SWEDISH FOUNDATION for STRATEGIC RESEARCH

18 April 2013
Announcement

Synergy grants for research in Medical Bioengineering in four prioritised areas:

Molecular Imaging
Tissue Engineering and Regenerative Medicine
Implanted sensors, Wearable sensors and Lab-on-a-chip
New Biomaterials

The Swedish Foundation for Strategic Research announces a total of SEK 250 million in a national Call for Proposals for problem- or application-driven research projects of the highest international scientific standards.

The strategic objective is to stimulate novel and ground-breaking research in four subareas (further described below) with strong generic or enabling potential, and between which there may exist common threads as well. This should open up for a wide range of investigators' interests and approaches in designing projects that

- address qualified medical and clinical needs with high prospective user value,
- build upon strengths in Swedish medical-technology related research to reinforce our international academic competitiveness, and that also
- have a high potential for innovation in existing or future medical-technology (and life-science) companies in Sweden

Synergy projects are expected to involve interdisciplinary research collaboration between a small number of researchers with complementary scientific expertise in line with the objectives and the multi- and cross-disciplinary nature of the overall area.

Selected projects, which should be of a size reasonable to reach critical mass, will be supported by a synergy grant in the range of SEK 5 – 7 million per year (incl. overhead costs) to be used for salaries, supplies etc. according to the needs of the project over a period of five years. Funding for the two last years will be dependent upon a successful mid-term evaluation.
An approved grant may be used for co-funding in EU-funded projects provided the core of the two projects overlap.

Importance of the medical technology sector

The medical technology industry develops and produces medical devices, an overarching term that represents some 500,000 products ranging from bandages, crutches and *in-vitro* diagnostic devices to implants, MR scanners and sophisticated life-support systems. Medical devices play a crucial and complementary role in the diagnosis, prevention, monitoring and treatment of diseases, in the improvement of the quality of life of people suffering from disabilities, in various healthcare services, etc. Important parts of the industry are characterised by a high degree of innovation, both incremental and breakthrough innovation. Important segments are based on multi-and cross-disciplinary research efforts spanning from high-energy physics to stem cell biology.

Prioritised topics in Medical Bioengineering

Bioengineering is a broad multidisciplinary field that may be defined in many different ways. For the purpose of illustrating the main area, the following description from Imperial College London may be cited:

> "Bioengineering is the use of engineering tools and techniques to solve problems arising from biology and clinical medicine. It is a remarkably broad field; research in bioengineering ranges from fundamental studies, such as understanding signalling processes in cells, to highly applied work such as the development of technology to assist patient rehabilitation. Bioengineering is fundamentally multidisciplinary, integrating engineering, mathematics, physics, chemistry, biology and clinical practice. It is the branch of engineering that has the most direct impact on human health, and brings together individuals who have a passion both for quantitative understanding and for the biomedical sciences."

Projects submitted in this call in Medical Bioengineering should be based on a clinical problem and at least one of the applicants must have relevant clinical expertise and experience. The projects should address one or several of the following four areas, where appropriate including a demonstrator.
The final distribution between the four areas will depend on the actual quality of the proposals.

Molecular Imaging

The exciting and growing field based on combining *hardware, software and wetware* (i.e. imaging techniques with molecular probes and biomarkers) will enable improved imaging of the biology of a system as well as of different stages of disease. Whereas contrast agents traditionally have been used to reveal anatomy, they now make it possible to study cellular function and molecular processes with high sensitivity (femtomolar concentrations, 10^{-15}) and high resolution in real time.

The integration of different imaging techniques like PET–CT, PET–MR, X-ray mammography – ultrasound etc. will open new areas of clinical use but also very early detection and assessment of risk for certain diseases. These developments are focused not only on increased sensitivity and specificity but also on quantification. The era of traditional imaging will also change toward a discipline for visualization and quantification of therapeutic response and validation of quality in healthcare.

Although these newer imaging technologies are advancing rapidly, exciting opportunities still exist in established methods such as high resolution fMRI – especially when coupled with complementary methods (e.g. EEG) – another example being targeted micro-bubble ultrasound. In addition, super-resolution techniques are now enabling true molecular imaging *in-vivo*. New associated technologies are driving imaging which range from chip-based methods for rapid near-patient radio-nuclei labeling of biomarkers and molecules for PET and SPECT through to emerging methods in photo-acoustics – the latter representing a considerable challenge for the future *in-vivo* imaging.

Tissue Engineering and Regenerative Medicine

The field of Tissue Engineering /Regenerative Medicine (TE/RM) is traditionally described as being based upon three fundamental approaches: Cell-based therapy, Scaffold-based approaches, and the use of Bioactive molecules. Although cell-based therapy, such as stem cell strategies, are the most commonly used, the use of smart biomaterials as scaffolds and the development of pharma-based bioactive molecules to control cell behaviour also have prominent and increasingly important roles. The field of stem cell therapy is moving from basic science to therapeutic clinical applications but the progress relies on new biomedical engineering strategies for controlling, characterisation and selection of cells for therapeutic use. Development of such enabling technologies for TE/RM is linked to other prioritised topics in this call, not least Molecular Imaging (e.g. in order to track the fate of cells over a period of years).

Mechanistic studies in patient are still needed to understand the basis of treatment and to control the fate of cells, e.g. to advance understanding of wound repair. In the longer term,

nanomaterials will become important. Stem cell research on the whole in Sweden benefits from the relatively liberal guidelines for human embryonic stem cell research compared to other countries, although the development of inducible pluripotent stem cells (iPS cells) has lessened this advantage in recent years, and there are a growing number of international groups in this area.

