# FP6

# WORK PROGRAMME

## 1.1.1 LIFE SCIENCES, GENOMICS AND BIOTECHNOLOGY FOR HEALTH

1. Life sciences, genomics and biotechnology for health

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## 1.1 INTRODUCTION

The sequencing of the human genome and many other genomes heralds a new age in human biology, offering unprecedented opportunities to improve 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.

The work programme describes the research areas in which project proposals can be presented. In the section on "Technical content" the topics selected for the first call are followed by preliminary indication of topics anticipated for the second call.

## 1.2 OBJECTIVES, STRUCTURE, AND OVERALL APPROACH

The content of this work programme and the research topics selected for the first call and indicated[2] for the second call has been influenced by various inputs including analysis of Expressions of Interest, 2002. In addition the work programme also takes into account the budget limitations, the urgency of the scientific actions and the possible overlaps between research topics.

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[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.

[2] The Work Programme for thematic priority 1, with the present content, will only be used for the first call for propsals. Topics for the second call will be reviewed before formal publication in the Official Journal. This Work Programme gives "indicative" topics for the second call, which means topics will be given a high priority in the process, but does not formally commit the Commission to including the topics.

In preparing proposals, applicants should consider the horizontal issues mentioned in the general introduction[3] 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[4] 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[5].

**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[6]. This thematic priority emphasises the importance of innovation and the integration of SMEs in order to reach the Lisbon goal. Therefore project consortia need to integrate all relevant competencies to address innovation related aspects[7], such as technology transfer, intellectual property rights, clinical trials, etc., with a view of ensuring optimal use of the generated knowledge. Research intensive and innovative SMEs play a vital role for exploiting the EU biotechnology and life sciences knowledge base and in fact 15% of the budget is reserved for SME participation.

**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

[3] See section "General Introduction".

[4] 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.

[5] See relevant sections in the "Guide for Proposers".

[6] See also "Life sciences and biotechnology - A strategy for Europe".

[7] See relevant section in the "Guide for Proposers".

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[8]. This clinical research may include clinical trials. Community contribution will however only be available for Phase I and II clinical trials. Within the context of the European and Developing Countries Clinical Trials Partnership, EDCTP, funding may be considered for Phase II and Phase III trials. In implementing a clinical research project consortia are encouraged to include small and medium sized enterprises (SMEs) wherever appropriate.[9]

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.

**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 legal and/or regulations of the country(ies) where the research takes place. [10, 11]

[8] See relevant section in the " Guide for Proposers".
[9] See relevant sections in the "Guide for Proposers".
[10] As stipulated in the decision of the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (http://europa.eu.int/eur-lex/en/dat/2002/l_294/l_29420021029en00010043.pdf). The following fields of research will not be financed under the 6th Framework Programme:

- Research activity aiming at human cloning for reproductive purposes.

**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" [12], which is a follow-up of the March 2001 Stockholm European Council.[13]

## 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. 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 first call:***

**LSH-2002-1.1.1-1: Development of advanced array technologies – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The focus should be on delivering advanced array technologies for the analysis, with high precision and sensitivity, of large sets of proteins, DNA and RNA and for functional cell arrays.

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- Research activity intended to modify the genetic heritage of human beings which could make such changes inheritable. Research relating to cancer treatment of the gonads can be financed.
- Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

The Council and the Commission agreed that detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells, which may be funded under the 6th Framework Programme, shall be established by 31 December 2003. The Commission stated that, during that period and pending establishment of the detailed implementing provisions, it will not propose to fund such research, with the exception of the study of banked or isolated human embryonic stem cells in culture. (Doc. 12739/02, RECH 156, ATO 116 from 4th October 2002). Note that this provision may change after December 2003 as a result of a decision of the Council.

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

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

[13] See section on "Specific Support Actions across Thematic Priority 1".

**LSH-2002-1.1.1-2: Development and application of high throughput proteomics technologies for the generation of a large data set of protein-protein interactions – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The focus should be to develop and apply high-throughput proteomics technologies for the identification of protein-protein interactions in complex biological samples and/or in the cell.

***Indicative topics for second call:***

**Global in situ gene expression analysis in mouse models and human tissues – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

- ***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 first call:***

**LSH-2002-1.1.2-1: The 3-D structure determination of membrane proteins – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Research should focus on developing and implementing new technologies to solve the bottlenecks that preclude the determination at high throughput of high-resolution structures of membrane proteins and membrane protein complexes.

**LSH-2002-1.1.2-2: Supramolecular analysis by 3-D -electron microscopy in situ – *NETWORK OF EXCELLENCE*.** The focus should be on bringing together different expertise from academic and industrial (including SMEs) laboratories to generate a joint programme of activities aiming at designing and developing approaches and new equipment for the supramolecular structural analysis by **3-D** -electron microscopy of the topology of large protein complexes within the cell.

**LSH-2002-1.1.2-3: Development of new hardware and software for the implementation of innovative automated technologies at synchrotron sites – *INTEGRATED PROJECT*.** The focus of the research should be on developing, assembling, standardising and providing highly integrated and automated technological platforms at synchrotron research centres for high throughput structural genomics.

***Indicative topics for second call:***

**Comparative structural biology of viral replication – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Structure determination of large protein complexes – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

- ***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 first call:***

**LSH-2002-1.1.3-1: Integrated tools for functional genomics of non-mammalian vertebrate models for human development and disease mechanisms – *INTEGRATED PROJECT*.** The focus should be on strengthening the research effort to develop and use high throughput tools, technologies and approaches in non-mammalian vertebrate models for harvesting large data sets on gene functions underlying development and disease.

**LSH-2002-1.1.3-2: Development of *in-vivo* imaging technologies for phenotyping and functional analysis in cells and animal models– *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.** The focus should be on developing, evaluating and applying tools and methods for high-resolution *in-vivo* imaging in cells and in animal models using expertise in biology, chemistry, physics and engineering.

***Indicative topics for second call:***

**Large scale RNA interference screening in *Arabidopsis* for the identification of important gene functions underlying biological processes relevant to health– *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Developing new molecular tools and approaches for phenotyping human populations – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Standardisation and integration of genomic and phenotypic information to characterise bacterial diversity with relevance to human health – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE* .**

**Coordination and standardisation of high throughput genotyping in human populations in Europe – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE* .**

- ***Bioinformatics***

  The objectives are to enable researchers to access efficient tools for managing and interpreting the ever-increasing quantities of genome data and for making it available to the research community in an accessible and usable form.

***Topics for first call:***

**LSH-2002-1.1.4-1: Developing methods and resources in bioinformatics to focus on the annotation of human and other genomes – *NETWORK OF EXCELLENCE*.** The focus should be on stimulating cooperation between life scientists and bioinformaticians to coordinate, via a joint programme of activities, the design and the development of new integrated bioinformatics tools and approaches for the annotation of the human and other genomes.

***Indicative topics for second call:***

**Bioinformatics and genomics grid for European research – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Development of an integrated software platform to tackle genomic sequence-structure-function relationships – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

- ***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 microorganisms, 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 first call:***

**LSH-2002-1.1.5-1: Integrated comparative and functional genomics approaches for studying the cell cycle – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The focus should be on applying multidisciplinary functional genomics approaches in different model organisms for elucidating the basic mechanisms controlling the cell cycle.

