THE SIXTH FRAMEWORK PROGRAMME
The Sixth Framework Programme covers Community activities in the field of research, technological development and demonstration (RTD) for the period 2002 to 2006

Work Programme

for the specific programme for research, technological development and demonstration:

"Integrating and strengthening the European Research Area"

PRIORITY 1: Life Sciences, Genomics and Biotechnology for Health

Commission Decision C

Table of Contents

I. FOCUSING AND INTEGRATING COMMUNITY RESEARCH

THEMATIC PRIORITY AREA 1: Life sciences, genomics and biotechnology for health

1.1 INTRODUCTION

This fourth main update to the Work Programme for Thematic Priority 1, covers calls for proposals with closing dates in 2005. It defines the priorities for the calls for proposals, the implementation plan and the criteria that will be used for evaluating proposals responding to these calls.

It should be recalled that the overall aim of the theme is to build on the sequencing of the human genome and many other genomes with the result of improving human health and to stimulate industrial and economic activity. In making its contribution to realising these benefits, this theme will focus on integrating post-genomic research, including research on related molecular mechanisms, into the more established biomedical and biotechnological approaches, and will facilitate the integration of research capacities (both public and private) across Europe to increase coherence and achieve critical mass. Integrated multidisciplinary research, which enables a strong interaction between technology and biology, is vital in this theme for translating genome data into practical applications. In addition, an essential element will be to involve key stakeholders, for example**,** as appropriate industry, healthcare providers and physicians, policy makers, regulatory authorities, patient associations, and experts on ethical matters, etc in implementing the theme. Furthermore, attention will be paid to childhood diseases and related treatments whenever appropriate, and gender aspects in the research will be taken into account[1].

This thematic priority will stimulate and sustain multidisciplinary basic research to exploit the full potential of genome information to underpin applications to human health. In the field of applications, the emphasis will be put on research aimed at bringing basic knowledge through to the application stage ("translational" approach), to enable real and consistent and coordinated progress at European level in medicine and improve the quality of life. This research may also have implications for research on areas such as agriculture and environment, which are addressed under other thematic priorities; such implications should be duly taken into account in the course of the implementation of the thematic priorities concerned.

This edition of the Work Programme sets out activities envisaged for 2005 and 2006.

[1] Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women, men and children. Therefore, all activities funded within this thematic priority must take the possibility of such differences into account in their research protocols, methodologies and analysis of results.

1.2 OBJECTIVES, STRUCTURE, AND OVERALL APPROACH

The content of this updated Work Programme and the research topics selected for this call reflects the input received from the Advisory Group for Theme 1, the Programme Committee, the response to the Expressions of Interest exercise 2002, various scientific conferences and workshops in the sector. In addition the Work Programme also takes into account the results of the previous calls announced in 2002-2004, the budget limitations, the urgency of the scientific actions and the possible overlaps between research topics.

The Work Programme will be implemented through a range of instruments as specified in the topic descriptions. In addition some activities may be taken forward through public procurement procedures (calls for tenders). These will help the Commission prepare new initiatives in a targeted manner that will complement the more "bottom" up approach offered by call for proposals. Calls for tender are clearly distinguished from calls for proposals in the Work Programme.

In preparing proposals, applicants should consider the horizontal issues mentioned in the general introduction[2] and the following issues which are specifically relevant to this theme:

Gender aspects in research

Gender aspects in research have a particular relevance to this theme as risk factors, biological mechanisms, clinical, manifestation, causes, consequences for disease and disorders may differ in men and women. The possibility of gender/sex differences[3] must therefore be considered in all areas of health research, unless it can be demonstrated that gender/sex is inappropriate, with respect to the health of the subjects or the objectives of the research. Gender/sex issues should be considered in:

- the formulation of research hypotheses, in the development of research protocols, choice of research methodologies and in the analysis of results
- biological, pre-clinical and epidemiological, behavioural research/studies on both human and animal subjects
- the use of cells, tissues and other specimen, where appropriate
- the choice for a particular study population that should be thoroughly justified and the sex of the participants described in full.

These aspects will be taken into account in the evaluation process[4].

Innovation aspects and SME participation

Life sciences and biotechnology, as frontier technologies, can contribute significantly to the Lisbon objective of Europe becoming the most competitive knowledge based economy in the world by 2010[5]. This thematic priority emphasises the importance of innovation and the integration of SMEs in order to reach the Lisbon goal by ensuring that new knowledge is disseminated and translated into new therapies and clinical practice. Although the inclusion of "high-tech" SMEs is particularly encouraged, SMEs providing a service e.g. management, intellectual property expertise are also eligible to participate.

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2 See section "General Introduction".

3 Because of the inconsistent and often confusing use of the terms sex and gender, their use should be clarified: sex refers to differences attributed to biological origins, gender refers to social influences that lead to differences. Males and females differ not only in their basic biology but also in ways they interact with and are treated by society.

4 See relevant sections in the "Guide for Proposers".

5 See also "Life sciences and biotechnology - A strategy for Europe".

As 15% of the budget for Thematic Priority 1 is reserved for SME participation, all proposal consortia should aim at having at least 15% of the budget allocated to SMEs. For Integrated Projects and Networks of Excellence, it is possible to reserve part of the budget for inclusion of SMEs at a later stage, however the activities must be clearly defined in the original proposal.

A special effort to stimulate the participation of SMEs in Thematic Priority 1 in the 4th call for proposals is done by introducing the Specific Targeted Research Projects (STREPs) dedicated to SMEs. These "SME-STREPs" are specifically designed to encourage SME efforts towards research and innovation. Such STREPs should be centred on the reinforcement of SME's scientific and technological knowledge and on the validation of innovative solutions. Research-intensive SMEs are expected to play leading roles[6] in the project with the possible participation of universities, research centres, other industries and industrial associations. Expected project results should clearly be of interest and potential benefit to SME(s). The requested EC contribution to participating SMEs must in all cases be substantial. All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs. (Subcontracting is discouraged[7]). Several STREP projects can be funded in each topic. Please note that the new Commission Recommendation 2003/361/EC[8] will apply to the definition of SMEs as from 1 January 2005.

EC contribution can be requested for costs in connection with Clinical Trials in areas/topics specifically indicated in the work programme. Approval for the clinical trial from the relevant ethical committee will be demanded.

Child health

Attention should be paid to childhood disease, whenever appropriate. Research on children has so far been very limited because children cannot give consent, which is a basic requirement for all research involving human beings. Providing appropriate ethical requirements are taken into consideration, research involving children should be taken into account.

Clinical research and clinical trials

Since the development of applications towards human health and the improvement of patient-oriented strategies will be important to the success of this priority, clinical research is expected to be a major tool used by the applicants to meet these objectives[9]. This clinical research may include clinical trials. Community contribution will however only be available for Phase I and II clinical trials. In implementing a clinical research project consortia are encouraged to include small and medium sized enterprises (SMEs) wherever appropriate.[10]

Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women, men and children. Therefore, all activities funded within this thematic priority must take the possibility of such differences into account in their research protocols, methodologies and analysis of results, in particular when conducting clinical research.

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6 Not necessarily co-ordinated by the participating SME(s)

7 Subcontracting is not taken into account in the calculation of the SME participation % and is anyhow strongly discouraged by the Commission

8 OJ L 124 p. 36, 20.5.2003, Full SME definition and a User Guide can be downloaded from http://europa.eu.int/comm/enterprise/enterprise_policy/sme_definition/index_en.htm

9 See relevant section in the " Guide for Proposers".

10 See relevant sections in the "Guide for Proposers".

Integration of ethical, social, legal and wider cultural aspects

Ethics has a special relevance in thematic priority 1. Ethical issues such as research with human beings (clinical trials in adults and children), use of human embryonic stem cells, use of biological materials of human origin and research with animals will be dealt with in this priority. Experts in ethics, law and social sciences are encouraged to participate actively in research projects. Transdisciplinary collaboration between all stakeholders should ensure that due account is taken of the ethical and societal concerns, our obligations towards future generations and the rest of the world. It should also allow for mutual education and dialogue, and ensure that ethicists have the means to continuously assess the societal relevance and adequacy of their analysis and evaluation.

Fostering ethical awareness in research and foresight attention in research

All applicants will be requested to address, in the application form, the potential ethical aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results. This should justify the research design, explain how ethical requirements will be fulfilled and indicate the relevant national laws and/or regulations of the country(ies) where the research takes place. [11]

International Cooperation

International co-operation is welcomed in all areas within the thematic priority. Project consortia are in particular encouraged to include organisations from the INCO target countries (see list of countries in Annex C) and from countries with Scientific and Technological cooperation agreements[12] according to the participation rules[13]. Funding will be provided to participants from the INCO target countries. Funding for organisations from other third countries may be provided on a case by case basis if considered essential for carrying out the project.

Within the theme, the area 'Confronting the major communicable diseases linked to poverty' places a particular emphasis on involving groups and organisations from developing countries.

Support to policies

This thematic priority will also contribute to the action plan of the Communication from the Commission entitled "Life sciences and biotechnology - A strategy for Europe" [14], which is a follow-up of the March 2001 Stockholm European Council.[15]

This thematic priority area will also foster the implementation and development of the health strategy of the European Community.

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[11] See "Annex B Common evaluation criteria for evaluating proposals – The ethical review of proposals" and the "Guide for Proposers".

[12] Countries with signed S&T agreements June 2005: Argentina, Australia, Brazil, Canada, China, Chile, Egypt, India, Mexico, Morocco, Russia, South Africa, Tunisia, Ukraine and United States

[13] Regulation (EC) No 2321/2002 of the European Parliament and of the Council of 16 December 2002 concerning the rules for the participation of undertakings, research centres and universities in, and for the dissemination of research results for, the implementation of the European Community Sixth Framework Programme (2002-2006)

[14] http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf

[15] See section on "Other actions across Thematic Priority 1".

