Engineering for Health:
A partner in the development of a knowledge-based society for the benefit of European healthcare

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Executive Summary

Engineering for Health encompasses the advancement of fundamental concepts in engineering, biology and medicine to develop innovative approaches and new devices, materials, implants, algorithms, processes and systems for the assessment and evaluation of technology; for prevention, diagnosis, and treatment of disease; for patient care and rehabilitation and for improving medical practice and health care delivery.

This position paper of the European Alliance of Medical and Biological Engineering and Science (EAMBES) was produced to promote the visibility and recognition of Engineering for Health and to inform national and European policy makers as well as other relevant stakeholders about the current situation and future perspectives of this multidisciplinary domain so important for our society.

Facing the challenges of a diminishing and ageing population, Europe needs an overall policy of growth to improve competitiveness and ensure economic stability in achieving the Lisbon goals and in its transition to a knowledge society. Innovation and development in biomedical engineering and technology are of increasing socio-economic importance for the health and well being of European citizens. Engineering for Health assumes an increasingly important role as an integrative platform involving all major actors and stakeholders, e.g. industry, research and academia, and healthcare organizations.

The EU medical technology market is the second largest market after the US and the wealth generation potential of the medical device and pharmaceuticals industry plays a major role in the EU economy. However, health related industries in Europe are losing in competitiveness compared to other regions of the world. Achieving and maintaining excellence in research and education is a major challenge for Europe's universities in support of global competitiveness and growth. Investment in necessary human resources must be geared towards maintaining promising human capital in Europe and attracting world-class researchers from abroad. Interdisciplinarity in research, the education and the retention of world-class researchers, and efficient mechanisms for creating internationally competitive research are essential driving forces for a European vision of a modern knowledge society, but it suffers from administrative barriers with respect to fragmented funding opportunities, proposal evaluation and training.

Engineering for Health research and innovation combine both social and economical benefits. Through modernizing modalities for prevention, diagnosis and treatments, it creates greater efficiency and savings in the health system and enormous benefits have been achieved with respect to quality of life and quicker return to health across a range of chronic conditions. These are vital elements with a huge potential for positive economic and employment benefits in an economy facing a predominant demographic shift towards an ageing society. The European "eHealth Action Plan" aims at delivering better quality health care for European citizens while reducing costs. Engineering for Health is intimately engaged in developing the required technological backbone for this ambitious knowledge-based approach to healthcare.

The inherently interdisciplinary nature of Engineering for Health will play a crucial role in fostering future university-based research as a relevant instrument in the European Research Area. Human resource development is an important prerequisite for the development and widespread introduction of new technologies in the health sector. Excellence in medical and biological engineering research and education has the capacity to be a dynamic and effective engine for the development of the knowledge society and economy and a magnet for international talents. In an era where many exact sciences have faced declining student numbers, the many-faceted aspects of biomedical engineering and science make it well suited to attracting top-quality talent and to keeping this creative intellectual potential firmly linked to an important core science for Europe’s transition to a knowledge society. Investments into University-industry relations in Engineering for Health will serve to reverse the transatlantic imbalance in health related industrial domains and to ensure that Engineering for Health can realize its potential for economical growth for Europe.

Engineering for Health has evolved into a key area supporting the long-term strategic objectives of the EU. From the initial steps taken more than a century ago, Medical and Biological Engineering and Science in Europe today is organized in national and trans-European societies and alliances and has established firm synergistic relationships with other relevant stakeholders.
The European Commission has recently put forward the concept of a "knowledge triangle" of research, education and innovation to help Europe realize its goal to become a genuinely competitive, knowledge-based economy. If Europe is to address the problem of sustainable development of the healthcare sector as a key factor in achieving this goal then it must establish the necessary policy and investment structures to support these endeavours. Through its activities and opportunities, *Engineering for Health* represents a major thrust in policy-oriented research and development and provides European added value in important areas identified as key EU policy targets.

A number of straightforward recommendations can be formulated as a result of the considerations and analyses provided in this report. These are:

- Include *Engineering for Health* as a *key strategic agenda in EU policy-making* within future Framework Programmes (e.g., as Technology Platform within the *Health* subject in FP7).
- Enhance *visibility and recognition* of *Engineering for Health* by identifying it as a separate, non-fragmented entity by the ESF and other existing or planned (e.g., ERC) EU funding bodies, including the establishment of appropriate review panels.
- *Increase the investment* in MBES S&T by providing special actions for research, innovation and technology transfer for the European biomedical industry, and clinical transfer actions aimed to promote a wider adoption of European medical technology in the European healthcare system
- Establish the *European Institutes of Health* and within it an Institute for Medical and Biological Engineering Research.
- Promote and support *education, training and professional development* of specialists necessary to carry out these activities.

These actions and involvements would provide an essential pillar that strengthens the European science base by supporting interdisciplinary research endeavours in an area that intrinsically benefits European citizens.

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Why this document?
Given the importance of the health and well-being of European citizens especially in the enlarged EU of 25 countries and the wealth generation potential of the medical device and pharmaceuticals industry in Europe, innovation and development in biomedical engineering and technology are of increasing socio-economic importance in today’s knowledge-based EU society.

In its aspiration (Lisbon 2000) to become the most competitive, knowledge-based economy in the world by 2010, the continuity of health care represents a major challenge for the EU, given the rise of an ageing population and considering the growing imbalance between the EU, and Japan and the US in this sector. This challenge is not only faced directly by the health care sector, but extends to the educational community and national research institutions (e.g. CNRS in France, the CSIC in Spain, the CNR in Italy, the Max Planck Institutes in Germany, etc.), as well as industry (EUCOMED, COCIR etc.), patient advocacy groups, and professional healthcare organisations.

With this position paper, the European Alliance of Medical and Biological Engineering and Science (EAMBES1) aims at promoting visibility and public awareness of Engineering for Health and at positively lobbying towards an increase of the European investments in research and technological development in this area. This position paper was produced to inform national and European policy makers, as well as other relevant stakeholders involved with biomedical engineering and related issues about the current situation and about our position on the future perspectives of this multidisciplinary domain so important for our society.

