Health, demographic change and wellbeing

TOPIC : Implementing the Strategic Research Agenda on Personalised Medicine

Topic identifier: SC1-HCO-03-2017
Publication date: 14 October 2015

Types of action: ERA-NET-Cofund ERA-NET Cofund
DeadlineModel: single-stage
Planned opening date: 29 July 2016 **Deadline:** 11 April 2017 17:00:00

Specific Challenge:

By providing the right intervention to the right person at the right time, personalised medicine[1] can improve quality of life and contribute to more sustainable healthcare at Member State level. It may drive new and faster development processes and products, providing European life sciences industries with a competitive edge that can secure growth and jobs. Today, development is uneven across and within sectors, regions and Member States due to fragmented activities, insufficient communication and lack of commonly accepted solutions and standards.

The FP7 funded coordination and support action "Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed)[2]" was launched in 2013 with the objective to develop a Strategic Research Agenda to progress personalised medicine in Europe. PerMed partners have strived to focus their strategy on concrete research actions, many of which should be addressed through transnational collaborative health research.

An ERA-NET Cofund action is therefore a suitable and timely tool to implement relevant parts of PerMed's Strategic Research and Innovation Agenda[3], which will be published in 2015.

Scope:

Proposals should pool the necessary financial resources from the participating national (or regional) research programmes with a view to implementing a joint call for proposals resulting in grants to third parties with co-funding in this area.

This call should aim at implementing a key area of the PerMed Strategic Research Agenda and be complementary with other funding programmes and activities at European and international level. Proposers are encouraged to include other joint activities including additional joint calls without EU co-funding. This work should be informed by the output of the coordination and support action envisaged in topic SC1-HCO-05-2016 - Coordinating personalised medicine research, without duplicating any of its work.

The proposed ERA-NET should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this. Participation of international partners is highly encouraged.

The Commission considers that a proposal requesting a contribution from the EU of EUR 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Deepened and extended coordination of national and transnational research in the field of personalised medicine.
- Streamlined national/regional and international practices in organising research funding.
- Increased interoperability of national research programmes.
- Increased sharing of data and knowledge.
- Increased networking of infrastructures and databases such as ESFRI infrastructures

[1]Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely

and targeted prevention. The term "personalised medicine" is used throughout this Work Programme with this definition in mind.

[2]www.permed2020.eu

[3]Available at http://www.permed2020.eu/1428.php

TOPIC : Global Alliance for Chronic Diseases (GACD)

Topic identifier: SC1-HCO-07-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 29 July 2016 **Deadline:** 11 April 2017 17:00:00

Topic details will be developed in line with the timetable of the GACD priority setting process and will be provided during the course of 2016.

TOPIC : Actions to bridge the divide in European health research and innovation

Topic identifier: SC1-HCO-08-2017
Publication date: 14 October 2015

Types of action: CSA Coordination and support action
DeadlineModel: single-stage
Planned opening date: 29 July 2016 **Deadline:** 11 April 2017 17:00:00

Specific Challenge:

Despite serious efforts deployed at national and European level, the European Union sees significant internal disparities in terms of research and innovation performance as also identified in the Innovation Union Scoreboard. The disparities are equally present in health research and innovation and this call seeks solutions specifically adapted to this domain.

The European Commission has been funding projects to analyse the roots of the divide in European health research and innovation (HCO-14 2014) and wishes to continue efforts in closing the gap.

Scope:

Any type of activities that can help less performing countries and regions to build capacities and exploit opportunities to eventually increase their participation in EU funded collaborative projects can be supported.

Beneficiaries of the activities should be low performing[1] Member States/regions that have identified health R&I as a priority in their Research and Innovation Strategies for Smart Specialisation (RIS3). Applicants shall seek synergies with European Structural and Investment Funds, the operational programmes and support from managing authorities.

The proposals will propose concrete measures for tackling structural barriers to health research and innovation, including those related to capacity, skills, policy, regulatory environment, and economic and socio-cultural factors including gender equality issues and gender dimension in research content.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 1 million would allow this specific challenge to be addressed appropriately. Nonetheless this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

The action should demonstrate good practice on how synergies between Structural Funds and Horizon 2020 can be exploited in the health R&I domain. This shall contribute to increased Horizon 2020 participation of low performing regions.

