

Proposal for a Council decision establishing the Specific Programme implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) –

Partial general approach 11. December 2012

PART III

SOCIETAL CHALLENGES

1. HEALTH, DEMOGRAPHIC CHANGE AND WELLBEING

Effective health promotion, supported by a robust evidence base, prevents disease, contributes to wellbeing and to contain costs. Promotion of health, active ageing, wellbeing and disease prevention also depend on an understanding of the determinants of health, on effective preventive tools, such as vaccines, on effective health and disease surveillance and preparedness, and on effective screening programmes.

Successful efforts to prevent, early detect, manage, treat and cure disease, disability, frailty and reduced functionality are underpinned by the fundamental understanding of their causes, processes and impacts, as well as factors underlying good health and wellbeing. Improved understanding of health and disease will demand close linkage between fundamental, clinical, epidemiological and socio-economic research. Effective sharing of data and the linkage of these data with real-world large scale cohort studies is also essential, as is the translation of research findings into the clinic, in particular through the conduct of clinical trials.

It is a societal challenge to adjust to the further demands on health and care sectors due to the ageing population. If effective health and care is to be maintained for all ages, efforts are required to improve decision making in prevention and treatment provision, to identify and support the dissemination of best practice in the healthcare sector, and to support integrated care. A better understanding of ageing processes and the prevention of age-related illnesses are the basis for keeping European citizens healthy and active throughout the course of their lives. Similarly important is the wide uptake of technological, organisational and social innovations empowering older persons in particular to remain active, productive and independent. Doing so will contribute to increasing, and lengthening the duration of their physical, social, and mental well-being.

The programme should address in the relevant activities chronic conditions and diseases including but not limited to: cardiovascular disease (CVD), cancer, metabolic diseases and risk factors including diabetes, chronic pain, neurological, neurodegenerative, mental health and substance use disorders, rare diseases, overweight and obesity, autoimmune diseases, rheumatic and musculoskeletal disorders and various diseases affecting different organs as well as acute conditions and various functional limitations. Likewise infectious diseases including but not limited to HIV/AIDS, tuberculosis and malaria, neglected and poverty related diseases, emerging epidemics as well as the threat of increasing anti-microbial resistance and occupational diseases and work related disorders should be addressed.

All of these activities will be undertaken in such a way as to provide support throughout the research and innovation cycle, strengthening the competitiveness of the European based industries and development of new market opportunities. Support will be given to translational approaches that integrate several steps of the innovation process in the health care industry.

Specific activities are described below.

1.1. Understanding health, wellbeing and disease

1.1.1. Understanding the determinants of health, improving health promotion and disease prevention

A better understanding of the determinants of health is required in order to provide evidence for effective health promotion and disease prevention, and will also allow the development of comprehensive health and wellbeing indicators in the Union based on existing data sources and

indicator systems. Environmental, behavioural (including life-style), psychological, organisational, cultural, socio-economic, biological and genetic factors, in their broadest senses will be studied. Approaches will include the long term study of cohorts and their linkage with data derived from "-omics" research, systems bio-medicine including relevant applications of systems biology and other methods.

In particular, a better understanding of the environment as a determinant of health will require an interdisciplinary approach integrating amongst others, molecular biological, epidemiological and toxicological approaches and resultant data to study the modes of action of various chemicals, combined exposures to pollutants and other environmental and climate related stressors; to perform integrated toxicological testing and to seek alternatives to animal testing. Innovative approaches to exposure assessment are needed using new-generation biomarkers based on 'omics' and epigenetics, human biomonitoring, personal exposure assessments and modelling to understand combined, cumulative and emerging exposures, integrating socio-economic, cultural, occupational, psychological and behavioural factors. Improved links with environmental data using advanced information systems will be supported.

In this way, existing and planned policies and programmes can be assessed and policy support provided. Similarly, improved behavioural interventions, prevention and education programmes can be developed including those pertaining to health literacy in nutrition, physical activity, vaccination and other primary care interventions.

1.1.2. Understanding disease

There is a need for an improved understanding of health and disease, throughout the human life cycle, so that new and better prevention measures, diagnosis, treatments and rehabilitation measures can be developed. Interdisciplinary, basic and translational research on the patho-physiology of disease is essential to improve the understanding of all aspects of disease processes, including a reclassification of normal variation and disease based on molecular data, and to validate and use research results in clinical applications.