**LSH-2002-1.1.5-2: Functional genomics of non-human embryonic stem cell differentiation – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The focus should be on using functional genomics approaches to understand the basic biological processes underlying differentiation and lineage commitment of non-human embryonic stem cells.

**LSH-2002-1.1.5-3: Functional genomics of erythroid development and disorders – *INTEGRATED PROJECT*.** The focus should be on applying functional genomics approaches to decipher the basic mechanisms of normal and pathological erythropoiesis.

**LSH-2002-1.1.5-4: Multidisciplinary approaches of functional genomics to study lymphangiogenesis – *INTEGRATED PROJECT OR NETWORK OF***

***EXCELLENCE.*** The focus should be on using innovative, high-throughput, and large-scale functional genomics approaches to identify new genes and corresponding modifying genetic factors, and to investigate their role in lymphangiogenesis in vertebrate models.

**LSH-2002-1.1.5-5: Epigenetics: chromatin dynamics, non-coding RNA, imprinting and silencing – *NETWORK OF EXCELLENCE*.** The joint programme of activities should focus on promoting a durable interaction between different areas of research in gene regulation to address the mechanisms underlying epigenetic regulation.

**LSH-2002-1.1.5-6: Multidisciplinary approaches of functional genomics to study chronic inflammation processes in human disease – *NETWORK OF EXCELLENCE*.** The focus should be on promoting co-ordination of research activities aiming at understanding the molecular basis of inflammation. Specific diseases relating to inflammatory disorders might be addressed in the joint programme of activities but the emphasis should clearly be on understanding the basic mechanisms of inflammation.

**LSH-2002-1.1.5-7: Functional genomics approaches to decipher ubiquitin-proteasome and/or related pathways – *NETWORK OF EXCELLENCE.*** The main goal should be the networking of research capacities in Europe, through the development of a joint programme of activities aiming at studying the fundamental aspects of the ubiquitin-proteasome and/or related pathways and their links to disease.

***Indicative topics for second call:***

**Functional genomics approaches in animal models to study human kidney disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Functional genomics approaches to the study of peroxisomes in health and disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Functional genomics of inner ear development and disorders – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Functional genomics of retina development and disorders – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**DNA damage and repair mechanisms in health and disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Functional genomics approaches in animal models to study human disease of the immune system – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Functional genomics approaches in animal models to study human disease of muscle – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Large epidemiological studies of X-linked syndromes – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

***Research areas for first call utilising STREP/CA/SSA:***

**LSH-2002-1.1.0-1:** For STREP and CA, research should focus on multidisciplinary functional genomics approaches (gene expression and proteomics, structural genomics, comparative genomics, population genetics and bioinformatics), in all organisms to decipher the basic mechanisms underlying the following processes: transcription activation, signal transduction, intracellular communication, the role of non coding genomic information, mechanisms of integration of genes.

Proposals dealing with *in silico* prediction of gene function and for the simulation of complex regulatory networks will also be considered. Proposals concerned with the development of new tools and approaches, including the standardisation of protocols, to facilitate generation of new knowledge in functional and structural genomics are also envisaged. Topics already addressed in the calls for new instruments will not be considered for STREP/CA.

**LSH-2002-1.1.0-2:** 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 fundamental genomics. The activities should aim at structuring research activities in fundamental genomics in important areas not yet addressed or newly emerging, including technology foresight meetings to identify future opportunities within the field. Furthermore they should address opportunities for start-up initiatives or strengthen the international dimension in fundamental genomics research, e.g. standardisation, structuring of international genomics initiatives, integration of activities.

***Indicative topics for second call , across the area, utilising STREP/CA/SSA:***

**Developing tools and approaches for detecting low abundance mRNAs and proteins.**

**Identifying and characterising multi-protein "nanomachines".**

**Functional genomics of programmed cell death across the eukaryotic kingdom.**

**Comparative genomics in protozoa in relation to human health.**

**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:

– ***Technological platforms 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 health care progress 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 **integration of SMEs** must be an integral part of projects and must be reflected in the consortia. The innovation aspect within the technological platforms need to be visible through clear dissemination and exploitation plans.

Considering the Community's interest in the Human Frontier Science Programme (HFSP) and the commonality of objectives with this theme, a contribution, which will provide the possibility for non G8 Member States to fully benefit from the programme, will be made available for 2003 and 2004 through subsidies. Subject to the continued Community's interest, this contribution can be made available for the following two years of the Framework Programme.

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 e.g. combinatorial biosynthesis, therapeutic targeting, 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 the first call:***

**LSH-2002-1.2.1-1: Screening for drug candidates targeting aberrant molecular signalling in protein phosphorylation pathways – *INTEGRATED PROJECT*.** The research should focus on the identification of new molecular targets and the screening/design of potential drug candidates applying genomics and proteomics tools. A close interaction of all involved scientific fields and the integration of research laboratories with clinical centres and pharmaceutical industry is essential. The research would lead to novel lead compounds interfering with aberrant protein phosphorylation pathways.

**LSH-2002-1.2.1-2: Genome-based individualised medicines – *NETWORK OF EXCELLENCE***. The work should focus on the structuring of efforts devoted to the characterisation of drug targets in order to optimise individual drug selection, dosage and delivery and to improve the benefit/risk ratio of drugs; epidemiological, social, regulatory and economic aspects as well as ethical issues and public perception will

have to be considered. This implies a close co-operation of research and clinical centres, ethical bodies, regulatory authorities, healthcare providers and pharmaceutical industry.

**LSH-2002-1.2.1-3: Genome-based therapeutic drugs for psychiatric disorders – *INTEGRATED PROJECT*.** The research should focus on the functional characterisation of the molecular mechanisms of psychiatric therapeutics, the disorder to be addressed in particular is depression. The implications of ethical, social, legal and public health aspects have to be considered. The research should lead to validated pharmacogenomic methods for symptom improvement, the prediction of response to psychiatric drug treatment and the reduction of adverse effects.

**LSH-2002-1.2.1-4: Novel antiviral therapeutic molecules targeting virus replication and integration – *INTEGRATED PROJECT*.** The research should focus on the development of new antiviral leads, including the pre-clinical testing and eventually clinical trials of the most promising candidates. A close interaction of all involved scientific fields and the integration of research laboratories with clinical centres and pharmaceutical industry is essential. The research would lead to new antiviral drug candidates ready for clinical studies.

**LSH-2002-1.2.1-5: Generation of blood substitutes for critical blood components, in particular oxygen carriers (hemopoietic stem cells are not in the scope of this line) – *STREP*.**

**LSH-2002-1.2.1-6: New drugs targeting G-protein coupled receptors through pharmacogenomics – *STREP*.**

**LSH-2002-1.2.1-7: Educational schemes utilising interdisciplinary approaches for the integration of pre-clinical and clinical research (e.g. training events, workshops) – *SSA*.**

***Indicative topics for the second call:***

**Medicines for paediatrics – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Computer assisted modelling for drug discovery and clinical trials – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Novel therapeutics for neurodegenerative diseases in CNS and PNS – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

- ***Development of new diagnostics***

  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 the first call:***

**LSH-2002-1.2.2-1: Non-invasive diagnostics and diagnostic procedures; development of markers for ante- and neo-natal screening – *NETWORK OF EXCELLENCE.*** The work should focus on the structuring of the efforts devoted to the development of non-invasive tools for prenatal diagnosis and the translation of genomics data into diagnostic applications; a close collaboration among academia, pharmaceutical industry, ethical bodies and regulatory authorities will be necessary. The area aims at expanding the set of markers for informed choice concerning the risk of birth defects in pregnancies.