[1]As defined by Widening Participation and Spreading Excellence: Member States below 70% of the EU average of the Composite Indicator of Research Excellence.

TOPIC : New concepts in patient stratification

Topic identifier: SC1-PM-02-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 29 July 2016
Deadline: 04 October 2016 17:00:00
2nd stage Deadline: 11 April 2017 17:00:00

Specific Challenge:

Despite the major advances in understanding disease in the post-genomic era, still a majority of all drugs are effective in only a limited number of patients. From a clinical perspective, implementing knowledge-based decisions on what therapeutics to use for which patients and, if relevant, in which combinations, are extremely challenging. The aspiration to provide more effective therapeutic interventions tailored to the individual or groups of individuals with common molecular phenotypes remains unfulfilled because of the variable response of individuals to such interventions.

Patient stratification aims at grouping patients into disease sub-groups, where the specific pathological processes involved are better defined (clinical/molecular phenotypes). This will lead to the development of targeted therapies, optimizing the intervention to individual patients, thus achieving greater success in treating or curing the patient.

Scope:

Proposals should deliver novel concepts for disease-mechanism based patient stratification to address the needs for stratified or personalised therapeutic interventions. The proposals should integrate multidimensional and longitudinal data and harness the power of -omics, including pharmacogenomics, systems biomedicine approaches, network analysis and of computational modelling. The new concepts of stratification should be validated in pre-clinical and clinical studies taking into account sex and gender differences. Applicants are encouraged to actively involve patient associations. The proposals should consider regulatory aspects of clinical practice and commercialisation opportunities. Proposals should focus on complex diseases having high prevalence and high economic impact.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- New models for patient stratification to inform clinical decision making.
- Accelerate the translation of biomedical and clinical research results to medical use.
- Increased cost-effectiveness of the novel concepts in comparison to already established practices.
- Increased research and innovation opportunities in this innovative industries-driven field, particularly small or medium-sized enterprises (SMEs).

TOPIC : Diagnostic characterisation of rare diseases

Topic identifier: SC1-PM-03-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Deadline: 11 April 2017 17:00:00

Planned opening date: 29 July 2016

Specific Challenge:

Rare diseases are diseases which affect not more than 5 per 10 000 persons in the European Union. It is estimated that rare diseases encompass between 6 000 and 8 000 different entities which affect altogether more than 30 million people in the EU. However, patient populations for individual rare diseases are small and dispersed, which makes international collaboration crucial. Despite the recent advances in understanding the molecular pathogenesis of these diseases, today many rare diseases still lack means of molecular diagnosis. An accurate molecular diagnosis is an essential starting point for the understanding of mechanisms leading to diseases as well as for adequate patient management and family counselling and it paves the way for therapy development.

Scope:

The aim of this research should be to apply genomics and/or other –omics and/or other high-throughput approaches for the molecular characterisation of rare diseases in view of developing molecular diagnoses for a large number of undiagnosed rare diseases. Undiagnosed rare diseases may range from a group of unnamed disorders with common characteristics to a phenotypically well described disease or group of diseases with an unknown molecular basis. Genetic variability due to geographical distribution and/or different ethnicity should be taken into account as well as genotype-phenotype correlation whenever applicable. In addition, age, sex and gender aspects should be included where appropriate. This large-scale proposal should promote common standards and terminologies for rare disease classification and support appropriate bioinformatics tools and incentives to facilitate data sharing. Existing resources should be used for depositing data generated by this proposal. Molecular and/or functional characterisation may be part of the proposal to confirm diagnosis. The proposal should enable and foster scientific exchange between stakeholders from countries and regions with different practices and strategies of rare disease diagnostics.

The selected proposal shall contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium IRDiRC (www.irdirc.org).

The Commission considers that requesting a contribution from the EU of around EUR 15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting other amounts.