Underpinning research will encompass and encourage development and use of new tools and approaches for the generation of biomedical data and include bio-imaging, "-omics", high throughput and systems medicine approaches. These activities will demand close linkage between fundamental and clinical research and with long term cohort studies (and the corresponding research domains) as described above. Close links with research and medical infrastructures (databases, bio-banks etc.) will also be required, for standardisation, storage, sharing and access to data, which are all essential for maximising data utility and for stimulating more innovative and effective ways of analysing and combining datasets.

1.1.3. Improving surveillance and preparedness

Human populations are under threat from new and emerging infections, including of zoonotic origin, as well as those which result from drug resistance to existing pathogens and from other direct and indirect consequences of climate change and from the international movement of people. New or improved methods for surveillance, diagnosis, early warning networks, health service organisation and preparedness campaigns are needed for the modelling of epidemics, for effective pandemic response as are efforts to maintain and enhance capabilities to combat drug resistant infectious disease.

1.2. Preventing disease

1.2.1. Developing effective prevention and screening programmes and improving the assessment of disease susceptibility

The development of prevention and screening programmes depends on the identification of early biomarkers (including functional and behavioural) of risk and of disease onset, and their design should be informed by internationally accepted criteria. Their deployment depends on the testing and validation of screening methods and programmes. Knowledge should be generated and methods

developed for identifying individuals and populations at a clinically relevant increased risk of disease. Identifying individuals and populations at high-risk of disease will allow personalised, stratified and collective strategies for efficacious and cost effective disease prevention to be developed.

1.2.2. Improving diagnosis and prognosis

An improved understanding of health, disease and disease processes throughout the life cycle is needed to develop new and more effective diagnostics and theranostics. Innovative and existing methods, technologies and tools will be developed with the goal of significantly improving disease outcomes through earlier, more accurate diagnosis and prognosis and by allowing for more patient-adapted treatment.

1.2.3. Developing better preventive and therapeutic vaccines

There is a need for more effective preventive and therapeutic interventions and vaccines and evidence-based vaccination schemes for an expanded range of diseases, including poverty-related diseases such as HIV/AIDS, tuberculosis, malaria and neglected infectious diseases and also for other major diseases. This relies on a better understanding of disease and disease processes and their consequent epidemics, and that clinical trials and associated studies are undertaken.

1.3. Treating and managing disease

1.3.1. Treating disease, including developing regenerative medicine

There is a need to support the improvement of cross-cutting support technologies for drugs, vaccines and other therapeutic approaches, including transplantation, surgery, gene and cell therapy and nuclear medicine; to increase success in the drug and vaccine development process (including alternative methods to replace classical safety and effectiveness testing *e.g.* the development of new methods); to develop regenerative medicine approaches, including approaches based on stem cells; to develop new biopharmaceuticals, including therapeutic vaccines; to develop improved medical and assistive devices and systems; to maintain and enhance our ability to combat diseases and undertake medical interventions that depend on the availability of effective and safe antimicrobial drugs; and to develop comprehensive approaches to treat co-morbidities at all ages and avoid polypharmacy.

These improvements will facilitate the development of new, more efficient, effective, sustainable and personalised treatments for disease and for the management of disability and frailty.

1.3.2. Transferring knowledge to clinical practice and scalable innovation actions

Clinical trials are an important means to transfer biomedical knowledge to application in patients and support for these will be provided, as well as for the improvement of their practice. Examples include the development of better methodologies to allow trials to focus on relevant population groups, including those suffering from other concomitant diseases and/or already undergoing treatment, the determination of comparative effectiveness of interventions and solutions, as well as enhancing the use of databases and electronic health records as data sources for trials and knowledge transfer. Similarly, support for the transfer of other types of interventions such as those related to independent living into real world environments will be provided.

1.4. Active ageing and self-management of health

1.4.1. Active ageing, independent and assisted living

Multidisciplinary advanced and applied research and innovation with socioeconomic, behavioural, gerontological, digital and other sciences is needed for cost effective user-friendly solutions for active, independent and assisted daily living (in the home, the workplace, public spaces, etc.) for the ageing population and people with disabilities taking into account gender differences. This applies in a variety of settings and for technologies and systems and services enhancing quality of life and human

functionality including mobility, smart personalised assistive technologies, service and social robotics, and ambient assistive environments. Research and innovation pilots to assess implementation and wide uptake of solutions will be supported. Involvement of end-users, user communities and formal/informal carers will be emphasised.

