

WORK PROGRAMME 2008

COOPERATION

THEME 1

HEALTH

(European Commission C(2007)5765 of 29 November 2007)

Cooperation Work Programme: Health Theme

This work programme replaces the version adopted on 11 June 2007.

The only substantive modifications that have been made to the content are as follows:

p63 – The budget figures for General Activities (EUR 10.80 million) have been added.

Note: This version was adopted at the end 2007, after closure of all calls included in the work programme. Accordingly, as compared to the previous version of June 2007, it does not introduce any change to the research topics, but only clarifies the breakdown of a limited additional budget to be allocated to the general activities in 2008.

Table of Contents

I	Context	5
	I.1 Policy context.....	5
	I.2 Approach	6
	I.3 Other activities	13
II	Content of Calls in 2007.....	15
	1. <u>Biotechnology, generic tools and medical technologies for human health</u>	15
	1.1. High-throughput research.....	15
	1.2. Detection, diagnosis and monitoring	16
	1.3. Predicting suitability, safety and efficacy of therapies	18
	1.4. Innovative therapeutic approaches and interventions	20
	2. <u>Translating research for human health</u>	22
	2.1. Integrating biological data and processes: Large-scale data gathering, systems biology	22
	2.1.1. Large-scale data gathering	22
	2.1.2. Systems biology	25
	2.2. Research on the brain and related diseases, human development and ageing	27
	2.2.1. Brain and brain-related diseases	27
	2.2.2. Human development and ageing	29
	2.3. Translational research in major infectious diseases: To confront major threats to public health.....	30
	2.3.1. Anti-microbial drug resistance including fungal pathogens.....	30
	2.3.2. HIV/AIDS, malaria and tuberculosis.....	32
	2.3.3. Potentially new and re-emerging epidemics.....	36
	2.3.4. Neglected infectious diseases	39
	2.4. Translational research in other major diseases.....	40
	2.4.1. Cancer	40
	2.4.2. Cardiovascular disease.....	43
	2.4.3. Diabetes and obesity	44
	2.4.4. Rare diseases.....	46
	2.4.5. Other chronic diseases	47
	3. <u>Optimising the delivery of health care to European citizens</u>	49
	3.1. Translating the results of clinical research outcome into clinical practice including better use of medicines, and appropriate use of behavioural and organisational interventions and health therapies and technologies.....	49
	3.2. Quality, efficiency and solidarity of health care systems including transitional health systems	51
	3.3. Enhanced health promotion and disease prevention	53
	3.4. Horizontal Coordination and Support actions across "Optimising	

the delivery of health care to European citizens"	55
3.5. Specific international cooperation actions for Health system research.....	56
4. <u>Other actions across the Health Theme</u>	57
4.1. Coordination and support actions across the Theme.....	57
4.2. Responding to EU policy needs	60
5. <u>Calls for tenders</u>	62
III Implementation of calls	65

1. HEALTH

Improving the health of European citizens and increasing the competitiveness and boosting the innovative capacity of European health-related industries and businesses, while addressing global health issues including emerging epidemics. Emphasis will be put on translational research (translation of basic discoveries into clinical applications including scientific validation of experimental results), the development and validation of new therapies, methods for health promotion and prevention including promotion of child health, healthy ageing, diagnostic tools and medical technologies, as well as sustainable and efficient health care systems.

I CONTEXT

1.1 Policy context

The aim of this Theme is to advance our understanding on how to more efficiently promote good health, to prevent and treat major diseases and to deliver health care by supporting world-class collaborative research with specific attention to translational research.

This Theme will stimulate and sustain multidisciplinary basic biomedical research where large scale collaboration at the EU level is essential to exploit the full potential of post-genomic information to underpin applications to human health. The large scale and objectives of such initiatives cannot be supported via the European Research Council grants.

In line with the European strategy on life sciences and biotechnology¹ and the Lisbon objectives, this Theme will help increase the competitiveness of European health care biotechnology and medical technology sectors where research intensive small and medium-sized enterprises (SMEs) are the main economic drivers and pharmaceutical industries. Furthermore, it is envisaged to support a Joint Technology Initiative for Innovative Medicines, aiming to overcome the research bottlenecks in the drug development process, in line with the recommendations made to improve the competitiveness of the European-based pharmaceutical industry².

This Theme will also contribute to the development of norms and standards for advanced therapies which are required for implementation of the new regulatory framework foreseen³. This Theme will also contribute to the development of alternatives to animal testing in biomedical research in line with the "The Three Rs" principle⁴.

¹ http://ec.europa.eu/biotechnology/index_en.htm

² G10 Medicines Report published on 7 May 2002. <http://ec.europa.eu/enterprise/phabiocom/p9.htm>

³ Commission proposal for a Regulation on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. COM(2005) 567 final of 16.11.2005.

⁴ Refining, Reducing and Replacing animal use. This activity contributes directly to the aims of the Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

This Theme will contribute to international efforts addressing global health problems, such as anti-microbial resistance⁵, HIV/AIDS, malaria, tuberculosis and emerging pandemics. In particular it supports the European and Developing Countries Clinical Trials Partnership (EDCTP) programme which focuses on advanced-clinical testing for the development of new vaccines, microbicides and drugs against HIV/AIDS, malaria and tuberculosis in sub-Saharan Africa. In addition, Specific International Cooperation Actions (SICA) will be implemented in the areas identified through bi-regional dialogues with third countries/regions on the basis of mutual interest and mutual benefit and some of the actions will contribute to the UN Millennium Development Goals.

This Theme will contribute to research into rare diseases in line with the Regulation on orphan medical products⁶ as well as to research in paediatric medicines in line with the proposed Regulation on medicinal products for paediatric use⁷. It will also interact with the European Centre for Disease Prevention and Control to help strengthen Europe's defences against infectious diseases.

The activity "*Optimising the Delivery of Health Care to European Citizens*" aims to ensure that the results of health research will ultimately reach European citizens. It will reinforce health policy-driven research at the European level and in particular through benchmarking, comparisons and analysis of models, systems and data of national databases, will generate new knowledge to underpin informed policy decisions on the efficiency and responsiveness of health care systems in Europe, and more effective strategies in health promotion, disease prevention, diagnosis and therapy. Furthermore, it will provide the scientific evidence needed to support the objectives of the proposed new Programme of Community Action in the field of Health (2007-2013)⁸. Research into the independence, life quality and mobility of the ageing population will be covered.

1.2 Approach

This work programme describes the research topics in which project proposals can be submitted in response to the first two calls for proposals with deadlines in 2007. The first call (deadline in April) will commit the 2007 budget. The second call (deadline in September) is still provisional because it will require approval of the 2008 budget.

Note: This version was adopted at the end 2007, after closure of all calls included in the work programme. Accordingly, as compared to the previous version of June 2007, it does not introduce any change to the research topics, but only clarifies the breakdown of a limited additional budget to be allocated to the general activities in 2008.

This work programme aims to ensure continuity with the previous programme and to start new activities, within the budgetary constraints, in particular during the first three years of the programme. The content of the research topics selected reflects the input received from different sources, such as the Advisory Group for the Health Theme, the Programme Committee and various scientific conferences and workshops in the sector. In addition, the work programme also takes into account the activities launched in FP6.

⁵ Support the "Community Strategy against Antimicrobial Resistance"

⁶ EC Regulation 141/2000

⁷ Commission Proposal COM(2005) 577

⁸ Commission Proposal COM(2006) 234

Aside from the area of alternatives to animal testing, which support important Community policy needs, the priority dedicated to *"Predicting suitability, safety and efficacy of therapies"* will be implemented entirely through the Joint Technology Initiative for Innovative Medicines. The Commission proposal to establish this Joint Technology Initiative was presented to the Council in May 2007⁹. Pending a favourable decision by the Council, its operation is foreseen to be set up in 2008. This activity will be implemented by a separate mechanism and the details of topics will not be elaborated in this work programme.

In the priority *"Innovative therapeutic approaches and interventions"*, research topics referring to related technologies, such as advanced targeted delivery systems, advanced implants and prosthetics, and non- or minimally-invasive technology-assisted interventions, which are new compared to the previous programme will be addressed in later work programmes.

Coordination of national and regional research programmes in the current work programme will be supported through one strategically important specific topic on cancer¹⁰ which will be subject to a joint call for ERA-NETs across the Themes as described in Annex 4. Potential funding for the continuation or widening of current ERA-NET activities¹¹ (ERA-NET plus) will be addressed in later work programmes, and following a thorough analysis of on-going projects and experiences with joint calls.

Cross-thematic approaches

Synergy and complementarity are ensured with the other Themes, which also deal with the health sector. In particular with:

- Theme 2 "Food Agriculture and Fisheries and Biotechnology", as regards system biology/bioinformatics, factors impacting health in relation to especially zoonoses, allergies and obesity. In this work programme complementary actions to Theme 2 are proposed on obesity (3 topics) and allergies (one topic on Immunotherapy of human food allergies) as well as five initiatives of common interest: one on zoonoses and four on generic topics on tools for system biology including bioinformatics.
- Theme 3 "Information and Communication Technologies" as regards medical information technologies and activities related to ageing, patient safety and virtual physiological human. In this work programme complementary actions to Theme 3 are proposed in the sector of medical imaging (6 topics), ageing (8 topics), patient safety (4 topics) as well as 8 topics in "Optimising the delivery of health care to European citizen" under areas 3.1 and 3.2. For those areas Theme 3 is expected to develop the IT-tools whilst Theme 1 will focus on their use and validation.

⁹ Commission Proposal COM(2007) 241

¹⁰ HEALTH-2007-2.4.1-13

¹¹ There are 10 ongoing ERA-NETs which relate to the Health Theme. In particular they target ageing (ERA-AGE), health emergency (HESCUAEP), organ donation and transplantation (ALLIANCE-O), genomics of human pathogenic microorganisms (PathoGenoMics), system biology and genomics (ERA-SysBio), guidelines on cancer best clinical practice (CoCanCPG), medicines for children (PRIOMEDCHILD), rare disease (E-RARE), neurosciences (NEURON) and new and emerging risks in occupational safety and health (NEW OSH ERA).

- Theme 4 "Nanosciences, Nanotechnologies, Materials and new Production Technologies" as regards biomaterials for health applications (e.g. tissue engineering), nanomedicine including nano-toxicology. In this work programme three initiatives of common interest are proposed in the sectors related to the development of novel targeted imaging probes, the assessment of the toxicological profile of nanoparticles used in diagnostics and improving targeted drug delivery to cancer cells.
- Theme 6 "Environment" and in particular as regards the sector of Environment and Health including alternative to animal testing. In this work programme one complementary action to Theme 6 is proposed in the field of Environment and health as regards cancer as well as one initiative of common interest on alternative to animal testing (as regards quantitative structure-activity relationship).

Synergy and complementarity will also be ensured with the infrastructures under the Capacities programme, which are of strategic importance for the development of this Theme. In particular, this work programme takes into account the 2007 priority list established for the health topics by the European Strategy Forum for research Infrastructure for new infrastructures as well as for the support to existing research infrastructures planned in a targeted call.

Funding schemes and limitation of page numbers of applications submitted to calls opened in this work programme

The work programme will be implemented through a range of funding schemes as specified in the description of each topic. The following funding thresholds will apply to different types of projects: For Small or medium-scale focused research projects requested EC contribution shall not exceed EUR3 000 000 unless otherwise indicated in the topic description and for Large-scale integrating projects the requested EC contribution shall be over EUR 6 000 000 and not exceed EUR 12 000 000 unless otherwise indicated in the topic description. **It is important to note that the above mentioned funding thresholds will be applied as eligibility criteria and that the proposals which do not respect these limits will be considered as ineligible.** The forms of the grants to be used for the funding schemes under this Theme are given in Annex 3. In addition, some activities may be taken forward through public procurement procedures (calls for tenders). These will help the Commission prepare new initiatives in a targeted manner that will complement the more bottom-up approach offered by call for proposals. Calls for tender are clearly distinguished from calls for proposals in the work programme.

For all calls of this work programme, there will be competition within and between topics on the basis of the quality of the proposals. This means that in some topics more than one proposal may be funded and in other topics no proposal may be funded.

All applications submitted to topics published in this work programme are subject to the page number restrictions stipulated in the guides for applicants for the various funding schemes. These limits will be strictly applied in the Health theme. Pages exceeding these limits will be disregarded for evaluation. Furthermore, texts presented in a size below the minimum of font 11 may also be disregarded for evaluation. No annexes to the presented material are allowed and under no circumstance will such material be considered in the evaluation.

Overarching issues of strategic importance

Child health

Support will be given in particular to specific clinical studies to provide evidence for the appropriate use of off-patent products currently used off-label in paediatric populations¹². In addition, specific topics¹³ will address the following research issues related to child health and paediatric diseases: Innovative approaches for the development of vaccines for young children, Childhood and adolescent mental disorders, Paediatric formulations of drugs against HIV/AIDS, malaria and tuberculosis, Combined forms of diabetes in children, Promoting healthy behaviour in children and adolescents, Addressing knowledge gaps in pregnancy malaria, and Health care intervention research – improving pre-natal and maternal care. Implications for child health and paediatric diseases should be taken into account whenever appropriate in all research projects in this Theme.

Health of the ageing population

A special emphasis will be made also on research on the health of the ageing population. The following research issues will be addressed by specific topics¹⁴, in particular: Novel approaches to reconstitute normal immune function at old age, Biomarkers of ageing, Increasing the participation of elderly in clinical trials, Understanding and combating age-related muscle weakness, Impairment of touch and proprioception at old age, Translational research aiming for a treatment of urinary incontinence, Health systems and long term care of the elderly, and Health outcome measures and ageing population. A specific topic for the development a road-map for ageing research is also included¹⁵. Whenever appropriate, the projects funded under this Theme should take into consideration the research aspects related to prevention, diagnostics and treatment of age-related diseases and the impact on quality of life of older people.

Gender aspects in research

The pursuit of scientific knowledge and its technical application towards society requires the talent, perspectives and insight that can only be assured by increasing diversity in the research workforce. Therefore, a balanced representation of women and men at all levels in research projects is encouraged.

Gender aspects in research have a particular relevance to this Theme as risk factors, biological mechanisms, causes, clinical manifestation, consequences and treatment of disease and disorders often differ between men and women. The possibility of gender/sex differences must therefore be considered in all areas of health research where appropriate.

¹² HEALTH-2007-4.2-1

¹³ HEALTH-2007-1.4-2, HEALTH-2007-2.2.1-10, HEALTH-2007-2.3.2-5, HEALTH-2007-2.4.3-2, HEALTH-2007-3.3-1, HEALTH-2007-2.3.2-4, HEALTH-2007-3.5-4

¹⁴ HEALTH-2007-2.2.2-1, HEALTH-2007-2.2.2-3, HEALTH-2007-2.2.2-4, HEALTH-2007-2.4.5-10, HEALTH-2007-2.4.5-8, HEALTH-2007-2.4.5-11, HEALTH-2007-3.2-2, HEALTH-2007-3.2-6

¹⁵ HEALTH-2007-3.4-5

SME relevant research

This Theme emphasises the importance of innovation and the integration of SMEs¹⁶ in health research projects in order to reach the Lisbon goal by ensuring that new knowledge is disseminated and translated into new therapies and clinical practice. The priority of this Theme is on the inclusion of 'high-tech' SMEs in projects throughout the Theme. However, SMEs providing a service, e.g. management or intellectual property expertise, are also eligible to participate.

SME efforts towards research and innovation are particularly encouraged in certain specific topics for Collaborative Projects (Small or medium-scale focused research projects) targeted to SMEs which are highlighted in the work programme¹⁷. The expected results of these projects should clearly be of interest and potential benefit to SME(s) and the consortia should have at least 40% of the requested EC contribution budget going to SMEs¹⁸.

International Cooperation

International cooperation is an integral part of the Theme and project consortia in all areas are encouraged to include organisations from third countries¹⁹, especially from the International Cooperation Partner Countries (ICPC) (Annex 1) and from countries with Scientific and Technological cooperation agreements²⁰ with the EU according to the participation rules. Funding will be provided to participants from the ICPCs, whereas funding for organisations from industrialised third countries may be provided on a case by case basis if considered essential for carrying out the project.

More specifically, international cooperation will be implemented via two mechanisms:

1. Opening of all activities of the Theme to international cooperation. Third country participation is particularly emphasised (enhanced international participation) in the areas addressing global health problems: Anti-microbial drug resistance, HIV/AIDS, malaria and tuberculosis, and emerging epidemics, as well as in certain individual topics in the other areas of the Theme, as indicated in the text.
2. Specific International Cooperation Actions (SICA) which aim to generate, share and use knowledge through research partnerships with third countries in the areas identified through bi-regional dialogues with third countries/regions and international fora, on the basis of mutual interest and mutual benefit. Research areas may include: health policy research, health systems and health care service research, neglected infectious diseases and emerging unforeseen policy needs in those regions, as well as other topics of strategic importance. **It is important to notice that Collaborative projects dedicated to SICA must involve at least two participants from two**

¹⁶ Commission Recommendation 2003/361/EC will apply to the definition of SMEs. Available at http://europa.eu.int/comm/enterprise/enterprise_policy/sme_definition/index_en.htm

¹⁷ HEALTH-2007-1.1-4, HEALTH-2007-2.3.3-4 and HEALTH-2007-2.4.3-6

¹⁸ Not necessarily co-ordinated by the participating SME(s)

¹⁹ Countries that are not EU Member States, Candidate or Associated Countries

²⁰ Countries with signed S&T agreements: Argentina, Australia, Brazil, Canada, China, Chile, Egypt, India, Mexico, Morocco, Russia, South Africa, Tunisia, Ukraine and United States

different Member States or Associated countries and at least two partners from two different ICPCs²¹.

List of Specific International Cooperation Actions (SICA):

1st Call:

Topics	Targeted Country/Region
HEALTH-2007-2.3.3-8: Influenza research in collaboration with Asian partners (Small or medium-scale focused research projects).	Asia

2nd Call:

Topics	Targeted Country/Region
HEALTH-2007-2.1.2-7: Traditional Chinese Medicine in post-genomic era. (Coordination or Support Action).	China
HEALTH-2007-2.2.1-10: Childhood and adolescent mental disorders (Small or medium-scale focused research projects).	EECA ²² and Western Balkans
HEALTH-2007-2.3.2-12: Highly innovative research in HIV/AIDS, malaria and tuberculosis between Indian and European partners (Small or medium-scale focused research projects).	India
HEALTH-2007-2.3.2-13: Coordination of European research activities with global initiatives, including Public-Private Partnerships (Coordination or Support Action).	ICPC
HEALTH-2007-2.3.2-14: Next generation of researchers for HIV/AIDS, malaria, tuberculosis and neglected infectious diseases (Coordination or Support Action).	ICPC
HEALTH-2007-2.4.1-14: Studying cancer aetiology in Latin America (Small or medium-scale focused research projects).	Latin America
HEALTH-2007-2.3.4-1: Development of new tools to control infections due to parasites of the Trypanosomatidae family (Small or medium-scale focused research projects).	ICPC
HEALTH-2007-2.3.4-2: Development of a Leishmania vaccine (Small or medium-scale focused research projects).	ICPC
HEALTH-2007-2.3.4-3: Bioprospecting for drug leads (Small or medium-scale focused research projects).	ICPC
HEALTH-2007-3.5-1: Epidemiological investigations into long-term trends of population health as consequence of socio-economic transitions, including life-style induced health problems (Small or medium-scale focused research projects).	MPC ²³ , Russia and EECA
HEALTH-2007-3.5-2: Universal and equitable access to health care	MPC, ACP ²⁴ ,

²¹ With the exception of Brazil, China, India and Russia, for which the required two or more ICPC participants can be located in the same countries. However, in this case, at least two different participants must come from two different provinces, oblasts, republics or states within Brazil, China, India or Russia.