Expected Impact:

Providing better and faster means of high quality and clinical utility for the correct diagnosis of undiagnosed rare diseases for which there is no or unsatisfactory diagnosis available.

• Contribute towards the IRDiRC objectives.

• Foster dissemination of scientific results and knowledge exchange between stakeholders.

• Develop knowledge management strategies, with the view of facilitating models of care and access to the data gathered.

• Providing better knowledge for improved family counselling as well as to improve follow-up for patients and research initiatives.

• Gather a big number of patients with similar phenotypes to facilitate match making, to avoid duplication and to unravel a considerable number of diagnoses.

• Pave the way to the development of new therapies and for a better treatment outcome in rare disease patients.

TOPIC : Promoting mental health and well-being in the young

Topic identifier: SC1-PM-07-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Deadline: 04 October 2016 17:00:00
Planned opening 29 July 2016
2nd stage Deadline: 11 April 2017 17:00:00

date:

Specific Challenge:

Mental well-being[1] is integral to population health and well-being and contributes to the functioning of individuals, families, communities and the social and economic prosperity of society. Mental and behavioural disorders including addictive behaviour place immense burdens on individuals, families and society; they also increase the risk of co-morbidities and social exclusion. Childhood and adolescence are crucial periods for laying the foundations for healthy development and mental well-being. There is compelling evidence that promotion of mental well-being and prevention interventions, when implemented effectively, can reduce risk factors for mental disorders, enhance protective factors for good mental and physical health and lead to lasting positive effects on a range of educational, social and economic outcomes for young people[2]. Medical and psychological factors, family and social factors (including working conditions) as well as digital environments are some of the different determinants impacting the health and well-being of the young. Resilience to adversity will enhance their ability to cope. There is a need for more robust evidence on resilience factors and on effective interventions promoting mental well-being. Developing these in the young offers the possibility of a positive influence on child development in critical/sensitive periods (childhood, adolescence, transition to young adulthood), thanks to early neuroplasticity.

Scope:

Proposals should develop population-oriented primary prevention[3] interventions to promote mental well-being of young people and assess them for their effectiveness. The interventions should build on but may go beyond existing state-of-the art knowledge on biological, psychological and social determinants of mental well-being such as societal, cultural, work life, lifestyle, epidemiological, economic and environmental perspectives. The proposals should aim at increasing resilience and mitigating the impact of biological, psychosocial and environmental risk factors. The target group should include young up to 25 years (or a subgroup there of), which is an age limit often used as many severe disorders start in this period.

The research design should be developed by means of a multidisciplinary approach and involve the young themselves and other relevant stakeholders. Innovative approaches in involving the young and gathering their inputs for the design of the intervention should be considered. The interventions should use a holistic approach, taking gender and health inequality aspects into account, in increasing resilience and empowering the young. The interventions to be developed should reflect the diversity of the different countries and regions in Europe and beyond. The research should pay particular attention to ethical issues. The interventions should be assessed for mental well-being outcomes as well as the economic and social benefits and impact on reducing inequalities. These analyses of impact and effectiveness should be presented in quantitative as well as qualitative terms, in a gender disaggregated way where relevant. The results should be disseminated throughout Europe and beyond in order that the evidence generated is fully exploited.

The Commission considers that proposals requesting a contribution from the EU of between EUR 2 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

Short or medium term impact, likely during the lifetime of the project:

- Improved mental well-being in the targeted group of young people.
- The innovative interventions will create a strong evidence base for mental well-being promotion programmes in Europe, contributing to greater health equity and improved societal benefits.

Longer term impact, likely beyond the lifetime of the project:

- Improved mental well-being in youth should contribute to reducing school and college/university dropout in the short term, strengthening personal confidence and cognitive function, improving educational efforts and enhancing employability.
- Preventative strategies are established which have a real effect of reducing the occurrence of mental disorders and co-morbidities associated with mental disorders later in life.