Introduction

What is Engineering for Health?
Engineering for Health encompasses all aspects of Medical and Biological Engineering and Science2 (MBES). It is an interdisciplinary field of science representing an integrative platform for all medical technology related applications. Through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice, Engineering for Health pursues
• the advancement of fundamental concepts in engineering, biology and medicine, and
• the improvement of human health and quality of life.

It is rooted in engineering, physics, mathematics, computational sciences, chemistry, biology, and the life sciences and encompasses:
• The acquisition of new knowledge and understanding of living systems from the molecular to the organ systems levels through the innovative and substantive application of experimental and analytical techniques based on the engineering sciences.
• The development of innovative approaches and new devices, materials, implants, algorithms, processes and systems for the assessment and evaluation of technology, for prevention, diagnosis, and treatment of disease, for patient care and rehabilitation, and for improving medical practice and health care delivery.

MBES is recognized by the International Council of Scientific Unions (ICSU), representing a global membership hat includes both national scientific bodies (103 members) and international scientific unions (27 members). A list of major areas of application is provided in Appendix A.

Brief History of Engineering for Health3
Interactions between engineering and medicine to improve human health can be traced back for centuries. Resulting achievements in medical technology range from early devices such as crutches, platform shoes, wooden teeth and limb prostheses, to more modern marvels, including pacemakers, the heart-lung machine, dialysis machines, diagnostic equipment and imaging technologies of every kind, and artificial organs, implants and advanced prosthetics.

The academic endeavours of biomedical engineering (BME) reach back to early developments in electrophysiology nearly 200 years ago and to research originating with the discovery of ionizing

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1 European Alliance of Medical and Biological Engineering and Science (www.eambes.org)
2 Adapted from definitions of the National Institutes of Health (www.nih.org), the Whitaker Foundation (www.whitaker.org), and the International Federation of Medical and Biological Engineering (www.ifmbe.org)
3 Based on material from the Whitaker Foundation (www.whitaker.org) and the IFMBE (www.ifmbe.org).
radiation in the late 19th century, which together formed the basis for establishment of a formal Ph.D. training program in Frankfurt in 1921. A historical overview is provided in Appendix B.

By the 1950’s, there were societies or groups of researchers identifying their area as biophysics, bioengineering, or medical electronics in several countries in Europe, North America, and Asia. The initially loose communications between them eventually led to the establishment of the International Federation of Medical and Biological Engineering (IFMBE) in 1959. In the early 1960s, the National Institutes of Health (NIH) took significant steps to support biomedical engineering in the US by establishing special study sections and a training grant. In addition to the professional societies, the field of biomedical engineering received a large ally when The Whitaker Foundation was created in 1975, which has become the largest private benefactor of biomedical engineering in the USA. By 2004, it had contributed more than $720 million to universities and medical schools to support faculty research, graduate students, program development, and construction of facilities. The American Institute for Medical and Biological Engineering (AIMBE) was created in 1992, born from the realization that an umbrella organization was needed to address the issues of public policy and public and professional education in BME. Since then, the numbers of BME departments and programs in the USA have risen to more than 90. A major development took place in late 2000 when the National Institute of Biomedical Imaging and Bioengineering (NIBIB) was created at the NIH. NIBIB’s mission is to improve health by promoting fundamental discoveries, design, development, and assessment of technological capabilities, and the transfer of such technologies to medical applications. The Bioengineering consortium BECON coordinates $900 million worth of research and training opportunities throughout NIH.

By the 1980’s, more than 20 national societies existed in Europe. In 1992, the European Society for Engineering and Medicine (ESEM) was founded, with the goal to establish a platform of cooperation between medicine and engineering on a European basis. In 2003, the European Alliance for Medical and Biological Engineering and Science (EAMBES) was founded as an umbrella organization that brings together numerous national scientific societies and academic institutions, with the goal of promoting medical and biological engineering at European and national levels. Among others, its major objectives are to address issues of MBES education, research and training activities; to promote research and development; to establish and maintain liaisons with national and European governments and agencies, to increase the visibility and to promote public awareness of Engineering for Health.

In contrast to the developments in the US, no European government agency exists to address policy issues of Engineering for Health or to coordinate available funding under one umbrella. The resulting loss of visibility and the fragmented nature of funding opportunities has led to a growing imbalance in MBES research, education, and development and innovation related to medical technology, with increasing socio-economic consequences.

**Past Success Stories and Current Endeavours**

In the past 50 years, most quantum leaps in medicine have been due to technological advancements made possible by Engineering for Health activities. A list of some prominent examples is provided in Appendix C. Success stories can be found in many diverse areas of medical technology and practice ranging from chronic diseases (e.g. cardiovascular disease, diabetes, etc.) to telemedicine applications and novel in-hospital best practices, as well as newer fields such as pervasive computing applications in home care, sports medicine, rehabilitation, and biometrics.

The ever-expanding array of medical technologies includes artificial hips and organs, endoscopy (enabling minimally invasive surgery), intelligent prosthetic devices (artificial limbs, hearing aids) and implantable devices (pacemaker, defibrillator), novel technologies used in cardiac catheterization, patient monitoring, and medical imaging. These developments have had a tremendous impact on the medical industry and have led to numerous technologies and medical devices without which modern medicine would be unthinkable.

Today’s activities range from nano- to information technology and involve such diverse applications as microsensors, artificial organs, physiological modelling, genomics, molecular imaging, home care monitoring, ergonomics, information processing, data management, and patient safety. A brief description of some prominent examples is given in Appendix D.