1.3 TECHNICAL CONTENT

i) ADVANCED GENOMICS AND ITS APPLICATIONS FOR HEALTH

a) FUNDAMENTAL KNOWLEDGE AND BASIC TOOLS FOR FUNCTIONAL GENOMICS IN ALL ORGANISMS

The strategic objective of this line is to foster the basic understanding of genomic information, by developing the knowledge base, tools and resources needed to decipher the function of genes and gene products relevant to human health and to explore their interactions with each other and with their environment. **The involvement of SMEs is encouraged in this area.** As a general guide, in "Fundamental knowledge and basic tools for functional genomics in all organisms", proposals for Integrated Projects and Networks of Excellence should not normally expect a Community contribution after contract negotiation of more than 12 million Euros per project.

Research actions will encompass the following:

- **Gene expression and proteomics**

  The objectives are to enable researchers to better decipher the functions of genes and gene products as well as to define the complex regulatory networks that control fundamental biological processes.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-1.1.1-1: A systems approach to understanding the regulation of gene transcription – *INTEGRATED PROJECT***. The project should focus on designing high-throughput technologies for studying the interactions of transcription factors in the context of intracellular communication, in conjunction with developing and validating systems biology methodologies, including modelling. The work should be highly focused on a model organism (and may include well designed comparative studies) but the approaches used should be of general applicability.

- **Structural genomics**

  The objective is to enable researchers to determine, more effectively and at a higher rate than is currently feasible, the 3-D structure of proteins and other macromolecules which is important for elucidating protein function and is essential for drug design.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-1.1.2-1: Structural genomics interdisciplinary initiative – *INTEGRATED PROJECT.*** The objective should be the high-throughput determination of the three-dimensional structure of macromolecules (proteins, RNA, complexes…) in an interdisciplinary and international effort, with special emphasis on the development of the necessary technologies and bioinformatics tools to achieve this, in particular for new folds or for macromolecules presenting particular difficulties for structural determination. The project should be organised around a common theme in terms of target selection.

- **Comparative genomics and population genetics**

  The objectives are to enable researchers to use well-characterised model organisms for predicting and testing gene function and to take full advantage of specific population cohorts available in Europe to determine the relationship between gene function and health or disease.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-1.1.3-1: Functional genomics in *Arabidopsis thaliana* - *INTEGRATED PROJECT*.** The research should focus on systematic multidisciplinary approaches to reveal and characterise functional interactions in *Arabidopsis thaliana* (such as protein/protein interactions, functional modules and regulatory networks). Tools, data and resources developed during the project should be made readily accessible to the scientific community.

  - **LSH-2005-1.1.3-2: High throughput phenotyping tools and approaches for large scale functional genomics studies – *INTEGRATED PROJECT***. The focus should be on standardising, developing new or improving existing phenotyping tools, approaches and technologies for high throughput phenotyping in a given model organism. The research and data storage should link with existing bioinformatics resources, including annotated databases.

  - **LSH-2005-1.1.3-3: Population cohorts for molecular epidemiological studies in European and other populations – *INTEGRATED PROJECT*.** The focus should be on molecular epidemiological studies using well characterised and comprehensive population cohorts, with an emphasis on standardising genotyping protocols, sample collection and data storage and analysis. The project should focus on generating new knowledge relevant to health and disease.

- **Bioinformatics**

  No topic for NoE or IP for the fourth call

- **Multidisciplinary functional genomics approaches to basic biological processes**

  The objectives are to enable researchers to study fundamental biological processes by integrating the above innovative approaches.

  Research will focus on the study of fundamental biological processes relevant to human health (including studies on micro-organisms, plants and animals where appropriate). This research will be of a multidisciplinary nature, involving the different disciplines of functional genomics: gene expression and proteomics, structural genomics, comparative genomics and population genetics and bioinformatics.

  Topics for fourth call, deadline 9 November 2005:

- **LSH-2005-1.1.5-1: Functional genomics of autosomal aneuploid syndromes - *INTEGRATED PROJECT.*** The focus should be on applying functional genomics approaches for studying gene dosage effects that are at the origin of autosomal aneuploid syndromes.

- **LSH-2005-1.1.5-2: The biological role of small regulatory RNAs - *INTEGRATED PROJECT*.** The focus should be on integrating functional genomics approaches in different model organisms to identify the functional importance of small regulatory RNAs in cell, tissue differentiation and development in normal and/or pathological situations. The research should address the understanding of regulatory networks.

Topics for Co-ordination Actions and Specific Support Actions, deadline 9 November 2005:

- **LSH-2005-1.1.0-1:** Proposals for Co-ordination Actions (CA) in functional genomics research (proteomics, gene expression, structural genomics, comparative genomics, population genetics, bioinformatics, multidisciplinary functional genomics approaches to basic biological processes) will also be considered.

- **LSH-2005-1.1.0-2:** Specific Support Actions (SSAs) can take the form of workshops, conferences, training activities, or publications. The activities supported should be in the context of wider research policy objectives but have a clear link to functional genomics. The activities should aim at structuring research activities in functional genomics (proteomics, gene expression, structural genomics, comparative genomics, population genetics, bioinformatics, multidisciplinary functional genomics approaches to basic biological processes) in important areas not yet addressed in the programme or preparatory actions in newly emerging areas. Proposals to strengthen the international dimension in functional genomics research will also be welcomed.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-1.1.0-3:** Proposals concerned with the development of tools and technologies for functional genomics (proteomics, gene expression, structural genomics, comparative genomics, population genetics, bioinformatics etc) will be eligible. Furthermore, research focusing on multidisciplinary functional genomics approaches to study basic biological processes will be considered. ***– STREPs dedicated to SMEs.***[16]

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b) APPLICATION OF KNOWLEDGE AND TECHNOLOGIES IN THE FIELD OF GENOMICS AND BIOTECHNOLOGY FOR HEALTH

The strategic objective of this line is to foster the competitiveness of Europe's biotechnology industry by exploiting the wealth of biological data produced by genomics and advances in biotechnology. Research actions will encompass the following:

[16] See "Innovation aspects and SME participation" in Section 1.2

- ***Technological platforms[17] for the developments in the fields of new diagnostic, prevention and therapeutic tools***: In the context of preventing and treating diseases, the objectives are to foster academic and industrial collaboration through technological platforms where multidisciplinary approaches using cutting edge technologies arising from genomic research may contribute to better health care and cost reduction through more precise diagnosis, individualised treatment and more efficient development pathways for new drugs and therapies (such as the selection of new drug candidates), and other novel products of the new technologies.

  Support will be aimed in particular towards innovative research in genomic start-ups and research-based SMEs to strengthen Europe's biotechnology industry. The **incorporation of SMEs** and, where appropriate, large industries must be an integral part of projects and reflected in the consortia. All project consortia should aim at having at least 15 % of the budget allocated to SMEs, either for named SMEs and/or, for Integrated Projects and Networks of Excellence a budget reserved for inclusion of SMEs at a later stage. The innovation aspects within the projects and the technological platforms need to be visible through clear dissemination and exploitation plans. As a general guide, in "Application of knowledge and technologies in the field of genomics and biotechnology for health" proposals for Integrated Projects and Networks of Excellence should not normally expect a Community contribution after contract negotiation of more than 12 million Euros per project.

  With a view to ensuring socially responsible choices, public acceptance and an efficient development pathway for these new technologies, an active and early involvement in the above activities of regulators, experts on ethics, patients and society at large will be necessary.

- **Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches**

  The emphasis shall be on the use and translation of the knowledge and methods derived from genomics into concrete applications for drug design and development, involving for instance combinatorial biosynthesis, therapeutic targeting or rational drug design. The innovative design and development of new, safer and more effective drugs, based on genomics information is the focus of this area.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-1.2.1-1: Marker profiling as a new tool for predictive toxicology - *INTEGRATED PROJECT*.** The project should address the drug development process at the stage of toxicity testing using selected marker profiling. It should aim to facilitate safety evaluation of new drugs developed through biotechnological techniques using surrogate biomarkers.

  - **LSH-2005-1.2.1-2: New tools to investigate ADME properties of drugs involving a carrier system – *STREP*.** This project should address the establishment of new tools for ADME (Absorption, Distribution, Metabolism and Excretion) investigations of therapeutics using selective carriers for targeting particular organs, tissues or cells. It should place special emphasis on the development of relevant read-out systems and

[17] "Technological Platforms" as defined in this Work Programme are focussed on exploitation and technology transfer activities and are different to the proposed and developing concept of "European Technology Platforms".

include the improvement of tools for early stage prediction of phase I and phase II metabolism.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-1.2.1-3: Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches – *STREPs dedicated to SMEs.***[18] The emphasis shall be on the use and translation of the knowledge and methods derived from genomics into concrete applications for drug design and development, involving for instance combinatorial biosynthesis, therapeutic targeting or rational drug design. The ultimate aim is the innovative design and development of new, safer and more effective drugs, based on genomics information .

- **Development of new diagnostics**

This area covers new diagnostic tests and development of new tools and non-invasive methods for early diagnosis, monitoring of disease progression and interpretation of in-vivo data so as to increase the possibilities and effectiveness of the existing therapies.

Topics for fourth call, deadline 9 November 2005:

- **LSH-2005-1.2.2-1: High throughput molecular diagnostics for hereditary diseases - *INTEGRATED PROJECT*.** The project should lead to the development of advanced tools by incorporation of genomics, proteomics and metabolomics in combination with advanced read-out technology. Deliverables must be the development of high throughput, sensitive, reliable and especially cost effective diagnostic and pre-symptomatic methods, which display clear advantages over currently available genetic tests. The project must address quality assurance issues and should offer opportunities for industrial exploitation and involve SMEs. Consideration may be given to ethical issues related to the diagnosis of hereditary diseases.

