

# Part III

## Societal Challenges

### 1. HEALTH, DEMOGRAPHIC CHANGE AND WELLBEING

Effective health promotion, supported by a robust evidence base, prevents disease, improves wellbeing and is cost effective. Health promotion 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, manage, treat and cure disease, disability and reduced functionality are underpinned by the fundamental understanding of their causes, processes and impacts, as well as factors underlying good health and wellbeing. 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.

An increasing disease and disability burden in the context of an aging population places further demands on health and care sectors. 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 and the uptake of technological, organisational and social innovations empowering older persons in particular to remain active and independent. Doing so will contribute to increasing, and lengthening the duration of their physical, social, and mental well-being.

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.

Specific activities are described below.

#### 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. Environmental, behavioural (including life-style), socio-economic 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, and other methods.

In particular, a better understanding of the environment as a determinant of health will require integrated molecular biological, epidemiological and toxicological approaches to investigate health-environment relationships, including studies of modes of action of chemicals, combined exposures to pollution and other environmental and climate related stressors,

integrated toxicological testing as well as 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 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, vaccination and other primary care interventions.

## **1.2. Developing effective screening programmes and improving the assessment of disease susceptibility**

The development of screening programmes depends on the identification of early biomarkers of risk and of disease onset, and their deployment depends on the testing and validation of screening methods and programmes. 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.

## **1.3. Improving surveillance and preparedness**

Human populations are under threat from new and emerging infections (including those resulting from climate change), from drug resistance to existing pathogens and from other direct and indirect consequences of climate change. Improved methods for surveillance, early warning networks, health service organisation and preparedness campaigns are needed for the modelling of epidemics, for effective pandemic response, for responses to non infectious disease consequences of climate change, as are efforts to maintain and enhance capabilities to combat drug resistant infectious disease.

## **1.4. Understanding disease**

There is a need for an improved understanding of health and disease, in people of all ages, so that new and better prevention measures, diagnosis and treatments can be developed. Interdisciplinary, translational research on the patho-physiology of disease is essential to improve the understanding of all aspects of disease processes, including a re-classification 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 "-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.

### **1.5. Developing better preventive vaccines**

There is a need for more effective preventive vaccines (or alternative preventive interventions) and evidence-based vaccination schemes for an expanded range of 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.

### **1.6. Improving diagnosis**

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

### **1.7. 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.

### **1.8. Treating disease**

There is a need to support the improvement of cross-cutting support technologies for drugs, vaccines and other therapeutic approaches, including transplantation, gene and cell therapy; 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 improved medical and assistive devices and systems; to maintain and enhance our ability to combat communicable, rare, major and chronic diseases and undertake medical interventions that depend on the availability of effective antimicrobial drugs; and to develop comprehensive approaches to treat co-morbidities at all ages and avoid poly-pharmacy. These improvements will facilitate the development of new, more efficient, effective and sustainable treatments for disease and for the management of disability.

### **1.9. Transferring knowledge to clinical practice and scalable innovation actions**

Clinical trials are the 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.

### **1.10. Better use of health data**

The integration of infrastructures and information structures and sources (including those derived from cohort studies, protocols, data collections, indicators, 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 and visualisation.

#### **1.11. Improving scientific tools and methods to support policy making and regulatory needs**

There is a need to support the development of scientific tools, methods and statistics for rapid, accurate and predictive assessment of the safety, efficacy and quality of health technologies including new drugs, biologics, advanced therapies and medical devices. This is particularly relevant for new developments in domains including those concerning vaccines, cell/tissue and gene therapies, organs and transplantation, specialist manufacturing, bio banks, new medical devices, diagnostic/treatment procedures, genetic testing, interoperability and e-health, including privacy aspects. Similarly, support for improved risk assessment methodologies, 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.

#### **1.12. Active ageing, independent and assisted living**

Multidisciplinary advanced and applied research and innovation with 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, etc.) for the ageing population and people with disabilities. 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.

#### **1.13. Individual empowerment for self-management of health**

Empowering individuals to improve and manage their health throughout life will result in cost savings to healthcare systems by enabling the management of chronic disease outside institutions and improve health outcomes. This requires research into behavioural and social models, social attitudes and aspirations in relation to personalised health technologies, mobile and/or portable tools, new diagnostics and personalised services which promote a healthy lifestyle, wellbeing, self-care, improved citizen/healthcare professional interaction, personalised programmes for disease and disability management, as well as support for knowledge infrastructures.

#### **1.14. Promoting integrated care**

Supporting the management of chronic disease 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, and for providing evidence for large scale deployments and market exploitation of novel solutions, including interoperable tele-health and tele-care services. Research and innovation to improve the organisation of long-term care delivery will also be supported.

**1.15. Optimising the efficiency and effectiveness of healthcare systems and reducing inequalities through evidence based decision making and dissemination of best practice, and innovative technologies and approaches.**

There is a need to support the development of health technology assessment and health economics, as well as the of gathering 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.

**1.16. Specific implementation aspects**

Support provided will cover the full spectrum of activities from knowledge and technology transfer to large scale demonstration actions, leading to scalable solutions for Europe and beyond.