In all these stories, Engineering for Health is the common ground and driving motor for development, innovation and success. Optimal exploitation of current and future research endeavours in Engineering for Health requires a concerted effort on a European level. It is increasingly imperative to maintain forward momentum in order to remain competitive and especially to advance ahead of worldwide competition.
The European Challenges in Medical Technology

According to the Lisbon Strategy put forward in 2000, Europe aims to become “the most competitive and dynamic knowledge-based economy in the world by 2010.” This goal was further underlined by the Barcelona objective in 2002 stating that “3% of GDP should be spent on research and development by 2010.” Two thirds of this investment should come from business, with the bulk of the remaining 1% coming from the public sector.

Current research spending is at 1.93% (EU average in 2000), against 2.69% in the US and 2.98% in Japan, with 56.3% through private financing, compared to the US with 68.2% and Japan with 72.4%. Business investment in R&D (BERD) in Japan stands at 1.27% of GDP and at 1.97% in the US, but only at 1.19% in the EU. Alarming, government-financed R&D is projected to decrease steadily over the next few years, with a “best-case scenario” of only 0.5% for Europe in 2010. An overall policy of growth is therefore necessary not only to improve competitiveness and ensure economic stability, but also to meet the needs of a knowledge-based economy, and especially to respond to challenges of a diminishing and ageing population.

Improving human health and quality of life

The EU currently holds the highest ‘human development index’ worldwide. This index combines three basic indicators of human well-being: leading a long life in good health, being well-educated, and having access to the resources necessary to enjoy a decent standard of living. On the other hand, Europe has the fastest growing percentage of elderly in the world. The proportion of elderly (≥ 65) in Europe’s population will have doubled to reach 28% in 2050, with, for the first time, more elderly than young (0-15) people in the EU by 2010, reaching 40% in some Member States by 2020. Health care expenditures are projected to increase by 1% to 3% of GDP over the period 2010-2050. The recent enlargement of the EU poses an additional challenge for the health sector, if acceding countries are to receive equal access to benefits.

Health care technology and services are therefore quickly becoming major socio-economical issues:

- **Patients demand optimal care.** The health sector is driven by scientific and technological progress. The latest developments are often communicated via the media, with the result that people’s expectations about healthcare provision have greatly increased. Patients want and expect access to the latest and best treatments.
- **Clinicians and health care systems.** Health professionals are a key factor in the success of any technology-based application, and thus their attitude towards IT and MBES is very important. For example, physicians use more online information services and the Internet will become more and more integrated into the daily life of medical staff, as part of their clinical practice or in care.
- **Lower health care costs.** Health is closely intertwined with economic growth and sustainable development. Healthcare expenditure can be significantly reduced through technological advances resulting in fewer complications and faster return to health. This will reduce social costs associated with sick leave, replacement at work, and lower productivity to early retirement.

Competitiveness in research and innovation

In terms of **scientific publications**, Europe is in the lead with 37.1% of the world total compared with 34.9% for the USA. In terms of **number of citations**, regarded as the best indicator of the quality and impact of research, however, Europe is behind the USA in most disciplines: about 26% more references are to US researchers, with almost 50% of the world’s publications. Japan’s citation share over the same period (1997-2001) was 8.4%.

A field-by-field analysis shows the citation gap is generally wider in the fields of basic research where an increase in knowledge is likely to have a particularly marked effect on competitiveness. While it is relatively small in fields such as the physical sciences, mathematics and engineering, the gap widens in medicine, and is particularly marked in basic life sciences, and pre-clinical medicine and health sciences. This difference in performance is confirmed by the number of Nobel Prize winners in Physiology/Medicine, Physics and Chemistry: between 1980 and 2003, there were 68 in Europe.

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against 154 in the USA, with the gap widening over the years. As is often noted, a large number of US winners were actually born or trained in Europe.\textsuperscript{7}

\textit{Innovation in medical technology and pharmaceuticals} is a major factor in modern health systems and in nations’ ability to compete. Health related industries play a major role in the EU economy. The health sector employs 10% of the EU active population and generated over 2 million jobs from 1995 to 2001 in the EU.\textsuperscript{8} With a 30% share of the world market, the value of EU medical technology market, at 55.2 billion euros, is the second largest market after the US (43%). The European medical technology industry invested on average 6.35% of its sales on R&D, against 12.9% for the US and 5.8% for Japan. The EU medical technology industry therefore spends almost 50% less than its US competitors on R&D investments.\textsuperscript{9} Although the EU medical device production has recorded growth rates well above the average of the manufacturing sector in recent years\textsuperscript{10}, the EU health care industry is losing in competitiveness compared to other regions of the world. Today’s cross-disciplinary R&D in MBES faces strong competition from researchers in the USA and Japan. Developments in orthopaedics serve as an illustrative example: In the 60s, most innovation in joint prostheses was accomplished in the UK (Charnley Group) and Switzerland (Muller Group), with important contributions also coming from Germany, France, and Italy. Europe had the first outcome register (Sweden), developed the first method to monitor implants (RSA, Sweden) and collected the most accurate information on the forces acting on total hip replacements (Germany). However, in the past decades, Europe has been losing ground against its major competitors, the USA and Asia due to mergers, takeovers and buyouts. These buyouts are usually followed by a progressive move of all R&D operations to the USA headquarters, leaving the EU out of the next innovation loops. Similar stories can be found for other sectors of the medical technology industry. There is a rising need to turn around this imbalance between the EU and the US by coordinated actions of all relevant stakeholders.

In addition, healthcare technology assessment and reimbursement of new medical technology products and treatment is faced by greatly differing approaches in different European Member States.\textsuperscript{11} Medical Device directives contain areas of regulatory uncertainty, which tend to result in a cautious approach to investment by venture capital organizations in Europe.