²² Eastern Europe and Central Asia

²³ Mediterranean Partner Countries

and health financing (Small or medium-scale focused research projects).	Asia and Latin America
HEALTH-2007-3.5-3: Health care intervention research – optimising hospital care (Small or medium-scale focused research projects).	Western Balkans
HEALTH-2007-3.5-4: Health care intervention research – improving pre-natal and maternal care (Small or medium-scale focused research projects).	ACP and MPC
HEALTH-2007-4.1-8: Promotion and facilitation of international cooperation in areas relevant to the objectives of this Theme (Coordination or Support Action).	ICPC

Dissemination actions

Special attention will be given to communicating research outcomes and engaging in dialogue with civil society, in particular with patient groups, at the earliest possible stage, of new developments arising from biomedical and genetics research. A wide dissemination and use of the results will be supported through the integration of dissemination and knowledge transfer actions within projects, specific dissemination actions which will take a proactive approach to disseminating results from across a range of projects and, initiatives to foster dialogue and debate on scientific issues and research results with a broader public beyond the research community²⁵. Open access to publications of research results is strongly encouraged. The activities undertaken in this Theme are also expected to contribute towards the education and training of research students.

Clinical research and clinical trials

As translation of basic discoveries into clinical applications is one of the main objectives of this theme, clinical research is expected to be a major tool used in the funded projects. This clinical research may include clinical trials. Community contribution will, however, only be available for Phase I and II clinical trials. In the topic HEALTH-2007-4.2-1 "Adapting off-patent medicines to the specific needs of paediatric populations", consideration may be given to studies up to and including Phase IV. Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women, men, children and the elderly. 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.

²⁴ African, Caribbean and Pacific Countries

²⁵ See Coordination and Support Actions across the Theme

Integration of ethical, social, legal and wider cultural aspects

Ethics has a special relevance in this Theme as it implies research involving human beings (clinical trials in adults and children), use of human embryonic stem cells²⁶, use of biological materials of human origin and research with animals. All applicants will be requested to address the potential ethical aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results. This should justify the research design, explain how ethical requirements will be fulfilled and indicate the relevant national laws and/or regulations of the country(ies) where the research will take place.

Experts in ethics, law and social sciences are encouraged to participate actively in research projects whenever appropriate. 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.

1.3 Other activities

Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSP)²⁷ will be made jointly with the "Information and Communication Technologies" theme. This will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research. Out of the total Community subscription of EUR 3.9 million for 2007, EUR 2.4 million will be paid from this Theme, and the remainder from the ICT Theme. The same level of subscription is foreseen for 2008.

National Contact Points (NCP) for FP7 Health Theme

The network of National Contact Points is seen as instrumental to facilitate access to FP7 calls, lowering barriers to entry for newcomers and raising the quality of submitted proposals. Coordination and support actions across the Theme include a topic for supporting trans-national cooperation of the NCP network.

Risk-Sharing Finance Facility

In addition to direct financial support to participants in RTD actions, the Community will improve their access to private sector finance by contributing financially to the 'Risk-Sharing Finance Facility' (RSFF) established by the European Investment Bank (EIB).

²⁶ The Commission will maintain the practice of the Sixth Framework Programme, which excludes from Community financial support, research activities destroying human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells.

²⁷ The European Community is a member of the HFSP Organisation (HFSP) and has funded HFSP under previous Framework Programmes.

The Community contribution to RSFF will be used, by the Bank, in accordance with eligibility criteria set out in the Work Programme 'Co-operation' (Annex 4). RSFF support is not conditional on promoters securing grants resulting from calls for proposals described herein, although the combination of grants and RSFF-supported financing from EIB is possible.

In accordance with the Specific Programme 'Cooperation', which stipulates that the Community contribution to RSFF will be funded by proportional contributions of all Themes, except Socio-economic Sciences and the Humanities, the Commitment Appropriations for this Theme to RSFF in 2007 will be EUR 31.94 million. This amount will be committed entirely in 2007, and will cover the 2007-2008 period. Further information on the RSFF is given in Annex 4 of this work programme.

II CONTENT OF CALLS IN 2007

1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH

This activity aims at developing and validating the necessary tools and technologies that will make possible the production of new knowledge and its translation into practical applications in the area of health and medicine.

1.1. HIGH-THROUGHPUT RESEARCH

The objective is to catalyse progress in developing new research tools for modern biology including fundamental genomics that will enhance significantly data generation and improve data and specimen (biobanks) standardisation, acquisition and analysis. The focus will be on new technologies for: sequencing; gene expression, genotyping and phenotyping; structural and functional genomics; bioinformatics and systems biology; other “omics”.

Expected impact: The development of groundbreaking technologies will support the competitiveness of Europe in the areas of genomics and proteomics, and their applications are expected to have a great impact in medicine and in the biotechnology industry (namely SME's). Proteomics techniques will help overcome bottlenecks in the investigation of protein functions in cells leading to a better understanding of biological processes in health and disease, and fostering European research excellence. New sequencing techniques should greatly reduce the cost of sequencing and genotyping and lead to wider applicability, e.g. in the clinic. An integrated genetic variation catalogue would be an immense boon to bioresearch, in areas such as: general understanding of human physiological processes in both health and disease; the ability to better analyse population genetic studies; the diagnosis and treatment of disease. An important goal is to achieve effective linkage between datasets in different areas (such as general genetic variation, cancer, cardiovascular disease, published studies, specific populations and pharmacogenomics) thereby enabling scientific results to be integrated across the entire corpus.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-1.1-1: Unifying human and model organism genetic variation databases.** The focus should be on developing a data and analysis structure by creating a hierarchy of bioinformatics grid-linked databases, tools and standards, centred on a generalised existing or novel genome browser. This major European initiative should integrate and link databases that contain genotype to phenotype relationships with the aim of creating a large integrated genetic variation catalogue. This should facilitate functional genomics research for human health and where relevant should take into account international perspectives in the field. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-1.1-2: Temporal and spatial proteomics to study biological processes relevant to human health.** The project should address defined important biological questions by gathering information (structural and kinetics) on networks of cellular proteins. The project should integrate the excellence in

Europe into a major multidisciplinary and collaborative effort aiming at developing innovative solutions to methodological bottlenecks. The data obtained will provide the basis for modelling the biological process involved. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-1.1-3: Groundbreaking techniques for DNA sequencing and genotyping.** The aim is to develop new tools for sequence decoding and genotyping that would allow for much wider use of these technologies. This ambitious project should integrate the critical mass of multidisciplinary expertise, including chemistry and engineering, needed to develop and validate these new techniques. The project should utilise the dynamics and specificity of biological molecules. The tools developed should increase the sensitivity, rapidity and efficiency of existing tools or even replace them with new concepts. The project should facilitate the development of an apparatus or bundling of technologies that would allow for routine use outside the laboratory and include validation of results. **Funding scheme:** Collaborative project (Large-scale integrating project).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-1.1-4: SME-driven collaborative research projects for developing tools and technologies for high-throughput research.** The focus should be on developing and improving tools and technologies for: cell based assays, sequencing; gene expression, proteomics, genotyping and phenotyping; structural genomics; bioinformatics and systems biology; metabolomics, other “omics”. These SME-driven projects should be specifically designed to encourage industry, preferably SME efforts towards research and innovation. The expected project results should clearly be of interest and potential benefit to SME(s). All consortia should have at least 40 % of the requested EC contribution budget going to SMEs. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects targeted to SMEs).

1.2. DETECTION, DIAGNOSIS AND MONITORING

The objectives are to develop visualisation, imaging, detection and analytical tools and technologies for biomedical research, for prediction, diagnosis, monitoring and prognosis of diseases, and for support and guidance of therapeutic interventions. The focus will be on a multidisciplinary approach integrating areas such as: molecular and cellular biology, physiology, genetics, physics, chemistry, biomedical engineering, nanotechnologies, microsystems, devices and information technologies. Non- or minimally- invasive and quantitative methods and quality assurance aspects will be emphasised.

Expected impact: Developments should particularly have an impact on non-invasive prediction, diagnosis, monitoring and prognosis of diseases. Projects should develop the necessary principles up to the demonstration of proof of principle of specific methodology. If appropriate they should also help evaluate therapies, develop new ones (such as new medicines, and gene and cell therapies) and support, plan and guide therapeutic interventions. All applications should be of benefit to patients and many should involve European industry, in particular SMEs.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-1.2-1: Development of a hybrid imaging system.** The aim is to develop a novel hybrid imaging system combining two or more different biomedical imaging modalities into a single system for concurrent measurement with the different modalities. Examples could be PET/MRI, MRI/Ultrasound, Ultrasound/Optical. The system should advance multi-modality imaging or enable new types of therapeutic intervention, and should be tested in preclinical studies with a view towards translational medicine. Special emphasis will be given on quantitative technologies. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **HEALTH-2007-1.2-2: Novel optical methodologies for detection, diagnosis and monitoring of disease or disease-related processes.** The aim is to develop novel methodologies that make use of light to aid in detection, diagnosis and/or monitoring of disease or disease-related processes. The methodology should provide *in vivo* functional information (e.g. blood flow, oxygenation, metabolism) or quantitative analysis of disease progression. It should make use of new and/or advanced approaches in optics (such as coherence, polarisation, tomography, non-linear processes or photon statistics) in order to improve the sensitivity, resolution and quantitation of optical imaging methods. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of € EUR 6 000 000/project).
- **HEALTH-2007-1.2-3: Novel targeted imaging probes for early *in vivo* diagnosis and/or evaluation of response to therapy** (in coordination with NMP-2007-4.0-4 in Theme 4). The aim is to develop highly sensitive agent(s) for established *in vivo* imaging modalities able to report and quantify cellular and/or molecular events in several major disease states or disease processes. The proposed procedure should be preclinically tested, including assessment of biodistribution. Potential toxicity and biocompatibility aspects should be considered in the early stage of agent design, in view of potential clinical translation. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-1.2-4: *In vivo* image-guidance for cell therapy.** The aim is to develop and validate imaging tools for novel cell therapies (e.g. immune cells or stem cells) allowing tracking of cells and assessment of cell fate (e.g. viability, differentiation, migration) and therapeutic effects, that could be tested in animal models with a view towards translational medicine. The developed tools should provide specific and quantifiable information with respect, for example, to cell homing, functional read-outs, tracking of differentiation or immune system response. **Funding scheme:** Collaborative project (Large-scale integrating project).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-1.2-5: Standardisation and improvement of pre-analytical procedures for *in vitro* diagnostics.** Provide pan-European quality assurance schemes and guidelines for pre-analytical procedures such as sample collection,

handling, transportation, processing and storing of clinical samples. Tissue samples, blood samples and perhaps other specimens should be considered. The project should focus both on the standardisation of existing pre-analytical procedures and on the identification of critical steps in the pre-analytical procedure which need further development and improvement. It should also include training aspects. Involvement of industry is highly recommended. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-1.2-6: High throughput molecular diagnostics in individual patients for genetic diseases with heterogeneous clinical presentation.** The project should lead to the development of new diagnostic tools exploiting the knowledge of the human genome in combination with advanced read-out technology. Deliverables must be the development of a high throughput, sensitive, reliable and especially cost effective diagnostic test per disease category, which displays clear advantages over currently available diagnostic strategies. Special attention should be given to disease categories with heterogeneous clinical presentation, and/or locus heterogeneity, such as primary immuno-deficiencies, muscle disorders, growth deficiencies, hearing or vision impairments and hemoglobinopathies. The project must address quality assurance issues and validation aspects, and should offer opportunities for industrial exploitation, preferably through SMEs. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

1.3. PREDICTING SUITABILITY, SAFETY AND EFFICACY OF THERAPIES

The objectives are to develop and validate the parameters, tools, methods and standards needed for bringing to the patient safe and effective new or improved biomedicines. The focus will be on approaches such as pharmacogenomics, developing and validating biological markers, targeting and delivery approaches, *in silico*, *in vitro* (including alternatives to animal testing) and *in vivo* methods and models.

For conventional medicines these issues (with exception to the topics referring to Alternative testing strategies) are expected to be covered by the Joint Technology Initiative for Innovative Medicines²⁸.

Alternative testing strategies

Expected impact: Joint European research in this area is expected to mobilise and integrate research excellence necessary for the promotion of new strategies for alternative testing. The research should progress towards alternative methods in order to reduce, refine or replace substantially the number of tests and laboratory animals involved in pharmaceutical discovery and development. Obtained results should establish a basis for international validation.

²⁸ EC contribution is envisaged for the Joint Technology Initiative for Innovative Medicines from the 2008 budget. This is subject of the Council decision for the setting up of the Innovative Medicines Initiative Joint Undertaking.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-1.3-1: Novel alternative testing strategies for use in pharmaceutical discovery and development.** Alternatives to determine the toxicology profiles of compounds in the late-discovery phase and in the early development phase. The aim is to develop new alternative testing strategies for more effective and faster development of pharmaceuticals that substantially decrease laboratory animal use. The following topics will be considered: reproductive toxicology, CNS toxicity, toxicogenomics, toxicokinetics, physiology based kinetic, high-throughput testing, cocktail effects and modelling. Regulators and other stakeholders should be involved at an early stage of the project. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-1.3-2: Bottlenecks in reduction, refinement and replacement of animal testing in pharmaceutical discovery and development.** Organisation of three workshops in order to determine the state of the art of each of the three R approaches in the EU27. The goal is the assessment of European strength and gaps in the 3R approach and the identification of rate limiting steps on the political, scientific, technological level. The results of the workshops should be summarised in consensus papers with suggestions for a roadmap. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-1.3-3: Promotion, development, validation, acceptance and implementation of QSARs (quantitative structure-activity relationship) for toxicology.** To develop tools to explore the full range of toxicological and phenotypic responses of biological systems to chemicals, in order to create a robust basis for predictive capabilities. The objective will be to deliver platform technologies for applications in health and other sectors. The work will involve the coordination of and provision of input to, activities involving partners at the EU and OECD levels. This action is launched in cooperation with the Environment theme in a joint effort on Replacement, Reduction and Refinement of Animal Testing. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-1.3-4: Alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics.** (in coordination with NMP-2007-1.3-2 and NMP-2007-4.0-4 in Theme 4). The aim of this topic is the development of alternative testing strategies in order to assess potential toxic effects of nanoparticles used in *in vivo* diagnostics. Research should focus on mechanistically-based *in vitro* models relevant to health risk assessment. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-1.3-5: *In silico* modelling for ADMET outcomes.** The purpose of this topic is to develop and validate, in comparison to existing methodologies, *in silico* simulation models for pharmaceutical compounds so as to predict ADMET outcomes, including rate and extent of absorption, bioavailability, blood-brain barrier penetration, volume of distribution, renal/hepatic clearance and half-life and toxicity profiling. Physiological based models need to be developed to model new ADMET endpoints. SME involvement is essential. **Funding scheme:** Collaborative project (Large-scale integrating project).

1.4. INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS

The objectives are to research, consolidate and ensure further developments in advanced therapies and technologies with broad potential application. The focus will be on gene and cell therapy, regenerative medicine, transplantation, immunotherapy and vaccines.

Expected impact: The main impact of this work will be developing European capability in therapy of diseases which are currently untreatable, where life is at stake, and in developing regenerative medicine where new tissues or organs are grown to replace diseased, damaged or defective ones. Since the three main areas of immunotherapy, gene therapy and regenerative medicine are interrelated and use a common set of research tools and technologies, broad-based projects are expected to generate synergies and lead to therapeutic applications in many different situations. Projects are expected to demonstrate proof of principle, carry out early clinical trials or pave the way towards therapeutic products according to the stage of development of the particular area. There will be interplay between clinical investigation and understanding of underlying processes. Work will boost the European biotechnology industry, especially the SME sector, and contribute to developing standards and regulations in the area.

Topics for first call, deadline 19 April 2007:

Immunotherapy

- **HEALTH-2007-1.4-1: Development and production of new generation antibodies.** Projects should aim at developing new, efficient and safe preventive strategies and/or therapies by combining high specificity and effector function with stable production, pre-clinical studies, scale-up and GMP. Projects should combine academic, clinical and industrial expertise and implement a translational approach towards clinical trials. SME participation is strongly encouraged. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **HEALTH-2007-1.4-2: Innovative approaches for the development of vaccines for young children.** Projects should exploit new knowledge in vaccinology and innate immunity with the ultimate goal of developing vaccines for infants and toddlers (0-2 years) which meet the challenge of protective efficacy and provide strong and sustained immune response. Research should include screening, selection and validation of promising tools, such as novel delivery systems, immunomodulators, adjuvants, immunization schedules and/or prime-boost immunisation strategies, together with *in vitro* and *in vivo* proof-of-principle, safety and scale-up studies. Projects should take a translational approach and aim towards clinical trials. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **HEALTH-2007-1.4-3: Immunotherapy of human food allergies.** The aim should be to exploit established and emerging immunotherapy trends, such as recombinant antigen production, antigen-specific T regulatory cells, DNA-based immunotherapies, etc, to develop novel, safe and efficient therapeutic strategies to treat human food allergies and hypersensitivities. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Topics for second call, deadline 18 September 2007:

Gene therapy

- **HEALTH-2007-1.4-4: Development of emerging gene therapy tools and technologies for clinical application.** This project should aim to exploit emerging gene therapy tools and technologies, such as use of genome editing and repair (RNAi, site specific recombination, etc.) to correct genetic defects, or new gene transfer techniques (novel virus vectors, targeted nanoparticles, bacterial DNA-based vector, bactofection, etc.), which overcome the limitations of existing tools and for which preclinical proof of concept has already been established. The project should address biological activity, pharmacokinetics and toxicology of the gene therapy vector, establish biomarkers and assays for the evaluation of clinical trials, and take a translational approach towards early clinical research for therapeutic intervention. It should mobilise industrial and academic partners and address ethical and regulatory issues. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-1.4-5: Gene therapy tools targeting the central nervous system.** Projects should aim to meet specific challenges posed by the central nervous system for gene therapy. Research should focus on developing and validating new gene therapy tools inducing long-lived, safe, cell-type specific and regulated transgene expression in the central nervous system for application in therapy of neurological disorders. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Regenerative medicine

- **HEALTH-2007-1.4-6: Stem cell lines for cell-based therapies.** The aim would be to take recent advances in stem cell therapy research forward towards the clinic and improve understanding of the biological processes involved. Projects should adopt a comparative approach to evaluating cell sources (embryonic, tissue, etc) in order to identify and validate the best source for specific and safe applications. Means should be developed for controlling cell proliferation and differentiation, and optimising cell survival and function after transplantation. Toxicity or other adverse effects of transplantation should be identified and overcome. Clinical application needs to be established from the outset; testing in appropriate *in vivo* disease models, addressing regulatory requirements and, where appropriate, clinical trials, should be included. Industry, particularly SMEs, should play a significant part, and the project must address relevant ethical and societal issues. **Funding scheme:** Collaborative projects (One or more Large-scale integrating projects).

- **HEALTH-2007-1.4-7: Development of stem cell culture conditions.** Projects should support progress in stem cell therapy through the development of common tools and standards for culturing stem cells, such as serum-free media, supporting biomaterials, cell amplification and differentiation techniques, surface markers for recognition, protocols for screening, separation and banking. GMP standards should be a particular goal. A range of stem cell types and clinical applications should be addressed full advantage should be taken from examining existing approaches and identifying best practice. Clinicians, industry (especially SMEs)

and regulatory bodies should be involved as appropriate. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-1.4-8: Stem cells for kidney regeneration.** Research should focus on identification and expansion of stem cells that could be used in stem cell therapy and tissue engineering approaches for recovery of kidney function. Research should aim to establish whether or not stem cell therapy might offer an alternative approach to organ transplantation for patients suffering from kidney failure. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-1.4-9: Adding value to EU stem cell therapy research: scientific communication and future perspectives.** The aim would be to bring together researchers using stem cells from different sources, e.g. adult, embryonic, blood, and in different contexts, e.g. therapy, toxicology, drug screening, underlying biology, to identify common interests and obtain mutual benefit. The project should add value to EU stem cell research and improve the effectiveness of EU stem cell research community through better communication between scientists. Work would consist of organising innovative scientific meetings and interactive discussion fora along with preparatory background material and write-up. In particular the project should aim to cross disciplinary boundaries by bringing together scientists and leaders of research projects who do not usually interact with each other. The coordination action would also repertory stem cell research in Europe and identify future research needs and priorities. Communication and dialogue with other stakeholders, e.g. patients groups, industry, regulators, patent offices, should also be envisaged. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

2. TRANSLATING RESEARCH FOR HUMAN HEALTH

This activity aims at increasing knowledge of biological processes and mechanisms involved in normal health and in specific disease situations, to transpose this knowledge into clinical applications including disease control and treatment, and to ensure that clinical (including epidemiological) data guide further research.