1.4.2. Individual awareness and empowerment for self-management of health

Empowering individuals to improve and manage their health throughout life will result in more cost-effective healthcare systems by enabling the management of chronic disease outside institutions and improve health outcomes. This requires research into socio-economic factors and cultural values, behavioural and social models, attitudes and aspirations in relation to personalised health technologies, mobile and/or portable tools, new diagnostics, sensors and devices for monitoring and personalised services including but not limited to nanomedicine-based tools which promote a healthy lifestyle, wellbeing, mental health, self-care, improved citizen/healthcare professional interaction, personalised programmes for disease and disability management, as well as support for knowledge infrastructures. Solutions will be developed and tested with the use of open innovation platforms such as large scale demonstrators for social and service innovation.

1.5. Methods and data

1.5.1. Improving health information and better use of health data

The integration of infrastructures and information structures and sources (including those derived from cohort studies, protocols, data collections, indicators, health examination surveys, etc.) as well as the standardisation, interoperability, storage, sharing of and access to data, will be supported to enable such data to be properly exploited. Attention should be given to data processing, knowledge management, modelling, visualisation, ICT-security and privacy related issues. In particular, availability of information and data on negative results and adverse effects of treatment need to be improved.

1.5.2. Improving scientific tools and methods to support policy making and regulatory needs

There is a need to support research and development of scientific tools, methods and statistics for rapid, accurate and predictive assessment of the safety, efficacy and quality of health interventions and technologies including new drugs, biologics, advanced therapies and medical devices. This is particularly relevant for new developments in domains including those concerning biopharmaceuticals, vaccines, antimicrobials, cell/tissue and gene therapies, organs and transplantation, specialist manufacturing, bio banks, new medical devices, combination products, diagnostic/treatment procedures, genetic testing, interoperability and e-health, including privacy aspects. Similarly, support for improved risk assessment methodologies, compliance frameworks, testing approaches and strategies relating to environment and health are required. There is also a need to support the development of relevant methods for assisting the assessment of ethical aspects of the above domains.

1.5.3. Using in-silico medicine for improving disease management and prediction

Computer simulation using patient specific data and building on systems medicine approaches and physiological modelling can be used to predict susceptibility to disease, disease evolution and the likely success of medical treatments. Model based simulation can be used to support clinical trials, predictability of treatment response, and the personalisation and optimisation of treatment.

1.6. Health care provision and integrated care

1.6.1. Promoting integrated care

Supporting the management of chronic disease, including patients with disabilities, outside institutions also depends on improved cooperation between the providers of health and social or informal care. Research and innovative applications will be supported for decision making based on distributed

information addressing both physical and mental health, and for providing evidence for large scale deployments and market exploitation of novel solutions, including interoperable telehealth and tele-care services. Particularly in the context of demographic change, research and innovation to improve the organisation of long-term care delivery as well as policy and management innovation will also be supported. Implementing new and integrated care solutions shall aim at personal empowerment and enhancement of existing capabilities as well as concentrate on compensation of deficits.

1.6.2. Optimising the efficiency and effectiveness of healthcare provision and reducing inequalities by evidence based decision making and dissemination of best practice, and innovative technologies and approaches

There is a need to support the development of a systemic approach to health technology assessment and health economics, as well as the gathering of evidence and dissemination of best practice and innovative technologies and approaches in the healthcare sector, including ICT and e-health applications. Comparative analyses of the reform of public health systems in Europe and in third countries and assessments of their mid to long-term economic and social impacts will be supported. Analyses of future health workforce needs both in terms of numbers and required skills in relation to new patterns of care will be supported. Research on the evolution of health inequalities, of their interplay with other economic and social inequalities and on the effectiveness of policies aiming to reduce them in Europe and beyond will be supported. Finally, there is a need to support the assessment of patient safety solutions and quality assurance systems, including the role of patients on safety and quality of care.

1.7. Specific implementation aspects

Implementation of the programme will include support for knowledge and technology transfer and other forms of dissemination, for large-scale piloting and demonstration actions, and for standardisation. In this way, market deployment of products and services will be accelerated, and scalable solutions for Europe and beyond will be validated. Such actions will not only support European industrial competitiveness and the involvement of innovative SMEs but will require the active involvement of all stakeholders. Synergies with other relevant programmes and activities, both public and private at Union, national and international levels will be sought. In particular, synergies with activities developed in the context of the Health for Growth Programme will be sought.

Consideration may be given to support relevant Joint Programming Initiatives (JPIs) and relevant public-public and public-private partnerships.

Appropriate links with the actions of relevant European Innovation Partnerships and the relevant aspects of the research and innovation agendas of European Technology Platforms will also be established.