univ Hosp, thorax surgeon, Team 7
	Ulf Hedin, Prof, Karolinska Institutet, vascular surgeon, Advisory Board
	PL: Thomas Laurell, Prof, Lund University
	Hans Lilja, Prof, UMAS, Laboratory Medicine & Sloan-Kettering Cancer Center, NY
	Johan Malm, Assoc Prof, UMAS Laboratory Medicine
	György Marko-Varga, Assoc Prof, LU Chemical Center
	PL: Bo Nilsson, Prof, Uppsala University
	Olle Korsgren, Prof, MD PhD, UU Clinical Immunology Unit
	Rolf Larsson, Adjunct Prof, UU Clinical Immunology Unit
	Peetra Magnusson, Postdoc, UU Clinical Immunology Unit
	Tim Bowden, Researcher, UU Materials Chemistry
	PL: Göran Stemme, Prof, KTH, Stockholm
	Hans Wigzell, Prof, MD PhD, Karolinska Institutet, Microbiology, Tumor and Cell Biology
	Lennart Svensson, Prof, Linköping University, Molecular Virology
	Wouter van der Wijngaart, Assoc Prof, KTH
	PL: Karin Wårdell, Prof, Linköping University
	Mattias Åström, PhD student, Linköping University, Biomedical Engineering
	Stefan Andersson-Engels, Prof, Lund University, Physics
Young Faculty Grants	**PL: Anders Eklund, Assoc. Prof, Umeå University**
27 October	Jan Malm, MD PhD, UmU & Univ Hospital, Clinical Neuroscience
	Richard Birgander, MD PhD, Umeå Univ Hospital, Neuroradiology
	PL: T Christian Gasser, PhD, KTH, Stockholm
	Joy Roy, MD PhD, Karolinska Institutet, Molecular Medicine and Surgery (MMK)
	PL: Madeleine Ramstedt, PhD, Umeå University

PL = Project Leader

LIST OF ACRONYMS

AAA	Abdominal Aortic Aneurysms
BME	Biomedical Engineering
CSF	Cerebrospinal Fluid
CT	Computed tomography
DBS	Deep Brain Stimulation
FEM	Finite Element Method
GMP	Good Manufacturing Practice
IBMIR	Instant Blood Mediated Inflammatory Response
ICP	Intracranial Pressure
IP	Intellectual Property
IPR	Intellectual Property Rights
JDRF	Juvenile Diabetes Research Foundation
MEMS	Micro-Electro-Mechanical Systems
MRI	Magnetic Resonance Imaging
MSC	Mesenchymal Stem Cells
MTBH	Medicinsk Teknik för Bättre Hälsa
PCa	Prostate Cancer
PCT	Patent Cooperation Treaty
PI	Principal Investigator
PSA	Prostate Specific Antigen
QCM	Quartz Crystal Microbalance
RF	Radiofrequency
SME	Small and Medium Enterprises
VEGF	Vascular Endothelial Growth Factor

SVENSK SAMMANFATTNING

Halvtidsutvärdering av programmet Medicinsk teknik för bättre hälsa

En halvtidsutvärdering har genomförts av de åtta projekt som 2007 beviljades bidrag inom utlysningen Medicinsk teknik för bättre hälsa. Utlysningen var en gemensam femårig satsning mellan Stiftelsen för Strategisk Forskning (SSF), Vetenskapsrådet (VR) och VINNOVA. Utvärderingen utgör grunden för beslut om fortsatt finansiering för år 2010-2011.

Utlysningen 2006 inom Medicinsk teknik för bättre hälsa var på totalt 81 miljoner kronor och syftet var att främja djärva projekt i samverkan mellan teknik och medicin. Utlysningen skedde i linje med rekommendationer från en internationell utvärdering av svensk forskning inom medicinsk teknik åren 1997-2004, genomförd 2005-2006. Totalt inkom 116 ansökningar, dels till rambidrag för tvärvetenskapliga projekt med minst två forskargrupper med teknisk och medicinsk såväl som klinisk kompetens (82 st), dels projektbidrag avsedda för yngre forskare (34 st). Av dessa beviljades fem respektive tre bidrag för år 1-3, dvs 2007-2009, totalt motsvarade det cirka 49 av de avsatta 81 miljoner kronorna.

Enligt utlysningen skulle bidragen för år 4-5 beslutas på basis av en halvtidsutvärdering. Det är denna som nu har genomförts i form av distansutvärdering med internationella experter inom de områden som projekten representerade, följt av besök av en internationell panel med andra experter med god överblick inom medicinsk teknik i stort och kunskap om förutsättningar för innovation och nyttiggörande. Panelen genomförde hearings med företrädare för projekten den 26-27 oktober 2009. På basis av distansutvärderarnas rapporter och egna iakttagelser sammanställde panelen en rapport.

Panelen bestod av följande experter:
- Professor Richard Kitney (ordförande), Imperial College, London, UK
- Professor Alicia El Haj, Keele University, Stoke-on-Trent, UK
- Assoc. Professor Claudine Gehin, Lyon Institute of Nanotechnology, Villeurbanne, FR
- Professor Roger D Kamm, Massachusetts Institute of Technology (MIT), Cambridge, MA, USA
- Professor Jean-Philippe Thiran, Swiss Federal Institute of Technology, Lausanne, CH

Panelen rekommenderade fortsatt finansiering av de sju projekt som sökt medel för förlängning . Ett åttonde projekt, som fått separat tilläggsfinansiering via Vetenskapsrådet, avstod från att söka mer. Utöver bedömningarna av de åtta projekten presenterade panelen ett antal allmänna observationer av övergripande art.

Panelen säger sig vara imponerad av den överlag höga kvaliteten på den forskning som presenterades. Den berömmer även projekten för deras ambitioner att skapa broar mellan de tekniska och kliniska disciplinerna. Panelen konstaterar att programmet har lett till att goda tvärvetenskapliga forskningsmiljöer har skapats, miljöer där ett antal doktorander och postdoktorer får möjlighet att skaffa sig värdefulla erfarenheter.

Panelen bedömer även att flera grupper bör ha möjlighet att kommersialisera sina idéer och att det inom projekten pågår utveckling av potentiella produkter som kan komma att få klinisk betydelse inom 5-10 år.

Utvärderingsprocessen planerades och sköttes av en grupp handläggare bestående av
Lena-Kajsa Sidén, SSF, Margareta Eliasson, VR och Pontus von Bahr, VINNOVA.