- **LSH-2005-1.2.2-2: Development of innovative methods for diagnosis of nervous system disorders – *STREP*.** The project should conform to the genomic and molecular approaches of this thematic priority. The project should have a clear and direct focus on medical applications in diagnosis and therapeutic follow-up. It should involve SMEs.

- **LSH-2005-1.2.2-3: Nanoparticles-based diagnostics – *STREP*.** The project in this topic should have a multidisciplinary approach, the subject should aim at developing high-sensitivity detection and labelling methods, promoting innovative approaches *in vitro* or *in vivo*, making use of nanoparticles and multiparametric devices. In case of *in vivo* components, the project should pay attention to biocompatibility, toxicity and effectiveness aspects. Potential transfers to industrial application should be explored. The involvement of SMEs is expected.

[18] See "Innovation aspects and SME participation" in Section 1.2

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-1.2.2-4: Development of new diagnostics – *STREPs dedicated to SMEs*[19].** This topic covers new diagnostic tests and development of new tools and non-invasive methods for prevention, early diagnosis, monitoring of disease progression and interpretation of in-vivo data so as to increase the possibilities and effectiveness of the existing therapies.

- **Development of new in vitro tests to replace animal experimentation**

This area will focus on the development of *alternatives* that will replace the need for animal experiments, reduce the number of animals required, or reduce significantly experimental animal suffering, according to the principle of "The Three Rs": replace, reduce and refine.

The topics must contribute and comply with policies regarding the protection of animals used for experimental and other scientific purposes. Priority will be given to the development of those alternative methods that will reach maturity for formal validation according to international standards for subsequent regulatory acceptance and finally for world-wide application in industry, regulatory establishments and elsewhere.

In vitro methods will play a major role under the new system of the Community on the Registration, Evaluation and Authorisation of Chemicals (REACH). *In vitro* methods should accelerate testing and render it more efficient. The challenge is therefore to develop robust and effective *in vitro* methods that will withstand the requirements of international validation.

Topics for fourth call, deadline 9 November 2005:

- **LSH-2005-1.2.3-1: Predictive *in vitro* testing strategies for human exposure to chemicals - *INTEGRATED PROJECT*.** This project should deliver a battery of non-animal test methods and models capable of predicting effects of human exposure to chemicals. It could focus on particular organs, such as skin, eye or lung. Since it should envisage hazard and risk evaluation studies, individual susceptibility factors, multiple agents of exposure and genomics will play a major role. The project must take into account existing legislation and recent regulatory initiatives.

- **LSH-2005-1.2.3-2: Workshop on business opportunities for *in vitro* pharmaceutical toxicology – *SSA*.** The aim is to enhance the link between researchers in the *in vitro* field and technology users, particularly in the pharmaceutical industry.

- **LSH-2005-1.2.3-3: Forum for researchers and regulators to meet manufacturers of toxicology test methods – *SSA*.** The aim is to provide a forum for stakeholders, especially coming from R&D, as well as from regulatory agencies, to identify the most urgent testing needs and the ways to respond to them. It should include participation of EU-funded projects.

[19] See "Innovation aspects and SME participation" in Section 1.2

Topics for SME-specific call, deadline 9 November 2005;

- **LSH-2005-1.2.3-4: Development of new in vitro tests to replace animal experimentation – *STREPs dedicated to SMEs*[20].** The focus of this topic is the development of *alternatives* that will replace animal experiments, reduce the number of animals required, or reduce significantly experimental animal suffering. The topics considered must contribute directly and comply with policies regarding the protection of animals used for experimental and other scientific purposes, as well as to the new system of the Community on the Registration, Evaluation and Authorisation of Chemicals (REACH). Priority will be given to the development of novel *in vitro* methods that will accelerate testing, rendering it more efficient and robust to the requirements of formal validation for subsequent international regulatory acceptance and finally for world-wide application in industry, regulatory establishments and elsewhere

- **Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies.**

  Cell and tissue engineering, including stem cell therapy, have the potential to meet the challenges posed by many diseases, increased human longevity and the concomitant public health challenges facing European society. The integration of different research activities in areas as diverse as genetics, fundamental and clinical research and ethics, will provide standardised research materials such as stem cell banks, clinical research protocols and novel preventive and therapeutic instruments at a European level. Collectively these will offer new solutions for diseases such as diabetes mellitus, Alzheimer's disease and haemopoietic disorders, which impose considerable significant impairments to citizens' quality of life, as well as burdens on health care services in Europe.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-1.2.4-1: Tissue engineering approaches to treating children with birth defects - *INTEGRATED PROJECT*.** This project should aim to use modern tissue engineering approaches to treat children with disorders present at birth, such as spina bifida or congenital heart disease. The project should strive to elucidate underlying mechanisms and take a translational route through *in vitro* and animal experiments to early clinical trials. Ethical, social and regulatory issues must be fully covered by the project. Industrial partners should be involved in the consortium.

  - **LSH-2005-1.2.4-2: Hepatitis C vaccine - *INTEGRATED PROJECT*.** This project should aim to meet the growing global threat posed by Hepatitis C through the development of an innovative vaccine, while addressing scientific, technical, regulatory and ethical constraints. It should develop a rational approach for screening promising innovative molecules, for the selection of expression systems and presentation systems, and include the development of reliable assays for pre-clinical studies. The project should focus European expertise from academia and industry on the key issues, include developing country participants as appropriate and reach early clinical trial stage.

  - **LSH-2005-1.2.4-3: Stem cell therapy for stroke patients – *STREP*.** This project would investigate the use of stem cells from different sources to repair damaged brain

[20] See "Innovation aspects and SME participation" in Section 1.2

tissue as a potential therapy for stroke. The research should take an *in vivo* animal model approach and examine such issues as compatibility and survival of transplanted cells. The research should lead to pre-clinical therapeutic protocols with the perspective of rapidly translating these to human trials.

- **LSH-2005-1.2.4-4: Methodological research to underpin stem cell banking - *STREP.*** The objective of this project would be to develop tools and techniques, such as methods for identification, characterisation, expansion or maintenance in culture, to underpin initiatives on the banking of stem cell lines aiming to provide uniform, stable and safe material for human therapeutic use.

- **LSH-2005-1.2.4-5: Understanding monogenic rare diseases using insight from stem cell lines – STREP.** The objective of this research is to use already-available human stem cell lines derived from disease-carrying embryos as the basis of a model system to understand better the underlying biology of monogenic rare diseases and in view of possible future therapeutic applications.

- **LSH-2005-1.2.4-6: Use of baculovirus as a vector in gene therapy (especially orientated towards small and medium sized companies) – *STREP.*** Baculovirus vectors are able to deliver very large DNA sequences into mammalian cells, allow for sustained gene expression and possess safety features. This project should exploit these qualities in the development of applications of this vector in human gene therapy. Due consideration should be given to regulatory aspects.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-1.2.4-7: Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies – *STREPs dedicated to SMEs.***[21] The integration of different research activities in areas as diverse as genetics, fundamental and clinical research and ethics, will provide standardised research materials such as stem cell banks, clinical research protocols and novel preventive and therapeutic instruments at a European level. Collectively these will offer new solutions for diseases such as diabetes mellitus, Alzheimer's disease and haemopoietic disorders.

- **Innovative research in post-genomics, which has high potential for application**

The objective is to use cutting edge technologies in a multidisciplinary approach to address areas of research that will benefit from the developments resulting from genomics. The **incorporation of industry and in particular SME**s, wherever appropriate, must be an integral part of projects and should be reflected in the consortia.

Topics for fourth call, deadline 9 November 2005:

[21] See "Innovation aspects and SME participation" in Section 1.2

- **LSH-2005-1.2.5-1: Application of post-genomics to xenotransplantation research – *INTEGRATED PROJECT.*** This project should take a multidisciplinary approach, using genomic and proteomic knowledge and techniques, to address the key issues of xenotransplantation: immunology, physiology and safety. It should take advances in knowledge up to the pre-clinical stage. The project should aim to consolidate proof of concept, to underpin the possible use of xenotransplantation in humans. Ethical, social (especially regarding communication with the public) and regulatory issues must be fully covered by the project. Industrial partners, especially SMEs, should be involved in the consortium.

- **LSH-2005-1.2.5-2: Post-genomic approaches exploiting aquatic molecular biodiversity for biomedical applications - *INTEGRATED PROJECT.*** This multidisciplinary project should focus on the development, using advanced post-genomic techniques, of potential products with therapeutically relevant activity to be used in preclinical and clinical research. These potential products should be the result of a target-oriented and proven concept for the sustainable exploitation of aquatic (marine and fresh water) molecular biodiversity, and should be based on established proofs of concepts. The involvement of SME(s) experienced in transfer of knowledge from academia to industry, scaling-up bioproduction, and designing and conducting clinical trials, will be essential.

- **LSH-2005-1.2.5-3: Use of cell lines to define new bioassays for the identification of therapeutic bio-molecules (especially orientated towards small and medium sized companies) - *STREP.*** This project aims to use cell lines together with advanced postgenomic techniques for the development of potential bio-therapeutics. Advanced postgenomic techniques may also be aimed to the definition of a signature of response of cells to different challenges (e.g: drugs, pathogens).

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-1.2.5-4: Innovative research in post-genomics, which has high potential for application – *STREPs dedicated to SMEs.***[22] The objective is to use cutting edge technologies in a multidisciplinary approach to address areas of research that will benefit from the developments resulting from genomics.