[1]The term mental well-being is often used in both policy and academic literature, interchangeably with positive mental health. The WHO has declared mental health to be the 'foundation for well-being and effective functioning for both the individual and the community' and defined it as a state 'which allows individuals to realise their abilities, cope with the normal stresses of life, work productively and fruitfully, and make a contribution to their community. World Health Organisation: *Promoting Mental Health; Concepts emerging evidence and practice. Summary report*, Geneva; World Health Organisation; 2004.

[2]Clarke, A.M., Morreale, S., Field, C.A., Hussein, Y., & Barry, M.M. (2015). What works in enhancing social and emotional skills development during childhood and adolescence? A review of the evidence on the effectiveness of school-based and out-of-school programmes in the UK. A report produced by the World Health Organization Collaborating Centre for Health Promotion Research, National University of Ireland Galway.

[3]Primary prevention is directed towards preventing the initial occurrence of a disorder (WHO Health Promotion Glossary 1998)

TOPIC : New therapies for rare diseases

Topic identifier: SC1-PM-08-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 29 July 2016
Deadline: 04 October 2016 17:00:00
2nd stage Deadline: 11 April 2017 17:00:00

Specific Challenge:

Rare diseases are diseases which affect not more than 5 per 10 000 persons in the European Union, as defined in the context of the EU legislation. A considerable amount of knowledge has been generated by biomedical research in recent years, yet most of the 6 000 to 8 000 rare diseases are lacking therapies despite many of these diseases being life-threatening or chronically debilitating.

Specific problems posed in therapy development for rare diseases include the small and dispersed patient populations and the nature of the therapies proposed, which are often highly specialised and novel. Amongst other challenges, this leads to the requirement for seeking early advice of regulatory authorities during development. In addition, despite the special incentives for the development of orphan medicinal products, and the often high prices of some of the developed therapies, the limited market for such therapies lead to a low commercial return, and/or limited access.

Scope:

Support will be provided to clinical trials on substances where orphan designation has been given by the European Commission, where the proposed clinical trial design takes into account recommendations from protocol assistance given by the European Medicines Agency, and where a clear patient recruitment strategy is presented. Clinical trials may focus on a range of interventions with an orphan designation, from small molecule to gene or cell therapy, may include novel interventions and/or repurposing of existing and known interventions. The intervention must have been granted the EU orphan designation at the latest on the date of the full proposal call closure. A concise feasibility assessment justified by available published and preliminary preclinical or clinical results and supporting data shall also be provided. Appropriate plans to engage with patient organisations, Member States health authorities and considerations of efficacy/potential clinical benefit as well as early indication on health economics should be integrated in the application. In addition to the clinical trial, proposals may also include limited elements of late stage preclinical research and/or experimental evaluation of potential risks which must be complementary/contribute to the clinical trial(s) carried out within the proposal. The centre of gravity must clearly be the clinical trial(s). The participation of SMEs is encouraged.

Selected proposals shall contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC (www.irdirc.org).

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

• In line with the objectives of the Union pharmaceutical legislation on orphan medicinal products, proposals shall contribute to advance the development of new therapeutic options with concrete benefits for patients living with rare diseases.

• Rapid progress in orphan drug development due to well-prepared clinical trials and a multinational multicentre clinical trial with an appropriate number of patients.

• Develop a preliminary assessment of the potential economic and public health aspects of the new therapeutic option.

• Contribute to growth of SMEs involved in drug development.

• In line with the Union's strategy for international cooperation in research and innovation, proposals shall contribute towards IRDiRC objectives.

TOPIC : Comparing the effectiveness of existing healthcare interventions in the adult population

Topic identifier: SC1-PM-10-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 29 July 2016
Deadline: 04 October 2016 17:00:00
2nd stage Deadline: 11 April 2017 17:00:00

Specific Challenge:

Effective health care and prevention may be improved by additional evidence as to the most effective health interventions. Growing numbers of patients affected by chronic diseases also call for efficiently managing co-morbidities.