**LSH-2002-1.2.2-2: Development of novel non-invasive and repeatable diagnostics using bioinformatic tools – *STREP.***

**LSH-2002-1.2.2-3: New diagnostic tools for prion associated diseases – *STREP.***

***Indicative topics for the second call:***

**Development of genetic tests allowing for harmonisation, validation and standardisation – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

***In vivo* molecular imaging: identification of new markers for diagnostic purposes and therapeutic monitoring – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

- ***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. The topics considered will have to contribute directly to the aims of Directive 86/609/EEC [14] regarding the protection of animals used for experimental and other scientific purposes, to be in line with the protocol annexed to the Treaty of Amsterdam on the welfare requirements of animals. Priority will be given to alternative methods developed that will reach the level of maturity for subsequent formal validation and wide industrial and economic application.

***Topics for the first call:***

**LSH-2002-1.2.3-1: Combination and application of *in vitro* cell and sensor technologies in the field of animal *in vivo* toxicology – *INTEGRATED PROJECT*.** The research should focus on *in vitro* cell-based toxicological and pharmacological tests (this includes also making use of stem cells, and genetically engineered cell lines) for screening drug compounds. The research would lead to novel techniques and methodologies for enhanced cell culture sustainability, determination of endpoints and markers of toxicity and the integration of *in vitro* model system(s) and sensing technologies. Data should be produced according to the requirements for formal validation (GLP&SOPs).

[14] OJ L 358, 18.12.1986, p. 1.

**LSH-2002-1.2.3-2: Alternative *in vitro* tests promoting industrial competitiveness in the product screening and development process stages of pharmaceutically-relevant lead compounds – *STREP*.**

**LSH-2002-1.2.3-3: Technology foresight meeting on test development, validation and implementation – *SSA*.**

**LSH-2002-1.2.3-4: Workshop on business opportunities in pharmaceutical toxicology – *SSA*.**

**LSH-2002-1.2.3-5: Partnership event on the development and manufacture of toxicology test methods for regulatory testing needs – *SSA*.**

**LSH-2002-1.2.3-6: Forum on the achievements in raising awareness on the use of alternative methods in Candidate Countries – *SSA*.**

***Indicative topics for the second call:***

**Optimisation of test batteries for human acute toxicity – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***

- ***Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies*[15]*, 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 hemopoietic disorders, which impose considerable significant impairments to citizens' quality of life, as well as burdens on health care services in Europe.

***Topics for the first call:***

**LSH-2002-1.2.4-1: Development and production of cell lines for cell based therapies[16] – *INTEGRATED PROJECT*.** The research should focus on the development and scale up of production of appropriate cell lines having a potential of repairing diseased or damaged tissues, by comparative evaluation of stem cells from embryonic, foetal and adult sources[17]. The envisaged clinical application should

[15] Id 10

[16] Id 10

[17] Id 10

include neurological and neuromuscular disorders. An early involvement of clinicians, patient organisations and industry in particularly SMEs will be essential. The integration of ethical, social and economic aspects in the development process including public dialogue will be a requirement. The research should lead to new identified and characterised cell populations for cell-replacement therapies, tested in disease models in-vivo, having optimised compatibility, survival and safety of transplanted cells.

**LSH-2002-1.2.4-2: Optimised allogeneic stem cell transplantation for haematological and neoplastic diseases – *INTEGRATED PROJECT.*** The research should focus on the combination of stem cell transplant procedures with immunotherapeutic and gene therapy approaches to prevent the major immunological post transplant complications; a translational approach from *in vitro* and animal experiments to clinical trials will be necessary; the participation of industrial partners, ethical and regulatory representatives will be a pre-requisite. The research would lead to new strategies for optimising the use of haematopoietic stem cell transplantation, based on the prediction and modulation of the immune responses in order to increase the engraftment potential, to generate selective anti-tumour immune responses and to provide protective immunity against opportunistic infections.

**LSH-2002-1.2.4-3: New advances in cell based therapies for the regeneration of connective tissue – *INTEGRATED PROJECT.*** The research should focus on application of the recent advances in mesenchymal stem cell research[18], gene transfer and tissue engineering for the treatment of connective tissue diseases. New genomic and proteomic technologies should be used for the characterisation of the stem cell populations as well as for defining clear quality and safety standards for successful tissue regeneration. Particular attention should be given to the participation of industry and regulatory bodies. The research would lead to new biological implants, capable of functional load bearing, based on advanced functional scaffolds and mesenchymal stem cell populations.

**LSH-2002-1.2.4-4: Development of a European databank comprising recent advances in genomics, proteomics and cell biology for immunotherapies – *STREP.***

**LSH-2002-1.2.4-5: Stem cell products for myocardial repair[19] - *STREP.***

**LSH-2002-1.2.4-6: Development of vaccine technologies targeted to dendritic cells – *STREP.***

**LSH-2002-1.2.4-7: Workshop on technology transfer and identification of bottlenecks (i.e. IPR, regulatory issues) for SMEs in the area of somatic gene and cell therapies – *SSA.***

[18] Id 10

[19] Id 10

***Indicative topics for the second call:***

**Improved gene delivery systems for the therapy of severe acquired diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Gene therapy of inherited diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Design of rational protocols for safety, quality and standardisation of stem cells**[20] **and establishment of a European registry of stem cells – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Regeneration therapies for vital organs**[21] **(i.e. pancreas, liver diseases) – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**New improved vaccine delivery systems, e.g. bacterial, synthetic, aimed at dendritic cells, genomic and proteomic targets – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**New chemokine modulators aimed at antigen-receptor interactions in autoimmune diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

- ***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.

***Topics for the first call:***

**LSH-2002-1.2.5-1: Post-genomic approaches for tackling asthma and auto-immune diseases – *INTEGRATED PROJECT.*** The research should focus on analysis of the interaction of the factors causing disease; molecular work will be combined with co-ordinated databases, biobanks, prospective cohorts, specific analytical design and software tools, as appropriate. Since work will involve using and exchanging human samples and medical/personal data, projects should include clearly identified components addressing the ethical issues and the socio-economic and public health perspective. The technological and methodological tools developed should be applicable to other diseases. The research would lead to identification of specific targets to enable the development of novel diagnostics and therapeutics.

**LSH-2002-1.2.5-2: Plant platforms for immunotherapeutic biomolecule production – *INTEGRATED PROJECT*.** The research should focus on pharmaceuticals for which a plant-based production system offers real advantage and potential. If so targeted, appropriate developing country participation in the

[20] Id 10

[21] Id 10

consortium should be included. Research should build in from the design stage safety features and minimise any ecological impact of the production method, e.g. prevent gene flow, restrict expression to utilised parts of the plant, prevent exudates, and should include a comprehensive environmental risk analysis. The research would lead to practical plant-based expression systems for vaccine or other immunotherapeutic molecule.