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ii) COMBATING MAJOR DISEASES

a) APPLICATIONS-ORIENTATED GENOMIC APPROACHES TO MEDICAL KNOWLEDGE AND TECHNOLOGIES

The strategic objective of this line is to develop improved strategies for the prevention and management – using also advanced technologies for health - of human disease and for living and ageing healthily. It will concentrate exclusively on integrating a genomic approach through all relevant organisms into more established medical approaches for investigating disease and

[22] See "Innovation aspects and SME participation" in Section 1.2

health determinants**.** The emphasis will be on translational research aimed at bringing basic knowledge through to clinical application. **The involvement of SMEs is highly encouraged in all topics in this area.** As a general guide, in "Applications-orientated genomic approaches to medical knowledge and technologies" proposals for Integrated Projects and Networks of Excellence should not normally expect a Community contribution after contract negotiation of more than 10 million Euros per project.

Research actions will focus on the following:

- **General (overarching)**

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-2.1.0-1: Genetic control of the pathogenesis of diseases based on iron metabolism – *STREP.*** The project should address several types of diseases linked to iron metabolism and aim at better understanding the genetic control of their pathogenesis. Research can include various aspects such as iron accumulation and should not be restricted to haematology. Clinical and therapeutic components can also be addressed.

- **Combating, cardiovascular disease, diabetes and rare diseases**

  The objectives are to improve the prevention and management of important causes of mortality and ill health in Europe and to pool Europe's research resources for tackling rare diseases.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-2.1.1-1: Genome-wide mapping and functional genomics of susceptibility to coronary artery disease – *INTEGRATED PROJECT.*** Genome-wide mapping approaches will lead to the identification of novel genes that confer susceptibility to coronary artery disease. These results will be used by functional genomic research to develop new treatments for this disease that is of major importance for European citizens.

  - **LSH-2005-2.1.1-2: Hypertension and cardiovascular disease – *NETWORK OF EXCELLENCE.*** The project should lead to the integration of research teams working on genetics, functional genomics and molecular mechanisms of hypertension and hypertension-related cardiac and vascular damage.

  - **LSH-2005-2.1.1-3: Molecular, genomic and applied genomic studies for the prevention of accelerated cardiovascular death in uraemia and end-stage renal disease - *STREP.*** The project should lead to the development of novel diagnostic and therapeutic approaches. It should bring together expertise in analytical techniques, functional genomics, clinical management of end-stage renal failure patients and industrial laboratories.

  - **LSH-2005-2.1.1-4: Functional genomics and regulatory networks in lipid metabolism and their effects on the development of atherogenic vascular disease - *STREP.*** The project should apply functional genomics approaches (such as lipidomics and metabolomics) and new clinical diagnostic tools to study the effects of differential regulation of lipid metabolism on pathophysiological events relevant for atherosclerosis.

- **LSH-2005-2.1.1-5: Gene-environment interaction on the incidence of type 2 diabetes - *INTEGRATED PROJECT.*** The project will aim at identifying genes/biomarkers or sets of genes which might have biologically plausible interaction with key lifestyle behaviours including diet and physical activity and possibly effect of drugs/environmental interaction. The causal nature of the interaction will be assessed by examining differential response to behaviour change in lifestyle intervention trials. Ascertained incident cases of diabetes will be at follow-up. The consortium will assess the benefits of genotype in a targeted prevention strategy. The project can be based on large existing studies.

- **LSH-2005-2.1.1-6: Molecular pathways underlying decreased beta cell mass in diabetes mellitus – *STREP.*** Increasing evidence suggests that a reduced beta cell mass is a common feature of both type 1 and type 2 diabetes mellitus. The project will identify the key pathways in the regulation of beta cell mass. A multidisciplinary approach, including functional genomics on both in vivo and in vitro models, should be employed for the identification of possible targets for intervention to preserve beta cell mass in diabetes mellitus.

- **LSH-2005-2.1.1-7: Rare inherited neuromuscular disorders: from molecular basis to cutting edge therapies - *NETWORK OF EXCELLENCE.*** This network of excellence will aim at sharing expertise leading to integration between basic and clinical academics and industrial partners in order to develop technological and methodological tools with a view to accelerate the elaboration of new therapies for rare neuromuscular diseases. Important tools include animal models, databases, biobanks, well-defined patients cohorts, methods for efficacy assessment. The participation of SMEs is highly encouraged.

- **LSH-2005-2.1.1-8: Rare disorders of protein folding** – ***STREP.*** Rare diseases of protein folding (e.g. systemic amyloidosis, serpinopathies) should be studied to reveal molecular mechanisms of disease and foster novel therapeutic approaches. Combined basic and clinical research should aim at accelerating the development of new diagnostic tools and treatments for these diseases. Neurodegenerative disorders (e.g. Alzheimer's disease, Huntington's disease, transmissible spongiform encephalopathies), cancers and cystic fibrosis will not be considered for funding.

- **LSH-2005-2.1.1-9: Rare diseases of connective tissues affecting bone and/or cartilage – *STREP.*** The project should focus on the molecular mechanisms to unravel the physiopathology of rare diseases of connective tissues with primary clinical manifestation in bone and/or cartilage (eg. osteogenesis imperfecta, chondrodysplasias). The acquired knowledge should pave the way for the development of new therapeutic strategies.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.1.1-10: Research on cardiovascular disease with strong SME involvement – *STREPs dedicated to SMEs.*[23]** The project should be clearly driven by the involved SME(s). It can address for example research on disease markers or on novel treatment modalities such as stem cell therapies and gene therapy approaches. Research on devices and on cerebrovascular disease is excluded.

[23] See "Innovation aspects and SME participation" in Section 1.2

- **LSH-2005-2.1.1-11: Development of preventive and therapeutic strategies for Type 1 diabetes with strong SME involvement – *STREPs dedicated to SMEs.*[24]** Research on devices for insulin delivery is excluded.

- **LSH-2005-2.1.1-12: Development of *in vitro* and/or animal models for rare diseases – *STREPs dedicated to SMEs.*[25]** Models for rare cancers will not be considered for funding.

- **Combating resistance to antibiotics and other drugs**

The objectives are to confront the major threat to public health caused by drug resistant pathogens. Research exclusively devoted to development or use of antimicrobials in the context of animal health without attention to human health will not be considered in this sub area

Topics for fourth call, deadline 9 November 2005:

- **LSH-2005-2.1.2-1: Control of antimicrobial resistance in hospital acquired and other health care associated infections – *INTEGRATED PROJECT.*** The focus should be to set up a comprehensive multidisciplinary approach to combat the emergence and spread of antimicrobial resistance in hospital acquired and other healthcare associated infections, and identify measures necessary to prevent dissemination into the community. The research should include intervention studies in the clinical setting, including controlled trials, studies on the dynamics and transmission of resistance, development and testing of new rapid and cost-effective diagnostic tests for important nosocomial pathogens with emphasis on multi-drug resistant bacterial strains. Behavioural and educational strategies may also be included. Countries with high incidence of resistance in nosocomial infections should be involved. Involvement of SMEs, especially for the development of rapid diagnostic tests, is strongly encouraged.

- **LSH-2005-2.1.2-2: Molecular ecology of antibiotic drug resistance – *STREP.*** The focus should be a multidisciplinary approach towards an improved understanding of antibiotic drug resistance ecology with emphasis on molecular population and evolutionary biology aspects. Research should address the links between opportunism and commensalism in relationship with the host, the protective role of commensals, effects of antibiotics on the human microflora and immunology, transfer of resistance between the animal and human population and the environment, impact of vaccination on the microflora, the role of reservoirs and ecological niches and the biological cost of resistance. Proposals may address all or some of the above aspects, but should lead to novel approaches to control resistance.

- **LSH-2005-2.1.2-3: Workshop exploring novel opportunities towards the development of vaccines that will have a significant impact on the control of anti-bacterial resistance - *SSA.*** The objective should be a future looking workshop to explore various promising approaches towards the development of bacterial vaccines**.**

[24] See "Innovation aspects and SME participation" in Section 1.2
[25] See "Innovation aspects and SME participation" in Section 1.2

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.1.2-4: Development of new diagnostic tests for the management and control of antimicrobial resistance – *STREPs dedicated to SMEs*[26].** Development of innovative cost-effective, rapid read-out diagnostic tests specifically designed to detect and identify resistant bacteria and fungi in clinical samples with a view to contribute to a more rational prescribing of anti-infective drugs in the hospital and/or the open clinic. Particularly encouraged is the development of tests targeting immuno-compromised patients.

- **LSH-2005-2.1.2-5: Development of novel principles for anti-microbial treatment – *STREPs dedicated to SMEs.***[27] Innovative approaches to exploit knowledge of host/pathogen interactions towards the development of new anti-bacterial and/or anti-fungal treatment and/or prophylaxis against micro-organisms resistant to antimicrobials. The development of immunotherapeutics, including human monoclonal antibody therapy, can also be addressed in this topic.

- **Studying the brain and combating diseases of the nervous system**

  The objectives are to use genome information to understand better the functioning and dysfunctioning of the brain, in order to gain new insight into mental processes, to combat neurological disorders and diseases, and to improve brain repair.

  Topics for fourth call, deadline 9 November 2005:

  - **LSH-2005-2.1.3-1: Neuroimaging: "Bridging genetics and neural function" – *INTEGRATED PROJECT.*** The project should aim at bridging available genomics information with neural function from the molecular level to more complex brain functions, using neuroimaging approaches. The project should involve human studies, and experimental animal models may be included where relevant. Both, normal brain function and brain pathologies should be addressed. The establishment and application of new neuroimaging technologies should offer possibilities for SMEs.

  - **LSH-2005-2.1.3-2: Functional genomics and neurobiology of epilepsy – *INTEGRATED PROJECT.*** This project will aim at understanding the genetic and molecular basis of neuronal excitability and brain function in epilepsy. The investigation of new therapeutic strategies (e.g. pharmacogenetic approaches) should also be addressed. The project should be relevant for epilepsy in children and adults.