\textbf{Knowledge society}

In the transition to a knowledge-based economy, both the EU and Japan lag behind the US in performance level\textsuperscript{12} (mostly because of higher overall productivity in the US), while Europe and Japan are slightly ahead of the US in terms of growth rate. Similarly, the latest figures of composite indicators for investment in the knowledge-based economy\textsuperscript{13} confirm that Europe is lagging behind the US and Japan in terms of both investment level and growth. Although Europe produces more new Science & Technology (S&T) PhDs per capita, the number of full-time researchers, is significantly lower in Europe compared to the US and Japan,\textsuperscript{4} since a large number of European PhDs are not employed in research or leave the European research system to work abroad, generally in the US, which offers appreciably higher salaries to attract top scientific talent. In addition, there are considerable cultural and political roadblocks for young scientists who want to return home after a post-doc period spent in the US.\textsuperscript{14} However, tighter immigration rules in the wake of the 2001 terrorist attacks have put increasing restrictions on the mobility and recruitment of foreign Science & Engineering talent to the United States,\textsuperscript{15,16} whereas new policy schemes by the EU Commission are designed to facilitate repatriation and to attract and maintain promising human capital by legal initiatives to improve the entry conditions of foreign researchers into the EU.\textsuperscript{17}

\textsuperscript{7} \textit{Europe and Basic Research}, Brussels, 14.1.2004 COM(2004) 9 final
\textsuperscript{8} \textit{Enabling Good Health for all. A reflection process for a new EU health strategy}. David Byrne, EU DG Health and Consumer Protection. 15 July 2004
\textsuperscript{9} \textit{The Medical Technology Market Place}, Eucomed Industry Profile 2003
\textsuperscript{10} \textit{Medical Devices - Competitiveness and impact on public health expenditure}, Independent Study by CERM, Rome, for the EU DG Enterprise, July 2005
\textsuperscript{11} L. Ryden, et al., Patient access to medical technology across Europe, \textit{Eur Heart J}, 25: 611-616, 2004
\textsuperscript{12} based on overall productivity (GDP per hour worked), technological performance (patents, EPO and USPTO), scientific performance (publications per capita)
\textsuperscript{13} based on R&D expenditure (GERD per capita), human capital (number of researchers per capita, new S&T PhDs per capita), overall investment (gross fixed capital formation per capita)
\textsuperscript{14} S. Goodman, Getting mobile in Europe, \textit{Nature} 427:868-869, 2004
\textsuperscript{15} G. Brumfiel, Security restrictions lead foreign students to snub US universities, \textit{Nature}, 431:231, 2004
\textsuperscript{16} \textit{Policy Implications of International Graduate Students and Postdoctoral Scholars in the United States}, National Academies report, May 10, 2005, \texttt{http://books.nap.edu/catalog/11289.html}
\textsuperscript{17} \textit{Taking Action to Stop EU Brain Drain}, EC Press release, IP/03/1051 July 18, 2003
Important points in the transition to a knowledge society have been recently summarized during a preparatory workshop for a Commission-sponsored conference on the future of university-based research and innovation:18

THE CHALLENGE OF THE KNOWLEDGE SOCIETY19

In a world where new ideas, new processes and new technologies can be communicated and implemented with unprecedented speed, the capacity of a society both to create and introduce beneficial innovation is vital to its economic success and its social and cultural vitality. Four essential requirements for this "knowledge society" are:

a) Efficient mechanisms for creating internationally competitive research, which is the bedrock of innovation;

b) Effective processes by which new knowledge can be transferred into use in society and business;

c) The education and retention of world class researchers;

d) High levels of education for the population, both to ensure, in a rapidly changing world, that they are able to adapt to change as individuals and contribute, as informed citizens, to democratic choices by society.

For MBES, the challenges regarding the transition to a knowledge society are characterized by the following considerations:

- **eHealth applications and services.** With the rapid evolution away from handwritten records and the development of medical techniques which are based on large numbers of data from various sources (e.g., laboratory results and imaging information, often from care providers at different locations) it is now becoming essential to move from fragmented delivery systems to integrated networks of care, with clinical information systems and electronic health records that operate under international information standards. Although general practitioners' use of IT has grown rapidly and widely, with 78% of GPs in the EU working with a PC in 2002, the actual role of IT in the healthcare sector remains significantly lower in Europe when compared to that in the US. The average spent on IT per hospital in Europe is 1.2% of the overall budget, compared to 2.0-2.5% in the USA. Moreover, differences in funding and reimbursement systems across the EU greatly affect acceptance of new technologies. According to the Lisbon goals and the action plan entitled "eEurope – an Information Society for All", the Institute for Prospective Technological Studies has put forth an ambitious vision outlining plans for the implementation of an infrastructure that provides user-friendly, validated and interoperable systems for medical care, disease prevention and health education through national and regional networks which connect citizens, practitioners, and authorities online.4 Innovations in health care technologies to facilitate access to information and communication, and to simplify diagnostic and therapeutic processes are needed. This involves significant engineering activity in its design, development and production. Assessment, evaluation, benchmarking and accreditation also represent major challenges.

- **Interdisciplinarity in Research and Education.** Research activity across multiple disciplines is firmly embedded in MBES. Interdisciplinarity is considered a "sign of methodological openness and moreover a driving force for a European vision of a modern knowledge society supported by EU policies", but it suffers from administrative barriers with respect to proposal evaluation, training, and funding opportunities. Removal of these barriers is essential if the European Research Area (ERA) is to promote cutting-edge research, which opens up new areas of knowledge. University structures along traditional disciplines are also reflected in the structures of the research-funding bodies. The result is that interdisciplinary research proposals tend to "fall between the cracks". This is especially true in areas related to MBES. For example, the European Science Foundation (ESF), while promoting multi-disciplinarity as one of its governing values, is essentially structured along traditional boundaries between disciplines and does not recognize MBES as a specific field in their scientific and funding activities, either in its Engineering or Life Sciences section.

- **Brain drain and mobility.** As outlined above, the availability of well-educated human capital is crucial in achieving the transition to a knowledge-based society. Implementation of the plans for a knowledge-based approach to health care requires human resource development in terms of

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21 *Interdisciplinarity in Research*, European Union Research Advisory Board, 04.009-FINAL, April 2004

research and in-depth understanding of the functional capabilities of new technologies and applications through appropriate education and training.  