2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY

• 2.1.1. Large scale data gathering

The objective is to use high-throughput technologies to generate data for elucidating the function of genes and gene products and their interactions in complex networks in important biological processes. The focus will be on: genomics; proteomics; “RNomics”; population genetics; comparative, structural and functional genomics.

Expected impact: The data generated by genomics and proteomics projects will continue to support the European research excellence in related fields by increasing our understanding of key biological processes and provide the foundation for more extensive functional studies concerning genetic variation, the way that genes interact to each other in health and disease, and to speed the search of genes that may underlie diseases in human. This in turn would aid the design of drugs and treatments, including

individualised treatments. For example, detailed analysis of membrane-transporters structure/function will allow identifying the critical regions in this important family of proteins that constitutes important drug targets and serve as templates for structure-based drug design, while lipidomics research will greatly contribute to the basic understanding and prevention of lipid-related disorders. The characterisation of the human microbial metagenome across European populations will assess the impact of the human microbial communities on chronic diseases, vaccine delivery and metabolism of drugs. Important new functions with potential industrial applications for health might also be uncovered, such as detoxification pathways, metabolic networks and new bioactive products. Other integrated, genome-wide association studies and insights from proteomic, metabolomic and transcriptomic studies performed on well characterised population cohorts will help to identify candidate susceptibility genes to multifactorial diseases. The integration of clinicians with the academic research community will facilitate the translation of this new knowledge into the clinic. On the other hand, synergies between different biobanking efforts in Europe will increase the success of establishing genetic and life style risk factors in human diseases. The norms and standards of general applicability that will be developed will dramatically change the way such activities are run in Europe. All projects submitted to this section should pay attention to have a well developed bioinformatics part.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.1.1-1: Networking biobanking initiatives across Europe: developing standards and norms for existing and future human sample biobanks.** The objectives are evolution and promulgation of standards and norms relevant to the management and coordination of existing and future human sample biobanks. The project should network the biobanking initiatives across Europe with the objective of ensuring future exploitation for co-ordinated large-scale biomarker discovery and validation, including studies of genetic predisposition and interactions with common environmental exposures. The norms and standards that must be delivered by this project should be defined in close collaboration with clinicians and should emphasise general applicability in relation to all biobanking initiatives. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.1-2: Molecular epidemiological studies in existing well characterised European (and/or other) population cohorts.** The project should focus on large-scale genetic studies on human samples from well characterised European (and/or other) population cohorts using innovative and standardised methodologies. As well as generation of new data, there will be an emphasis on the integration of large-scale data generated by existing initiatives across Europe in the interests of improved power, better wide-applicability and standardisation of analysis using robust tools for statistical evaluation. The project should harness the power of large cohorts to identify susceptibility genes and identify aetiological pathways for several multifactorial diseases. Clinicians should be associated with the project in order to facilitate the translation of the research outcomes into the clinic. Anonymised data and knowledge generated by this project should be made accessible to the scientific community. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.1.1-3: Comparative studies of genetic variation in humans: towards a reference population in Europe.** The aim is to carry out genome wide SNP (or other markers)-mapping and/or resequencing from volunteers from different regions, and ethnic minorities of Europe. This project should generate new knowledge about human development and evolution. In addition, a common “pooled” control population should arise from this work, representing European population diversity, and providing a reference for ongoing and new studies on genetic diversity in Europe. Anonymised data must be publicly released. The project should, where appropriate, build links to international efforts and existing cohort in gathering and analysing these data. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.1-4: Characterisation and variability of the microbial communities in the Human Body.** This large project should structure the European contribution towards the international initiatives to characterise the genomic content of microbes present in the human body. The project will also study the variability of the Human Microbial Metagenome in different European populations in function of sex, age, environment, food and medication and address its impact on health and disease. The focus could be on one particular niche (e.g. mouth, gut, etc.). **Funding scheme** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.1-5: Structure-function analysis of membrane-transporters and channels for the identification of potential drug target sites.** The project should focus on applying high throughput approaches for structure-function analysis of membrane-transporters and channels. This large multidisciplinary and integrated effort should use different technology for structure determination (NMR, X-Ray crystallography and Electron microscopy) and should also combine computational and experimental analyses. This should help to identify potential new target sites for drugs to alleviate the burden of the diseases involving membrane-transporters and channels. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.1-6: High throughput analysis of lipids and lipid-protein interactions.** The project should focus on using high-throughput tools and other technologies and appropriate bioinformatics approaches including temporal and spatial analysis for the high-throughput detection and characterisation of lipid and lipid- protein interactions at organelle or cell levels. This large multidisciplinary project should network the necessary critical mass of excellence in Europe and should structure the European contribution towards international initiatives where appropriate and should make the data accessible to the scientific community. The knowledge generated by this project will provide the basis for elucidating the function of lipids and lipid-protein interactions in normal and pathological situations. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.1-7: Genome-wide association studies in mammalian non-rodent models for the identification of genes relevant to human health and disease.** The focus should implement genome-wide association studies in cohorts of mammalian non-rodent models for which large panels of highly inbred strains

are available. The informative pedigrees of such animal models that develop diseases analogous to those seen in human make such models invaluable for studying the genetic basis of these diseases. The objective is to carry out whole genome scans for association between genotype and phenotypic traits. The research must be done according to strict national guidelines paying attention to best practice for animal welfare. This large multidisciplinary project should have a structuring effect on the research community and should coordinate the European contribution towards international initiatives in the field. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **2.1.2. Systems biology**

The focus will be on multidisciplinary research that will integrate a wide variety of biological data and will develop and apply system approaches to understand and model biological processes in all relevant organisms and at all levels of organisation.

Expected impact: Projects on system biology should integrate dispersed capabilities and assemble the critical mass necessary to enable systems approaches, by networking the necessary expertise to secure European excellence and competitiveness and to explore new directions for the field. They should deliver new knowledge on basic biological processes relevant to health and diseases. The quantitative data delivered should serve as the basis to design robust models using computational biology and systems approaches. From biological pathways in unicellular eukaryotic organisms to human cells and organs, there is a need to combine and integrate and extend existing data sources and screen the different heterogeneous data resources. The study of known pathways and gene regulatory networks associated with complex diseases will clarify the role of specific mutations or other changes in key genes and proteins in these pathways. As an example, models for T-cell activation process based on integrating quantitative data will have a strong impact in the fight against infectious diseases, cancer and several autoimmune diseases such as rheumatoid arthritis and multiple sclerosis.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.1.2-1: A system approach to eukaryotic unicellular organism biology.** The project should deliver detailed dynamic models of biomedically relevant, conserved biological pathways and/or signalling systems. These models should have predictive value after iterative optimisation and systematic experimental perturbations. Modelling should make use of existing and new quantitative data sets (derived from genetic, proteomic, transcriptomic, metabolomic and bioimaging approaches). The integrated multidisciplinary effort should include the use of generic high-throughput experimental approaches to gather quantitative data and innovative computational tools for analysis and modelling and other approaches (e.g. mutagenesis) for testing, perturbing and validating the models generated. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.2-2: Modelling of T-cell activation.** The project should focus on generating and integrating quantitative data (e.g. transcriptomics, proteomics, metabolomics) on the T-cell activation process in health and disease. The project should also apply biological systems approaches to produce reliable

models of T-cell activation and validate their relevance in the pathological context. This large multidisciplinary effort should integrate the critical mass of excellence in Europe that is necessary for generating and validating models of T-cell activation using systems biology approaches. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.1.2-3: Fundamental approaches to stem cell differentiation.** The focus should be on integrating research by integrating the excellence in Europe on stem cell biology to provide the knowledge base for future systems biology approaches to stem cell differentiation. This project should be a federating force in the field by linking research activities on all types of stem cells from different organisms, by integrating research on relevant biological processes (e.g. epigenetics, signal transduction, etc.), by developing common standards for research, by promoting training and education and encouraging outreach activities. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.1.2-4: Developing an integrated *in vitro*, *in vivo* and systems biology modelling approach to understanding apoptosis in the context of health and disease.** The focus will be on developing and applying a relevant model repository consisting of known pathways and gene regulatory networks associated with apoptosis and the role of specific changes in key genes / gene products in these pathways. Quantitative experimental and clinical data should be combined with theoretical models that guide analyses, including *in silico* models of signalling pathways. This large multidisciplinary effort should integrate the critical mass of excellence in Europe that is necessary for generating and validating models of apoptosis using systems biology approaches **Funding scheme:** Collaborative project (Large-scale integrating project).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.1.2-5: Multidisciplinary fundamental genomics and molecular biology approaches to study basic biological processes relevant to health and diseases.** Projects should be multidisciplinary and should focus on collecting, analysing and applying quantitative data to enable system biological approaches addressing basic biological processes at all appropriate levels of system complexity. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.1.2-6: Coordination and Support Actions in large-scale data gathering and systems biology.**
 - **International activities in large scale data gathering for functional genomics.** The focus should be on organising and coordinating endeavours aiming at collecting, integrating and curating genomics, proteomics, population genetics, comparative and functional genomics data and/or samples of relevance to human health. The projects should have a strong international character and involve participants from relevant third countries. Projects should also have a structuring effect on the international research community by avoiding overlaps and ensuring access to data. The partnership should include as appropriate stakeholders, such as academia,

industry, science journals, regulators and funding agencies. They should take stock of existing and planned activities internationally and contribute to setting research standards. A “business plan” should address the way in which the gathering of data, samples or resources should be organised and shared between the stakeholders and how it should be financed.

- **Preparing for the future challenges of systems biology.** The focus should be to promote and support the networking and co-ordination of research activities (in Europe and world-wide, where appropriate) in functional genomics of biological processes relevant to human health in order to lay the groundwork for systems biology.

Funding scheme. Coordination and Support Action (Coordination or Support action).

Topic for Specific International Cooperation Action (SICA), deadline 18 September 2007:

- **HEALTH-2007-2.1.2-7: Traditional Chinese Medicine in post-genomic era.** The focus should be to promote and support networking and coordination of research activities applying functional genomics in the context of Traditional Chinese Medicine. Specific International Cooperation Action. Targeted region: China. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING

• 2.2.1. Brain and brain-related diseases

The objectives are to better understand the integrated structure and dynamics of the brain, and to study brain diseases including relevant age related illness (e.g. dementia, Parkinson’s disease) and search for new therapies. The focus will be to gain a global understanding of the brain by exploring brain functions, from molecules to cognition including neuroinformatics, and brain dysfunction, from synaptic impairment to neurodegeneration. Research will address neurological and psychiatric diseases and disorders, including regenerative and restorative therapeutic approaches.

Expected impact: Projects funded under this area will contribute to a better understanding of brain function and of dysfunction in disease. This knowledge will feed into translational clinical and industrial development leading to better diagnosis of brain diseases, new therapies or innovative brain-machine interfaces. Translational brain research will be a core element of each topic and may contribute to an improved management of brain diseases with the potential to reduce the high health care costs related to the treatment and care of patients. Potential user sector(s) can be biomedical/pharmaceutical, software or robotics industry. Expected mechanisms for disseminating and promoting uptake of the research will be via publications in high impact journals and international high level conferences, and/or via patents.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.2.1-1: Stroke and mechanisms underlying ischemic brain damage.** Research should focus on the pathophysiological mechanisms and the neurological consequences of ischemic stroke. The project should also investigate innovative therapeutic strategies (e.g. novel neuroprotectants, nanotechnology, gene or cell therapy) to prevent the development and propagation of ischemic brain damage and/or to repair such brain damage to improve neurological outcome. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.2.1-2: Coding in neuronal assemblies.** Research should focus on mechanisms of coding at the level of neuronal assemblies or microcircuits, aimed at understanding the interface between neuronal activity and behavioural performance. The project should develop interaction between experimentation and modelling, and therefore include a strong neuroinformatics dimension. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.2.1-3: Neurobiology of anxiety disorders.** Research should focus on the neurobiological mechanisms underlying fear and anxiety, including examination of genetic and environmental risk factors, and characterisation of animal models. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.2.1-4: Memory loss: underlying mechanisms and therapy.** Research will focus on the molecular and biological mechanisms underlying memory loss occurring in various conditions (for example neurodegenerative or psychiatric diseases, stroke, brain tumours, epilepsy, neuroinfectious diseases, or aging), and on the development of therapies counteracting memory deficits. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.2.1-5: From basic spinal mechanisms to spinal cord disease and trauma.** Research will focus on mechanisms of spinal cord development and function and translate this knowledge into developing new neuroprotective or repair strategies for spinal cord diseases or injury. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.2.1-6: Neuron-glia interactions in health and disease.** Research should focus on the molecular and cellular mechanisms of neuron-glia interactions under normal development and function as well as under disease conditions. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.2.1-7: Restorative approaches for therapy of neurodegenerative diseases.** Research should focus on basic mechanisms of brain plasticity and brain repair in neurodegenerative diseases and translate this knowledge into new neuroprotective or restorative therapeutic approaches. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).

- **HEALTH-2007-2.2.1-8: From mood disorders to experimental models.** Research should focus on the pathophysiology of mood disorders, including animal models, and aim at introducing experimental medicine models at the interface between Phase I and Phase II clinical trials. Projects on anxiety disorders are excluded. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.2.1-9: Neuronal mechanisms of vision and related diseases.** Research should focus on neuronal mechanisms of vision from receptor cell level to cortical visual centres. Physiological as well as pathophysiological neuronal mechanisms should be addressed in visual pathways. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Topic for Specific International Cooperation Action (SICA), deadline 18 September 2007:

- **HEALTH-2007-2.2.1-10: Childhood and adolescent mental disorders.** The research should be aimed at investigating paediatric mental disorders that have a high prevalence in countries of Central and Eastern Europe. The projects should use population genetics/genomics approaches and include bioinformatics/biostatistics to increase knowledge of the patterns of disease prevalence and develop possible diagnostic and therapeutic strategies as well as address prevention. Specific International Cooperation Action. Target regions: Eastern Europe and Central Asia and Western Balkans. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

• **2.2.2. Human development and ageing**

The objective is to use a wide variety of methodologies and tools to better understand the process of life-long development and healthy ageing. The focus will be on the study of human and model systems, including interactions with factors such as environment, genetics, behaviour and gender.

Expected impact: Joint, multidisciplinary European research in this area will integrate and mobilise excellence, contributing to the understanding of the process of human development and ageing, creating a significant impact on healthy life expectancy, cost savings in the health care sector, improved quality of life and strengthening competitiveness of European health and biotechnology industry.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.2.2-1: Novel approaches to reconstitute normal immune function at old age.** Research should apply a multidisciplinary approach to determine the underlying mechanisms of dysregulation of the immune system during ageing and should aim to restore immune function. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.2.2-2: Termination of developmental processes and their reactivation in adult life.** The developmental processes that lead to the establishment of the body plan of an organism are controlled by complex regulatory networks. Much needs to be known on how these developmental processes terminate once reaching adult stage and how under certain circumstances such a

process can be reactivated later in life as a repair or regenerative mechanism (e.g. wound healing). Uncontrolled reactivation of such developmental processes may lead to disease. The aim of proposals should be at integrating research in relevant models organisms to better understand the complex regulatory networks that control the termination of developmental processes and their reactivation. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.2.2-3: Biomarkers of ageing.** Environmental, stochastic and genetic effects result in a different rate of ageing of individuals. Within a given individual these effects cause a different rate of ageing at the level of cells, tissues and organs. The purpose of this topic is to integrate existing and yet to be acquired physiological and molecular parameters in order to provide an outline of the biological age of humans. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.2.2-4: Increasing the participation of elderly in clinical trials.** Although elderly account for proportionally high drug consumption, they tend to be underrepresented in clinical trials. The generalisability of trials may improve by considering the specific situation of this patient group such as changed metabolism, multiple chronic conditions and polypharmacy. The objective of this topic is to increase the participation of elderly in clinical trials. Activities may include the collection of supporting data in order to develop new ethical standards for clinical trials. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.2.2-5: Research on human development and/or healthy ageing across the EU:** Workshops and conferences to assess the state of the art of research on molecular aspects of human development and/or healthy ageing and to establish a roadmap to further support of international policy objectives. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH

• 2.3.1. Anti-microbial drug resistance including fungal pathogens

The strategic objective of this area is to confront the increasing emergence and spread of antimicrobial drug resistant pathogens in Europe and the rest of the world at broad fronts and in a multi-disciplinary approach through the development of effective infection prevention and control strategies. Focus will be on combining basic research on molecular mechanisms of resistance, microbial ecology and host-pathogen interactions with clinical research towards new interventions.

Expected impact: Reinforced research integration of European excellence in the field of antimicrobial drug resistance will be targeted towards a set of clearly defined objectives with the following expected impact: Identification of novel targets and lead compounds will pave the way towards new and urgently needed antibiotics. The knowledge generated by studying host-pathogen interactions in bacterial infections will facilitate identification of new targets for drugs and vaccines. An integrated research platform for the

development and clinical evaluation of new point-of-care diagnostic and susceptibility tests will accelerate the implementation of cost-effective tests in the clinical setting as a support for optimised prescription of anti-infective drugs. Increased understanding of the epidemiology of new highly virulent multi-drug resistant strains of bacterial pathogens will help to develop more effective and rapid tools to control them and prevent the emergence of new ones. An improved understanding of the global medical and financial burden posed by antimicrobial resistance will help to focus future resource allocations more appropriately in the overall combat against drug resistance. Finally, an analysis of the European research capacity in the field of staphylococcal research will pave the way for future focused research actions.

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.3.1-1: Novel targets for drugs against Gram negative bacteria.** The objective is to identify and validate novel drug targets in order to select lead compounds, which may be derived from natural resources or from synthetic compounds, for future development of a new class of anti-infective drugs against Gram negative bacteria. Significant industrial involvement, particularly by SMEs, is foreseen in this topic. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR6 000 000/project).
- **HEALTH-2007-2.3.1-2: Host-pathogen interactions in infections by *Streptococcus pneumoniae*.** The objective is to provide the basic knowledge needed for future development of novel prevention, diagnostic and treatment tools against pneumococcal infections. Emphasis will be placed on studies into fundamental molecular aspects of the interactions between *S. pneumoniae* and the human host, in particular the cell biology of bacteria. Experimental approaches will include the use of cell cultures and animal models of pneumococcal diseases, the study of virulence mechanisms, as well as the molecular epidemiology of drug resistance. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.1-3: An integrated platform for development and clinical evaluation of point-of-care diagnostic devices for microbial detection, antibiotic susceptibility determination and biomarkers.** The objective is to establish a European diagnostic platform, supported by microbial strain genome collections, to develop and validate, in the clinical setting, cost-effective, simple, sensitive, specific, ubiquitous, fully automated, miniaturised, user friendly and rapid point-of-care diagnostic devices for microbial detection, antibiotic susceptibility determination and biomarkers with the aim to facilitate optimised prescription of antibiotics. The devices may be developed for use in hospitals, primary care settings, pharmacies and/or at patients' homes and should be pre-clinically and clinically evaluated to assess their impact on the prescription of antibiotics. Proposals should address the optimal integration and implementation of point-of-care diagnostic tests into healthcare programmes and identify approaches to overcome hurdles to use these rapid tests in patient management, taking into account social, ethical, environmental, and economical factors that influence the adoption of new diagnostic technologies into health systems. Strong commitment by biotechnology companies is foreseen. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.3.1-4: Molecular epidemiology to control nosocomial and community spreading of highly virulent multi-drug resistant strains of bacterial pathogens.** The objective is to undertake epidemiological and physiological studies of new highly virulent multi-drug resistant strains of bacterial pathogens, causing particular concern to hospitals and the community, such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and the Gram negative isolates producing Extended-Spectrum Beta-Lactamases (ESBL) or Metallo-Beta-Lactamases (MBL), with the aim to develop novel control measures. Particular attention will be on studies of how nosocomial pathogens adapt for efficient spread in the community. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
 - **HEALTH-2007-2.3.1-5: Health and economic cost of antimicrobial resistance.** The objective is to undertake studies attempting to assess the increase in health and economic costs due to infections by drug resistant micro-organisms. A better knowledge of the burden of antimicrobial resistance would encourage implementation of strategies to fight resistance. Projects should aim to provide a broad view of the problem, by addressing the issue in many different regions both in developed and developing countries. They should also model future burden for a variety of scenarios given (a) alternative assumptions about the emergence and transmission of resistance, and (b) alternative assumptions about the current implementation of strategies to fight resistance. Participation of ICPC partner countries is highly encouraged. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
 - **HEALTH-2007-2.3.1-6: Conference on genetic and biochemical tools for post-genomic physiological analysis of *Staphylococcus*, in particular MRSA.** The objective is to define, support, coordinate and expand the European capacity in the field of staphylococcal research by promoting interest in the very basic microbiological tools that allow post-genomic physiological analysis. The goal will be reached by organising one or several conferences/workshops and by working on the preparation of a consensus document. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **2.3.2. HIV/AIDS, malaria and tuberculosis**

The focus will be on developing new therapies, diagnostic tools, preventive tools such as vaccines and chemical transmission barriers such as HIV microbicides. Research efforts will confront the three diseases at global level, but will also address specific European aspects of the three diseases as well as Hepatitis. Preclinical and early clinical research activities will be emphasised, and where relevant (e.g. for HIV/AIDS vaccines) collaboration with European and global initiatives is foreseen.