  - **LSH-2005-2.1.3-3: Cortical information processing – *STREP.*** This project should focus on cortical information processing involving sensory and motor cortical areas and thus lead to a better understanding of cognition and sensory/motor behaviour and the underlying neuronal networks. It should involve animal models and may include techniques from molecular to systems level (e.g. gene expression, neurophysiological and computational approaches).

  - **LSH-2005-2.1.3-4: Schizophrenia: from genotype to phenotype – *STREP.*** This project should lead to a better understanding of the molecular etiology and clinical

[26] See "Innovation aspects and SME participation" in Section 1.2
[27] See "Innovation aspects and SME participation" in Section 1.2

phenotype of schizophrenia by identifying genetic and environmental determinants and their potential interaction in the development, severity and outcome of the disease.

- **LSH-2005-2.1.3-5: Initiative in neuroinformatics – *SSA*.** The purpose is to grant support for an initiative in co-ordinating neuroinformatics activities. Support can be granted for administrative/scientific management and running costs, organisation of workshops, meetings, co-ordination and dissemination activities, and for preparing future community RTD activities. This action can be undertaken in the frame of the European Research Area, but also promoting dialogue and co-ordination with non-EU members like US and Japan.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.1.3-6: Neuroscience-oriented new technologies – *STREPs dedicated to SMEs*[28].** Projects should focus on the development and use of innovative technologies for neuroscience research. Areas to be addressed may include: automata techniques for electrical recording, high throughput techniques for expression profiling or proteomics of extremely small tissue/single cells, or optical imaging techniques. The project should bring together developers of brain-oriented new technologies with users of such technologies in brain research.

- **LSH-2005-2.1.3-7: Characterisation and use of animal models for neurological and psychiatric diseases – *STREPs dedicated to SMEs*[29].** This topic may especially address phenotypical characterisation of existing or new animal models using behavioural, physiological test systems, or adapting imaging technologies to small experimental animals. This should lead to a better use of animal models for studying brain diseases and testing new therapies.

- **LSH-2005-2.1.3-8: Early markers and new targets for neurodegenerative diseases – *STREPs dedicated to SMEs*[30].** This project should focus on the development of new markers for the early and accurate diagnosis of neurodegenerative diseases and aim at the identification, development and proof of principle of new targets for innovative treatment approaches.

- **LSH-2005-2.1.3-9: Perinatal brain damage: early markers and neuroprotection – *STREPs dedicated to SMEs*[31].** This project should focus on perinatal hypoxic/ischemic damage to brain white and grey matter. New approaches for early diagnosis (markers) and therapy (neuroprotection) should be addressed.

- **Studying human development and the ageing process**

  The objective is to better understand human development, with special emphasis on the ageing process, in order to develop the evidence base for improving public health strategies to promote healthy living and healthy ageing.

  Topics for fourth call, deadline 9 November 2005:

[28] See "Innovation aspects and SME participation" in Section 1.2
[29] See "Innovation aspects and SME participation" in Section 1.2
[30] See "Innovation aspects and SME participation" in Section 1.2
[31] See "Innovation aspects and SME participation" in Section 1.2

- **LSH-2005-2.1.4-1: Integration of research in development and ageing - *NETWORK OF EXCELLENCE*.** The aim of the project is to determine the influence of genetic, environmental, and stochastic effects during development on the ageing process. The project should integrate the corresponding research in invertebrate and vertebrate model systems and their application in humans.

- **LSH-2005-2.1.4-2: Attracting researchers to ageing research - *SSA*.** In addition to being a discipline in itself, the study of many, if not most, biological processes can be examined under the perspective of basic biological research into the ageing process. The aim of this SSA is to organize a conference or a workshop with the goal to improve the awareness for ageing research in related fields of research.

Topic for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.1.4-3: Understanding the responsiveness of elderly people towards vaccination and infectious diseases – *STREPs dedicated to SMEs*[32].** Application of multidisciplinary approaches to determine the mechanisms responsible for lacking immune responses in the elderly. In a combination of epidemiological and post genomic studies responders to infections and to vaccinations against infective agents such as influenza and/or S. pneumonia will be compared to non-responders. Strategies to compensate immunosenescence should be envisaged with a public health perspective.

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b) COMBATING CANCER

The objective is to combat cancer by developing improved patient-oriented strategies, from prevention to more effective and earlier diagnosis and better treatment with minimal side effects. The research will therefore concentrate on translating the knowledge being created by genomics and other fields of basic research into applications that improve clinical practice and public health. **The involvement of SMEs is highly encouraged in all topics in this area**. As a general guide, in "Combating cancer" proposals for Integrated Projects and Networks of Excellence should not normally expect a Community contribution after contract negotiation of more than 10 million Euros per project.

The patient-oriented approach will include four interlinked components. Research will focus on:

– ***Establishing facilities and developing initiatives for the exploitation of research on cancer in Europe****; encouraging the development of evidence-based guidelines for good clinical practice and improved public health strategies by accelerating the translation of existing research results into applications.*

– ***Supporting clinical research****, particularly clinical trials, aimed at validating new and improved interventions***.**

[32] See "Innovation aspects and SME participation" in Section 1.2

– ***Supporting translational research*** *aimed at bringing basic knowledge through to applications in clinical practice and public health.*

– ***Other issues related to cancer****, such as ageing and cancer, regional differences, psycho-social aspects, palliative care and guidance to support groups.*

Topics for third call in this area, deadline 9 November 2005:

- **LSH-2005-2.2.0-1: Broadening the knowledge base on the molecular mechanisms underlying chemotherapy resistance, therapeutic escape, efficacy and toxicity** – ***INTEGRATED PROJECT.*** Research efforts should focus on molecular mechanisms underlying resistance to, and inefficacy and toxicity of clinically used chemotherapy regimens. Collaborative research that exclusively addresses toxicity to chemotherapy will be excluded from this topic.

- **LSH-2005-2.2.0-2: Modulation of apoptosis in cancer prevention and therapy** – ***STREP.*** The project will aim at unravelling and targeting critical apoptotic signalling pathways relevant to the formation of solid tumours. Multidisciplinary consortia should focus on the development and (pre)clinical validation of novel anti-cancer drugs with a wide therapeutic index that address apoptotic evasion and stimulate programmed cell death in solid tumours. Studies that tackle P53, conventional cytotoxic chemotherapeutic agents or cell-based immunotherapy will be excluded from this topic.

- **LSH-2005-2.2.0-3: Innovative diagnostic approaches and novel therapies of childhood cancers – *STREP.*** Translational research efforts should focus on furthering the understanding of molecular mechanisms of childhood cancers and include the development of relevant diagnostic tools, preclinical models, and the validation of novel targets that specifically take into account the unique physiological parameters of children. Childhood tumours, such as leukaemia, brain tumours, neuroblastoma, Wilms' tumor, lymphoma, Rhabdomyosarcoma, retinoblastoma, osteosarcoma and Ewing's sarcoma will be considered. Proposals should not be restricted to one malignancy only but include several of the above.

- **LSH-2005-2.2.0-4: Innovative research on palliative care in patients with advanced stages of cancer – *STREP.*** Research efforts should focus on palliative care in advanced cancer patients suffering from the consequences of the disease. Collaborative efforts should address the cancer-related symptoms pain, depression or fatigue.

- **LSH-2005-2.2.0-5: Exploring the patient's cancer stem cell as a novel therapeutic target – *STREP.*** Collaborative research should focus on multidisciplinary, translational research on several of the pertinent issues of cancer stem cells such as identification, isolation and characterization of cancer stem cells, elucidating signalling pathways that drive their growth and the application of this knowledge to novel treatment strategies. Research on stem cells in other diseases will not be considered in this topic.

- **LSH-2005-2.2.0-6: Conference on cell differentiation, plasticity and cancer – SSA.**

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.2.0-7: Innovative technological approaches for cancer therapy –**

***STREPs dedicated to SMEs*[33].** Multidisciplinary consortia should develop innovative technological approaches for cancer therapies focusing on the following commercially mature areas: Light Ion Hadron Therapy (LIHT), Electrochemotherapy, Photodynamic Therapy, Hyperthermia Therapy or Tumor-specific vaccination should be further improved, refined and translated into clinical applications. Research focusing on imaging devices will be excluded from this topic.

- **LSH-2005-2.2.0-8: Small-ligand libraries: improved tools for exploration and prospective anti-tumor therapy – *STREPs dedicated to SMEs*[34].** Collaborative efforts combining bioinformatics, pharmacology and chemistry should aim at improving library design. Areas that could be covered are *in-silico* prediction of drug-like properties, prediction of ADME parameters, predictive toxicology and creation of virtual libraries.

- **LSH-2005-2.2.0-9: Improving resolution of current imaging devices relevant to cancer diagnosis and therapy – *STREPs dedicated to SMEs*[35].** Combined efforts should be directed towards the generation and validation of innovative means to improve resolution of current state-of-the-art imaging modalities, such as SPECT, PET, CT, MRI, MRS and optical imaging used in cancer research and diagnosis of cancer patients.

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c) CONFRONTING THE MAJOR COMMUNICABLE DISEASES LINKED TO POVERTY

The strategic objective of this line is to confront the global emergency caused by the three major communicable diseases – HIV/AIDS, malaria and tuberculosis – through the development of effective disease interventions, particularly for use in developing countries. It is envisaged that developing countries will be significant partners in the implementation of this line and, as appropriate, participate directly in specific activities within it, in particular through the clinical trials programme.

Research will focus on: developing promising candidate interventions (vaccines, therapies, and microbicides) against the target diseases by sponsoring research over the full spectrum from basic molecular research, taking advantage of microbial genomics, through to pre-clinical testing and proof-of-principle; establishing a clinical trials programme to unite and support Europe's clinical trials activities specifically targeted at interventions for use in developing countries; establishing an AIDS Therapy Trials Network in Europe to improve the coherence and complementarities of clinical trials of AIDS therapies for human use.