**Meeting the Challenges**

The objective is to help Europe exploit, in this post-genomic era, the unprecedented opportunities for generating new knowledge and translating it into applications that enhance human health. Both fundamental and applied research, with an emphasis on integrated, multidisciplinary, and coordinated efforts will help to increase the competitiveness of the European healthcare system.

**Challenge: HEALTH and QUALITY OF LIFE**

*Engineering for Health* research and innovation easily combines both social and economical benefits. The past decades have seen tremendous improvements in the provision of healthcare and as a result, people are living longer and healthier lives. This success is based on a combination of factors: better informed patients, skilled clinicians, scientific discoveries, and technological innovation. Through modernizing modalities for prevention, diagnosis and treatments, *Engineering for Health* creates greater efficiency and savings in the health system. Already, the use of diagnostic and therapeutic modalities of medical technology brings about improved patient outcomes. Enormous benefits have been achieved with respect to quality of life and quicker return to health across a range of chronic conditions. In cardiac care, prominent examples include the use of coronary artery stents, implantable defibrillators and pacemakers, and intelligent ambulatory heart monitoring systems. Advances in orthopaedics, minimally invasive surgery, and biomaterials have resulted in safer operations, faster recoveries and improved end results. These and other advancements have significantly reduced mortality rates, improved patient quality of life and freed up health care resources by reducing both frequency and length of hospitalizations. Although an overall cost-effectiveness analysis is hampered due to lacking harmonisation and coordination in the use of evidence-based medicine and health technology assessment of Member States and the lack of a coherent European Database on Medical Devices (EUDAMED), studies on specific health care areas have concluded that enormous net cost savings can be achieved.  

Substantial steps ahead, particularly in areas such as regenerative medicine, nanomedicine, minimally invasive sensors and surgical technologies, tissue engineering, medical imaging, and telemedicine will revolutionize diagnosis, treatment and rehabilitation. Technological advancements realized through *Engineering for Health* innovation and research will positively and widely affect the quality of life of EU citizens not only in relation to disease, but will extend to tangible outcomes regarding the efficacy, safety, ergonomics and comfort in all aspects of empowering, re-enabling, or assisting the human body in normal activities (i.e. children, disabled, and elderly) as well as in exceptional activities (i.e. work, sports, security, and the exploration of hostile environments).

**Challenge: COMPETITIVENESS in RESEARCH AND INNOVATION**

The health sector is driven by scientific and technological progress, and health is a productive economic factor in terms of employment, innovation, and sustainable development and growth. Areas where *Engineering for Health* R&D contributes significantly to enhanced competitiveness in research and innovation include tissue and organ engineering, biological and physiological systems analysis, computer-integrated surgery systems, human-environmental interfaces, diagnostic technologies, and all aspects of telecare and independent living devices in health care. *Engineering for Health* plays a significant role in health care technology assessment, thereby supporting the implementation of innovative technology in the interests of European citizens. These are vital elements with a huge potential for positive economic and employment benefits in an economy facing a predominant demographic shift towards an ageing society.

Job opportunities for biomedical engineers are bright, with more than double the average predicted rate of increase in other fields and bodies such as the EAMBES are expected to help create many new jobs in the future.

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24 *Making the economic case for medical technology*, The Medical Technology Group, UK, 2003  
25 *The value of investment in health care: Better care, better lives*, Advanced Medical Technology Association (AdvaMed), USA, 2004  
EU-wide initiatives are needed to establish more balanced and harmonized reimbursement schemes and an appropriate common regulatory environment in order to ensure a more equitable level of patient and clinician access to innovative treatments across the EU and to create favourable conditions to make the EU more attractive for R&D activities in Engineering for Health. Necessary steps in achieving global competitiveness will also include harmonization of the EU patent systems to facilitate intellectual knowledge transfer.

Achieving and maintaining excellence in research and education is a major challenge for Europe’s universities in support of global competitiveness and growth. The inherently interdisciplinary nature of Engineering for Health will play a crucial role in fostering future university-based research as a relevant instrument in the European Research Area for creating European centres of excellence and improving innovation and production of new knowledge. Investments into University-industry relations in Engineering for Health will serve to reverse the transatlantic imbalance in MBES related industrial domains and to ensure that Engineering for Health can realize its potential for economical growth for Europe.

Challenge: KNOWLEDGE SOCIETY

The European “eHealth Action Plan” adopted on April 30, 2004 aims at delivering better quality health care for European citizens while reducing costs, with one of its major targets to create by the end of the decade a borderless European health information space.

MBES is intimately engaged in developing the required technological backbone for this ambitious knowledge-based approach to healthcare, which ranges from the development of electronic health records to creating an ‘intelligent environment’ that allows ubiquitous management of each person’s health status and high-quality access to telecare, independent living services, and online health services (information on healthy living and illness prevention, electronic health records, teleconsultation and e-reimbursement, etc.). Related key research and technology areas encompass telematic biomedical implants (bioinformatics, DNA/protein sensors, self-powered micro and nano-systems), standards and interoperability, human-environment interfaces (personalized ambient intelligence, for augmented and virtual reality), secure communications and networking (incl. Personal and Body Area Networks), health information management (data mining, decision support systems, applications of GRID technologies, etc.), the modelling and simulation of complex systems (such as those needed for the Virtual Patient), and methodologies for the effective and efficient assessment of complex technology-based systems prototypes.

Human resource development is an important prerequisite for the development and widespread introduction of new technologies in the health sector. Central to its support is the need for public awareness and recognition of the importance of science, and to improve the image of researchers within society.

In this aspect, Engineering for Health holds an advantageous position through the tangible personal benefits experienced by European citizens as a result of research in Engineering for Health. Investment in necessary human resources must be geared towards maintaining promising human capital in Europe and attracting world-class researchers from abroad. In an era where many exact sciences have faced declining student numbers because of loss of appeal, the many-faceted aspects of biomedical engineering and science make it well suited to attracting top-quality talent and to keeping this creative intellectual potential firmly linked to an important core science for Europe’s transition to a knowledge society. In study programs incorporating biomedical sciences, the number of students increases. In particular it has been demonstrated that MBES is an attractive field for women. At present, programmes with a biomedical engineering component have a considerably higher percentage of female students than most other engineering programs.