Expected impact: The expected impact of this area is the creation of a European research environment, where highly innovative ideas are conceived and new approaches to prevention, treatment and management of HIV/AIDS, malaria and tuberculosis can be developed. The emphasis will be on promoting translational research aimed at bringing basic knowledge through to clinical application. The integration of expertise from different disciplines will be essential in this area, and the formation of partnerships

between public and private institutions, as well as the involvement of research groups from developing countries is a major goal.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.3.2-1: HIV/AIDS Drug Discovery and Preclinical Development.** Projects should establish a network of academic and/or industrial partners to discover, develop and/or validate new targets for more efficient anti-HIV drugs. Projects are expected to focus on preclinical development of new anti-HIV drugs or concepts for infected children, pregnant women and/or adults. Special emphasis should be given to products of broad anti-HIV spectrum that are affordable and easy to administer to target populations in low-income countries. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-2: Highly innovative approaches for research into host-pathogen interaction in tuberculosis.** Highly innovative projects are sought in the area of host-pathogen interaction with a focus on the discovery of biological processes related to disease or protection and identifying and validating potential antigens or new drug targets for *M. tuberculosis*. Projects may either involve investigations of genetic variations of importance for the host-pathogen interaction, or comprise studies of the metabolomics and host adaptation for TB, including specific studies of relevant metabolic processes of using state-of-the-art technologies. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-3: Development of fast tests for the diagnosis of Multi-Drug-Resistant strains of HIV, malaria and tuberculosis and of latent tuberculosis infection (LTBI).** Advanced, robust and affordable technologies are needed to rapidly and unambiguously diagnose the target diseases. One of the main objectives should be to identify specific markers of drug resistant variants of HIV, malaria and/or TB. For tuberculosis, developments of new diagnostic tests to distinguish between drug-sensitive and different MDR-strains, and to distinguish latent from active infection, are particularly relevant. The diagnostics should represent a clear improvement over existing tests. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-4: Addressing knowledge gaps in pregnancy malaria.** This topic invites research on mechanisms and timing of immunopathogenesis of malaria in pregnancy, and how these have impact on maternal and foetal health. Project outcomes must be relevant for the design of new, or the revision of existing therapeutic and/or preventive interventions. Participation of research groups from disease-endemic countries is highly encouraged. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-5: Paediatric formulations of drugs against HIV/AIDS, malaria and tuberculosis.** Projects should aim at investigating the optimal drugs, drug combinations and drug dosing for paediatric treatment of HIV/AIDS, malaria and tuberculosis in developed and developing countries. Projects are expected to involve industry and relevant stakeholders from public health sectors to foster the

development of better treatments and drug formulations for children. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

- **HEALTH-2007-2.3.2-6: New HIV Vaccines inducing broadly-reactive neutralising antibodies.** Projects should aim at designing new immunogens and adjuvants capable of eliciting neutralising antibodies of broad spectrum against HIV. The final goal should be producing a safe and efficient vaccine that could induce a humoral response against the virus. For this purpose, projects could combine vector, immunogen and adjuvant design for the induction of effective polyvalent immune responses. Projects could address standardised measurement of immune responses, identification of correlates of protection, appropriate animal model testing, preclinical validation, and proof of principle testing in humans. **Funding scheme:** Collaborative project (Large-scale integrating project).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.3.2-7: Network on HIV and anti-HIV drug resistance.** Proposals are expected to present a pan-European (with special emphasis on Eastern Europe) or global network for surveillance and basic research activities on current HIV and anti-HIV drug resistant strains. The successful project (s) will include the main actors in the field and will monitor how resistances develop and evolve, in order to better understand mechanisms of resistance development and to better fight against new resistances in the clinical settings. Projects should include molecular epidemiology studies and should provide a strategy to evaluate and limit the emergence and transmission of HIV drug resistance, include training and dissemination activities, and support evidence-based public health policy and action. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.3.2-8: HIV and Hepatitis co-infection.** Projects are expected to study the immunological interaction occurring during co-infection by the human immunodeficiency virus and hepatitis B and/or C. A better understanding of the physiopathology and evolution of co-infection should provide information for developing better treatment and prevention options. Coordination of cohort studies on HIV and Hepatitis co-infection, including liver transplantation, with an aim to provide better treatment options will also be considered. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.3.2-9: Blocking the transmission of malaria: the mosquito vector target.** Successful attempts to malaria control in the past rested on controlling the mosquito vector. Exploiting available knowledge on the biology of the malaria vector including population biology and behavioural genetics, its interaction with the malaria parasite and the transmission of the parasite to humans should yield new targets and concepts for transmission-refractory interventions. Participation of research groups from disease-endemic countries is highly encouraged. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-10: European network for study and clinical management of TB drug resistance.** Multi-Drug-Resistant-TB strains are spreading in Eastern Europe at alarming rate. Proposals should aim at coordinating at European and international level basic and clinical research on TB drug

resistance. The project should support epidemiological studies and coordinate activities to limit the spread of MDR strains. Standardisation of tools for TB diagnosis and control should be envisaged, including international collaboration with public-private partnerships. Participation of Eastern European countries is highly encouraged. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.3.2-11: Support platform for the development of PRD vaccines** Available technological know-how on industrial vaccine development, product development and platform and adjuvant selection as well as regulatory requirements shall be grouped under a coordinated action to support academia and SMEs to carry forward promising PRD vaccine into proof-of-principle testing. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

Topics for Specific International Cooperation Actions (SICA), deadline 18 September 2007:

- **HEALTH-2007-2.3.2-12: Highly innovative research in HIV/AIDS, malaria and tuberculosis between Indian and European partners.** Projects should explore new concepts and ideas in the area of poverty-related diseases research, which are of particular relevance for the cooperating countries, and where joining research activities are expected to generate synergies. Other ICPCs are also encouraged to join. Specific International Cooperation Action. Targeted Region: India. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.2-13: Coordination of European research activities with global initiatives, including Public-Private Partnerships.** The projects will support and promote collaboration between EC funded research activities and global research initiatives, including product development Public-Private Partnerships (PDPs) in the area of HIV/AIDS, malaria, tuberculosis or neglected infectious diseases. Support may be given to support translational research activities of promising new vaccine or drug candidates, and with an emphasis on coordinating European research activities with those performed at a global level. Specific International Cooperation Action. Targeted Regions: ICPC. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.3.2-14: Next generation of researchers for HIV/AIDS, malaria, tuberculosis and neglected infectious diseases.** Support will be given to targeted support measures aiming at attracting and improving career prospects for young researchers from Europe and disease-endemic countries into research in PRD and neglected infectious diseases. High quality science contents, demonstrated organisation and management abilities and clear indications of sustainability and impact will be prerequisites of selected actions. Specific International Cooperation Action. Targeted Regions: ICPC. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

• **2.3.3. Potentially new and re-emerging epidemics**

The focus will be on confronting emerging pathogens with pandemic potential including zoonoses (e.g. SARS and highly pathogenic influenza). Call topics aim to cover the full "value chain" of health research: from innovative basic research to early stage clinical trials of new prevention, diagnostic and therapeutic measures all the way to implementation research supporting effective public health responses. This includes the vital need for new rapid and reliable diagnostic tools, the search for more efficient and broadly protecting vaccines, and the study of alternative treatment strategies and non-pharmaceutical approaches in patient management. While the current situation justifies a strong focus on the threat of pandemic influenza, efforts will also be made to strengthen the European research capacity for other potential causes of infectious epidemics and to foster networking of scientists with expertise in the early identification of new pathogens – where appropriate in collaboration with scientists from affected third countries. The involvement of SMEs is paramount for a number of topics in this area and a dedicated call topic encourages the involvement of early-stage researchers with innovative and high-risk projects.

Expected impact: The results of research in this area will integrate European scientific excellence and make Europe better prepared for emerging epidemics: Earlier identification of new pathogens will give scientists and public health authorities precious time to prepare and implement containment and emergency measures. With regard to influenza, studies on the immunological basis of vaccination, standardisation of relevant assays and the development of a broadly protective influenza vaccine will improve the prevention against this health threat. Development of point-of-care diagnostic tests will deliver an important tool for public health preparedness especially in the early stages an influenza pandemic. Research into additional treatment strategies will provide proof-of-concept for urgently needed new patient management options. Pandemic influenza containment and mitigation strategies are a vital tool to limit spread, once clusters of human-to-human transmission have emerged and research in this area should deliver a better evidence-base for public health policies in Europe and world-wide. Involvement of partners from disease-endemic countries will strengthen the international collaboration in this area. Taken together, research in this area will deliver a broad and effective evidence-based strategy to protect the health of citizens in Europe and in affected regions. Support of research into vaccines, adjuvants and improved vaccine strategies will also help to maintain and improve the competitiveness of the European pharmaceutical and biotech industry in this field.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.3.3-1: Development of broadly protective influenza vaccine candidates.** The objective is to develop, from basic mechanistic studies to early stage clinical trials, a vaccine generating a broadly protecting immune response against different influenza subtypes or at least against variants of the same subtype. This ambitious goal may be pursued by a wide range of approaches, including conserved epitopes or live attenuated vaccines. Projects should examine convenient, robust, affordable routes of administration and dosing schemes. Strong involvement of SMEs and/or the vaccine manufacturing industry in the consortium

is expected. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).

- **HEALTH-2007-2.3.3-2: Identifying immunological mechanisms of protection for influenza vaccines.** The aim is to facilitate research on pandemic influenza vaccines by addressing knowledge gaps regarding immune correlates of protection, including issues such as cross-protection and seroconversion without overt disease. Projects should also address these issues in special populations such as the elderly, immunocompromised patients, pregnant women or neonates. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.3-3: Standardisation of immunological assays including surrogate markers for evaluation of new influenza vaccines in clinical trials.** The aim is to gather scientists from academia, industry and regulatory authorities to agree on standardised criteria for immunological and serological assays for the evaluation of new influenza vaccines in clinical trials. The expectation is that the project results in the publication of consensus guidelines and the definition of future research needs in this area. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.3.3-4: Innovative point-of-care diagnostic tests for influenza.** The objective is to develop and validate affordable, reliable, and rapid diagnostic tests for influenza infections with designated viruses. Research outcomes should be applicable to surveillance and early detection of an epidemic outbreak and suitable for point-of-care use in both developed and developing countries, addressing early biological markers and/or late surveillance. User-friendliness, relevance of the clinical read-out and availability of the tests at large scale should be important criteria. The expected project results should clearly be of interest and potential benefit to industry, preferably SME(s). Consortia should have at least 40% of the requested EC contribution budget going to SMEs. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects targeted to SMEs).
- **HEALTH-2007-2.3.3-5: Development of additional treatment strategies for patients suffering from highly pathogenic influenza.** The objective is to develop novel components of current treatment and case management options, using either new or neglected approaches, such as antibody or cytokine-based therapies. Consideration of resource-saving management options will be an asset. Involvement of partners from affected regions is particularly encouraged. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.3-6: Development of pandemic influenza containment and mitigation strategies.** The objective is to develop effective pandemic influenza containment strategies. The programme should include the development of tools to identify biological and behavioural "super-spreaders", contact tracking tools and modelling the impact of public health measures (such as border closures, the role of public transport, schools and workplaces, household prophylaxis etc.) as well as research into the social acceptance of such measures. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-2.3.3-7: Supporting highly innovative inter-disciplinary research on influenza.** In contrast to other, more closely defined topic descriptions, this topic encourages a broad range of small-scale, high-risk, innovative projects, which could produce knowledge and insight that bear a potential for new therapeutic or prophylactic interventions in the area of influenza. Projects should clearly go beyond the current state-of-art in areas where traditional approaches have been unsuccessful and explore new ideas to overcome known problems. Consortia should be small, with a limited budget and a maximum duration of two years. Proposals from young researchers are particularly encouraged. Collaboration of partners with very diverse expertise will be an asset. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 1 500 000/project).

Topic for Specific International Cooperation Action (SICA), deadline 19 April 2007:

- **HEALTH-2007-2.3.3-8: Influenza research in collaboration with Asian partners.** The goal is to support innovative research approaches in the broad area of influenza research. This might include the identification or verification of new targets or drug candidates, as well as projects with more clinical or public health components regarding prophylactic (vaccines as well as containment and mitigation) and therapeutic approaches or surveillance research. Specific International Cooperation Action. Targeted regions: Asia. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.3.3-9: Strengthening research on prediction, identification, modelling and surveillance of newly emerging infectious diseases in humans.** The aim is to develop a network of scientists involved in identifying at an early stage new potential infectious threats to human health. The scope of the project should be broad and interdisciplinary in order to tackle emerging epidemics at all fronts. Research fields and methods covered in the project should include, but are not limited to, prediction and modelling, surveillance and epidemiology (including the study of discrete ecological changes facilitating the emergence of epidemics), molecular epidemiology, microbial genomics, public health, health systems research and emergency preparedness. The emphasis and thrust of the activities supported here should be directed to future, poorly known infectious threats and the re-emergence and spread of known pathogens such as Dengue, West Nile virus and Chikungunya. The project's activities may include influenza and antimicrobial drug resistance but these subject areas should not be its exclusive focus since they are also covered in other parts of the work programme (see areas 2.3.1 and 2.3.3). Inclusion of partners working on zoonoses and surveillance of domestic and wild animals is encouraged, but the research capacity and intent to apply this work to the early detection and identification of human epidemics needs to be demonstrated. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.3.3-10: Definition of research needs and priorities in Europe in the area of Emerging Infectious Epidemics.** Since this specific area is new in the work programme of FP7, broad-based input is needed into its further definition, scope, structuring and development. Issues that will have to be addressed are existing research capacities, the definition of "emerging infectious epidemics" and

the way research programmes can address this evolving and rapidly changing area, risk assessment and priority setting, public health needs in (and possibly outside) Europe and the contribution that different levels of research (basic, translational, clinical, public health) can make to these needs. The goal should be a broad involvement of all stakeholders resulting in an overview and foresight document, including a future research agenda for this area. One or several conferences/workshops and work on the preparation of a consensus document will be required in order to achieve this goal, but it may also include a more in-depth study of one or several issues. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

- **2.3.4. Neglected infectious diseases**

The aim is to establish an integrated approach for the development of preventive, therapeutic and control tools for neglected infectious diseases. This call will focus on diseases caused by Trypanosomatidae species (e.g. Trypanosomiasis, Chagas Disease, Leishmaniasis), however, during subsequent calls it is expected that a wider range of vector-borne diseases (e.g. dengue, schistosomiasis, river blindness and filariasis), as well as other neglected infectious diseases (e.g. leprosy, Buruli ulcer, soil-transmitted helminths), including childhood infections, will be addressed.

Projects should address transmission control, preclinical and early clinical activities targeted to ICPC and other third countries. Research should take into account the ecological aspects of the different diseases, their modes of transmission, and possible control strategies. Technology transfer and training activities should also be part of the projects. Proposals involving an integrated multidisciplinary approach will be strongly encouraged.

Expected impact: With the aim of expediting the development of new diagnostics, drugs, vaccines and tools for transmission control for effective prevention, treatment and control, consortia will be established to address selected neglected infectious diseases.

Topics for Specific International Cooperation Actions (SICA), deadline 18 September 2007:

- **HEALTH-2007-2.3.4-1: Development of new tools to control infections due to parasites of the Trypanosomatidae family.** In the perspective of recent scientific advances in areas such as genomics, vector biology, treatment and epidemiology (Trypanosomiasis, Chagas disease, Leishmaniasis) the objective is to develop and validate effective control strategies and interventions. These may include affordable, reliable and rapid diagnostic tests, the development of new drugs or drug combinations and innovative interventions for transmission control. The research outcome should be applicable and affordable for use in disease endemic countries. The projects may contain genomic and proteomic approaches, and should include a distinct component aiming at strengthening capacity building of endemic countries for understanding and control of these diseases through networking and training scientists. The participation of SMEs in the consortium is encouraged and could include international collaboration with public-private partnerships. Specific International Cooperation Action. Targeted regions: ICPC. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-2.3.4-2: Development of a Leishmania vaccine.** The objective is to develop a safe and efficient vaccine generating a broadly protecting immune response against different leishmania species in particular those responsible for Visceral Leishmaniasis (VL). This ambitious goal may be pursued by a wide range of approaches. Proposals could include coordination of basic, preclinical and/or clinical research on Leishmaniasis vaccine. Involvement of SMEs and/or the vaccine manufacturing industry in the consortium is encouraged. Participation of diseases endemic countries is highly expected. Specific International Cooperation Action. Targeted regions: ICPC. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.3.4-3: Bioprospecting for drug leads.** The project will collect, isolate and investigate potential drug leads from terrestrial and marine biodiversity sources. The aim is to build/enhance libraries of biological compounds that can be tested as drug leads for a variety of infectious diseases (e.g. virostatica, antihelminthic or antimycoplasmic compounds). The project must respect international agreements on sustainable use of biodiversity and equitable benefit sharing and include work packages on IPR and other legal issues of access and use of those compounds. Specific International Collaboration Action. Target area: ICPC. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES

• 2.4.1. Cancer

The focus will be on disease aetiology; new medicines and therapies; identifying and validating drug targets and biological markers that aid in the prevention, early diagnosis and treatment; and assessing the effectiveness of preventive, prognostic, diagnostic and therapeutic interventions.

Expected impact: The activities funded in this area will further understanding of the basic mechanisms underlying cancer and therefore help translate this into the clinical setting. It is expected that projects will successfully exploit this knowledge to develop novel drugs and new treatment strategies. Validated biomarkers and prevention research should lead to better strategies in primary and secondary cancer prevention and clinical research will improve patient care. In the long run, the impact of the investment in this area will contribute to reaching the aims of reducing cancer's incidence and mortality and improving quality of life for patients. The public health impact is therefore potentially high.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.4.1-1: Translating the knowledge on non-coding RNAs linked to the aetiology of cancer into novel diagnosis and therapy strategies.** The successful program should focus on the identification and role of non-coding RNAs in cancerogenesis and on aberrant expression patterns of genes causally involved in the aetiology and/or progression of human cancers. Collaborative efforts should include the development and preclinical validation of new diagnostic and prognostic tools and spur preclinical research into the discovery, design, development and testing of novel anti-cancer compounds based on non-coding

RNAs. **Funding scheme:** Collaborative projects (Small or medium scale focused research projects).