Implanted sensors, Wearable sensors and Lab-on-a-chip

Biosensor technology is becoming an increasingly mature field and in industry it is dominated by glucose measurement. Important opportunities still exist in this area which include new methods for informatics (associated with life style and decision support); in *in-vivo* continuous monitoring; and in simultaneous methods to compensate for hematocrit. Beyond glucose, exciting new opportunities exist in other areas of biosensing, particularly those focused upon nucleic acid technologies (DNA, RNA) – exploring the genomics of infectious diseases and drug resistance, for example. Delivering such technologies in handheld, low cost formats will provide real challenges. Looking to the future, in the long term, new formats for non-invasive methods, new formats delivered through synthetic biology, and label free detection, will all be important.

In wearable sensors, testing on patients is a bottleneck as clinical trials are time-consuming and expensive. Many academic projects therefore are tested on a patient simulator or on an inappropriate phantom. A key problem is the *sensor-patient interface* – the major source of *signal artefact* (e.g. due to movement) – which is also critical to *patient comfort and compliance*. Research is needed to address these obstacles to safe clinical use as a prerequisite for commercialisation and requires collaboration between researchers in electronics, IT, textiles, etc. on the sensor side, and degradation and turnover in-vivo may be studied with molecular imaging modalities.

New Biomaterials

Bold discovery-oriented approaches to novel and alternative biomaterials for studies of feasibility for biomedical and clinical needs, also including soft-tissue applications, are needed. (Improvement of traditional materials already in use e.g. for implants such as metallic and synthetic polymeric biomaterials, will not be prioritised.) Examples include, but are not limited to, biomaterials that are naturally occurring such as purified collagens, chitosans, alginates, hyaluronans, and extracellular matrix. Biomaterials research should progress beyond bench-top and *in-vitro* cell culture studies into *in-vivo* models. This work could include preclinical animal models and eventually human clinical trials.

Important aspects of biomaterial development in addition to biocompatibility are immunocompatibility and surface design which enable cell matrix interaction and integration within the body. In addition, new evidence indicates the role of mechanical composition of materials influencing the cell behaviour. Control and stability of structure remains a major challenge. Advanced multi-scale modelling techniques will advance and inform the subject, particularly in the context of implants. Chemistry, nanotechnology and processing technologies are expected to contribute.

This area can link to the Molecular imaging topic by the design of new biomaterials in which degradation and turnover in-vivo may be studied with molecular imaging modalities.

Eligibility

The application shall be submitted by a main applicant who should be a prominent scientist associated with a Swedish university, university college or a public or private non-profit research institute. In the latter case, at least one of the co-applicants must be working at a university. The main applicant (project leader and scientific coordinator of the proposed project) must be prepared to assume the scientific responsibility for the project during the entire grant period. The number of co-applicants should be proportionate to the amount applied for, preferably not exceeding three persons with relevant complementary

profiles of expertise, from the same or different research group(s). A maximum of 25% of the grant may be used for salary for the main applicant and/or the co-applicants (i.e the senior scientists), but only to cover up to a maximum of 25 % of the salary of each applicant. An applicant cannot submit more than one proposal as a main applicant and also may not assume the role of co-applicant in more than one application. In this call at least one of the applicants must have relevant clinical expertise and experience.

Application

To be complete, an application must contain, among other data specified in the Foundation's electronic portal, a full description of the research programme and full details of the relevant expertise of the participating parties. It should contain a clear account of the strategic as well as the scientific significance of the research programme.

Each proposal shall clearly describe the state of the art within the area(s) addressed and how the proposed approach and expected results will have the potential to outperform present golden standards or otherwise competing solutions. Clinical, medical (or biological) needs and expected endpoints should be identified along with a vision for industrial application and any other expressions of strategic relevance and impact. Projections of future device or system (corresp.) performance factors should be supplied wherever possible, as should the applicants' vision for utilisation/exploitation in Sweden within a time span of 5–15 years after completion of the project. It is also important for the proposal to give a clear picture of the resources available and to show that the proposed constellation of the research team will be effective in view of its objectives.

The application is to be submitted via the SSF portal at: http://apply.stratresearch.se. To obtain a complete view of all data required for submission it is necessary to consult the portal, thus please log on to the portal well in advance before the deadline for submission.

Evaluation

Applications will be assessed by an evaluation committee, including international scientists from academia and industry that together represent broad expertise in relevant areas of engineering as well as life science/medicine incl. clinical expertise. In a first selection the applications will be judged primarily on their strategic relevance and scope (according to the areas described above). Furthermore, applications that, according to the committee, will not be able to compete in the final step or are too incomplete to be assessed will not pass this first step. The selected applications will be assessed regarding their scientific quality and potential for clinical and/or industrial utilization. The result of the scientific assessment and the strategic value of the applications will be weighed together in order to produce a final recommendation on which the board of the Foundation will base its decision.

The applications will be reviewed using the following criteria:

- Conformity to the scope as outlined above
- Scientific quality; originality, strengths, weaknesses, multi-/cross-disciplinarity, and feasibility of the research plan
- Qualification of the applicants, previous scientific achievements, experience from collaboration between engineering and medicine, international experience, networks
- Strategic relevance to Swedish industry, healthcare and/or society and importance of the proposed research (including potential for actual utilisation in a clinical environment)

Time table

Deadline for submission of proposals:
Tuesday, 17 September, 14.00 hrs.

Decision by the SSF board (preliminary):
The final granting decision is expected to be made during April 2014. The grants will become available from July 2014.

No material reaching SSF after deadline will be considered.

Note that SSF follows the Principle of public access to official records. For this reason, do not submit any material that could prevent potential patenting.

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