- **Developing new promising candidate vaccines and therapies**

  New effective interventions have to be developed through to pre-clinical and early human testing (phase I clinical trials) using the integration of different disciplines and approaches, while pursuing rational and systematic concepts and comparative evaluation procedures. Training activities are an important component of these projects and should be included in

[33] See "Innovation aspects and SME participation" in Section 1.2
[34] See "Innovation aspects and SME participation" in Section 1.2
[35] See "Innovation aspects and SME participation" in Section 1.2

Network of Excellence and Integrated Projects. The involvement of SMEs and relevant research groups from developing countries is highly encouraged in all topics in this area.

Topics for fourth call, deadline 9 November 2005:

- **LSH-2005-2.3.0-1: HIV/AIDS therapeutic clinical trials network - *NETWORK OF EXCELLENCE*.** The project is expected to create a European network for clinical research in HIV/AIDS therapeutic approaches. Proposals should aim at designing, standardising, following up, and coordinating clinical trials and data gathering on HIV/AIDS at European level. The goal of the network should be to define optimal strategies for management of HIV infection, and to guide for the implementation of optimal interventions. Participation of new Member States and countries from Eastern Europe is particularly encouraged.

- **LSH-2005-2.3.0-2: HIV/AIDS vaccines/microbicides network - *NETWORK OF EXCELLENCE*.** The project is expected to establish a European network on HIV/AIDS vaccines and/or microbicides. Research studies should take advantage of the knowledge and complementarity of different approaches on HIV vaccines and microbicides. The network should strengthen the coherence of European actions and cooperate with global initiatives. The project may include activities leading to the design and standardisation of common clinical and laboratory standards, clinical protocols, sample collection and data handling.

- **LSH-2005-2.3.0-3: Rational design of malaria vaccine - *INTEGRATED PROJECT*.** European research efforts shall be focused in a more systematic and rational approach to malaria vaccine development. Comparative and continuous evaluation of vaccine candidates must be combined with effective decision-making processes to select and promote the development of the best candidate(s). Proposals should cover the development pipeline from antigen discovery to early proof-of-principle, but should also address process development aspects and validation of new surrogate markers for protective immunity. Groups from developing countries should be essential partners.

- **LSH-2005-2.3.0-4: New approaches for research into host/vector-pathogen interaction for HIV/AIDS, malaria and tuberculosis – *STREP*.** Small-scale, high-risk, innovative projects are expected which could produce new knowledge and insight that bear a potential for new therapeutic or prophylactic interventions, including microbicides. Projects should clearly go beyond the current state- of- art in areas where traditional approaches have been unsuccessful or to explore new ideas to overcome known problems. Examples of topics could be innate and adaptive immunity, mechanisms of latency, persistence and reactivation or entry points of pathogen into vector/host systems. Consortia should be small, have a financial range of about €1 million, and a maximum period of 2 years and preferably include researchers from disease-endemic countries. Proposals from young researchers are particularly encouraged.

- **LSH-2005-2.3.0-5: Undesirable consequences of drugs and vaccines for poverty-related diseases – *STREP*.** Support will be given to basic studies of the mechanisms causing undesirable effects of drugs and vaccines for PRD. Projects may address the specific pathways leading to undesirable immunological reactions, development of resistance or focus on the loss of efficacy of vaccines and drugs in patients with multiple concurrent infections, e.g. TB and HIV. Studies on adverse effects elicited by partially effective vaccines and drugs are also encouraged.

- **LSH-2005-2.3.0-6: Integration and coordination of European clinical research on poverty-related diseases – *SSA/CA*.** Projects are expected to facilitate coordination and integration of European clinical research activities and cooperate with global initiatives where relevant. Supported projects may also include activities for developing common

clinical and laboratory standards, with emphasis on standardising assays, protocols, sample collection and data storage and analysis.

- **LSH-2005-2.3.0-7: Promotion of poverty-related diseases research – *SSA/CA.*** This action is expected to stimulate, encourage and facilitate the participation of young scientists in EU-funded projects on PRD. Projects should develop strategies to ensure a broader recruitment of scientists to PRD research, in particular from developing countries and the New Member States.

- **LSH-2005-2.3.0-8: European network for vaccine development covering the three diseases – *SSA/CA.*** Supported projects are expected to establish a network for translational research in vaccines. The network should consist of research institutions, private as well as public, comprising expertise in preclinical evaluation, product development, GMP manufacturing and early clinical testing. Participation of regulatory agencies would be an additional asset. The ambition of the network should be to establish an organisation that can provide advice, guidance and active support in moving vaccine candidates through all phases of development from discovery to early human trials.

- **LSH-2005-2.3.0-9: Improving participation of the private sector in poverty-related diseases research – *SSA/CA.*** This action should develop a theoretical model to quantify and compare the potential impact of public incentives on private sector research in PRD. The model should be validated against available data and be suitable to prioritise potential new incentives to policy makers and other stakeholders.

Topics for SME-specific call, deadline 9 November 2005:

- **LSH-2005-2.3.0-10: SME-driven innovations for poverty-related diseases – *STREPs dedicated to SMEs*[36].** Support will be given to projects using highly innovative concepts to identify new drugs or vaccine candidates for HIV/AIDS, malaria and/or tuberculosis. Projects may include discovery activities, testing of new therapeutic interventions *in vitro and in vivo*, lead optimisation, safety-and toxicology testing, early clinical testing as well as pilot-scale production of new chemical entities and biologicals.

- **LSH-2005-2.3.0-11: Development of fast tests for diagnosis of poverty-related diseases suitable for use in resource-poor settings – *STREPs dedicated to SMEs*[37].** Poor case-finding is one of the most important limiting factors for the expansion of disease control strategies worldwide. New diagnostics are needed that are instant, cheap and suitable for developing countries. Projects are expected to develop new diagnostic techniques for the detection of latent or active HIV/AIDS, malaria or TB, either sensitive or resistant to commonly used drugs. The diagnostics should represent a clear improvement over existing tests in resource-poor settings.

- **LSH-2005-2.3.0-12: Innovative delivery mechanism for treatment and depot therapy in poverty-related diseases – *STREPs dedicated to SMEs*[38].** New mechanisms for drug delivery could be explored with the aim of facilitating or improving treatment of PRD. Furthermore, the development of depot or slow- release drugs will greatly simplify the treatment, which, in turn, will improve diseases control and prevent the development of drug-resistance. Projects are expected aiming at the development of depot preparations for the treatment of PRD or focused on new delivery mechanisms.

[36] See "Innovation aspects and SME participation" in Section 1.2
[37] See "Innovation aspects and SME participation" in Section 1.2
[38] See "Innovation aspects and SME participation" in Section 1.2

- **Establishing a programme for advanced clinical trials**

  The second component of this action line is the implementation of the European and Developing Countries Clinical Trials Partnership (EDCTP)[39]. The EDCTP focuses on new clinical interventions of promising vaccine and drug candidates in Sub-Saharan Africa. While the EDCTP is part of the overall strategy of this action line and is funded under FP6, activities supported by the EDCTP are not part of this call. The EDCTP operates instead as a separate legal entity with its own guidelines, including calls for proposals and appropriate selection and evaluation procedures[40]. Information is available under webpage www.edctp.org.

  No further budgetary commitments envisaged for 2005 and 2006

[39] OJ L 169, 8.7.2003, p.1.
[40] http://www.edctp.org

OTHER ACTIONS ACROSS THEMATIC PRIORITY 1

Specific Support Actions

As described in the "General Introduction"[41] to the Work Programme, and in addition to the SSAs identified in the individual research areas of the theme, the objectives of specific support actions under this priority are to help implement the ERA. Only proposals that contribute to the strategic objectives of the thematic priority 1 as a whole, will be considered for support.

For each horizontal objective, a number of strategic actions are detailed and proposals addressing these actions will be given high priority for support:

- **LSH-2005-3-1: Promoting collaboration between SMEs and academia**: Innovative activities aiming at stimulating and strengthening collaboration between SMEs and researchers in specific areas supported by the Theme will also be considered for support.

- **LSH-2005-3-2: Stimulating international co-operation:** Promotion and facilitation of international co-operation in areas relevant to the objectives of this priority. Particular emphasis will be on activities involving countries having S&T co-operation agreements[42] with the EU. Actions should aim at networking scientists for stimulating the creation of research consortia and the identification of priorities of common interest in areas supported by the Theme.

- **LSH-2005-3-3: Promotion of co-operation with Associated Candidate Countries (ACC)[43]:** Stimulation, encouragement and facilitation of the participation of organisations from the Associated Candidate Countries (at the time of publication Romania, Turkey and Bulgaria).

- **LSH-2005-3-4: Realising ERA objectives:** Activities contributing to the strategic objectives of the European research area in fields covered by this priority, such as pilot initiatives on benchmarking, cartography, the debate on human values and technology options, or the collective management of the knowledge infrastructures of the future, etc. Activities leading to the creation of European technology platforms bringing together technological know how, industry, regulators and financial institutions to develop a strategic agenda for leading technologies could be supported through this call.

- **LSH-2005-3-5: Life sciences and biotechnology – a strategy for Europe.** Specific Support Actions will be funded as necessary to implement any of the thirty Actions relevant to this thematic priority, listed in the Action Plan attached to COM(2002)27 (http://europa.eu.int/comm/biotechnology).

- **LSH-2005-3-6: Supporting policy development:** Activities supporting future research policy developments such as prospective and foresight studies, analysis and evaluation of impact of past and current EU research activities in a particular sector. Prospective studies on impact of research policy on other policies (i.e. industry, health, trade, etc) and vice versa will also be considered for support. A foresight study focusing on the development of biotechnology within the health sector with a 2015 vision is particularly welcomed. This study should be relevant to the European Union, as well as Candidate Countries and Associated Countries and it should in particular focus on identifying areas in which Europe can develop a leading position within a global context.