Scope:

Proposals should compare the use of currently available preventative or therapeutic (pharmacological as well as non-pharmacological) healthcare interventions in adults[1]. While there is no restriction on the diseases or interventions to be the focus of proposals, preference will be given to proposals focusing on interventions with high public health relevance and socio-economic impact, i.e. interventions addressing conditions that are particularly frequent, may lead to co-morbidities, have a high negative impact on the quality of life of the individual and/or are associated with significant costs or where savings can be achieved. A cost effectiveness analysis must be included. Given the focus on existing interventions, proposals will aim to contribute to improve interventions, take decisions about the discontinuation of interventions that are less effective or less cost-effective than others, and make recommendations on the most effective and cost-effective approaches. A comprehensive array of clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health systems) for chosen populations should be assessed. Agreed core outcome sets (COS) should be used as endpoints in conditions where they already exist, in other cases efforts should be made to agree on such COS. Randomised controlled trials, pragmatic trials, observational studies, large scale databases and meta-analyses may be considered for this topic. Where relevant the study population should address gender as well as socio-economic differentials in health and/or any other factors that affect health equity.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

This topic is to provide the required evidence base for:

- more effective and safer interventions at individual and population level;
- enhanced compliance with healthcare interventions in the adult population;
- the use of health technology assessment methodology in this target group.

In particular:

- Improvement of individual patient outcomes and health outcome predictability through tailoring of interventions.
- Improvement of guideline development for prevention or treatment of diseases and the management of comorbidities.
- Provision of more accurate information to patients, caregivers and prescribers.

[1]Screening and / or the involvement of elderly populations are not excluded.

TOPIC : Personalised coaching for well-being and care of people as they age

Topic identifier: SC1-PM-15-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 20 September 2016 **Deadline:** 31 January 2017 17:00:00

Specific Challenge:

The activity aims at developing and validating radically new ICT based concepts and approaches for empowering and motivating people in need of guidance and care due to age related conditions, in cooperation with their carers where relevant, and to help them improve and maintain their independence, functional capacity, health status as well as preserving their physical, cognitive, mental and social well-being.

Scope:

Proposals should develop a proof of concept of radically new solutions for a personalised "virtual coach", building upon intelligent ICT environments, access to relevant physiological and behavioural data, new forms of accessible interaction based on tangible user interaction concepts, open platforms[1] and emotional computing. Usability and ease of user interaction should be essential design elements of the "coach".

The "coach" should provide personalised advice, guidance and follow-up for key age related issues in daily life which impact the person's ability to remain active and independent, for example diet, physical activity, risk avoidance, preventive measures, lifestyle and activity management, leisure, social participation and overall wellness. The goal should be to preserve physical, cognitive, mental and social well-being for as long as possible and to facilitate interaction with carers (where relevant).

Solutions should build on and apply multi-disciplinary research and include intelligent algorithms beyond state-of-the-art capable of reasoning, autonomous learning and adaptation to personal needs, emotional and behavioural patterns, conditions and preferences as well as the users' living environment and their social connections. Solutions should be integrated seamlessly in existing every-day activities and provide desired information in fast and efficient manner. Attention theft by ICT (consuming too much of the user's time) should be avoided.

Proposals should address relevant ethics and gender aspects and should also assess related legal and regulatory questions such as ownership of data, data protection/privacy, liability and consumer protection. It is crucial that users are involved and drive the innovation at all stages of design and development, including user acceptability, satisfaction and impact in realistic settings.

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

The proposal should present methodologies and metrics as appropriate for measuring its progress towards the expected impact in:

- Usefulness and effectiveness of personalized recommendations and follow-up in terms of the goals of preserving physical, cognitive, mental and social well-being for as long as possible;

- Validation of non-obtrusive technology for physical, cognitive, social and mental well-being;
- Evidence of user-centred design and innovation, new intuitive ways of human-computer interaction, and user acceptance;
- Potential cost-effectiveness due to enhanced self-care, life-style and care management.

[1]Proposers are encouraged to work with open platforms like FIWARE and UniversAAL where relevant.