- **HEALTH-2007-2.4.1-2: Translating clinical 'omics'-technology (genomics, proteomics, metabolomics) into innovative cancer biomarkers aiding in early diagnosis, prognosis and treatment selection of cancer patients.** Acquired oncogenomics, oncoproteomics, oncometabolomics and molecular pathology knowledge should be employed in the clinical setting and -using exclusively patient samples- to identify, evaluate and validate biomarkers useful for early detection, prognosis, monitoring and treatment selection of the disease(s) and assessment of potential response to therapy. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.1-3: Genomic instability and genomic alterations in pre-cancerous lesions and/or cancer.** Collaborative, translational research efforts should be conducted to understand the underlying mechanisms of genomic aberrations/alterations in various types of cancer and to exploit comprehensive, standardised, large-scale genomic and/or proteomic analyses as diagnostic and therapeutic opportunities for better clinical management. Findings are expected to lead to novel therapeutic and/or prevention strategies, as well as to facilitate tumour diagnosis, prognosis, and monitoring. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.1-4: Novel cancer screening methods.** Consortia should identify novel biomarkers and/or develop methods or technologies to deliver cost-effective approaches for the earliest possible detection of cancer or pre-cancerous lesions. A feasibility study showing proof of principle of potential usefulness for screening should be included. Particular attention should be paid to patient comfort in developing easy to use, non- or minimally- invasive methods. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.1-5: Optimising research on end of life care of cancer patients.** Proposers should study and compare approaches in Europe and exchange experiences and best practices on research for end of life care for cancer patients. The following issues should be taken into consideration: signs and symptoms of approaching death, psychological and psychosocial support to patients, families and caretakers, end of life decisions, complementary comfort care, voluntary service, as well as needs assessment and evaluation of quality indicators and technologies to improve quality of care and develop new approaches. **Funding scheme:** Coordination and Support Action (Coordination action).
- **HEALTH-2007-2.4.1-6: Understanding and fighting metastasis.** Functional, collaborative studies should be conducted to understand early mechanisms of dissemination, and outgrowth of metastases of primary human cancers. Particular attention should be focussed on understanding the interplay of disseminating cancer cells and the cells of the organ microenvironment as well as investigating possibilities for therapeutic intervention. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.1-7: Improving targeted drug delivery to cancer cells for cancer therapeutics other than gene therapy** (in coordination with NMP-2007-

4.0-4 in Theme 4). Multidisciplinary consortia should focus on innovative solutions to overcome the current problems with drug delivery to cancer cells using for example innovative nanotechnology-, peptide- or antibody- based targeting strategies. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-2.4.1-8: Developing high-throughput bioassays and models for human cancers in lower species.** Collaborative efforts should combine novel, high-throughput bioassays and models for rapid drug validation and testing using lower species, such as *Drosophila*, *Xenopus*, *Caenorhabditis*, *Danio* and/or other multicellular lower species. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.4.1-9: Innovative combination clinical trials for multimodal cancer therapy.** Collaborative efforts combining novel radiation therapy strategies with either chemotherapy, immunotherapy and/or other biologically-based therapeutic strategies in a phase I or II setting should result in improving quality of life and/or survival of patients suffering from cancer. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.4.1-10: Role of inflammation in tumour initiation and progression.** The programme will aim at translating knowledge on the molecular machinery underpinning inflammatory processes driving tumour initiation and progression in various cancers, into functional, validated therapeutic anti-cancer approaches. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.4.1-11: Epidemiology of gene-environment interactions involved in carcinogenesis.** Multidisciplinary research should be undertaken in order to identify gene-environment interactions involved in the development of cancer and define prevention strategies. Validated technology platforms to collect genomic data should be combined with innovative biostatistics and bioinformatics solutions to further define and quantify the role of major cancer risk factors in specific individuals. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.4.1-12: Translating the hypoxic tumour microenvironment.** The programme will aim at translating knowledge on the molecular machinery responsible for survival and spread of metastatic tumour cells under hypoxic conditions into innovative and validated molecular targets with therapeutic applicability that target the cancer cell or tumour stroma. Consortia should include participants with ample clinical expertise to guarantee a clinical proof-of-principle. **Funding scheme:** Collaborative project (Large scale integrating project).

Topic for joint call for ERA-NETs, deadline 31 July 2007:

- **HEALTH-2007-2.4.1-13: ERA-NET on optimisation of the use of cancer registries for cancer research purposes²⁹.** Improve the linking and efficient integration of national/regional programmes for cancer registration for better data collection and registry coverage, optimised use of valuable cancer data, samples and resources in support of research disease management and amelioration of cancer control. Activities in the new member states are particularly encouraged. **Funding scheme:** Coordination and Support Action (Coordination action).

Topic for Specific International Cooperation Action (SICA), deadline 18 September 2007:

- **HEALTH-2007-2.4.1-14: Studying cancer aetiology in Latin America.** International consortia should conduct and coordinate epidemiological studies to identify risk factors for cancers with high incidence in Latin America (e.g. gastrointestinal cancers, head and neck cancer, etc.), including genetic susceptibility, infections, diet, lifestyle, or environmental exposures. Specific International Cooperation Action. Targeted region: Latin America. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **2.4.2. Cardiovascular disease**

The focus will be on diagnosis, prevention, treatment and monitoring of heart and blood vessel diseases (including vascular aspects of stroke) using broad multidisciplinary approaches.

Expected impact: The knowledge gained from research performed in this area will lead to an improvement in the prevention and treatment of cardiovascular diseases, which are a major cause of ill health and death in Europe and world wide. This can for example be through the identification and validation of novel drug targets, devising and validating diagnostic tests or imaging approaches, or the development and validation of strategies for prevention and clinical management of the diseases, as appropriate.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.4.2-1: Molecular basis of the inflammatory response and associated vascular remodelling in arteriosclerosis.** Project should aim to better understand the role of vessel wall remodelling in the development of arteriosclerosis. Research should include molecular, genomic, and functional genomics studies. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.4.2-2: Vascular remodelling in aneurysmal disease.** Project should aim to better understand the role of vessel wall remodelling in the development of aneurysms: from molecular mechanisms to novel diagnostics (e.g. imaging) and treatment approaches. Feasible and cost effective diagnostics should

²⁹ This topic will be subject of a joint call for ERA-NETs across the Themes – See Annex 4. Indicative maximum EC contribution for this ERA-NET is € 2 M.

be considered. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.4.2-3: Combating stroke.** The project should lead to the integration of research teams working on vascular aspects of stroke such as cerebrovascular biology, stroke prevention, stroke imaging, cerebral reperfusion. This should lead to better prevention and treatment of stroke via the neurovascular unit of the brain (for neurological aspects of stroke, see topic HEALTH-2007-2.2.1-1). **Funding scheme:** Collaborative project (Large-scale integrating project).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.4.2-4: Congenital pathologies affecting the heart.** Research should focus on mechanisms of normal and abnormal heart development leading to congenital heart diseases, including studies on genetic basis (e.g. transcription factor genes) and the interaction between genes and environment in the development of heart defects and should build on the existing epidemiological data. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
 - **HEALTH-2007-2.4.2-5: Cell therapies for the treatment of heart ischemia.** Different aspects can be addressed: e.g. optimising cell preparations for use in transplantation studies, support for intermediate scale clinical trials. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
 - **HEALTH-2007-2.4.2-6: Organ imaging in CVD.** Intermodality comparison of non-invasive imaging approaches for the reproducible quantification of cardiovascular function should be performed and tested in an early clinical trial, to show that imaging measurements are reliable endpoints to use in trials. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
 - **HEALTH-2007-2.4.2-7: Integrating pharmacogenomic approaches into the treatment of CVD.** Research should address the pharmacogenomics of therapeutic approaches to CVD. Genetic variation of the drug target, genetic variation in drug metabolism and/or modulation of gene expression can be addressed. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **2.4.3. Diabetes and obesity**

For the former, the focus will be on aetiologies of the different types of diabetes, and their related prevention and treatment. For the latter, the focus will be on multidisciplinary approaches including genetics, life style and epidemiology. For both diabetes and obesity, special attention will be given to juvenile diseases and factors operating in childhood.

Expected impact: It is expected that the following topics will contribute not only to research breakthroughs in the diabetes/obesity treatments but also in prevention and treatment of complications. Considering the heavy toll taken on life expectancy of these diseases, particular attention should be given to paediatric aspects, when ever possible. Healthy life styles being a pre-requisite to any stabilisation of escalating costs of diabetes/obesity, projects should also examine how their results will contribute to the societal issues linked to the diseases.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.4.3-1: Early processes in the pathogenesis of type 1 diabetes and strategies for early prevention.** Project should focus on translational research for better understanding of the pathophysiological processes in the development of type 1 diabetes with emphasis on early events. Research should improve early diagnosis and lead to approaches for tackling prevention of type 1 diabetes. A multidisciplinary approach (diabetologists, allergy specialists, virologists, beta cell experts, immunologists etc.) is required. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **HEALTH-2007-2.4.3-2: Combined forms of diabetes in children.** Study of the function of the endocrine pancreas in the progression towards diabetes in overweight children. The projects should lead to better understanding of the factors underlying the progression of various forms of diabetes in children. Approaches for treatment for these children are expected outcomes of the project. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **HEALTH-2007-2.4.3-3: Insulin resistance as a key factor in the development of diabetes and metabolic syndrome.** Project may address insulin resistance as a consequence of altered energy homeostasis due to environmental and genetic factors, and should lead to novel treatments, possibly addressing complications of diabetes and metabolic disturbances. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.3-4: Pathophysiological mechanisms related to excess fat.** Study of adipokine-mediated crosstalk of adipose tissues with other peripheral tissues including periorganic adipose tissues, with the objective to design drugs that reduce or reverse adipokine-mediated adverse interactions and the obesity-associated inflammatory drift. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.3-5: A road-map for diabetes research.** Broad review of the entire state-of-the art science in the European Union with respect to all types of diabetes. Identification of existing programmes in Member States, recent research advances, and identification of gaps should allow the study to propose possible road maps for the future of diabetes research in Europe, with different scenario. International developments as well as the Innovative Medicines Initiative should be taken into account. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-2.4.3-6: Nutritional signals and the development of new diabetes/obesity therapeutic agents.** This project will focus on the effects of alternative compounds which improve carbohydrate/lipid metabolism or modify body weight, and could be used in the development of new therapeutics in the treatment of hyperglycemia and hyperlipidemia. This project should have at least

40% of its funding going to SMEs. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects targeted to SMEs with maximum EC contribution of EUR 6 000 000/project).

- **HEALTH-2007-2.4.3-7: Markers and treatment for diabetic neuropathy complications.** The project should analyse the pathophysiological basis of diabetic neuropathy. The results should lead to better markers of these complications and to approaches for intervention. All types of diabetes can be specifically addressed in this project. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
 - **HEALTH-2007-2.4.3-8: Geno- and phenotypical differentiation of type 2 subjects and monogenic subjects.** Development of diagnostic tools based on geno- and phenotypical characterisation to differentiate patient subgroups in order to tailor approach to the diseases. **A particular effort should be dedicated to identify patients with early development of vascular complications and/or initial pancreatic beta cell dysfunction.** **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
 - **HEALTH-2007-2.4.3-9: Use of beta cell imaging in diabetes mellitus.** Identification and application of novel approaches based on beta cell imaging (sophisticated life cell imaging of islets and the pancreas), in particular to investigate beta cell mass regulation (loss and neogenesis) *in vitro* and *in vivo*. The project should clearly demonstrate the clinical perspectives. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with maximum EC contribution of EUR 6 000 000/project).
- **2.4.4. Rare diseases**

The focus will be on Europe-wide studies of natural history, pathophysiology and on development of preventive, diagnostic and therapeutic interventions. This sector will include rare Mendelian phenotypes of common diseases.

Expected impact: This area should help identifying and mobilising the critical mass of expertise in order (i) to shed light on the course and/or mechanisms of rare diseases, or (ii) to test diagnostic, preventive and/or therapeutic approaches, to alleviate the negative impact of the disease on the quality of life of the patients and their families, as appropriate depending on the level of knowledge concerning the specific (group of) disease(s) under study.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.4.4-1: Natural course and pathophysiology of rare diseases.** Support will be given to innovative, multidisciplinary projects investigating the natural course (on a Europe-wide scale) and pathophysiology of non-infectious, non-malignant rare diseases in the following six areas: endocrine, immunological and metabolic diseases; diseases principally affecting the genitourinary tract; diseases principally affecting the digestive system; diseases principally affecting the respiratory system. Attention should be given to the development of adequate

models (*in vitro* and animal models). The acquired knowledge will provide the bases for future development of diagnostic, therapeutic and potentially preventive approaches. Research on disorders affecting the nervous system is excluded. Children health and ageing aspects should be taken into consideration whenever appropriate. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-2.4.4-2: Research capacity-building in the field of rare diseases.** This action is dedicated to developing a team- and project-building platform to help researchers in the field of rare diseases setting up efficient, multidisciplinary teams tackling rare diseases research challenges. This action should offer the opportunity for potential multinational teams to exchange ideas and strategies, for instance through workshops or teleconferences, with a view to structuring future research proposals. Of particular importance is that EU27 is fairly represented. This action is not intended to provide direct support to individual consortia for preparation of their specific project. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

- **2.4.5. Other chronic diseases**

The focus will be on non-lethal diseases with a high impact on the quality of life at old age such as functional and sensory impairment and other chronic diseases (e.g. arthritis, rheumatic and musculo-skeletal diseases and respiratory diseases including those induced by allergies).

Expected impact: Collaborative research in this area will develop improved diagnostics and/or intervention strategies with the expected impact of delaying the onset of chronic diseases and improving quality of life.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-2.4.5-1: Osteoarthritis.** Significant research and coordination efforts have to be made to develop new pathways in Osteoarthritis research. Excellent clinical and basic research centres should be brought together to investigate better insights into pathogenetic, diagnostic and prognostic factors of Osteoarthritis towards translating results into clinical application. **Funding scheme:** Collaborative project (Large-scale integrating project).
- **HEALTH-2007-2.4.5-2: Inflammatory bowel disease.** Support will be given to multidisciplinary projects investigating the etiology, pathogenesis and innovative therapeutic intervention. Research should include the identification of mucosal protease polymorphisms in the human population, the association of specific protease gene variants with inflammatory bowel disease, the characterisation of expression regulation and biochemical properties and the interaction of proteases with the microflora. Special attention should be given to human studies and to the development of new mouse models of IBD. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.5-3: Osteoporosis: signalling pathways in bone formation and homeostasis.** Research will focus on signalling mechanisms involved in bone formation and maintenance in order to develop therapeutic approaches for bone

regeneration. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-2.4.5-4: Genetic factors of Osteoporosis.** Osteoporosis is a multifactorial disorder with a complex genetic component. Research should apply advanced statistical analysis in order to genotypic and phenotypic data obtained or to be obtained from large patient cohorts to identify susceptibility genes. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.5-5: Intervertebral disc degeneration: prevention and repair.** Intervertebral disc degeneration is strongly determined by the patient's genotype. Research will focus on functional genetic studies of disc degeneration in order to develop novel approaches for diagnosis, prevention and repair. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.5-6: Innovative concepts in chronic obstructive pulmonary disease pathogenesis (COPD).** Support will be given to multidisciplinary projects investigating innovative concepts and critical gaps in the pathogenesis of COPD in order to increase the knowledge of the pathology of the disease. The research should focus on the translational aspects with integration of biological data with clinical data and on the identification of biomarkers and molecular targets in order to pave the way for better diagnostics and treatment of the disease. User friendly and cost effective diagnostic should be considered. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.5-7: Hearing impairment and degeneration.** Coordination of basic research actors from different disciplines with clinical research activities. It is expected to link the European research activities and foster European translational research in these fields, linking also projects and activities from FP5 and FP6. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.4.5-8: Impairment of touch and proprioception at old age.** The decline of cutaneous sensation and proprioception is a neglected area within sensory impairment research. The purpose of this CSA is to assess state of the art, European readiness and research needs in order to define future research strategies. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-2.4.5-9: Visual impairment and degeneration.** Objectives: Grouping and coordination of basic research actors from different disciplines with clinical research activities. It is expected to link the European research activities and foster European translational research in these fields, linking also projects and activities from FP5 and FP6. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

Topics for second call, deadline 18 September 2007

- **HEALTH-2007-2.4.5-10: Understanding and combating age-related muscle weakness.** The gradual loss of function of the musculo-skeletal apparatus

contributes to frailty at old age. The purpose of this topic is to carry out research in order to understand and combat age-related muscle weakness. In a translational research approach basic biological data are integrated with clinical and epidemiological data in order to describe the ageing process of the musculo-skeletal apparatus. Research should aim at maintaining individual mobility at old age. The development of mechanical devices to restore mobility is not covered by this topic. **Funding scheme:** Collaborative project (Large-scale integrating project).

- **HEALTH-2007-2.4.5-11: Translational research aiming for a treatment of urinary incontinence.** Gradual loss of urinary tract function has a major impact on the quality of life at old age. The purpose of this topic is to carry out research in order to understand and combat urinary incontinence. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-2.4.5-12: Early processes in the pathogenesis of chronic inflammatory diseases.** Translational research to obtain mechanistic insights into the early processes underlying chronic inflammatory diseases, such as asthma, rheumatoid arthritis and autoimmune conditions. Emphasis should be placed on identifying and validating molecular networks involved in the establishment and persistence of the chronic inflammatory reaction, with the aim of developing novel and specific anti-inflammatory treatments. A multidisciplinary approach (immunologists, cell biologists, molecular biologists, bioinformaticians) and the use of animal models amenable to genetic testing and manipulation are required. **Funding scheme:** Collaborative project (Large-scale integrating project).

3. OPTIMISING THE DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS

This activity aims at developing new research methods and generating the necessary scientific basis to underpin informed policy decisions on health systems and more effective and efficient evidence-based strategies of health promotion, disease prevention, diagnosis and therapy. It is recognised that the health systems of the EU are a central part of Europe's high levels of social protection and contribute to social cohesion and social justice as well as to sustainable development. The health systems of the EU reflect the overarching values of universality, access to good health care, equity and solidarity, aiming to make provision that is patient-centred and responsive to individual need. The principal target users of new knowledge within the Commission include the Directorate-General for Health and Consumer protection and the Directorate-General for Employment, Social Affairs and Equal Opportunities. In particular the research undertaken will generate the scientific evidence to meet the objectives of the proposed new Programme of Community Action in the field of Health (2007-2013). The principal targeted users outside the Commission include the Member States (Health Ministries and Public Health Institutes), the WHO (both Headquarters and the Regional Office for Europe), the OECD as well as clinicians, service providers, patients and other stakeholders.

3.1. TRANSLATING THE RESULTS OF CLINICAL RESEARCH OUTCOME INTO CLINICAL PRACTICE INCLUDING BETTER USE OF MEDICINES, AND APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES

Special attention will be given to patient safety, including adverse effects of medication: to identify the best clinical practice; to understand decision making in clinical settings in primary and specialised care; and to foster applications of evidence-based medicine and patient empowerment. Focus will be on the scientific benchmarking of strategies; investigating outcomes of different interventions including medicines, scientifically tested complementary and alternative medicines, and new health therapies and technologies taking into consideration prescription strategies, some aspects of pharmacovigilance evidence, specificities of the patient (e.g. genetic susceptibility, age, gender and adherence) and cost benefits.

Expected impact: Projects should advance the application of evidence-based medicine in Europe. The improved use of clinical research findings in clinical diagnosis and treatment as well as patient self-management of disease should be demonstrated and the cooperation between researchers in Europe and other geographic regions enhanced to promote integration and excellence of European research in the area. Findings should be scientifically validated in different settings and be applicable beyond the national level. Scientific methodologies that allow tools for benchmarking and comparative analysis at the European level will be considered an asset.