Efforts to enhance student and researcher mobility, e.g. through the Marie Curie Actions, and building a European Research Area will create a multicultural space for science and research with attractive research training and working conditions for young researchers. Excellence in MBES research and education has the capacity to be a dynamic and effective engine for the development of the knowledge society and economy and a magnet for international talents.

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Conclusions: The Road Ahead

*Engineering for Health* has evolved into a key area supporting the long-term strategic objectives of the EU. From the initial steps taken more than a century ago, Medical and Biological Engineering and Science in Europe today is organized in national and trans-European societies and alliances and has established firm synergistic relationships with other relevant stakeholders and European organisations, such as Health First Europe.\(^{30}\)

The European Commission has recently put forward the concept of a "knowledge triangle" of research, education and innovation to help Europe realize its goal to become a genuinely competitive, knowledge-based economy.\(^ {31}\) If Europe is to address the problem of sustainable development of the healthcare sector as a key factor in achieving this goal then it must establish the necessary policy and investment structures to support these endeavours.

The contribution of *Engineering for Health* to economic growth and competitiveness in this area is an essential ingredient for achieving the Lisbon goals in Europe, which have recently been reconfirmed in the March 2005 European Council. The objectives set out in the proposed 7th Framework Programme\(^ {32}\) are aimed at supporting the Lisbon agenda through Community funded research activities. Such research plays a critically important role in promoting growth and prosperity, building the European knowledge base including research capacities and developing an integrated and strengthened European Research Area.

Through its activities and opportunities, *Engineering for Health* represents a major thrust in policy-oriented research and development and provides European added value in important areas identified as key EU policy targets.

Strategic Recommendations

A number of straightforward recommendations can be formulated as a result of the considerations and analyses provided in this report. These are:

- Include *Engineering for Health* as a key strategic agenda in EU policy-making within future Framework Programmes (e.g., as Technology Platform within the Health subject in FP7).
- Enhance the visibility and recognition of *Engineering for Health* by identifying it as a separate, non-fragmented entity by the ESF and other existing or planned (e.g., ERC) EU funding bodies, including the establishment of appropriate review panels.
- *Increase the investment* in MBES &T by providing special actions for research, innovation and technology transfer for the European biomedical industry, and clinical transfer actions aimed to promote a wider adoption of European medical technology in the European healthcare system.
- Establish the *European Institutes of Health* and within it an Institute for Medical and Biological Engineering Research.
- Promote and support *education, training and professional development* of the specialists necessary to carry out these activities.

These actions and involvements would provide an essential pillar that strengthens the European science base by supporting interdisciplinary research endeavours in an area that intrinsically benefits European citizens.

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\(^ {30}\) [www.healthfirsteurope.org](http://www.healthfirsteurope.org)

\(^ {31}\) *Building the ERA of knowledge for growth*, COM(2005) 118 final, Brussels, 6.4.2005

Appendices

A. Engineering for Health: Research Areas and Activities
(from EAMBES CHART website http://web.gbt.tfo.upm.es/chart/index.html)

- Artificial Organs:
- Biochemical Engineering
- Bioinformatics:
- Biomaterials:
- Biomeasurements
- Biomechanics and Biofluid mechanics
- Biomedical Engineering Education
- Biomedical Imaging
- Biomedical Sensors
- Biosignal and Image Processing
- Cardiovascular Engineering
- Cellular and Molecular Engineering
- Clinical Engineering
- Health Technology
- Information Technology in Medicine
- Medical Image Processing
- Medical Specialties
- Modelling of Physiological and Biological Systems
- Neural Engineering
- Neuroinformatics
- Orthopaedic Engineering
- Prosthetic devices / Prosthetics
- Pulmonary Engineering
- Rehabilitation Engineering
- Surgical Techniques
- Tissue Engineering
### B. Engineering for Health: Historical Overview