**LSH-2002-1.2.5-3: Combinatorial biosynthesis as a tool for generating new drug candidates – *STREP.***

**LSH-2002-1.2.5-4: Exploiting postgenomics to produce optically-active therapeutic biomolecules by biocatalysis – *STREP.***

**LSH-2002-1.2.5-5: Development of precision technology platforms exploiting advances in post-genomics (especially orientated towards involvement of health-related SMEs) – *STREP.***

**LSH-2002-1.2.5-6: Workshop for identifying new tools in molecular plant biology for medical applications – *SSA.***

***Indicative topics for the second call:***

**RNA as a human therapeutic tool – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Post-genomic approaches to the study of human pathogens – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Pre-clinical and clinical applications of post-genomics information - *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Induction of transplant tolerance using post-genomic approaches - *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**ii) Combating major diseases**

**a) Application-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 health determinants**.** The emphasis will be on translational research aimed at bringing basic knowledge through to clinical application.

Research actions will focus on the following:

- ***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.

***<u>Topics for first call:</u>***

**LSH-2002-2.1.1-1: Molecular pathogenesis of Coronary Artery Disease (CAD) and diagnostic tools for prevention and treatment – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The project will generate or use population genetics data to identify new information on the causes of CAD through the identification of novel genes and variants, proteins and signalling pathways implicated in atherosclerosis and arterial thrombosis. In addition it should characterise the functions and physiological roles of these parameters and assess the impact in the population.

**LSH-2002-2.1.1-2: Novel molecular targets for the treatment of obesity in the context of diabetes – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Identification of novel molecular targets for treatment of obesity considering also phenotype characterisation of animal and clinical models. Targets include e.g. nuclear receptors, ghrelin and its signalling pathways and neuroendocrinological pathways. Involvement of SMEs will ensure rapid exploitation of the results for the benefit of patients, which include more and more young people.

**LSH-2002-2.1.1-3: The role of pancreatic ion channels in defective insulin secretion in type 2 diabetes – *INTEGRATED PROJECT*.** The project should elucidate the molecular mechanisms underlying human pancreatic islet cell electrical activity and the regulation of insulin secretion by use of a multidisciplinary approach. Investigation of plasma membrane and intracellular ion channels is foreseen. Genes encoding ion channels and accessory proteins will be analysed for their association with type 2 diabetes. This will include the analysis of polymorphisms in these genes.

**LSH-2002-2.1.1-4: Rare disorders of mitochondria or of nuclear organisation with broader implications for biological processes – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Rare diseases with an emphasis on the defects of mitochondrial oxidative phosphorylation system or defects of nuclear envelope proteins (laminopathies) should be studied to reveal molecular mechanisms of the diseases. Combined basic and clinical research should have an impact on the treatment of these diseases.

**LSH-2002-2.1.1-5: Genomics of heart muscle development and disease - *NETWORK OF EXCELLENCE* .** This project will include activities which promote the translation of new knowledge to the treatment of complications of heart disease such as heart failure and arrhythmias. The objective is the durable integration of researchers addressing the normal and abnormal development of the heart. Congenital cardiovascular malformation is of particular relevance to the health of children. Research on disease of cardiac blood vessels is excluded.

**LSH-2002-2.1.1-6: Genomics of vascular disease and atherothrombosis – *NETWORK OF EXCELLENCE* .** The project will integrate research spanning the clinical-basic interface in the area of endothelial and muscle cell dysfunction and atherothrombosis. This includes networking of research on animal and cellular models faithfully reproducing human disease and integration of relevant facilities. The participation of biotechnology companies in the network will be encouraged.

**LSH-2002-2.1.1-7: Rare disorders of plasma membrane transporters for amino-acids, lipids and sugars - *STREP.*** A multidisciplinary approach bringing together genomics, proteomics, structural and functional studies with clinical investigation should lead to the development of new treatments.

**LSH-2002-2.1.1-8: Aetiology, pathology and prediction of type 1 diabetes in Europe - *CA*.** Advanced genomics will be used to detect triggers of autoimmunity and regulators of progression as well as mechanisms of β cell death in well-characterised patient cohorts and experimental model systems with the aim of identifying targets for prevention, diagnosis and treatment.

**LSH-2002-2.1.1-9: Network for early clinical trials in rare diseases - *CA.*** This action is aimed at fostering the realisation of phase 1 and 2 clinical trials by linking and developing the available resources in this field, thus achieving a sufficient number of patients.

**LSH-2002-2.1.1-10: Overcoming the challenges of translational research in cardiovascular disease - *SSA.*** Workshop to identify tools and teams who could bridge between basic and clinical research, in order to apply state-of-the-art technologies for the benefit of patients.

**LSH-2002-2.1.1-11: Type II diabetes and obesity - *SSA.*** Aimed at presenting the latest strategies for tackling obesity in the context of type II diabetes, this workshop will promote the participation of SMEs in the development of new treatments.

**LSH-2002-2.1.1-12: Co-ordination of rare disease research in Europe, with various stakeholders from research, SMEs and patient organisations – *SSA.*** The scope is to strengthen the links between the different parties involved in the design and development of new treatments. One of the aims of this action will be to encourage the participation of SMEs, which are expected to play a critical role in this context.

***Indicative topics for the second call:***

**Eicosanoids and nitric oxide: mediators of cardiovascular, cerebral and neoplastic diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Hypertension and heart failure – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Molecular basis of exercise effects on the metabolic syndrome – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Genomics of type II diabetes – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Prader-Willi Syndrome: gene expression, obesity and mental health – *STREP.***

**Rare autoimmune disorders: from genes to individualised medicine – *STREP.***

**Molecular basis of stroke – *STREP.***

**Combating genetic skin disorders – *CA.***

**Combating metabolic disorders – *CA.***

- ***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 first call:***

**LSH-2002-2.1.2-1: Management of respiratory tract infections –*NETWORK OF EXCELLENCE* .** The focus should be to address current fragmentation by integrating microbial and human genomics with clinical research and cost-benefit/cost-effectiveness studies towards a common understanding of an improved evidence-based management of community acquired lower respiratory infections with the aim of reducing antibiotic resistance. The activities should take into account validation and implementation of novel treatment, prevention and diagnostic approaches for various bacterial and viral respiratory pathogens.

**LSH-2002-2.1.2-2: Testing anti-viral drug resistance and understanding resistance development – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** The focus should be on setting up a broad approach towards testing and following up antiviral drug resistance in human virus infections, such as hepatitis B, hepatitis C and influenza. The approach should integrate basic, clinical, pharmacological, immunological and virological research in order to address the resistance development against existing as well as new antiviral drugs that will come into general use during the project duration.

**LSH-2002-2.1.2-3: Broadening the knowledge base on the molecular mechanisms behind resistance – *STREP/CA*.** The focus should be to unravel the fundamental molecular and genetic mechanisms responsible for antimicrobial resistance, including aspects of pathogen-host interactions and transmission of resistance, with the aim of opening up new opportunities for future research initiatives. Projects may focus on one or several classes of resistance mechanisms.

**LSH-2002-2.1.2-4: Workshop on the structuring of European research activities to more effectively combat drug resistant hospital infections - *SSA*.** The aim is to stimulate the scientific community to address the issue of hospital acquired infections in a later call.

**LSH-2002-2.1.2-5: Workshop on strategies to address antimicrobial resistance through the exploitation of microbial genomics - *SSA*.** The aim is to further explore how emerging genome data can best be exploited at the European level to be used in later calls.