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-3.1-1: Implementation of research into healthcare practice.** Develop and validate a methodology for measuring how new knowledge is implemented in different health care settings (such as primary care, specialised care, hospital) by different target groups. Identify and validate factors determining the successful and timely implementation of new recommendations/guidelines/procedures, including learning cycles from adverse events in the context of patient safety. Issue recommendations for closing the research-practice gap in the implementation of clinical guidelines in Europe. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.1-2: Self-medication and patient safety.** Develop and validate a methodology to assess the impact of patient self-medication on patient safety and the associated risk of adverse events in the primary care setting. Research should focus on the prescriber and the tools needed to track and control the extent of patient self-medication, the provision of education and information to all concerned on safe self medication, and possible strategies for maximising benefit and minimising risk for safe and effective self-medication practices. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.1-3: Patient Safety Research Network.** To establish a network of researchers in the field of patient safety to strengthen information and broker knowledge where the quality of health care systems on patient safety is concerned, focussing on leadership and patient safety culture in health care organisations taking into account the different national contexts in Europe and existing international cooperation. **Funding scheme:** Coordination and Support Action (Coordination action).
- **HEALTH-2007-3.1-4: Improving clinical decision making.** Development and validation of a methodology to measure the quality of clinical decisions. The

methodology should be applied to explain variations of care in seemingly similar populations resulting from the clinical decision making process in different health care settings to allow comparative analyses of quality of care. This research should strengthen the clinical governance process for measurable improvements in clinical decision making. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-3.1-5: Better use of medicines.** Analysis of influential factors concerning prescription of medicines and compliance of their use for different clinical sectors, health care settings, and population segments including persons with limited decision-making ability (e.g. children, the mentally ill, etc.). Causes of inappropriate prescribing and poor compliance should be identified and policy recommendations for safe, effective and cost-effective use of medicines in Europe developed. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.1-6: Continuity of clinical care.** Analysis of clinical care at the primary care/hospital interface and its effect on quality in terms of health outcome and costs in different settings. Identify and validate factors determining the outcome of integration in different settings for a provision of a continuum of quality clinical care at the primary care/hospital interface. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.1-7: Patient self-management of chronic disease.** Develop and validate models for sustainable impact of self-management tools and education for different chronic diseases including mental disorders in different settings applicable to the general population for an improved and sustained quality of self-management of chronic diseases. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

3.2. QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTH CARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS

The objective is to provide, in the light of new knowledge, scientifically validated tools to allow countries to learn from the experience of other health systems and their sustainability, taking into account the importance of national contexts and population characteristics (ageing, mobility, migration, education, socioeconomic status and the changing world of work etc). Focus will be on organisational, financial and regulatory aspects of health systems (assessing the cost, efficiency and benefits of different interventions including as regards patient safety), their implementation and their outcomes in terms of effectiveness, efficiency and equity (including disadvantaged groups). Special attention will be paid to investment issues and human resources, including home care strategies.

Expected impact: Projects should advance the state of the art in the field of health systems research and enhance cooperation between researchers in Europe and other geographic regions to promote integration and excellence of European research in the field. This research should develop the scientific evidence base that supports the Member States to better organise their health systems according to the common principles of equity, solidarity, and universality. The knowledge generated should empower the policy and

decision maker to better manage and reform health care systems in view of common challenges and within the common framework of the European Union.

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-3.2-1: Evaluation of disease management programmes.** Develop and validate a methodology to establish comparative analysis of disease management programmes (e.g. algorithm-guided collaborative care systems) addressing the growing burden of chronic diseases including psychiatric disorders taking into account the diversity of European health care systems (including such factors as financing regimes, status of family practitioners, degree of medical autonomy, the existence of specialised home nursing systems etc.). Apply this method to evaluate large-scale population-based disease management programmes and their effect on cost, quality, and health outcomes to identify best practice. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-2: Health systems and long term care of the elderly.** Develop and validate a methodology to analyse the provision of long-term care across European health systems. Develop a model that ensures quality of services, provides incentives for prevention and rehabilitation, supports informal care providers, and adequately links to health care services. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-3: Mobility of health professionals.** Analyse mobility of different cadres of health professionals to, from, and within the European Union (extent; factors reducing or facilitating mobility; effects on remaining staff, health care services, and health outcomes; economic costs). Evaluate the effectiveness of existing financial and non-financial incentive schemes and policy responses addressing mobility trends. Develop recommendations for strengthening human resource policies in European and targeted third countries. The participation of organisations from the targeted third countries and regions is considered an asset to reinforce the impact of the action (see ICPC-list in annex 1 of the Work Programme). **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-4: Health care human resource planning in nursing.** Establish and validate a methodology to forecast in a quantitative and qualitative way the demand and supply of human resources for health care in nursing at the national level over the next 10 to 30 years. Influencing factors such as migration, mobility, demographics, health care structure, education and training, economic costs, etc should be evaluated to enable more effective human resource strategies at national and European level. The participation of organisations from the targeted third countries and regions is considered an asset to reinforce the impact of the action (see ICPC-list in annex 1 of the Work Programme). **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-5: Clinician working time and patient safety.** Analyse how changes in the duty hours standards affect the rate of medical errors and outcomes over time among patients treated at hospitals in Europe. Identify and validate factors determining the effectiveness of strategies that limit work hours and on-call

periods, manage the consequences of limited work hours, and positively change the behaviour of clinicians and the culture of health care organisations to reduce exhaustion and fatigue for better health outcomes. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-3.2-6: Health outcome measures and population ageing.** Develop and validate innovative assessment instruments based on the International Classification of Functioning, Disability and Health for cross-population comparative analysis. These methods should produce comparable longitudinal data on non-fatal physical and mental health outcomes, quality of life, and well-being in an ageing population. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-7: Trends of population health.** Develop a methodology that allows a longitudinal and cross-sectional assessment of population health that relates disease and mortality patterns to demographic and socio-economic trends taking into account the diversity of European health systems. Validate this model using existing national and European population-based registries and databases. Apply this model to non-European countries in three different stages of development. Develop strategic and policy recommendations for European, national and local policy makers and health care managers. The participation of organisations from the targeted third countries and regions is considered an asset to reinforce the impact of the action (see ICPC-list in annex 1 of the Work Programme). **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.2-8: European system of Diagnosis-related groups (DRG).** To explore and develop ways to establish a European Diagnosis-related groups (DRG) system to allow a meaningful comparisons of cost and prices for in-patient services, incorporating the experiences of the different Member States and considering the different input prices as well as different preferences in medical practice and new and emerging technologies. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION

The objective of this area is to provide scientific evidence for the best public health measures in terms of life styles, work and living circumstances and interventions at different levels and in different contexts. Focus will be on the wider determinants of health and how on the basis of new knowledge they interact at both the individual and community level (e.g. diet, stress, tobacco, alcohol and other substances, physical activity, cultural context, socio-economic and environmental factors). In particular, mental health will be addressed in a life-course perspective.

Expected impact: Projects should advance the state of the art in the field of health promotion and primary prevention research and enhance cooperation between researchers in Europe and other geographic regions to promote integration and excellence of European research in the area. This research should provide the evidence base to empower the individual to change and sustain healthy behaviour and the policy and decision makers at European, national and local level to develop and implement effective public health interventions and incorporate health goals in the definition and implementation of all

policies. Findings should be applicable to the general population and be validated in different settings, translating research into practice. Where applicable scientific methodologies that allow tools for benchmarking and comparative analysis at the European level will be considered an asset.

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-3.3-1: Promoting healthy behaviour in children and adolescents.** Multidisciplinary analysis (including sociological, psychological, economical facets) of impact and utility of financial and non-financial incentive schemes on extrinsic and intrinsic factors determining healthy behaviour in children and adolescents. The influence of existing schemes on different populations, settings, and purposes should be examined and new schemes developed and validated for improved capacity to encourage and sustain the adoption of healthy behaviours. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.3-2: Interventions addressing the gradient of health inequalities.** Evaluation of the effectiveness of public health interventions and alternative public health policy options on different segments of the population. The causes for low impact of public health interventions in specific population segments should be identified; public health policy options for the local, national, and European level to decrease the health inequalities gradient should be identified and validated. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.3-3: Public health interventions addressing the abuse of alcohol.** Population-based effectiveness research on strategies addressing alcohol use (e.g. taxes, pricing, packaging, availability, access, advertisement, traffic control, early diagnosis and treatment of disease, relapse prophylaxis, etc.) in multiple settings, geographical regions, gender and age groups to guide integrated policy making for prevention of alcohol abuse. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.3-4: Evaluation of suicide prevention strategies across and within European countries.** Develop and validate a methodology to contribute to the elaboration of suicide prevention strategies. Focus should be on creating consensus on definitions, specifications of interventions and address the challenges of field research. Systematically review and evaluate current strategies and identify best practices regarding development and evaluation of effective suicide prevention interventions. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.3-5: Improve vaccination coverage.** Develop and validate a methodology to evaluate the effectiveness and cost-effectiveness of public health interventions and policies aimed at improving the coverage of recommended vaccinations against infectious diseases in different population segments and settings. Apply this model to identify and define best practice across Europe. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

3.4. HORIZONTAL COORDINATION AND SUPPORT ACTIONS ACROSS "OPTIMISING THE DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS"

Expected impact: These small and targeted Coordination and Support actions should help achieving the objectives across the activity "Optimising the delivery of health care to European citizens".

Topics for second call, deadline 18 September 2007:

- **HEALTH-2007-3.4-1: Disease networks of centres of reference.** Scoping study on the feasibility of developing guidelines, criteria and areas to develop European networks of centres for diseases requiring a particular concentration of resources or expertise, which would also be focal points for research, information dissemination and evaluation and medical training. **Funding scheme:** Coordination and Support Action (Support action).
- **HEALTH-2007-3.4-2: Effectiveness of health investments.** Scoping study to review recent health investments in order to assess the way they meet the needs of the population, the decision making process and the choice between alternative projects in the old and the new Member States, taking into account cost- effective investments and optimal ways for assessing and deciding on the choice of projects. **Funding scheme:** Coordination and Support Action (Support action).
- **HEALTH-2007-3.4-3: Patient mobility and access to information.** A scoping study to examine the feasibility of developing a minimum data set that would be required to ensure reliable information about cross border care, allowing analysis of how this data set could fit into the regular data mechanisms and identifying the optimal structures for providing the information and monitoring activities. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-3.4-4: Brokering research into policy.** Scoping study on the way in which new and existing knowledge can be transferred - concepts and organisational models - into policy initiatives/mechanisms/practices to allow comparative research on the organisation and management of health care information systems. **Funding scheme:** Coordination and Support Action (Support action).
- **HEALTH-2007-3.4-5: A road-map for ageing research.** Identification of existing research programmes in Member States, recent advances, and identification of gaps to identify potential road maps for the future of ageing research in Europe. **Funding scheme:** Coordination and Support Action (Coordination or Support action).
- **HEALTH-2007-3.4-6: Health Services Research conference.** The present situation in Europe should be explored and challenges for the future identified. **Funding scheme:** Coordination and Support Action (Support action).
- **HEALTH-2007-3.4-7: Mental health research conference.** **Funding scheme:** Coordination and Support Action (Support action).

- **HEALTH-2007-3.4-8: Public Health intervention research conference.** **Funding scheme:** Coordination and Support Action (Support action).

3.5. SPECIFIC INTERNATIONAL COOPERATION ACTIONS FOR HEALTH SYSTEM RESEARCH

The objective is to support research in order to provide a scientific base for International Cooperation Partner Countries (ICPC, see annex I) to improve their health service delivery, including aspects of accessibility, effectiveness, efficiency and quality of care and user-friendliness. It also covers public health concepts and interventions beyond health services through cross-sectorial and multi-disciplinary research approaches. Global initiatives such as the Millennium Development Goals (MDGs) should be taken into account.

Expected impact: Topics under this area have direct relevance to the international dimension of the public health policy of the European Community by contributing to health protection, prevention and promotion, while at the same time generating new knowledge relevant to social, environmental and economic issues. Through cross-sectoral and multi-disciplinary approaches the research will contribute to initiatives such as the Millennium Development Goals, the Ministerial Declarations on Global Health Research and the European policy framework for attainment of the health MDGs. The principal targeted users include the Commission (in particular DG Health and Consumer Protection and DG Development), Member States (Health Ministries and Public Health Institutes), stakeholders in the various ICPC Regions including Ministries of Health, the WHO (both Headquarters and the Regional Office for Europe), and various NGO stakeholders in the global health research community.

Topics for Specific International Cooperation Actions (SICA), deadline 18 September:

- **HEALTH-2007-3.5-1: Epidemiological investigations into long-term trends of population health as consequence of socio-economic transitions, including life-style induced health problems.** Investigations into tackling the burden of chronic diseases such as diabetes, cardiovascular and liver diseases, for identifying strategies at the population level to implement effective solutions to improve health. Specific International Cooperation Action. Targeted regions: Mediterranean Partner countries, Russia, Eastern European and Central Asia. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.5-2: Universal and equitable access to health care and health financing.** Research into support of policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage in health sectors with poor resource allocations. Specific International Cooperation Action. Targeted regions: Mediterranean Partner Countries, ACP, Asia and Latin America. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).
- **HEALTH-2007-3.5-3: Health care intervention research – optimising hospital care.** Investigation into the implications of health care reform for the secondary care sector in the light of existing knowledge including evidence-based decision making, best/good practice, health inequalities, financing mechanisms, and outcome oriented health care investments, in order to develop and validate relevant policy options. Specific International Cooperation Action. Targeted region: Western Balkans. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

- **HEALTH-2007-3.5-4: Health care intervention research – improving pre-natal and maternal care.** Investigation into the gaps in knowledge and underlying causes of underutilisation of interventions known to be effective in preventing pre-natal mortality and morbidity. Sustainable strategies should be identified and validated to improve health care in this field. Specific International Cooperation Action. Targeted regions: ACP and Mediterranean Partner Countries. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

4. OTHER ACTIONS ACROSS THE HEALTH THEME

4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME

The objective of these actions is to contribute to the implementation of the Framework Programmes and the preparation of future Community research and technological development policy.

Topics for first call, deadline 19 April 2007:

- **HEALTH-2007-4.1-1: Reinforcing the network of National Contact Points (NCP) for the Seventh Framework Programme under Health Theme by promoting trans-national co-operation.** The action will focus on identifying and sharing good practices. This may entail various mechanisms such as benchmarking, joint workshops, training, and twinning schemes. Practical initiatives to benefit cross-border audiences may also be included, such as trans-national brokerage events. The specific approach should be adapted to the nature of the theme and to the capacities and priorities of the NCPs concerned. Special attention will be given to helping less experienced NCPs rapidly acquire the know-how accumulated in other countries. Proposals are expected to include all NCPs who have been officially appointed by the relevant national authorities. Other participants from the EU and associated countries are ineligible. If certain NCPs wish to abstain from participating, this fact should be explicitly documented in the proposal. The action may also involve official FP7 contacts from the international cooperation partner countries. The Commission expects to receive a single proposal under this heading. **Funding scheme:** Coordination and support action (Coordination or Support action).

Expected impact: An improved NCP service across Europe, therefore helping simplify access to FP7 calls, lowering the entry barriers for newcomers, and raising the average quality of submitted proposals. A more consistent level of NCP support services across Europe.

- **HEALTH-2007-4.1-2: Promoting participation of high-technology research intensive SMEs, operating in the biomedical engineering and other medical technology sectors relevant to Health Theme.** The objectives are: (i) Promoting participation in the incoming FP7 calls, of high-technology research intensive SMEs working in the biomedical engineering and other medical technology sectors relevant to Health Theme. The promotional activity should include participation in relevant events and organisation of at least one major European conference complemented by workshops, as appropriate, with special attention to new member states, acceding and candidate countries. (ii) Facilitate the access of the above

mentioned SMEs to existing support structures available to SMEs working in the Health sector. The project should complement, with a synergistic approach, and collaborate with, existing support structures like National Contact Points and already funded projects relevant for SMEs working in health sector. **Funding scheme:** Coordination and Support Action (Support action).

Expected impact: The promotional activity targeted towards the new research areas now open for funding, will support the increase of SMEs participation in the Health Theme, enhancing Lisbon objective for contribution to technological evolution, competitiveness of European industry, economic growth and employment. Mobilisation of high-technology research intensive SMEs will enhance the dissemination and exploitation of research results generated in the activities funded by this Theme.

- **HEALTH-2007-4.1-3: Assessment and valorisation of project outcome for high-technology and research intensive SME participating to Framework Programmes of Research in the healthcare sector.** The objective are (i) to perform a study to identify successful SMEs participating in projects funded in the theme of Life sciences, genomics and biotechnology for health of the sixth framework programme and of the “Health” theme in seventh framework programme, assessing in qualitative and quantitative terms the longer term impact of the project outcome; (ii) the participant(s) shall help those SMEs in the valorisation of projects outcome, its promotion, identification of marketing and financial opportunities, and particularly provide support to facilitate access to additional funding possibilities and the related stakeholders. The project should complement, with a synergistic approach and collaborate with existing support structures like National Contact Points and already funded projects relevant for SMEs working in health sector. **Funding scheme:** Coordination and Support Action (Support action).

Expected impact: Assessment of project outcomes will help policy makers to define new research policy objectives and intermediate performance targets for FP7. Valorisation of research results will enhance dissemination and uptake of the research generated in the Health-related projects in FP6 and FP7.

- **HEALTH-2007-4.1-4: Identifying patients' needs in the clinical trials context.** The goal of this topic is to identify the needs of patients as related to clinical outcome: How can patients be better mobilised and empowered in the clinical trials landscape and which are the clinical outcomes that really matter to patients, how can they be integrated into clinical trials. These questions should be addressed involving patients, clinicians, regulators, and researchers (industrial and academic) on a broad basis in order to cover a broad spectrum of diseases. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

Expected impact: This project will mobilise involved stakeholders and generate the necessary knowledge on needs, methodology, outcomes etc of patient-centred clinical-trials with a view to optimise clinical testing , including also the patient perspective

- **HEALTH-2007-4.1-5: Science communication actions.** Projects should elaborate strategies and/or products to communicate the results and activities of contemporary health sciences to the general public, using information from EU-

funded projects. Products may incorporate various types of support (e.g. television, audiovisuals, exhibitions, internet, animation films, books for children, etc.) and the wide distribution should be envisaged. **Funding scheme:** Coordination and Support Action (Support action).

Expected impact: Diffusion of the output of EU health research projects to the general public. Contribution to the improvement of the understanding of health sciences in the general public.

- **HEALTH-2007-4.1-6: Initiatives to foster dialogue and debate on health research issues of interest to the public.** Such activities should be oriented towards the engagement of the general public and/or targeted groups (e.g. patients, young people, public representatives, non-governmental organisations, etc.). Participation of renowned scientists (with good communication skills) to ensure the highest scientific quality is required as well as professional facilitators to lead the debate. Media-oriented events and initiatives (audiovisual, press, etc.) are encouraged. Innovative dissemination plans and strategies to maximise the impact of the initiative at the European level should be incorporated (press coverage, publicity on the outcome, secondary actions, etc.). **Funding scheme:** Coordination and Support Action (Support action).

Expected impact: To foster the debate between scientists and the general public on questions and concerns related to health research issues including its related new developments and applications.

- **HEALTH-2007-4.1-7: Studies on the impact of EU legislation on health research and related developments and applications.** The objective is on the basis of scientific analysis to evaluate the consequences of specific current EU legislation and related guidelines, including where applicable the way they are implemented at the national level, on specific research activities supported within this theme including related developments and applications. Each project is expected to address a specific issue, which has to relate to an EU legislation of major importance for the research and outcome performed within this theme. Such EU legislation relate in particular to the legal protection of biotechnological inventions, or clinical trials, or orphan medicinal products, or the protection of vertebrate animals used for experimental and other scientific purposes, or the standards of quality and safety of human tissues and cells. **Funding scheme:** Coordination and Support Action (Support action).

Expected impact: To better assess the consequences of EU legislation on research activities and related developments supported within this theme using scientific analysis based on facts and figures. In particular, such projects are expected to constitute the evidence base that will help the Commission to anticipate the needs for eventual revision of current EU legislation or elaboration of new ones.

Topic for Specific International Cooperation Action (SICA), deadline 18 September 2007:

- **HEALTH-2007-4.1-8: Promotion and facilitation of international cooperation in areas relevant to the objectives of this Theme.**³⁰ Actions should aim at networking scientists for stimulating the creation of research consortia and the identification of priorities of common interest in health research. Specific International Cooperation Action. Targeted regions: ICPC. **Funding scheme:** Coordination and Support Action (Coordination or Support action).

Expected impact: Facilitation of the collaboration with 3rd countries, especially in terms of synergising with existing national funds in those countries and identifying topics for future calls. Support to interaction between European and International Collaboration Partner Countries' researchers.

4.2. RESPONDING TO EU POLICY NEEDS

Paediatric medicinal products

It is envisaged that several projects will be funded under this topic with a total indicative budget of EUR 30 000 000 .