<table>
<thead>
<tr>
<th>Date</th>
<th>EU</th>
<th>US</th>
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<tr>
<td>1000 B.C.</td>
<td>Oldest known limb prosthesis: a wooden prosthetic tied to a mummy’s foot to serve as a big toe. Egyptians also used hollow reeds to look and listen to the internal goings on of the human anatomy.</td>
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<tr>
<td>1816</td>
<td>French physician Rene Laennec used a rolled up newspaper to listen to chest sounds, triggering the idea for his invention that led to today’s stethoscope.</td>
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<td>1848</td>
<td>The German Emil DuBois Reymond published the widely recognized &quot;Untersuchungen über tierische Elektricität.&quot; His contemporary, Hermann von Helmholtz, is credited with applying engineering principles to problems in physiology and identifying the resistance of muscle and nervous tissues to direct current.</td>
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<td>1895</td>
<td>Wilhelm Röntgen accidentally discovered X-rays. This set off a line of research into the tissue-interaction of X-rays that ultimately produced the modern array of medical imaging technologies and virtually eliminated the need for exploratory surgery.</td>
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<tr>
<td>1901</td>
<td>Nobel Prize in Physics for discovery of X-rays</td>
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<td>1903</td>
<td>Nobel Prize in Physics for discovery of spontaneous radioactivity and radiation phenomena</td>
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<td>1921</td>
<td>The Oswalt Institute for Physics in Medicine was established in Frankfurt, Germany. It is a forerunner of the Max Planck Institute fur Biophysik. The Institute's founder, Friedrich Dessauer, pioneered research into the biological effects of ionizing radiation.</td>
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<td>1924</td>
<td>Nobel Prize for discovery of the electrocardiogram</td>
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<td>1930</td>
<td>Nobel Prize for discovery of blood groups</td>
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<td>1939</td>
<td>Nobel Prize in Physics for invention of the cyclotron</td>
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<tr>
<td>1940</td>
<td>First formal training: The Oswalt Institute and the University in Frankfurt established formal ties that led to a Ph.D. program in biophysics. Research topics included the effects of X-rays on tissues and the electrical properties of tissues.</td>
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<tr>
<td>1943</td>
<td>A biophysical society was formed in Germany</td>
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<td>1945</td>
<td>Nobel Prize for discovery of Penicillin</td>
<td>First conference of engineering in medicine and biology convened under the auspices of the Institute of Radio Engineers (IRE), the American Institute for Electrical Engineering (AIEE), and the Instrument Society of America (ISA).</td>
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<tr>
<td>1948</td>
<td>IRE formed a Professional Group on Medical Electronics. In 1952, the AIEE, the IRE and the ISA formed the Joint Executive Committee on Medicine and Biology, which began organizing annual conferences and later evolved into the IEEE-EMB society.</td>
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<tr>
<td>1951</td>
<td>Earliest academic programs: Johns Hopkins University, University of Rochester, University of Pennsylvania, and Drexel University</td>
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<td>1953</td>
<td>Nobel Prize for invention of phase contrast microscope</td>
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<td>1956</td>
<td>Nobel Prize for discoveries concerning heart catheterization and pathological changes in the circulatory system Nobel Prize in Physics for research on semiconductors and discovery of the transistor effect</td>
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<td>1962</td>
<td>Nobel Prize for discovery of DNA structure and function</td>
<td>The AIEE and the IRE merged to form the Institute of Electrical and Electronics Engineering (IEEE).</td>
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<td>1963</td>
<td>Early 1960s</td>
<td>NIH created a committee under the General Medical Sciences Institute to evaluate</td>
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<td>1967</td>
<td>Nobel Prize for discovery concerning primary visual processes in the eye</td>
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<td>1968</td>
<td>The Biomedical Engineering Society (BMES) was formed “to promote the increase of biomedical engineering knowledge and its utilization.” BMES is the lead society for the accreditation of biomedical and bioengineering programs.</td>
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<td>1969</td>
<td>The Alliance for Engineering in Medicine and Biology was formed (dissolved in 1988).</td>
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<tr>
<td>1960's-70's</td>
<td>Stimulated by an important NIH initiative to support the development of the field, a second generation of biomedical engineering programs and departments was founded at 12 renowned research universities.</td>
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<td>1971</td>
<td>Nobel Prize in Physics for invention and development of the holographic method</td>
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<td>1975</td>
<td>The Whitaker Foundation was created. The foundation has become the largest private benefactor of biomedical engineering by supporting faculty research, graduate students, program development, and construction of facilities.</td>
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<td>1979</td>
<td>Nobel Prize for development of computer assisted tomography</td>
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<td>1986</td>
<td>Nobel Prize in Physics for invention of the electron microscope and scanning tunnelling microscope</td>
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<td>1990</td>
<td>Nobel Prize for discoveries concerning organ and cell transplantation in the treatment of human disease</td>
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<td>1992</td>
<td>Foundation of the European Society for Engineering and Medicine (ESEM) with the mission to establish a platform of cooperation between medicine and engineering on a European basis</td>
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<td>1998</td>
<td>Nobel Prize in Physiology or Medicine for discoveries concerning nitric oxide as a signalling molecule in the cardiovascular system</td>
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<td>2000</td>
<td>Nobel Prize in Physics for invention of the integrated circuit</td>
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<tr>
<td>2000</td>
<td>Creation of the American Institute for Medical and Biological Engineering (AIMBE) as an umbrella organization to address issues of public policy and public and professional education. Today, its 17 society members work to “establish a clear and comprehensive identity for the field of medical and biological engineering, and improve intersociety relations and cooperation within the field of medical and biological engineering.”</td>
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<tr>
<td>2002</td>
<td>Nobel Prize in Chemistry for the development of mass spectrometry and NMR spectrometry, methods for identification and structure analyses of biological macromolecules</td>
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<tr>
<td>2003</td>
<td>The European Alliance of Medical and Biological Engineering and Science (EAMBES) was founded as an umbrella organization with the major goal of promoting medical and biological engineering at European and national levels.</td>
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<tr>
<td>2003</td>
<td>EAMBES attains official status. Membership in 2005: 22 national societies, 5 transnational societies and 30 academic institutions</td>
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C. Engineering for Health: Past Success Stories

Many Nobel prizes linked to medical technology and research are directly related to Engineering for Health, including those for the discovery of x-rays (1901), heart catheterization (1956), computer assisted tomography (1979), electron microscope and scanning tunnelling microscope (1986), mass spectrometry and NMR spectrometry (2000), and most recently, for discoveries concerning magnetic resonance imaging (MRI) in 2003.

The examples below list some achievements that have led to numerous technologies and medical devices that are in daily use in medical practice and had a tremendous impact on the advancement of health care and on the medical industry.

Artificial hips: One of the early pioneering achievements of MBES was the development of the total hip replacement by Sir John Charnley in England in the 1950s. His interdisciplinary approach, for example, by applying dental polymeric methacrylate biomaterials as bone cement to anchor the metallic hip prosthesis to the bone, typifies the benefits of looking beyond the boundaries of one’s own speciality.

Heart Catheterization: The diagnosis and treatment of one of the most prevalent cardiovascular diseases in Western society, atherosclerosis, has been greatly influenced by the development of heart catheterization and balloon angioplasty. The German Werner Forssmann (Nobel Prize 1956) was the first to develop a technique for the catheterization of the heart. This he did in 1929 by inserting a cannula into his own antecubital vein, through which he passed a catheter for 65 cm and then walked to the X-ray department, where a photograph was taken of the catheter lying in his right auricle. Forssmann was immediately fired for his self-experimentation, and the medical establishment ignored the significance of his discovery for more than a decade.