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[41] See section "Specific Support Actions" of the "General Introduction".

[42] Countries with signed S&T cooperation agreements June 2005: Argentina, Australia, Brazil, Canada, China, Chile, Egypt, India, Mexico, Morocco, Russia, South Africa, Tunisia, Ukraine and United States

[43] See section "Cross cutting issues", para b on Proposers in Associated States of the "General Introduction"

- **LSH-2005-3-7: Scientific and project management:** Activities aiming at training and support to scientists wanting to develop management skills for scientific and innovation management. Actions in particularly addressing young scientists are welcomed.

- **LSH-2005-3-8:** Mapping and identifying recent and current European research efforts and contributions from Framework Programmes in the context of the European Community's Public Health Programme[44], in the fields of health information, health threats and health determinants, with particular regard to mental health, reducing health risks, and preventing major as well as specific diseases. The aim is to provide information and data for eventual input to an EU public health portal under development by Commission services[45].

- **LSH-2005-3-9:** Mapping and identifying recent and current European health research efforts and contributions from Framework Programmes in the context of the European Environment and Health Action Plan [46], in the fields of gene-environment interactions, respiratory diseases, neuro-developmental disorders, cardiovascular diseases and cancers, with particular regard to children's health. The aim is to provide information and data for eventual input to an EU public health portal under development by Commission services [47].

- **LSH-2005-3-10: European human embryonic stem cell registry.** The aim is to gather detailed information on the different human embryonic stem cell (hESC) lines available for research purposes, which have been created in Europe. Because the proposed registry should be an inventory and not a bank, the activities normally associated with a bank, such as ethical and intellectual property issues, training, etc. should not be part of this SSA. This registry should operate through an internet website that should contain high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location. The management group that will supervise and manage the activities of this registry should include top European scientists in the field of human embryonic stem cell derivation. Their commitment to the development of such a registry should be demonstrated. Networking between the different European countries that allow the derivation of hESC lines will be essential in order to access the information. This European registry should complement the already existing National Institutes of Health (NIH) hESC registry in the USA. Links with already existing registries of hESC lines will be considered as crucial if they are located in Europe and will be considered as a clear added value if they are located outside Europe.

- **LSH-2005-3-11: Life Sciences research project public funding database.** An action to link public information databases of European Life Sciences research funding organisations. The outcome of the SSA should be a searchable database of existing publicly funded research projects in the Member States.

- **LSH-2005-3-12: Strengthening vaccine research in Europe.** This project should combine prospective studies with an impact assessment of past and current EU actions for vaccine research in the private and public sector. Activities should support the development of a policy for strengthening public and private vaccine research in Europe, including recommendations for vaccine technology and research structures.

[44] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) *Official Journal L 271 , 09/10/2002 P. 0001 - 0012*

[45] European Commission, Directorate-General for Health & Consumer Affairs, (http://europa.eu.int/comm/health/ph_information/dissemination/dissemination_en.htm)

[46] European Environment and Health Action Plan COM (2004) 416 final

[47] European Commission, Directorate-General for Health & Consumer Affairs, (http://europa.eu.int/comm/health/ph_information/dissemination/dissemination_en.htm)

Proposals for SSA have to plan a starting date for the intended activity at least six months after the deadline for this call for proposals

Public Procurement Procedures

In addition, some horizontal objectives may be taken forward through public procurement procedures (calls for tenders). These will help the Commission prepare new initiatives in a targeted manner that will complement the more "bottom" up approach offered by calls for proposals. Areas that may be covered:

- Impact assessment of FP6 Thematic Priority 1 *(estimated maximum cost – 800.000€, expected publication – November 2005, open procedure)*

Further details will be provided in the text of any call for tenders launched.

1.4 LINKS TO OTHER RESEARCH TOPICS

Co-ordination within this thematic priority

The general principles for the submission of proposals are that proposals must clearly address the objectives and priorities set out in the relevant work programme section and should be submitted to the priority area to which they are most closely linked.

Co-ordination with other thematic priorities for research

There will be close interaction between activities in this and the other thematic priorities, in particular:

1.1.2 Information society technologies – coordination with the Strategic objective on eHealth.
1.1.3 Nano-technologies and nano-sciences; knowledge based multifunctional materials and new production processes and devices
1.1.5 Food quality and safety
1.1.6 Sustainable development, global change and ecosystems
1.2 .1 Policy support and anticipating scientific and technological needs
  i) Policy oriented research
  ii) Research to explore new and emerging scientific and technological problems and opportunities

Further information on this can be found in the "Guide for Proposers".

1. 5 IMPLEMENTATION PLAN AND RELATED ISSUES

For general aspects of the evaluation procedure, refer to the **FP6 "Guidelines on Proposal Evaluation Procedures"** available from Cordis [http://www.cordis.lu/fp6/eval-guidelines] and to the general Annex B to this Work-Programme.

All applicants are advised to consult the relevant "Guide for Proposers".

The weightings of the evaluation criteria and thresholds for this thematic area are detailed in Annex B of the Work Programme.

The selected topics may be open only for the call indicated and it is envisaged that up to one project utilising a new instrument will be funded for each topic. Several projects can be funded under topics utilising STREP, CA or SSA. There may be competition between proposals submitted to address different topics areas as well as proposals submitted to address the same topic. This may result in some topics not being supported. For each topic the instrument to be used is clearly and explicitly indicated. In a small number of topics the option is given between two clearly indicated kind of instruments. Proposals utilising an instrument other than the one(s) indicated will be considered ineligible.

The European Community, as a member of the Human Frontier Science Programme Organisation (HFSPO) since 12 September 1990, will provide annual contributions in 2005 and 2006 to the HFSPO (which runs the HFSP) from this Thematic Priority. Financial support allows non-G8 Member States to fully benefit from the Programme, which shares a number of objectives with this theme. Out of the total Community contribution of 3.606M€ for 2005, 2.106.00M€ will be paid from Thematic Priority 1, and the remainder from Thematic priority 2. For 2006, the Community contribution will be 3.750M€ of which 2.250M€ will be paid from Thematic Priority 1, and the remainder from Thematic priority 2. These financial contributions will be paid through specific support actions according to article 9.2a of the Rules of Participation.

Finally, the Commission will continue to examine and validate its objectives and identify new policy directions with the help of workshops and conferences.

INDICATIVE BUDGET DISTRIBUTION FOR 3RD and 4th CALL FOR PROPOSALS

Area	3rd Call Indicative budget Deadline November 2004 (M €)	4th Call Indicative budget for traditional call (M €)	4th Call Indicative budget for SME call (M €)	4th Call Total Indicative Budget (M €)
i a) Fundamental knowledge and basic tools for functional genomics in all organisms	**133.4**	**80.4**	**35**	**115.4**
i b) Application of knowledge and technologies in the field of genomics and biotechnology for health	**142.2**	**94.5**	**46**	**140.5**
ii a) Application-orientated genomics approaches to medical knowledge and technologies	**139.6**	**104.7**	**45**	**149.7**
b) Combating cancer	**97.3**	**49**	**25**	**74**
c) Confronting the major communicable diseases linked to poverty	**59.5**	**47**	**20**	**67**
Strategic Specific Support Actions across thematic priority 1	**6.3**	**6**	**0**	**6**
Public procurement activities				**0.8**
Human Frontier Science Programme	**2.1**			**2.2**
Total (M €)	**580.4***	**381.6**	**171**	**555.6****

* The indicative budget for the 3rd call as published in the call text was adjusted in line with receipts from Associated Candidate Countries and Associated Countries. 482.7 M € of the call will be committed under 2005 credits and 97,7 M € under 2006 credits.

** 555.6 M € will be committed under 2006 credits

1.6 CALL INFORMATION

Call fiche – Fourth Call of Priority 1: Thematic Call

1. **Specific Programme**: Integrating and strengthening the European Research Area

2. **Activity**: Priority thematic area of research "Life sciences, genomics and biotechnology for health".

3. **Call title**: Thematic call in the area of "Life sciences, genomics and biotechnology for health".

4. **Call identifier:** FP6-2005-LIFESCIHEALTH-6

5. **Date of publication**[48]: 15 June 2005

6. **Closure date**[49]: 9 November 2005 at 17.00 (Brussels local time).

7. **Total indicative budget:** 381.6 million €, broken down as follows:

Instrument[50]	€ (millions)
IP or NOE	252.1- 282.1
STREP or CA or area specific SSA	93.5 - 123.5
Strategic SSA across Thematic priority 1	6

8. **Areas called and Instruments**:

Proposals are invited in the following areas, which are described using activity codes only. For the full title and definition of topic, applicants must refer to the Work Programme (Section 1.3 Technical Content). The evaluation of proposals will be based on the full definition of topic as described in the Work Programme. For the topic the instrument to be used is indicated.

i) **Advanced genomics and its applications for health**

a) **Fundamental knowledge and basic tools for functional genomics in all organisms**

Topic Ref.	**Instrument**
• ***Gene expression and proteomics***	
LSH-2005-1.1.1-1	IP
• ***Structural genomics***	
LSH-2005-1.1.2-1	IP
• ***Comparative genomics and population genetics***	
LSH-2005-1.1.3-1	IP
LSH-2005-1.1.3-2	IP

[48] The director-general responsible for the publication of this call may publish it up to one month prior or after its envisaged publication date.

[49] When the envisaged date of publication date is advanced or delayed (see previous footnote), closure date(s) will be adjusted, if needed, accordingly.