Topic for second call, deadline 18 September 2007:

- **HEALTH-2007-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations.** Support will be given to studies dedicated to provide evidence for specific paediatric use of off-patent medicinal products currently used off-label. Studies include the assessment of pharmacokinetics (as well as data analysis and extrapolation by means of *in silico* models), efficacy and safety, and/or the development of appropriate formulations. Project proposals must take account of the priority list of Off-Patent Medicinal Products of the Paediatric Working Party of the European Medicines Agency (EMA), and of the Regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) N° 1768/92, Directive 2001/83/EC and Regulation (EC) N° 726/2004, Brussels, 29.9.2004, COM(2004) 599 final, 2004/0217 (COD). The priority list is available at the following address: <http://www.emea.europa.eu/pdfs/human/peg/49677706en.pdf>. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects with a maximum EC contribution of EUR 6 000 000/project).

Expected Impact: The projects will provide evidence for a better use of off-patent medicinal products in paediatric populations. The acquired knowledge should aim at eventual new Paediatric Use marketing authorisations (PUMAs).

³⁰ See also Capacities programme

Drug safety research

Topic for second call, deadline 18 September 2007:

- **HEALTH-2007-4.2-2: Relative safety of non-steroidal anti-inflammatory drugs (NSAIDs).** The objective is to analyse the relative cardiovascular and/or gastrointestinal safety profile of NSAIDs, including especially COX-II inhibitors. Specific research outputs will be the generation and analysis of data that will allow for a robust and reliable comparison of the relative risks of different drug substances to be made and for the identification of at-risk patient groups. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Expected Impact: The results of this research should allow for evidence-based regulatory and treatment decisions to be made.

Living and work conditions

Topic for first call, deadline 19 April 2007:

- **HEALTH-2007-4.2-3: Research to assess the economic dimension of occupational health and safety.** The focus will be on the economic impact of health at work, in particular the effects of quality of work and employment upon Europe's competitiveness in a changing work environment [e.g. ageing of the workforce, gender balance, precarious situations and decrease in the size of the companies (more SMEs)]: this includes issues such as the overall investment on risk prevention at work, business case, costs and benefits connected to improvement of work environment (including accidents at work, occupational diseases, related absenteeism), and the development of management and accounting tools integrating the occupational health and safety dimension. **Funding scheme:** Coordination and Support Action (Support action).

Expected Impact: To provide evidence for policy development aiming at improving occupational health and safety in the context of profound changes of work and society.

Health statistics

Topic for first call, deadline 19 April 2007:

- **HEALTH-2007-4.2-4: Health statistics and rare events.** Develop and validate an improved methodology for data collection on rare events (disability, accidents and more generally severe health events or conditions including polytrauma). **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Expected impact: Projects should contribute to the methodological improvement of official statistics to address the increasing burden on respondents, reduce costs, streamline data collection, and adapt to new technologies. Findings should meet the quality criteria used by the European Statistical System and be applicable at national and European level.

Framework Convention on Tobacco Control³¹

Topic for second call, deadline 18 September 2007:

- **HEALTH-2007-4.2-5: Effectiveness of fiscal policies for tobacco control in Europe.** Develop and validate a methodology to allow analysis, comparison and assessment of the effectiveness of pricing policies across Europe and their impact on tobacco use, cessation and relapse behaviour in multiple population subgroups. This research should address differential price and income effects as well as substitution, emergence of grey/illegal markets and the relation to smoking restriction policies. **Funding scheme:** Collaborative projects (Small or medium-scale focused research projects).

Expected impact: Provide evidence base to improve market regulation of tobacco products for more effective and equitable control of tobacco use in Europe.

5. Calls for Tenders

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

- Communication/dissemination actions related to EU RTD activities in Health (Open call for tenders, estimated maximum cost EUR 500 000 in 2007 and EUR 500 000 in 2008).
- Ex-post evaluation and impact assessment of EU RTD funding in Health (Open call for tenders, estimated maximum cost EUR 500 000 in 2007 and EUR 500 000 in 2008).

Further details will be provided in the text launching the service request.

³¹ Framework Convention on Tobacco Control, 2004/513/EC

Indicative budget for the Health Theme for the 2007-2008 Work Programme **

	Total ³²	2007 EUR million	2008 ³³ EUR million
CALL FP7-HEALTH-2007-A	637.00	637.00*	
CALL FP7-HEALTH-2007-B	549.00		549.00
GENERAL ACTIVITIES (ANNEX 4)	62.75	20.01***	10.80
OTHER ACTIVITIES:			
• Evaluations:	17.16	11.50	5.66
• HFSP:	4.80	2.40	2.40
• Calls for tenders:	2.00	1.00	1.00
ESTIMATED TOTAL BUDGET ALLOCATION	1 272.71	671.91	568.86

* This amount includes an indicative amount of EUR 2 million for the ERA-NETs foreseen under this Theme – See Annex 4 (Table 2 - Overview of Activities and Topics mentioned in Cooperation Themes which are part of the FP7-ERANET-2007 – RTD joint call).

** The Innovative Medicines Initiative, as presented to the Council in the Commission Proposal COM(2007) 0241, will be implemented by a separate mechanisms and is, therefore, not featured here.

*** An amount of EUR 31.94 million was transferred in 2007 from the Health Theme to the newly created budget line for the Risk Sharing Finance Facility. This amount corresponds to the Health Theme contribution for RSFF for 2007 and 2008 (see page 14).

Summary of budget allocation to general activities for 2007 and 2008

	2007 EUR million	2008 EUR million
Cordis	1.39	1.34
Eureka/Research organisations	0.16	0.05M
COST	5.95	5.76
ERA-NET	12.51	3.65
Total	20.01	10.80

³² The total funding is shown, together with the breakdown of how this is financed through the annual budgets.

³³ Under the condition that the preliminary draft budget for 2008 is adopted without modifications by the budget authority.

Indicative budget breakdown between activities

Activity	FP7- HEALTH- 2007-A EUR million	FP7- HEALTH- 2007-B* EUR million
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH	142.00	96.00
2. TRANSLATING RESEARCH FOR HUMAN HEALTH	475.00	270.00
3. OPTIMISING THE DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS³⁴	-	91.00
4. ACTIONS ACROSS THE THEME	20.00**	92.00 ***
ESTIMATED TOTAL BUDGET	637.00	549.00

* 2008 Budget figures given under the condition that the preliminary draft budget for 2008 is adopted without modifications by the budget authority.

** Including EUR 6 million for Specific International Cooperation Actions (SICA) across the Theme

*** Including EUR 30 million for the topic Adapting off-patent medicines to the specific needs of paediatric populations and EUR 58 million for Specific International Cooperation Actions (SICA) across the Theme

³⁴This activity will be covered only in call FP7-HEALTH-2007-B.

III IMPLEMENTATION OF CALLS

Please note that the call fiche has been updated with respect to the version published on CORDIS on 26 February 2007. The substantive modifications are as follows:

- A budget of EUR 549.00million has been given to Call FP7-HEALTH-2007-B from the 2008 budget, under the condition that the preliminary draft budget for 2008 is adopted without modifications by the budget authority.
- Date of publication of the Call FP7-HEALTH-2007-B has been postponed till 18 June 2007 (previously 11 May 2007).

Call identifier: FP7-HEALTH-2007-A

- Date of publication: 22 December 2006
- Deadline: 19 April 2007, at 17.00.00, Brussels local time
- Indicative budget: EUR 637.00 million from 2007 budget
- Topics called:

Activity/Area	Topic	Funding scheme
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.1. HIGH-THROUGHPUT RESEARCH		
1.1.	HEALTH-2007-1.1-1: Unifying human and model organism genetic variation databases.	Collaborative project (Large-scale integrating project)
1.1.	HEALTH-2007-1.1-2: Temporal and spatial proteomics to study biological processes relevant to human health.	Collaborative project (Large-scale integrating project)
1.1.	HEALTH-2007-1.1-3: Groundbreaking techniques for DNA sequencing and genotyping.	Collaborative project (Large-scale integrating project)
1.2. DETECTION, DIAGNOSIS AND MONITORING		
1.2.	HEALTH-2007-1.2-1: Development of a hybrid imaging system.	Collaborative project (Small or medium-scale focused research project)
1.2.	HEALTH-2007-1.2-2: Novel optical methodologies for detection, diagnosis and monitoring of disease or disease-related processes.	Collaborative project (Small or medium-scale focused research project)
1.2.	HEALTH-2007-1.2-3: Novel targeted imaging probes for early in vivo diagnosis and/or evaluation of response to therapy.	Collaborative project (Large-scale integrating project)
1.2.	HEALTH-2007-1.2-4: In vivo image-guidance for cell therapy.	Collaborative project (Large-scale integrating project)
1.3. PREDICTING SUITABILITY, SAFETY AND EFFICACY OF THERAPIES		
1.3.	HEALTH-2007-1.3-1: Novel alternative testing	Collaborative project

	strategies for use in pharmaceutical discovery and development.	(Large-scale integrating project)
1.3.	HEALTH-2007-1.3-2: Bottlenecks in reduction, refinement and replacement of animal testing in pharmaceutical discovery and development.	Coordination and support action (Coordination or support action)
1.3.	HEALTH-2007-1.3-3: Promotion, development, validation, acceptance and implementation of QSARs (quantitative structure-activity relationship) for toxicology.	Collaborative project (Small or medium-scale focused research project)
1.3.	HEALTH-2007-1.3-4: Alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics.	Collaborative project (Small or medium-scale focused research project)
1.3.	HEALTH-2007-1.3-5: In silico modelling for ADMET outcomes.	Collaborative project (Large-scale integrating project)
1.4. INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4.	HEALTH-2007-1.4-1: Development and production of new generation antibodies.	Collaborative project (Small or medium-scale focused research project)
1.4.	HEALTH-2007-1.4-2: Innovative approaches for the development of vaccines for young children.	Collaborative project (Small or medium-scale focused research project)
1.4.	HEALTH-2007-1.4-3: Immunotherapy of human food allergies.	Collaborative project (Small or medium-scale focused research project)
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY		
2.1.1. Large scale data gathering		
2.1.1.	HEALTH-2007-2.1.1-1: Networking biobanking initiatives across Europe: developing standards and norms for existing and future human sample biobanks.	Collaborative project (Large-scale integrating project)
2.1.1.	HEALTH-2007-2.1.1-2: Molecular epidemiological studies in existing well characterised European (and/or other) population cohorts.	Collaborative project (Large-scale integrating project)
2.1.1.	HEALTH-2007-2.1.1-3: Comparative studies of genetic variation in humans: towards a reference population in Europe.	Collaborative project (Large-scale integrating project)
2.1.1.	HEALTH-2007-2.1.1-4: Characterisation and variability of the microbial communities in the Human Body	Collaborative project (Large-scale integrating project)
2.1.1.	HEALTH-2007-2.1.1-5: Structure-function analysis of membrane-transporters and channels	Collaborative project (Large-scale

	for the identification of potential drug target sites.	integrating project)
2.1.1.	HEALTH-2007-2.1.1-6: High throughput analysis of lipids and lipid-protein interactions.	Collaborative project (Large-scale integrating project)
2.1.1.	HEALTH-2007-2.1.1-7: Genome-wide association studies in mammalian non-rodent models for the identification of genes relevant to human health and disease.	Collaborative project (Large-scale integrating project)
2.1.2. Systems biology		
2.1.2.	HEALTH-2007-2.1.2-1: A system approach to eukaryotic unicellular organism biology.	Collaborative project (Large-scale integrating project)
2.1.2.	HEALTH-2007-2.1.2-2: Modelling of T-cell activation.	Collaborative project (Large-scale integrating project)
2.1.2.	HEALTH-2007-2.1.2-3: Fundamental approaches to stem cell differentiation.	Collaborative project (Large-scale integrating project)
2.1.2.	HEALTH-2007-2.1.2-4: Developing an integrated in vitro, in vivo and systems biology modelling approach to understanding apoptosis in the context of health and disease	Collaborative project (Large-scale integrating project)
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.1. Brain and brain-related diseases		
2.2.1.	HEALTH-2007-2.2.1-1: Stroke and mechanisms underlying ischemic brain damage.	Collaborative project (Large-scale integrating project)
2.2.1.	HEALTH-2007-2.2.1-2: Coding in neuronal assemblies.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-3: Neurobiology of anxiety disorders.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-4: Memory loss: underlying mechanisms and therapy.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-5: From basic spinal mechanisms to spinal cord disease and trauma.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-6: Neuron-glia interactions in health and disease.	Collaborative project (Small or medium-scale focused research project)
2.2.2. Human development and ageing		
2.2.2.	HEALTH-2007-2.2.2-1: Novel approaches to	Collaborative project

	reconstitute normal immune function at old age.	(Large-scale integrating project)
2.2.2.	HEALTH-2007-2.2.2-2: Termination of developmental processes and their reactivation in adult life.	Collaborative project (Large-scale integrating project)
2.2.2.	HEALTH-2007-2.2.2-3: Biomarkers of ageing.	Collaborative project (Large-scale integrating project)
2.2.2.	HEALTH-2007-2.2.2-4: Increasing the participation of elderly in clinical trials.	Coordination and support action (Coordination or support action)
2.2.2.	HEALTH-2007-2.2.2-5: Research on human development and/or healthy ageing across the EU	Coordination and support action (Coordination or support action)
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.1 Anti-microbial drug resistance including fungal pathogens		
2.3.2. HIV/AIDS, malaria and tuberculosis		
2.3.2.	HEALTH-2007-2.3.2-1: HIV/AIDS Drug Discovery and Preclinical Development.	Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-2: Highly innovative approaches for research into host-pathogen interaction in tuberculosis.	Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-3: Development of fast tests for the diagnosis of Multi-Drug-Resistant strains of HIV, malaria and tuberculosis and of latent tuberculosis infection (LTBI).	Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-4: Addressing knowledge gaps in pregnancy malaria.	Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-5: Paediatric formulations of drugs against HIV/AIDS, malaria and tuberculosis.	Coordination and support action (Coordination or support action)
2.3.2.	HEALTH-2007-2.3.2-6: New HIV Vaccines inducing broadly-reactive neutralising antibodies.	Collaborative project (Large-scale integrating project)
2.3.3. Potentially new and re-emerging epidemics		
2.3.3.	HEALTH-2007-2.3.3-1: Development of broadly protective influenza vaccine candidates.	Collaborative project (Small or medium-scale focused research project)
2.3.3.	HEALTH-2007-2.3.3-2: Identifying immunological mechanisms of protection for	Collaborative project (Small or medium-

	influenza vaccines.	scale focused research project)
2.3.3.	HEALTH-2007-2.3.3-3: Standardisation of immunological assays including surrogate markers for evaluation of new influenza vaccines in clinical trials.	Coordination and support action (Coordination or support action)
2.3.3.	HEALTH-2007-2.3.3-4: Innovative point-of-care diagnostic tests for influenza.	Collaborative project (Small or medium-scale focused research project targeted to SMEs)
2.3.3.	HEALTH-2007-2.3.3-5: Development of additional treatment strategies for patients suffering from highly pathogenic influenza.	Collaborative project (Small or medium-scale focused research project)
2.3.3.	HEALTH-2007-2.3.3-6: Development of pandemic influenza containment and mitigation strategies.	Collaborative project (Small or medium-scale focused research project)
2.3.3.	HEALTH-2007-2.3.3-7: Supporting highly innovative inter-disciplinary research on influenza.	Collaborative project (Small or medium-scale focused research project)
2.3.3.	HEALTH-2007-2.3.3-8: Influenza research in collaboration with Asian partners.	SICA: Collaborative project (Small or medium-scale focused research project)
2.3.4. Neglected infectious diseases		
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.1. Cancer		
2.4.1.	HEALTH-2007-2.4.1-1: Translating the knowledge on non-coding RNAs linked to the aetiology of cancer into novel diagnosis and therapy strategies.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-2: Translating clinical 'omics'-technology (genomics, proteomics, metabolomics) into innovative cancer biomarkers aiding in early diagnosis, prognosis and treatment selection of cancer patients.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-3: Genomic instability and genomic alterations in pre-cancerous lesions and/or cancer.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-4: Novel cancer screening methods.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-5: Optimising research on end of life care of cancer patients.	Coordination and support action (Coordination action)

2.4.1.	HEALTH-2007-2.4.1-6: Understanding and fighting metastasis.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-7: Improving targeted drug delivery to cancer cells for cancer therapeutics other than gene therapy.	Collaborative project (Small or medium-scale focused research project)
2.4.1.	HEALTH-2007-2.4.1-8: Developing high-throughput bioassays and models for human cancers in lower species.	Collaborative project (Small or medium-scale focused research project)
2.4.2. Cardiovascular disease		
2.4.2.	HEALTH-2007-2.4.2-1: Molecular basis of the inflammatory response and associated vascular remodelling in arteriosclerosis.	Collaborative project (Large-scale integrating project)
2.4.2.	HEALTH-2007-2.4.2-2: Vascular remodelling in aneurysmal disease.	Collaborative project (Large-scale integrating project)
2.4.2.	HEALTH-2007-2.4.2-3: Combating stroke.	Collaborative project (Large-scale integrating project)
2.4.3. Diabetes and obesity		
2.4.3.	HEALTH-2007-2.4.3-1: Early processes in the pathogenesis of type 1 diabetes and strategies for early prevention.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-2: Combined forms of diabetes in children.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-3: Insulin resistance as a key factor in the development of diabetes and metabolic syndrome.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-4: Pathophysiological mechanisms related to excess fat.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-5: A road-map for diabetes research.	Coordination and support action (Coordination or support action)
2.4.4. Rare diseases		
2.4.4.	HEALTH-2007-2.4.4-1: Natural course and pathophysiology of rare diseases.	Collaborative project (Small or medium-scale focused research project)
2.4.4.	HEALTH-2007-2.4.4-2: Research capacity-building in the field of rare diseases.	Coordination and support action

		(Coordination or support action)
2.4.5. Other chronic diseases		
2.4.5.	HEALTH-2007-2.4.5-1: Osteoarthritis.	Collaborative project (Large-scale integrating project)
2.4.5.	HEALTH-2007-2.4.5-2: Inflammatory bowel disease.	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-3: Osteoporosis: signalling pathways in bone formation and homeostasis.	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-4: Genetic factors of Osteoporosis.	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-5: Intervertebral disc degeneration: prevention and repair.	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-6: Innovative concepts in chronic obstructive pulmonary disease pathogenesis (COPD).	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-7: Hearing impairment and degeneration.	Coordination and support action (Coordination or support action)
2.4.5.	HEALTH-2007-2.4.5-8: Impairment of touch and proprioception at old age.	Coordination and support action (Coordination or support action)
2.4.5.	HEALTH-2007-2.4.5-9: Visual impairment and degeneration.	Coordination and support action (Coordination or support action)
4. OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1.	HEALTH-2007-4.1-1: Reinforcing the network of National Contact Points (NCP) for the Seventh Framework Programme under Health Theme by promoting trans-national co-operation.	Coordination and support action (Coordination or support action)
4.1.	HEALTH-2007-4.1-2: Promoting participation of high-technology research intensive SMEs, operating in the biomedical engineering and other medical technology sectors relevant to Health Theme.	Coordination and support action (Support action)
4.1.	HEALTH-2007-4.1-3: Assessment and	Coordination and

	valorisation of project outcome for high-technology and research intensive SME participating to Framework Programmes of Research in the healthcare sector.	support action (Support action)
4.1.	HEALTH-2007-4.1-4: Identifying patients' needs in the clinical trials context.	Coordination and support action (Coordination or support action)
4.1.	HEALTH-2007-4.1-5: Science communication actions.	Coordination and support action (Support action)
4.1.	HEALTH-2007-4.1-6: Initiatives to foster dialogue and debate on health research issues of interest to the public.	Coordination and support action (Support action)
4.1.	HEALTH-2007-4.1-7: Studies on impact of EU legislations on health research and related developments and applications.	Coordination and support action (Support action)
4.2. RESPONDING TO EU POLICY NEEDS		
4.2.	HEALTH-2007-4.2-3: Research to assess the economic dimension of occupational health and safety.	Coordination and support action (Support action)
4.2.	HEALTH-2007-4.2-4: Health statistics and rare events.	Collaborative project (Small or medium-scale focused research project)

- Evaluation procedure:
 - The general eligibility criteria are set out in Annex 2 to this work programme.
 - A one-stage submission procedure will be followed.
 - Proposals may be evaluated remotely.
 - The evaluation criteria (including weights and thresholds) and subcriteria, together with the eligibility, selection and award criteria, for the different funding schemes are set out in Annex 2 to this work programme.
- Indicative evaluation and contractual timetable:

Evaluations are expected to be carried out during the months May-July 2007. It is expected that the contract negotiations for the shortlisted proposals will be opened in July/August.
- Consortium agreements: Participants in Large-scale integrating projects are required to conclude a consortium agreement.
- Particular requirements for participation, evaluation and implementation:

It is important to note that the following funding thresholds will be applied as eligibility criteria and that the proposals which do not respect these limits will be considered as ineligible:

- Small or medium-scale focused research projects: the requested EC contribution shall not exceed EUR 3 000 0000 unless otherwise indicated in the topic description.