***Indicative topics for the second call:***

**Functional genomics of antibiotics-producing organisms – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**New molecular targets for the development of drugs against pathogens causing severe resistance problems – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Control of hospital acquired infections – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Microbial ecology: Host/bacterial and bacterial/bacterial interactions, resistance epidemiology and role of reservoirs – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Multidisciplinary approaches to control antifungal drug resistance – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Novel approaches to treat infections through non-antimicrobial based therapies – *STREP/CA*.**

**Scientific support to the European Community network for epidemiological surveillance and control of communicable diseases – *STREP/CA*.**

**Workshop on the translation of results emerging from research on antimicrobial resistance into clinical practice - *SSA*.**

**State-of-the-art meeting on the possible link between the use of antibiotics in agriculture and antibiotic resistance in humans - *SSA*.**

**Workshop exploring novel opportunities towards the development of vaccines that will have a significant direct or indirect impact in the control of antimicrobial resistance - *SSA*.**

- ***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 first call:***

**LSH-2002-2.1.3-1: Genomics and neurobiology of affective disorders – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Combined efforts should be directed towards the identification of genes involved in affective disorders. This information should be used for establishing databases and animal models, which will be the basis for functional studies including cell biology, *in vivo* imaging and neuropsychiatry.

**LSH-2002-2.1.3-2: Eating disorders, from genes to behaviour – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***. The project should follow a broad multidisciplinary approach aiming at the identification of new candidate genes and the implementation of new animal models for feeding and feeding disorders, as well as addressing neuroimaging and neuropsychological studies.

**LSH-2002-2.1.3-3: Role and mechanisms of protein aggregation in neurodegenerative diseases – *INTEGRATED PROJECT.*** Research should focus on abnormal protein aggregation and deposits in Alzheimer's disease, Parkinson's disease, Huntington's disease, motor neuron disease and prion diseases. Priorities will be the identification of novel disease-related genes, their role in the pathophysiology of those diseases with an emphasis on possible common features, and the implementation of suitable animal models.

**LSH-2002-2.1.3-4: Rare hereditary neurological disorders: ataxias – *INTEGRATED PROJECT*.** This project will focus on hereditary ataxias. The identification of novel genes and establishment of new models will be essential to improve our understanding of the pathogenesis of these disorders and ultimately facilitate the identification of new therapeutic targets.

**LSH-2002-2.1.3-5: Molecular and cellular basis of brain development – *NETWORK OF EXCELLENCE*.** This network should lead to an improvement in the coordination of multidisciplinary European activities on brain development. It should provide and share technical expertise from molecular biological methods to animal models and integrate human resources and infrastructure, including SMEs.

**LSH-2002-2.1.3-6: Human brain tissue research – *NETWORK OF EXCELLENCE.*** This network should facilitate the integration and structuring of European research on human brain tissue. It will especially facilitate research and studies on genetic and environmental influences on brain diseases. The network should address important issues such as standardisation of tissue sampling, shared use, and diagnosis including ethical issues, clinical history, genotyping, accessibility and training.

**LSH-2002-2.1.3-7: Rare monogenic neurological disorders – *STREP/CA.*** This project should focus on the cell biology underlying the neuropathology of rare monogenic neurological disorders (excluding ataxias and rare forms of non-rare diseases such as familial Parkinson's or Alzheimer's disease).

**LSH-2002-2.1.3-8: Genetics and neurobiology of pain – *STREP/CA*.** This project should focus on the basic processes underlying pain (such as neuropathic pain or headache), ranging from genetic to functional studies and response to treatment.

**LSH-2002-2.1.3-9: Schizophrenia: from genotype to phenotype – *STREP/CA*.** This project should lead to a better understanding of the molecular etiology of schizophrenia by identifying genetic and environmental determinants and their potential interaction in the development of the disease.

**LSH-2002-2.1.3-10: Specific brain research support actions – *SSA*.** The aim is to grant support for the organisation of high impact scientific workshops, courses, or dissemination activities in the fields of basic and clinical neuroscience, including social and ethical issues.

***Indicative topics for the second call:***

**Genomics, mechanisms and treatment of addiction – *INTEGRATED PROJECTOR NETWORK OF EXCELLENCE*.**

**Neuronal networks, learning and memory: from genes to behaviour – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Cortical development – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Molecular mechanisms of neuronal degeneration and regeneration – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.**

**Stem cells and nervous system – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE* .**[22]

**Specific brain research support actions – *SSA*.**

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

  Human genome sequence, genomic and postgenomic research will be applied to understand human development and healthy ageing in order to develop the evidence base for improving public health strategies and to promote healthy living and healthy ageing.

***Topics for the first call:***

**LSH-2002-2.1.4-1: Genetic factors of longevity and healthy ageing – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*.** The objective is to compare, in a European dimension, health status and history of members of different

[22] Id 10

age and gender groups with their genetic background, to identify genetic markers and expression profiles for the prediction of healthy ageing versus frailty, and long versus short life.

**LSH-2002-2.1.4-2: Molecular and cellular processes underlying the development of mesodermal organ systems – *NETWORK OF EXCELLENCE.*** The goal is to integrate developmental genetics and experimental embryology of vertebrate and invertebrate systems with genomic and advanced cell biological methodologies to study diseases of the mesodermal organ system. An improved knowledge basis for new diagnostic and therapeutic approaches is anticipated through the identification and characterization of genes engaged in organogenesis.

**LSH-2002-2.1.4-3: Molecular mechanisms of bone homeostasis – *STREP.*** Efforts should be directed towards elucidating the molecular mechanisms of bone anabolic effectors to provide a perspective for the prevention or treatment of osteoporosis.

***Indicative topics for second call:***

**Mitochondrial dysfunction as a cause for morbidity – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Molecular mechanisms of embryo implantation – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Molecular markers of congenital anomalies – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Disorders in development and ageing caused by aberrant steroid signalling– *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE* .**

**Biochemistry of reactive oxygen species – *STREP/CA.***

**Coordinating European research in ageing and longevity – *STREP/CA.***

### 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 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.*

– ***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 first call:***

**LSH-2002-2.2.0-1: Translating basic knowledge of functional oncogenomics into cancer diagnosis and treatment – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Large-scale gene functional analysis will be conducted with a view to 1) identify relevant signalling pathways including oncogenes and tumor suppressor genes; 2) assess the role of epigenetic mechanisms and genomic instability in cancer pathophysiology; 3) depict relevant candidate genes and gene products aimed at identifying new molecular targets for anticancer drug discovery.

**LSH-2002-2.2.0-2: Multidisciplinary research to explore and validate molecular targets for innovative treatment – *INTEGRATED PROJECT.*** Validation of new targets and pathways for innovative treatment will require multidisciplinary research linking molecular pharmacology, immunology, molecular pathology, genomic, proteomic, bioinformatics, imaging, and drug development approaches with a view to confirm their capacity for cancer therapy purposes.

**LSH-2002-2.2.0-3: Networking for treatment *and/or* prevention clinical trials (phase I and II) aimed at improving clinical practice in the light of new molecular knowledge – *NETWORK OF EXCELLENCE.*** The main objective of the network will be to integrate acquired cross-disciplinary input, with the aim to facilitate its translation into improvements in the clinical and public health context. Trials should be aimed at proof-of-principle.

**LSH-2002-2.2.0-4: Innovative research in radiation therapy – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***. The objective will be to validate and develop strategies for optimised treatment delivery of new therapeutic radiation therapies (e.g. conformal radiation techniques including related techniques using protons and ions, intra-operative radiotherapy, stereotactic radiotherapy, biological modifiers, etc.) in order to favour their application.