Angioplasty and interventional cardiology: The American Charles Dotter first envisioned the circulatory system of the body as a highway in which therapy could be delivered. He first used catheters in 1964 to open blocked arteries in peripheral vessels (leg). Scorned with scepticism and rejection in the U.S. for nearly 15 years, Dotter’s techniques were embraced and expanded by investigators in Europe. The German Andreas Grüntzig refined the technique in 1977 by inserting a catheter into a patient’s coronary artery and inflating a tiny balloon, thus successfully opening a blockage and restoring blood flow to a human heart. Today over two million coronary angioplasties are performed worldwide each year, making it more common than bypass surgery. In the past decade, stents, rotational atherectomy devices, radiation catheters, intravascular ultrasound, gene therapy, angiogenesis, and other innovations have ushered in a new era in interventional medicine.

Implantable devices: The miniaturization of sensors, safe and long-lasting power supplies, and sophisticated integrated circuits have made possible the development of the implantable defibrillator, pacemaker, insulin pump, and cochlear implant.

Artificial Organs: The Dutchman Willem Kolff invented the first artificial kidney-dialysis machine (in 1943), which inspired the development of blood oxygenators (heart-lung machine) and the first artificial heart. He recently embarked on the development of a wearable artificial lung by combining blood oxygenators with a minimally invasive left heart assist device.

Medical Imaging: A multitude of invasive and non-invasive medical imaging methods have been developed with ever increasing sophistication: computer-assisted tomography (CT, Nobel Prize 1979), magnetic resonance imaging (MRI, Nobel Prize 2003), ultrasound (also intravascular with catheter-mounted crystal), imaging based on ultrasound (echocardiography), light optical coherence tomography and electron interactions (single photon emission tomography, positron emission tomography). Many of these imaging methodologies advanced alongside the development of biological markers or contrast enhancing materials that made functional imaging possible.

Prostheses: From tooth replacements to artificial hip or knee joints, prosthetic devices have come a long way from the ubiquitous “wooden leg”. Research today extends to control of artificial limbs or paralyzed extremities by connections to remaining functional nerves, and “growing” prostheses based on the controlled release of spring energy within a softening polymer for limb extensions.
D. Engineering for Health: Current Research Endeavours

*Information Technology in Medicine:* In homecare, pervasive computing and telemedicine applications are used for ubiquitous and unobtrusive delivery of health services. Intelligence embedded into portable microdevices for recording, processing and interpretation of biosignals and bioparameters, access and integration with the GRID infrastructure, and new molecular based information regarding the individual are the basis for quality personalised continuous health care delivery. Other important areas include the growing use of electronic smart cards, medical image transfer and data communication, Telematics, and novel identification systems based on Biometrics.

*Minimally invasive surgery:* By applying a man-machine systems approach and intelligent interface techniques, new technologies are developed to improve surgeon-patient interaction, including miniaturization of tools, ergonomic steerable devices with tactile and visual feedback, 3-D roadmaps for navigation, and robotic drills for orthopaedic surgery.

*Biomedical Sensors:* Starting from the biosensors and electronics, to the algorithms used for ECG processing in real time, new trends are in nano-technologies, wearable sensors, and seamless communication modules between the body recording sites, the contact centres and the medical personnel.

*Medical Imaging and visualization:* Advanced 3-D modelling and rendering is used for reconstructive surgery and minimally invasive treatment planning. Image fusion techniques and molecular imaging provide not only information about a patient’s organ geometry, but also about material properties, biochemical processes and function of the organ, e.g. brain images obtained by computer-assisted tomography (CT) and positron emission tomography (PET) are used in schizophrenia research. Multi-slice CT has reduced the time to obtain 3-D reconstructions of the chest at unprecedented resolution (<0.4 mm) to less than 30 sec.

*Intelligent Materials:* One of the principal fields of biomaterial research is that of so-called “intelligent” materials, for example, biodegradable shape-memory polymers, which can alter their molecular conformation by temperature modulation, and permit activation of, for example, a drug-delivery system. Furthermore, nanofabrication of biomaterials and the synthesis of self-assembly nanostructures are providing novel means of controlling cell function.

*Tissue engineering:* Replacement of diseased organs is giving way to the concept of promoting the body’s own regenerative capacity. A major strategy is to combine a three-dimensional biomaterial scaffold or matrix, containing important bioactive signal molecules, such as growth factors, and seeded with the patient’s own cells. Coupled with this is the entire field of bioreactor technology to enable rapid proliferation of a functional cell population for such strategies.

*Vascular Genomics:* This new field integrates post-genome research into the more established biomedical and biotechnological approaches to cardiovascular disease. Important determinants of the cardiovascular disease such as endothelial dysfunction, plaque instability and therapeutic angiogenesis to recover ischemic organ function and reduce heart failure are prominent areas of vascular genomics. Each of these areas has potential for development of new diagnostic and therapeutic strategies that will provide permanent benefit for patients.

*Nanotechnology:* This research area plays an increasing role in disease detection e.g. by tagging disease indicators such as HIV antibodies or cancer cells with light-emitting semi-conductor nanocrystals. Injected in patients’ bloodstreams, the targets can be revealed by shining light on the nanocrystals. Nested-sphere molecules currently used for circuit design are being developed for specialized drug-delivery by encapsulating medicine within a container layer, and an outer surface to which seeker agents can be attached which carry the sphere to its target where the drug is released. Another new development is under-the-skin implants that deliver drugs at precisely regulated dosages through custom-matched porous membranes.

*Modelling of physiological systems:* Reliable numerical models are a useful tool in understanding and predicting the behaviour of physiological systems in response to changes in their mechanical or biological environment. Comprehensive models of biological systems can provide a key to pharmaceutics and drug design. The Physiome Project33 is one of the most ambitious efforts in this area. It aims to provide a quantitative description of functioning organism in normal and pathophysiological states by developing integrative models across multiple scales of biological organisation, from genes and proteins to cells, tissues, and whole organ structure-function relations.