- Large-scale integrating projects: the requested EC contribution shall be over EUR 6 000 000 and not exceed EUR 12 000 000 unless otherwise indicated in the topic description.

The minimum number of participating legal entities required, for all funding schemes, is set out in the Rules for Participation and presented in relevant parts below.

Funding scheme	Minimum conditions
Collaborative project	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.
Collaborative project for specific cooperation actions dedicated to international cooperation partner countries (SICA)	At least 4 independent legal entities. Of these, 2 must be established in different MS or AC. The other two must be established in different international cooperation partner countries
Co-ordination and support action (coordination action)	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.
Co-ordination and support action (support action)	At least 1 independent legal entity
Research for the benefit of specific groups, such as SMEs	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.

For Small or medium-scale focused research projects targeted to SMEs all consortia should aim at having 40 % of the requested EC contribution budget going to SMEs.

- The forms of grant and maximum reimbursement rates which will be offered are specified in Annex 3 to the Cooperation work programme.

Call identifier: FP7-HEALTH-2007-B

- Date of publication: 18 June 2007³⁵
- Deadline: 18 September 2007, at 17.00.00, Brussels local time³⁶
- Indicative budget: EUR 549.00million from 2008 budget³⁷
- Topics called:

Activity/Area	Topic	Funding scheme
1. BIOTECHNOLOGY, GENERIC TOOLS AND MEDICAL TECHNOLOGIES FOR HUMAN HEALTH		
1.1. HIGH-THROUGHPUT RESEARCH		
1.1.	HEALTH-2007-1.1-4: SME-driven collaborative research projects for developing tools and technologies for high-throughput research	Collaborative project (Small or medium-scale focused research project targeted to SMEs)
1.2. DETECTION, DIAGNOSIS AND MONITORING		
1.2.	HEALTH-2007-1.2-5: Standardisation and improvement of pre-analytical procedures for in vitro diagnostics.	Collaborative project (Large-scale integrating project)
1.2.	HEALTH-2007-1.2-6: High throughput molecular diagnostics in individual patients for genetic diseases with heterogeneous clinical presentation.	Collaborative project (Small or medium-scale focused research project)
1.3. PREDICTING SUITABILITY, SAFETY AND EFFICACY OF THERAPIES		
1.4. INNOVATIVE THERAPEUTIC APPROACHES AND INTERVENTIONS		
1.4.	HEALTH-2007-1.4-4: Development of emerging gene therapy tools and technologies for clinical application.	Collaborative project (Large-scale integrating project)
1.4.	HEALTH-2007-1.4-5: Gene therapy tools targeting the central nervous system.	Collaborative project (Small or medium-scale focused research project)
1.4.	HEALTH-2007-1.4-6: Stem cell lines for cell-based therapies.	Collaborative project (Large-scale integrating project)
1.4.	HEALTH-2007-1.4-7: Development of stem cell culture conditions.	Collaborative project (Small or medium-scale focused research project)
1.4.	HEALTH-2007-1.4-8: Stem cells for kidney	Collaborative project

³⁵ The Director-General responsible for the call may publish it up to one month prior to or after the envisaged date of publication.

³⁶ At the time of the publication of the call, the Director-General responsible may delay this deadline by up to two months.

³⁷ Under the condition that the preliminary draft budget for 2008 is adopted without modifications by the budget authority.

	regeneration.	(Small or medium-scale focused research project)
1.4.	HEALTH-2007-1.4-9: Adding value to EU stem cell therapy research: scientific communication and future perspectives.	Coordination and support action (Coordination or support action)
2. TRANSLATING RESEARCH FOR HUMAN HEALTH		
2.1. INTEGRATING BIOLOGICAL DATA AND PROCESSES: LARGE-SCALE DATA GATHERING, SYSTEMS BIOLOGY		
2.1.1. Large scale data gathering		
2.1.2. Systems biology		
2.1.2.	HEALTH-2007-2.1.2-5: Multidisciplinary fundamental genomics and molecular biology approaches to study basic biological processes relevant to health and diseases.	Collaborative project (Small or medium-scale focused research project)
2.1.2.	HEALTH-2007-2-1-2-6: Coordination and Support Actions in large-scale data gathering and systems biology.	Coordination and support action (Coordination or support action)
2.1.2.	HEALTH-2007-2.1.2-7: Traditional Chinese Medicine in post-genomic era.	SICA: Coordination and support action (Coordination or support action)
2.2. RESEARCH ON THE BRAIN AND RELATED DISEASES, HUMAN DEVELOPMENT AND AGEING		
2.2.1. Brain and brain-related diseases		
2.2.1.	HEALTH-2007-2.2.1-7: Restorative approaches for therapy of neurodegenerative diseases.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-8: From mood disorders to experimental models.	Collaborative project (Large-scale integrating project)
2.2.1.	HEALTH-2007-2.2.1-9: Neuronal mechanisms of vision and related diseases.	Collaborative project (Small or medium-scale focused research project)
2.2.1.	HEALTH-2007-2.2.1-10: Childhood and adolescent mental disorders.	SICA: Collaborative project (Small or medium-scale focused research project)
2.2.2. Human development and ageing		
2.3. TRANSLATIONAL RESEARCH IN MAJOR INFECTIOUS DISEASES: TO CONFRONT MAJOR THREATS TO PUBLIC HEALTH		
2.3.1. Anti-microbial drug resistance including fungal pathogens		
2.3.1.	HEALTH-2007-2.3.1-1: Novel targets for drugs against Gram negative bacteria.	Collaborative project (Small or medium-scale focused research project)

2.3.1.	HEALTH-2007-2.3.1-2: Host-pathogen interactions in infections by Streptococcus pneumoniae.	Collaborative project (Small or medium-scale focused research project)
2.3.1.	HEALTH-2007-2.3.1-3: An integrated platform for development and clinical evaluation of point-of-care diagnostic devices for microbial detection, antibiotic susceptibility determination and biomarkers.	Collaborative project (Large-scale integrating project)
2.3.1.	HEALTH-2007-2.3.1-4: Molecular epidemiology to control nosocomial and community spreading of highly virulent multi-drug resistant strains of bacterial pathogens.	Collaborative project (Small or medium-scale focused research project)
2.3.1.	HEALTH-2007-2.3.1-5: Health and economic cost of antimicrobial resistance.	Coordination and support action (Coordination or support action)
2.3.1.	HEALTH-2007-2.3.1-6: Conference on genetic and biochemical tools for post-genomic physiological analysis of Staphylococcus, in particular MRSA.	Coordination and support action (Coordination or support action)
2.3.2. HIV/AIDS, malaria and tuberculosis		
2.3.2.	HEALTH-2007-2.3.2-7: Network on HIV and anti-HIV drug resistance.	Collaborative project (Large-scale integrating project)
2.3.2.	HEALTH-2007-2.3.2-8: HIV and Hepatitis co-infection.	Coordination and support action (Coordination or support action)
2.3.2.	HEALTH-2007-2.3.2-9: Blocking the transmission of malaria: the mosquito vector target.	Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-10: European network for study and clinical management of TB drug resistance.	Collaborative project (Large-scale integrating project)
2.3.2.	HEALTH-2007-2.3.2-11: Support platform for the development of PRD vaccines	Coordination and support action (Coordination or support action)
2.3.2.	HEALTH-2007-2.3.2-12: Highly innovative research in HIV/AIDS, malaria and tuberculosis between Indian and European partners.	SICA: Collaborative project (Small or medium-scale focused research project)
2.3.2.	HEALTH-2007-2.3.2-13: Coordination of European research activities with global initiatives, including Public-Private Partnerships.	SICA: Coordination and support action (Coordination or support action)
2.3.2.	HEALTH-2007-2.3.2-14: Next generation of researchers for HIV/AIDS, malaria, tuberculosis	SICA: Coordination and support action

	and neglected infectious diseases.	(Coordination or support action)
2.3.3. Potentially new and re-emerging epidemics		
2.3.3.	HEALTH-2007-2.3.3-9: Strengthening research on prediction, identification, modelling and surveillance of newly emerging infectious diseases in humans.	Collaborative project (Large-scale integrating project)
2.3.3.	HEALTH-2007-2.3.3-10: Definition of research needs and priorities in Europe in the area of Emerging Infectious Epidemics.	Coordination and support action (Coordination or support action)
2.3.4. Neglected infectious diseases		
2.3.4.	HEALTH-2007-2.3.4-1: Development of new tools to control infections due to parasites of the Trypanosomatidae family.	SICA: Collaborative project (Small or medium-scale focused research project)
2.3.4.	HEALTH-2007-2.3.4-2: Development of a Leishmania vaccine.	SICA: Collaborative project (Small or medium-scale focused research project)
2.3.4.	HEALTH-2007-2.3.4-3: Bioprospecting for drug leads	SICA: Collaborative project (Small or medium-scale focused research project)
2.4. TRANSLATIONAL RESEARCH IN OTHER MAJOR DISEASES		
2.4.1. Cancer		
2.4.1.	HEALTH-2007-2.4.1-9: Innovative combination clinical trials for multimodal cancer therapy.	Collaborative project (Large-scale integrating project)
2.4.1.	HEALTH-2007-2.4.1-10: Role of inflammation in tumour initiation and progression.	Collaborative project (Large-scale integrating project)
2.4.1.	HEALTH-2007-2.4.1-11: Epidemiology of gene-environment interactions involved in carcinogenesis.	Collaborative project (Large-scale integrating project)
2.4.1.	HEALTH-2007-2.4.1-12: Translating the hypoxic tumour microenvironment.	Collaborative project (Large-scale integrating project)
2.4.1.	HEALTH-2007-2.4.1-14: Studying cancer aetiology in Latin America.	SICA: Collaborative project (Small or medium-scale focused research project)
2.4.2. Cardiovascular disease		
2.4.2.	HEALTH-2007-2.4.2-4: Congenital pathologies affecting the heart.	Collaborative project (Small or medium-scale focused research project)
2.4.2.	HEALTH-2007-2.4.2-5: Cell therapies for the treatment of heart ischemia.	Collaborative project (Small or medium-scale focused research project)

		project)
2.4.2.	HEALTH-2007-2.4.2-6: Organ imaging in CVD.	Collaborative project (Small or medium-scale focused research project)
2.4.2.	HEALTH-2007-2.4.2-7: Integrating pharmacogenomic approaches into the treatment of CVD.	Collaborative project (Small or medium-scale focused research project)
2.4.3. Diabetes and obesity		
2.4.3.	HEALTH-2007-2.4.3-6: Nutritional signals and the development of new diabetes/obesity therapeutic agents.	Collaborative project (Small or medium-scale focused research project targeted to SMEs)
2.4.3.	HEALTH-2007-2.4.3-7: Markers and treatment for diabetic neuropathy complications.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-8: Geno- and phenotypical differentiation of type 2 subjects and monogenic subjects.	Collaborative project (Small or medium-scale focused research project)
2.4.3.	HEALTH-2007-2.4.3-9: Use of beta cell imaging in diabetes mellitus.	Collaborative project (Small or medium-scale focused research project)
2.4.4. Rare diseases		
2.4.5. Other chronic diseases		
2.4.5.	HEALTH-2007-2.4.5-10: Understanding and combating age-related muscle weakness.	Collaborative project (Large-scale integrating project)
2.4.5.	HEALTH-2007-2.4.5-11: Translational research aiming for a treatment of urinary incontinence.	Collaborative project (Small or medium-scale focused research project)
2.4.5.	HEALTH-2007-2.4.5-12: Early processes in the pathogenesis of chronic inflammatory diseases.	Collaborative project (Large-scale integrating project)
3. OPTIMISING DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS		
3.1. TRANSLATING THE RESULTS OF CLINICAL RESEARCH OUTCOME INTO CLINICAL PRACTICE INCLUDING BETTER USE OF MEDICINES, AND APPROPRIATE USE OF BEHAVIOURAL AND ORGANISATIONAL INTERVENTIONS AND NEW HEALTH THERAPIES AND TECHNOLOGIES		
3.1.	HEALTH-2007-3.1-1: Implementation of research into healthcare practice.	Collaborative project (Small or medium-scale focused research project)
3.1.	HEALTH-2007-3.1-2: Self-medication and	Collaborative project

	patient safety.	(Small or medium-scale focused research project)
3.1.	HEALTH-2007-3.1-3: Patient Safety Research Network.	Coordination and support action (Coordination action)
3.1.	HEALTH-2007-3.1-4: Improving clinical decision making.	Collaborative project (Small or medium-scale focused research project)
3.1.	HEALTH-2007-3.1-5: Better use of medicines.	Collaborative project (Small or medium-scale focused research project)
3.1.	HEALTH-2007-3.1-6: Continuity of clinical care.	Collaborative project (Small or medium-scale focused research project)
3.1.	HEALTH-2007-3.1-7: Patient self-management of chronic disease.	Collaborative project (Small or medium-scale focused research project)
3.2. QUALITY, EFFICIENCY AND SOLIDARITY OF HEALTH CARE SYSTEMS INCLUDING TRANSITIONAL HEALTH SYSTEMS		
3.2.	HEALTH-2007-3.2-1: Evaluation of disease management programmes.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-2: Health systems and long term care of the elderly.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-3: Mobility of health professionals.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-4: Health care human resource planning in nursing.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-5: Clinician working time and patient safety.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-6: Health outcome measures and population ageing.	Collaborative project (Small or medium-scale focused research project)
3.2.	HEALTH-2007-3.2-7: Trends of population health.	Collaborative project (Small or medium-

		scale focused research project)
3.2.	HEALTH-2007-3.2-8: European system of Diagnosis-related groups (DRG).	Collaborative project (Small or medium-scale focused research project)
3.3. ENHANCED HEALTH PROMOTION AND DISEASE PREVENTION		
3.3.	HEALTH-2007-3.3-1: Promoting healthy behaviour in children and adolescents.	Collaborative project (Small or medium-scale focused research project)
3.3.	HEALTH-2007-3.3-2: Interventions addressing the gradient of health inequalities.	Collaborative project (Small or medium-scale focused research project)
3.3.	HEALTH-2007-3.3-3: Public health interventions addressing the abuse of alcohol.	Collaborative project (Small or medium-scale focused research project)
3.3.	HEALTH-2007-3.3-4: Evaluation of suicide prevention strategies across and within European countries.	Collaborative project (Small or medium-scale focused research project)
3.3.	HEALTH-2007-3.3-5: Improve vaccination coverage.	Collaborative project (Small or medium-scale focused research project)
3.4. HORIZONTAL COORDINATION AND SUPPORT ACTIONS ACROSS "OPTIMISING THE DELIVERY OF HEALTH CARE TO EUROPEAN CITIZENS"		
3.4.	HEALTH-2007-3.4-1: Disease networks of centres of reference.	Coordination and support action (Support action)
3.4.	HEALTH-2007-3.4-2: Effectiveness of health investments.	Coordination and support action (Support action)
3.4.	HEALTH-2007-3.4-3: Patient mobility and access to information.	Coordination and support action (Coordination or support action)
3.4.	HEALTH-2007-3.4-4: Brokering research into policy.	Coordination and support action (Support action)
3.4.	HEALTH-2007-3.4-5: A road-map for ageing research.	Coordination and support action (Coordination or support action)
3.4.	HEALTH-2007-3.4-6: Health Services Research conference.	Coordination and support action (Support action)
3.4.	HEALTH-2007-3.4-7: Mental health research	Coordination and

	conference.	support action (Support action)
3.4.	HEALTH-2007-3.4-8: Public Health intervention research conference.	Coordination and support action (Support action)
3.5. SPECIFIC INTERNATIONAL COOPERATION ACTIONS FOR HEALTH SYSTEM RESEARCH		
3.5	HEALTH-2007-3.5-1: Epidemiological investigations into long-term trends of population health as consequence of socio-economic transitions, including life-style induced health problems.	SICA: Collaborative project (Small or medium-scale focused research project)
3.5	HEALTH-2007-3.5-2: Universal and equitable access to health care and health financing.	SICA: Collaborative project (Small or medium-scale focused research project)
3.5	HEALTH-2007-3.5-3: Health care intervention research – optimising hospital care.	SICA: Collaborative project (Small or medium-scale focused research project)
3.5	HEALTH-2007-3.5-4: Health care intervention research – improving pre-natal and maternal care.	SICA: Collaborative project (Small or medium-scale focused research project)
4. OTHER ACTIONS ACROSS THE HEALTH THEME		
4.1. COORDINATION AND SUPPORT ACTIONS ACROSS THE THEME		
4.1.	HEALTH-2007-4.1-8: Promotion and facilitation of international cooperation in areas relevant to the objectives of this Theme.	SICA: Coordination and support action (Coordination or support action)
4.2. RESPONDING TO EU POLICY NEEDS		
4.2.	HEALTH-2007-4.2-1: Adapting off-patent medicines to the specific needs of paediatric populations.	Collaborative project (Small or medium-scale focused research project)
4.2.	HEALTH-2007-4.2-2: Relative safety of non-steroidal anti-inflammatory drugs (NSAIDs).	Collaborative project (Small or medium-scale focused research project)
4.2.	HEALTH-2007-4.2-5: Effectiveness of fiscal policies for tobacco control in Europe.	Collaborative project (Small or medium-scale focused research project)

- Evaluation procedure:

- The general eligibility criteria are set out in Annex 2 to this work programme.
- A one-stage submission procedure will be followed.
- Proposals may be evaluated remotely.
- The evaluation criteria (including weights and thresholds) and subcriteria, together with

the eligibility, selection and award criteria, for the different funding schemes are set out in Annex 2 to this work programme.

- Indicative evaluation and contractual timetable:

Evaluations are expected to be carried out during the months October-December 2007. It is expected that the contract negotiations for the shortlisted proposals will be opened in January 2008.

- Consortium agreements: Participants in Large-scale integrating projects are required to conclude a consortium agreement. Participants in other types of projects are encouraged, but not required, to conclude a consortium agreement.

- Particular requirements for participation, evaluation and implementation:

It is important to note that the following funding thresholds will be applied as eligibility criteria and that the proposals which do not respect these limits will be considered as ineligible:

- Small or medium-scale focused research projects: the requested EC contribution shall not exceed EUR 3 000 000 unless otherwise indicated in the topic description.
- Large-scale integrating projects: the requested EC contribution shall be over EUR 6 000 000 and not exceed EUR 12 000 000 unless otherwise indicated in the topic description.

The minimum number of participating legal entities required, for all funding schemes, is set out in the Rules for Participation and presented in relevant parts below:

Funding scheme	Minimum conditions
Collaborative project (Large-scale integrating project and Small or medium-scale focused research project)	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.
Collaborative project for specific cooperation actions dedicated to international cooperation partner countries (SICA)	At least 4 independent legal entities. Of these, 2 must be established in different MS or AC. The other two must be established in different international cooperation partner countries
Coordination and support action (coordination action)	At least 3 independent legal entities, each of which is established in a MS or AC, and no two of which are established in the same MS or AC.
Coordination and support action (support action)	At least 1 independent legal entity

For Small or medium-scale focused research projects targeted to SMEs all consortia should aim at having 40 % of the requested EC contribution budget going to SMEs.

- The forms of grant and maximum reimbursement rates which will be offered are specified in Annex 3 to the Cooperation work programme.