**LSH-2002-2.2.0-5: Molecular imaging for early detection of tumours and monitoring of treatment – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Multidisciplinary research will be needed to exploit, in the pre-clinical and clinical setting, imaging agents and technologies (e.g. PET, SPECT, MRS, optical imaging) potential, with a view to speed up their application in early

stage diagnosis and therapeutic and prognosis assessment (including in-vivo tissue diagnosis and ex-vivo cellular diagnosis).

**LSH-2002-2.2.0-6: Networking of quality controlled cancer registries and repositories for molecular epidemiology and quality assessment –*NETWORK OF EXCELLENCE***. Innovative research enabling the efficient integration and optimised use of valuable cancer data, samples and specimens resources, in support of research disease management and assessment of treatment or other interventions' impact.

**LSH-2002-2.2.0-7: Molecular mechanisms involved in organ-specific metastatic growth processes in breast cancer – *STREP/CA*.** The focus should be on the understanding of the mechanisms governing the interaction of cancer cells with the organ microenvironment.

**LSH-2002-2.2.0-8: Translational research on promising predictive and prognostic markers – *STREP/CA*.** The focus should be on their correlation with tumour progression and development of therapy resistance.

**LSH-2002-2.2.0-9: Molecular mechanisms of cancer-related pain – *STREP/CA*.** The aim will be to get insight into the specific process of pain induction by different types of cancer.

**LSH-2002-2.2.0-10: Workshop on correlative laboratory studies relevant to therapeutic clinical studies – *SSA*.**

***Indicative topics for future calls:***

**Research and development of relevant models for preclinical tests and evaluation of new therapies – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Innovative research into the prevention of cancer in high-risk populations - *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Networks on prevention, detection and treatment of familial cancers – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE .***

**Tumour-host interactions – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Research into immune control of tumours for prevention and therapy – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Research on virus-associated tumours – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Molecular oriented detection and treatment of minimal disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.***

**Development of European networks to promote research into uncommon cancers - *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE .***

## 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 complementarity of clinical trials of AIDS therapies for human use.

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

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 both the Network of Excellence and Integrated Projects. The involvement of relevant research groups from developing countries is highly encouraged.

***<u>Topics for first call:</u>***

**LSH-2002-2.3.0-1: Development of an HIV vaccine – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Projects should aim to develop innovative approaches to HIV vaccine which will lead to new promising vaccine candidates. Pre-clinical testing and GMP production associated with the development of vaccine candidates for phase I clinical trials should be an intrinsic part of the projects.

**LSH-2002-2.3.0-2: HIV microbicides – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Projects should address the development of HIV microbicides of wide acceptability in developing countries, of potential rapid application and capacity for empowering women. Systematic studies using a biologically defined approach should be considered. The projects should aim to develop new candidates up to phase I clinical trials.

**LSH-2002-2.3.0-3: Biology and pathology of the malaria parasite – *NETWORK OF EXCELLENCE.*** Projects should promote the understanding of the biology of the

malaria parasite including mechanisms of host-pathogen interaction involved in the pathogenesis and parasite-vector interaction essential for transmission of the parasite. The activities of the projects should be of direct relevance to the search for new effective drugs and vaccines. The projects should address the current fragmentation, ensuring coherent and complementary research strategies and full exploitation of synergies.

**LSH-2002-2.3.0-4: Tuberculosis vaccine development – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.*** Projects should aim to develop new vaccine candidates and advance the existing ones to phase I clinical trials. Focus should be on rational selection and comparative evaluation of candidate antigens and delivery systems. Essential pre-clinical testing and GMP production of vaccine candidates should be an intrinsic part of the project.

**LSH-2002-2.3.0-5: Development of mucosal vaccines for poverty-related diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***. This cross-cutting topic should cover more than one of the three diseases. Projects should aim to clarify the basic principles of mucosal immunity and its exploitation for mucosal vaccine development with the objective of bringing candidate vaccines to phase I clinical trials.

***Indicative topics for future calls:***

**Development of a Malaria Vaccine – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***.

**Antimalarial Drugs – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***.

**Anti-tuberculosis Drugs – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***.

**AIDS Therapy Trials – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***.

**Neonatal vaccination strategies for poverty-related diseases – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE***.

- ***Establishing a clinical trials programme***

The second component of this action line is the implementation of the European and Developing Countries Clinical Trials Partnership (EDCTP)[23]. One of the main goals of the EDCTP is to support phase II and phase III clinical trials of promising candidates in developing countries. While the EDCTP is part of the overall strategy of this action line and is funded under the FP6, activities supported by the EDCTP are not part of the calls foreseen. The EDCTP will have a separate legal entity with its

[23] COM(2002)474: Proposal for the European and Developing Countries Clinical Trials Partnership

own operational procedures, including calls for proposals and appropriate selection and evaluation procedures.

## 1.3 Specific Support Actions across thematic priority 1

In addition to the general SSAs to be supported across the work programme and identified in the individual research areas of the theme, proposals that contribute to the following areas will be considered (Topic ref: LSH-2002-0.0.0-1):

- **Promotion of SME participation**
- **Stimulating international co-operation**[24]
- **Linking with Candidate Countries**
- **Stimulating exploitation:** Promotion and facilitation of assessment, dissemination, transfer, exploitation, and/or broad take-up of research results stemming from past and present EU programmes. These activities must aim over and above the standard diffusion and exploitation activities of individual projects, and may include modelling, experience-sharing or other fact-finding activities at the junction of initiatives of public and private partners involved in biotechnology innovation.
- **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, networking, the debate on human values and technology options, or the collective management of the knowledge infrastructures of the future, etc.
- **EU Strategy for Life Sciences and Biotechnology.** Specific Support Actions will be funded as necessary to implement any of the thirty Actions listed in the Action Plan attached to COM(2002)27.Particular attention will be paid to support those actions relating to the Resource Base: investing in education and training, research, exploitation of Intellectual property, the capital base and networks in Europe; to Governing Life Sciences and Biotechnology: social scrutiny and dialogue, consideration of ethical values and societal goals and to those actions relating to the European response to Global Challenges: international collaborations, poverty related diseases and the developing world.
- **Supporting policy development:** Activities supporting future research policy developments such as prospective and foresight studies, analysis and evaluation of impact of past EU research programmes. Prospective studies on impact of research policy on other policies (i.e. industry, health, trade, etc).and vice versa are also welcomed.

[24] See relevant section in the "Guide for Proposers"

## 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 [*address to be completed*] 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.

There will be one closing date for the first call in 2003 for all proposals submitted to Theme 1.

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. 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.

## INDICATIVE ROAD MAP FOR CALL FOR PROPOSALS AND BUDGET

| | Deadline March 2003 | Deadline November 2003 |
|---|---|---|
| **Area** | **Indicative Budget M €*** | **Indicative Budget M €** |
| **i a) Fundamental knowledge and basic Tools for functional genomics in all Organisms** | **121** | **129** |
| **i b) Application of knowledge and Technologies in the field of genomics And biotechnology for health** | **116** | **168** |
| **ii a) Application-orientated genomics Approaches to medical knowledge and Technologies** | **109** | **118** |
| **b) Combating Cancer **** | **92** | **0** |
| **c) Confronting the major communicable diseases linked to poverty** | **75** | **0** |
| • Developing new promising candidate vaccines, therapies and microbicides | | |
| • *EDCTP* | ***200*** | |
| **Total (M€)** | **713** | **415** |

*** Includes 1.5-2% for Specific Support Actions**

****Other cancer related topics are expected to be supported up to 140 M€ from the total budget, under "Advanced genomics and its application for health"**

## 1.6 CALL INFORMATION

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**: [26]

5. **Date of publication**[27]: 17 December 2002.