TOPIC : In-silico trials for developing and assessing biomedical products

Topic identifier: SC1-PM-16-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 08 November 2016 **Deadline:** 14 March 2017 17:00:00

Specific Challenge:

In biomedical, pharmaceutical and toxicology research, the safety and efficacy of biomedical products are ultimately tested on humans via clinical trials after prior laboratory testing in vitro and/or in vivo on animal models. The complete development chain of a new biomedical product and its introduction to the market is very long and expensive. Alternative methodologies to reduce the animal and human testing are needed in order to answer both the ethical issues and the imperfection of predictions issued from laboratory and animals when applied to humans. Computer modelling and simulation is currently used to a certain degree in pharmacokinetics, pharmacodynamics or mechanical simulations (e.g. fluid dynamics simulations). A research and technological roadmap for "in-silico clinical trials" is currently being developed. Preliminary results show the strong interest/potential benefit to expand the computer-modelling in drugs and other biomedical products including bioactives, medical foods research by developing new ways for in-silico testing.

Scope:

Proposals will develop innovative in-silico trials for designing, developing and assessing drugs, radiation and other biomedical and bioactive products. They will build on comprehensive biological and biomedical knowledge management and advanced modelling paradigms in order to be able to simulate the individual human physiology and physiopathology at the biological levels relevant for the biomedical product under study (at the cell level, tissue level or organism level) and the interaction with the product, thus taking into account the variability among individuals (for example, molecular pathways, cellular microenvironments, microbiota, genetics, gender characteristics, behaviours, comorbidities, development, diet). Virtual populations of individual patients will be built for simple or composite diseases, for example, from the patient-specific models by variations of different parameters and will allow simulating the action of the products and predicting the treatments outcomes in order to develop a personalised medicine approach. The proposed in-silico trials will be the result of a multidisciplinary effort (e.g. within the fields of computational modelling, systems biology, tissue mechanics, biology, pharmaceutics, medicine) and will also explore and inform of the reasons of fails and suggest improvements. To help establishing such computer simulated trials, measures for validation (human trials, animal studies, validation in cell cultures) of the in-silico models shall also be included in the proposed projects. The benefit for human health, environment and animal welfare should be analysed and quantified. Contact with regulators and consideration of the regulatory framework issues are highly recommended.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Reducing the size and the duration of the human clinical trials
- A more effective human clinical trials design
- Leading to a significant reduction of animal testing

- Innovative medical products on the market with lower development costs and/or shorter time-to-market
- Improving prediction of human risks for new biomedical products including medical foods
- Improving drug repositioning
- Potential of re-use of the developed in-silico models in the chemical testing.
- Setting standards for in-silico trials.
- Providing libraries of virtual patients that can be re-used in pre- and post-competitive testing of biomedical products

TOPIC : Personalised computer models and in-silico systems for well-being

Topic identifier: SC1-PM-17-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 08 November 2016 **Deadline:** 14 March 2017 17:00:00

Specific Challenge:

There is continuous progress in systems medicine, multi-scale modelling and patient-specific modelling aspects. But these opportunities have been inconstantly explored for the entire chain of health and disease. Thus, there are very few in well-being, prevention or rehabilitation while these areas are crucial for reducing healthcare needs, building sustainable healthcare and for assuring a healthy and motivated workforce. More, innovative methods are needed for better understanding and analysing brain, neurobiological and the gut-brain axis and the stress-related disorders or whole body data (e.g. where the development of multiscale and high spatiotemporal resolution imaging methods are critical) and their interactions with social, environmental, lifestyle, occupational, economic etc. factors that promote well-being and health. Well-being is a consequence of resilience to challenges and illness and of better prevention adapted to predispositions and behaviours (including gender), of better consideration given to the functional troubles, of better recovery and rehabilitation after illness.