[50] IP = Integrated project; NOE = Network of excellence; STREP = Specific targeted research project; CA = Coordination action; SSA = Specific support action

LSH-2005-1.1.3-3	IP
• ***Bioinformatics***	
• ***Multidisciplinary functional genomics approaches to basic biological processes***	
LSH-2005-1.1.5-1	IP
LSH-2005-1.1.5-2	IP
• ***Across the area***	
LSH-2005-1.1.0-1	CA
LSH-2005-1.1.0-2	SSA

b) Application of knowledge and technologies in the field of genomics and biotechnology for health

Topic Ref.	**Instrument**
• ***Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches***	
LSH-2005-1.2.1-1	IP
LSH-2005-1.2.1-2	STREP
• ***Development of new diagnostics***	
LSH-2005-1.2.2-1	IP
LSH-2005-1.2.2-2	STREP
LSH-2005-1.2.2-3	STREP
• ***Development of new in vitro tests to replace animal experimentation***	
LSH-2005-1.2.3-1	IP
LSH-2005-1.2.3-2	SSA
LSH-2005-1.2.3-3	SSA
• ***Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies***	
LSH-2005-1.2.4-1	IP
LSH-2005-1.2.4-2	IP
LSH-2005-1.2.4-3	STREP
LSH-2005-1.2.4-4	STREP
LSH-2005-1.2.4-5	STREP
LSH-2005-1.2.4-6	STREP
• ***Innovative research in post-genomics, which has high potential for application***	
LSH-2005-1.2.5-1	IP
LSH-2005-1.2.5-2	IP
LSH-2005-1.2.5-3	STREP

ii) <u>Combating major diseases</u>

a) Application-orientated genomic approaches to medical knowledge and technologies

Topic Ref.	**Instrument**
• ***General***	
LSH-2005-2.1.0-1	STREP

• ***Combating, cardiovascular disease, diabetes and rare diseases***	
LSH-2005-2.1.1-1	IP
LSH-2005-2.1.1-2	NoE
LSH-2005-2.1.1-3	STREP
LSH-2005-2.1.1-4	STREP
LSH-2005-2.1.1-5	IP
LSH-2005-2.1.1-6	STREP
LSH-2005-2.1.1-7	NoE
LSH-2005-2.1.1-8	STREP
LSH-2005-2.1.1-9	STREP
• ***Combating resistance to antibiotics and other drugs***	
LSH-2005-2.1.2-1	IP
LSH-2005-2.1.2-2	STREP
LSH-2005-2.1.2-3	SSA
• ***Studying the brain and combating diseases of the nervous system***	
LSH-2005-2.1.3-1	IP
LSH-2005-2.1.3-2	IP
LSH-2005-2.1.3-3	STREP
LSH-2005-2.1.3-4	STREP
LSH-2005-2.1.3-5	SSA
• ***Studying human development and the ageing process***	
LSH-2005-2.1.4-1	NoE
LSH-2005-2.1.4-2	SSA

b) Combating cancer

Topic Ref.	**Instrument**
LSH-2005-2.2.0-1	IP
LSH-2005-2.2.0-2	STREP
LSH-2005-2.2.0-3	STREP
LSH-2005-2.2.0-4	STREP
LSH-2005-2.2.0-5	STREP
LSH-2005-2.2.0-6	SSA

c) Confronting the major communicable diseased linked to poverty

Topic Ref.	**Instrument**
LSH-2005-2.3.0-1	NoE
LSH-2005-2.3.0-2	NoE
LSH-2005-2.3.0-3	IP
LSH-2005-2.3.0-4	STREP
LSH-2005-2.3.0-5	STREP
LSH-2005-2.3.0-6	SSA/CA
LSH-2005-2.3.0-7	SSA/CA
LSH-2005-2.3.0-8	SSA/CA
LSH-2005-2.3.0-9	SSA/CA

SSAs across Thematic Priority 1

Topic Ref.	Instrument
LSH-2005-3-1	SSA
LSH-2005-3-2	SSA
LSH-2005-3-3	SSA
LSH-2005-3-4	SSA
LSH-2005-3-5	SSA
LSH-2005-3-6	SSA
LSH-2005-3-7	SSA
LSH-2005-3-8	SSA
LSH-2005-3-9	SSA
LSH-2005-3-10	SSA
LSH-2005-3-11	SSA
LSH-2005-3-12	SSA

9. Minimum number of participants[51]:

Instrument	Minimum number of participants
IP, NoE, STREP and CA	3 independent legal entities from 3 different MS or AS, with at least 2 MS or ACC.
SSA	1 legal entity from a MS or AS.

10. Restriction on participation: None.

11. Consortia agreements:

- Participants in IP and NOE are required to conclude a consortium agreement.
- Participants in STREP, CA and SSA resulting from this call are encouraged, but not required, to conclude a consortium agreement.

12. Evaluation procedure:

- The evaluation shall follow a single stage procedure;
- Proposals will not be evaluated anonymously;
- The evaluation process may involve "remote" evaluation of proposals;
- Applicants may be invited to discuss their proposal.

13. Evaluation criteria: See Annex B of the work programme for the applicable criteria (including their individual weights and thresholds and the overall threshold) per instrument.

14. Indicative evaluation and contractual timetable:

- Evaluation results: expected to be available some 4 months after the closure date
- Contract signature: it is estimated that the first contracts related to this call will come into force in by the end of 2006.

[51] MS = Member States of the EU; AS (incl. ACC) = Associated States; ACC = Associated candidate countries. Any legal entity established in a Member State or Associated State and which is made up of the requested number of participant may be the sole participant in an indirect action.

Call fiche – Fourth Call of Priority 1: STREPs dedicated to SMEs

1. **Specific Programme**: Integrating and strengthening the European Research Area

2. **Activity**: Priority thematic area of research "Life sciences, genomics and biotechnology for health".

3. **Call title**: Call for STREPs dedicated to SMEs in the area of "Life sciences, genomics and biotechnology for health".

4. **Call identifier:** FP6-2005-LIFESCIHEALTH-7

5. **Date of publication**[52]: 15 June 2005

6. **Closure date**[53]: 9 November 2005 at 17.00 (Brussels local time).

7. **Total indicative budget:** 171 million €, broken down as follows:

Instrument[54]	€ (millions)
STREP	171

8. **Areas called and Instruments**:

Proposals are invited in the following areas, which are described using activity codes only. For the full titles and definition of areas, applicants must refer to the Work Programme (Section 1.3 Technical Content). The evaluation of proposals will be based on the full definition as described in the Work Programme.

i) **Advanced genomics and its applications for health**

a) **Fundamental knowledge and basic tools for functional genomics in all organisms**

Topic Ref.	**Instrument**
• ***Across the area***	
LSH-2005-1.1.0-3	STREP

b) **Application of knowledge and technologies in the field of genomics and biotechnology for health**

Topic Ref.	**Instrument**
• ***Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches***	
LSH-2005-1.2.1-3	STREP
• ***Development of new diagnostics***	
LSH-2005-1.2.2-4	STREP

[52] The director-general responsible for the publication of this call may publish it up to one month prior or after its envisaged publication date.

[53] When the envisaged date of publication date is advanced or delayed (see previous footnote), closure date(s) will be adjusted, if needed, accordingly.

[54] STREP = Specific targeted research project

• ***Development of new in vitro tests to replace animal experimentation***	
LSH-2005-1.2.3-4	STREP
• ***Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies***	
LSH-2005-1.2.4-7	STREP
• ***Innovative research in post-genomics, which has high potential for application***	
LSH-2005-1.2.5-4	STREP

ii) <u>Combating major diseases</u>

a) Application-orientated genomic approaches to medical knowledge and technologies

Topic Ref.	**Instrument**
• ***Combating, cardiovascular disease, diabetes and rare diseases***	
LSH-2005-2.1.1-10	STREP
LSH-2005-2.1.1-11	STREP
LSH-2005-2.1.1-12	STREP
• ***Combating resistance to antibiotics and other drugs***	
LSH-2005-2.1.2-4	STREP
LSH-2005-2.1.2-5	STREP
• ***Studying the brain and combating diseases of the nervous system***	
LSH-2005-2.1.3-6	STREP
LSH-2005-2.1.3-7	STREP
LSH-2005-2.1.3-8	STREP
LSH-2005-2.1.3-9	STREP
• ***Studying human development and the ageing process***	
LSH-2005-2.1.4-3	STREP

b) Combating cancer

Topic Ref.	**Instrument**
LSH-2005-2.2.0-7	STREP
LSH-2005-2.2.0-8	STREP
LSH-2005-2.2.0-9	STREP

c) Confronting the major communicable diseased linked to poverty

Topic Ref.	**Instrument**
LSH-2005-2.3.0-10	STREP
LSH-2005-2.3.0-11	STREP
LSH-2005-2.3.0-12	STREP

9. Minimum number of participants[55]:

Instrument	Minimum number of participants
STREP	3 independent legal entities from 3 different MS or AS, with at least 2 MS or ACC.

10. Restriction on participation: All consortia should aim at having 30-50 % of the requested EC contribution budget going to SMEs.

11. Consortia agreements:

- Participants in STREP resulting from this call are encouraged, but not required, to conclude a consortium agreement.

12. Evaluation procedure:

- The evaluation shall follow a single stage procedure;
- Proposals will not be evaluated anonymously;
- The evaluation process may involve "remote" evaluation of proposals;
- Applicants may be invited to discuss their proposal.

13. Evaluation criteria: See Annex B of the work programme for the applicable criteria (including their individual weights and thresholds and the overall threshold) per instrument.

14. Indicative evaluation and contractual timetable:

- Evaluation results: expected to be available some 4 months after the closure date
- Contract signature: it is estimated that the first contracts related to this call will come into force by the end of 2006.

[55] MS = Member States of the EU; AS (incl. ACC) = Associated States; ACC = Associated candidate countries. Any legal entity established in a Member State or Associated State and which is made up of the requested number of participant may be the sole participant in an indirect action.