6. **Closure date(s)**[28]: 25 March 2003 at 17.00 (Brussels local time).

7. **Total indicative budget: 513 million €, broken down as follows:**

| Instrument[29] | € (millions) |
|---|---|
| IP or NOE | 385 – 410 |
| STREP or CA | 92 – 121 |
| SSA | 8 – 10 |

8. **Areas called and Instruments**:

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

| TopicRef. | Short Titles of Topics | Instrument |
|---|---|---|
| | • ***Gene expression and proteomics*** | |
| LSH-2002-1.1.1-1 | Development of advanced array technologies. | IP or NOE |
| LSH-2002-1.1.1-2 | Development and application of high throughput proteomics technologies for the generation of a large data set of protein-protein interactions. | IP or NOE |
| | • ***Structural genomics*** | |
| LSH-2002-1.1.2-1 | The 3D-structure determination of membrane proteins. | IP or NOE |

[26] The call identifier shall be given in the published version of this call.

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

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

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

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| LSH-2002-1.1.2-2 | Supramolecular analysis by 3D-electron microscopy in situ. | NOE |
| LSH-2002-1.1.2-3 | Development of new hardware and software for the implementation of innovative automated technologies at synchrotron sites. | IP |
| | • ***Comparative genomics and population genetics*** | |
| LSH-2002-1.1.3-1 | Integrated tools for functional genomics of non-mammalian vertebrate models for human development and disease mechanisms. | IP |
| LSH-2002-1.1.3-2 | Development of *in-vivo* imaging technologies for phenotyping and functional analysis in cells and animal models. | IP or NOE |
| | • ***Bioinformatics*** | |
| LSH-2002-1.1.4-1 | Developing methods and resources in bioinformatics to focus the annotation of human and other genomes. | NOE |
| | • ***Multidisciplinary functional genomics approaches to basic biological processes*** | |
| LSH-2002-1.1.5-1 | Integrated comparative and functional genomics approaches studying the cell cycle. | IP or NOE |
| LSH-2002-1.1.5-2 | Functional genomics of non-human embryonic stem cell differentiation. | IP or NOE |
| LSH-2002-1.1.5-3 | Functional genomics of erythroid development and disorders | IP |
| LSH-2002-1.1.5-4 | Multidisciplinary approaches of functional genomics to study lymphangiogenesis | IP or NOE |
| LSH-2002-1.1.5-5 | Epigenetics: chromatin dynamics, non-coding RNA, imprinti and silencing. | NOE |
| LSH-2002-1.1.5-6 | Multidisciplinary approaches of functional genomics to study chronic Inflammation processes in human disease | NOE |
| LSH-2002-1.1.5-7 | Functional genomics approaches to decipher ubiquitin-proteasome and/or related pathways | NOE |
| | • ***Across the area*** | |
| LSH-2002-1.1.0-1 | Research should focus on multidisciplinary functional genomics approaches (gene expression and proteomics, structural genomics, comparative genomics, population genetics and bioiformatics) in all organisms to decipher the basic mechanisms underlying the following processes: transcription activation, signal transduction, intracellular communication, the role of non coding genomic information, mechanisms of integration of genes. | STREP/CA |

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| | Proposals dealing with *in silico* prediction of gene function and for the simulation of complex regulatory networks will also be considered. Proposals concerned with the development of new tools and approaches, including the standardisation of protocols, to facilitate generation of new knowledge in functional genomics are also envisaged. Topics already addressed in the calls for new instruments will not be considered for Specific Targeted Research Project/CA. | |
| LSH-2002-1.1.0-2 | 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 fundamental genomics. The activities should aim at structuring research activities in fundamental genomics in important areas not yet addressed or newly emerging, including technology foresight meetings to identify future opportunities within the field. Furthermore, they should address opportunities for start-up initiatives or strengthen the international dimension in fundamental genomics research, eg. Standardisation, structuring of international genomics initiatives, integration of activities. | SSA |

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

| Topic Ref. | Short Titles of Topics | Instrument |
|---|---|---|
| | • ***Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches*** | |
| LSH-2002-1.2.1-1 | Screening for drug candidates targeting aberrant molecular signalling in protein phosphorylation pathways | IP |
| LSH-2002-1.2.1-2 | Genome-based individualized medicines | NOE |
| LSH-2002-1.2.1-3 | Genome-based therapeutic drugs for psychiatric disorders | IP |
| LSH-2002-1.2.1-4 | Novel antiviral therapeutic molecules targeting virus replication and integration | IP |
| LSH-2002-1.2.1-5 | Generation of blood substitutes for critical blood components, in particular oxygen carriers | STREP |
| LSH-2002-1.2.1-6 | New drugs targeting G-protein coupled receptors through pharmacogenomics | STREP |

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| LSH-2002-1.2.1-7 | Educational schemes utilising interdisciplinary approaches for the integration of pre-clinical and clinical research (e.g. training events, workshops) | SSA |
| | • ***Development of new diagnostics*** | |
| LSH-2002-1.2.2-1 | Non-invasive diagnostics and diagnostic procedures; development of markers for ante- and neo- natal screening | NOE |
| LSH-2002-1.2.2-2 | Development of novel non-invasive and repeatable diagnostics using bioinformatics tools | STREP |
| LSH-2002-1.2.2-3 | New diagnostic tools for prion associated diseases | STREP |
| | • ***Development of new in vitro tests to replace animal experimentation*** | |
| LSH-2002-1.2.3-1 | Combination and application of *in vitro* cell and sensor technologies in the field of animal *in vivo* toxicology | IP |
| LSH-2002-1.2.3-2 | Alternative *in vitro* tests promoting industrial competitiveness in the product screening and development process stages of pharmaceutically- relevant lead compounds | STREP |
| LSH-2002-1.2.3-3 | Technology foresight meeting on test development, validation and implementation | SSA |
| LSH-2002-1.2.3-4 | Workshop on business opportunities in pharmaceutical toxicology | SSA |
| LSH-2002-1.2.3-5 | Partnership event on the development and manufacture of toxicology test methods for regulatory testing needs | SSA |
| LSH-2002-1.2.3-6 | Forum on the achievements in raising awareness on the use of alternative methods in Candidate Countries | SSA |

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| | • ***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-2002-1.2.4-1 | Development and production of cell lines for cell based therapies | IP |
| LSH-2002-1.2.4-2 | Optimised allogeneic stem cell transplantation for haematological and neoplastic diseases | IP |
| LSH-2002-1.2.4-3 | New advances in cell based therapies for the regeneration of connective tissue | IP |
| LSH- | Development of a European databank comprising recent | STREP |

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| 2002-1.2.4-4 | advances in genomics, proteomics and cell biology for immunotherapies | |
| LSH-2002-1.2.4-5 | Stem cell products for myocardial repair | STREP |
| LSH-2002-1.2.4-6 | Development of vaccine technologies targeted to dendritic cells | STREP |
| LSH-2002-1.2.4-7 | Workshop on technology transfer and identification of bottlenecks (i.e. IPR, regulatory issues) for SMEs in the area of somatic gene and cell therapies | SSA |
| | • ***Innovative research in post-genomics, which has high potential for application*** | |
| LSH-2002-1.2.5-1 | Post-genomic approaches for tackling asthma and autoimmune diseases | IP |
| LSH-2002-1.2.5-2 | Plant platforms for immunotherapeutic biomolecule production | IP |
| LSH-2002-1.2.5-3 | Combinatorial biosynthesis as a tool for generating new drug candidates | STREP |
| LSH-2002-1.2.5-4 | Exploiting post genomics to produce optically active therapeutic biomolecules by biocatalysis | STREP |
| LSH-2002-1.2.5-5 | Development of precision technology platforms exploiting advances in post genomics (especially towards involvement of health-related SMEs) | STREP |
| LSH-2002-1.2.5-6 | Workshop for identifying new tools in molecular plant biology for medical applications | SSA |

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

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

| **Topic Ref/** | **Short Titles of Topics** | **Instrument** |
|---|---|---|
| | • ***Combating, cardiovascular disease, diabetes and rare diseases*** | |
| LSH-2002-2.1.1-1 | Molecular pathogenesis of Coronary Artery Disease (CAD) and diagnostic tools for prevention and treatment | IP or NOE |
| LSH-2002-2.1.1-2 | Novel molecular targets for the treatment of obesity in the context of diabetes. | IP or NOE |

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| LSH-2002-2.1.1-3 | The role of pancreatic ion channels in defective insulin secretion in type 2 diabetes | IP |
| LSH-2002-2.1.1-4 | Rare disorders of mitochondria or of nuclear organisation with broader implications for biological processes. | IP or NOE |
| LSH-2002-2.1.1-5 | Genomics of heart muscle development and disease. | NOE |
| LSH-2002-2.1.1-6 | Genomics of vascular disease and atherothrombosis. | NOE |
| LSH-2002-2.1.1-7 | Rare disorders of plasma membrane transporters for amino-acids, lipids and sugars | STREP |
| LSH-2002-2.1.1-8 | Aetiology, pathology and prediction of type 1 diabetes in Europe | CA |
| LSH-2002-2.1.1-9 | Network for early clinical trials in rare diseases | CA |
| LSH-2002-2.1.1-10 | Overcoming the challenges of translational research in cardiovascular disease | SSA |
| LSH-2002-2.1.1-11 | Type II diabetes and obesity | SSA |
| LSH-2002-2.1.1-12 | Coordination of rare disease research in Europe, with various stakeholders from research, SMEs and patient organisations | SSA |
| | • ***Combating resistance to antibiotics and other drugs*** | |
| LSH-2002-2.1.2-1 | Management of respiratory tract infections. | NOE |
| LSH-2002-2.1.2-2 | Testing anti-viral drug resistance and understanding resistance development. | IP or NOE |
| LSH-2002-2.1.2-3 | Broadening the knowledge base on the molecular mechanisms behind resistance | STREP/CA |
| LSH-2002-2.1.2-4 | Workshop on the structuring of European research activities to more effectively combat drug resistant hospital infections | SSA |
| LSH-2002-2.1.2-5 | Workshop on strategies to address antimicrobial resistance through the exploitation of microbial genomics | SSA |
| | • ***Studying the brain and combating diseases of the nervous system*** | |

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| LSH-2002-2.1.3-1 | Genomics and neurobiology of affective disorders | IP or NOE |
| LSH-2002-2.1.3-2 | Eating disorders, from genes to behaviour | IP or NOE |
| LSH-2002-2.1.3-3 | Role and mechanisms of protein aggregation in neurodegenerative diseases | IP |
| LSH-2002-2.1.3-4 | Rare hereditary neurological disorders: ataxias | IP |
| LSH-2002-2.1.3-5 | Molecular and cellular basis of brain development | NOE |
| LSH-2002-2.1.3-6 | Human brain tissue research | NOE |
| LSH-2002-2.1.3-7 | Rare monogenic neurological disorders | STREP/CA |
| LSH-2002-2.1.3-8 | Genetics and neurobiology of pain | STREP/CA |
| LSH-2002-2.1.3-9 | Schizophrenia: from genotype to phenotype | STREP/CA |
| LSH-2002-2.1.3-10 | Specific brain research support actions | SSA |
| | • ***Studying human development and the ageing process*** | |
| LSH-2002-2.1.4-1 | Genetic factors of longevity and healthy ageing | IP or NOE |
| LSH-2002-2.1.4-2 | Molecular and cellular processes underlying the development of mesodermal organ system | NOE |
| LSH-2002-2.1.4-3 | Molecular basis of bone homeostasis | STREP |

**b) Combating Cancer**

| Topic Ref. | Short Titles of Topics | Instrument |
|---|---|---|
| LSH-2002-2.2.0-1 | Translating basic knowledge of functional oncogenomics into cancer diagnoses and treatment. | IP or NOE |

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| LSH-2002-2.2.0-2 | Multidisciplinary research to explore and validate molecular targets for innovative treatment. | IP |
| LSH-2002-2.2.0-3 | Networks for treatment and/or prevention clinical trials aimed at improving clinical practice in the light of new molecular knowledge. | NOE |
| LSH-2002-2.2.0-4 | Innovative research in radiation therapy. | IP or NOE |
| LSH-2002-2.2.0-5 | Molecular imaging for early detection of tumours and monitoring of treatment. | IP or NOE |
| LSH-2002-2.2.0-6 | Networking of quality controlled cancer registries and repositories for molecular epidemiology and quality assessment | NOE |
| LSH-2002-2.2.0-7 | Molecular mechanisms involved in organ-specific metastatic growth processes in breast cancer | STREP/CA |
| LSH-2002-2.2.0-8 | Translational research on promising predictive and prognostic markers | STREP/CA |
| LSH-2002-2.2.0-9 | Molecular mechanisms of cancer-related pain | STREP/CA |
| LSH-2002-2.2.0-10 | Workshop on correlative laboratory studies relevant to therapeutic clinical studies | SSA |

**c) Confronting the major communicable diseases linked to poverty**

| **Topic Ref.** | **Short Titles of Topics** | **Instrument** |
|---|---|---|
| | • ***Developing new promising candidate vaccines, therapies and microbicides*** | |
| LSH-2002-2.3.0-1 | Development of an HIV vaccine. | IP or NOE |
| LSH-2002-2.3.0-2 | HIV microbicides. | IP or NOE |
| LSH-2002-2.3.0-3 | Biology and pathology of the malaria parasite. | NOE |
| LSH-2002-2.3.0-4 | Tuberculosis vaccine development. | IP or NOE |

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| LSH-2002-2.3.0-5 | Development of mucosal vaccines for poverty-related diseases. | IP or NOE |

**SSA across thematic priority 1**

| **Topic Ref.** | **Short Titles of Topics** |
|---|---|
| LSH-2002-0.0.0-1 | Promotion of SME participation |
| | Stimulating international cooperation |
| | Linking with candidate countries |
| | Simulating exploitation |
| | Realising ERA objectives |
| | Contributing to the EU strategy for Life Science and Biotechnology |
| | Supporting policy developments |

**9. Minimum number of participants**[30]:

| Instrument | Minimum number of particpants |
|---|---|
| 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.

[30] 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.

**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: estimated to be available within 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 2003.