Scope:

Proposals should aim at the development of new integrative dynamic computer-models and simulation systems of acceptable validity, with the potential to being reused, build on open service platforms and with application in well-being, health and disease. The projects have to support computer modelling and simulations able to aggregate various information sets e.g. molecular, biochemical, medical imaging, social, lifestyle, economic, occupational, microbiome, environmental, developmental, psychological, gender etc. into robust predictors for resilience in coping with and overcoming challenges and stresses and for recovery after challenges and illness. They will process and apply individual/patient-specific information in a multi-scale approach required for integrating information at a certain biological level within a wider context (at least one biological level from molecule to entire body). Proposals will focus on multi-disciplinary research in medicine, SSH and ICT and should take advantage when relevant of existing large databases in clinical medicine, biomedical or occupational research, environmental sciences, Social Sciences and Humanities (SSH), so enabling and facilitating the accumulation and relinking of complex and heterogeneous data collections. The models integrated in these multi-scale and multi-disciplinary approaches will have their predictive capability validated by state-of-the-art clinical and/or laboratorial studies and/or against large health registries. Whenever relevant, proposals will integrate data collected over time in order to inform on individual trajectories with periods of well-being and periods of illness and on the heterogeneity of resilience and recovery that can be different during the individual lifetime.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Benefit for health and well-being: new personalised interventions for increasing resilience and recovery.
- Advancements in medical computer-modelling and simulation that takes into account time and spatial scales.
- Supporting predictive and preventive approaches in medicine, neurosciences and life sciences.
- Improving knowledge about well-being and association with life circumstances.

TOPIC : PPI for uptake of standards for the exchange of digitalised healthcare records

Topic identifier: SC1-PM-19-2017
Publication date: 14 October 2015

Types of action: PPI Public Procurement of Innovative solutions
DeadlineModel: single-stage
Planned opening date: 08 November 2016 **Deadline:** 14 March 2017 17:00:00

Specific Challenge:

The use of interoperability standards is essential to the wider deployment of an EU eHealth single market. Despite previous Framework Programmes investments, there is still a profound lack of deployed interoperability between healthcare systems and services delivering healthcare and a need to stimulate the public procurement of eHealth solutions and integrated care services addressing complex organisational structures and interactions among people (recipients of care, care-givers, and others).

Scope:

Proposals should address as primary aim public procurement of innovative solutions (PPI) to facilitate the deployment of an eHealth infrastructure taking into consideration the European eHealth Interoperability Framework and EU guidelines adopted by the eHealth Network. The PPI(s), and any accompanying innovation activities in particular by participating procurers themselves to facilitate the uptake of newly developed solutions, should focus on clear target outcomes such as allowing the sharing of health information, the use of semantically interoperable Electronic Health Records (EHRs) for safety alerts, decision support, care pathways or care coordination. The scope of the PPI(s) is to specify, purchase and deploy innovative ICT based solutions which can deliver sustainable, new or improved healthcare services across organisational boundaries while implementing eHealth interoperability standards and/or specifications (e.g. EN13606, HL7, Continua Alliance, IHE...).

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Wider uptake of eHealth interoperability standards
- Increased suppliers opportunities from wider market uptake of innovative solutions and services by forming a critical mass on the public demand side
- Better solutions specifications designed from a demand side perspective
- More forward-looking, concerted, public sector approach to eHealth interoperability
- Achieve the wider deployment of eHealth services
- Create a European role model in the eHealth interoperability field
- Increasing jobs in health and ICT and contributing to economic growth in the EU in the long-term
- Support forward looking, concerted public-sector investment strategies that benefit from jointly implementing PPIs across different countries around Europe

TOPIC : Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector

Topic identifier: SC1-PM-20-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 29 July 2016
Deadline: 11 April 2017 17:00:00

Specific Challenge:

This topic will be developed during the course of 2016.

Nanotechnologies, advanced materials and advanced manufacturing

TOPIC : Development of a reliable methodology for better risk management of engineered biomaterials in Advanced Therapy Medicinal Products and/or Medical Devices

Topic identifier: NMBP-12-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 11 May 2016
Deadline: 27 October 2016 17:00:00
2nd stage Deadline: 04 May 2017 17:00:00

Specific Challenge:

The development of new biotechnology-based products needs to be complemented with a scientifically valid identification of the potential hazards from these biomaterials to human health and to the environment, together with the monitoring and reduction of the risk that these new technologies pose. Current knowledge is still incomplete and the established methods may be inappropriate for specific materials in view of their eventual deployment. The necessary integration of physical, chemical, biochemical and clinical methods is an open challenge. Hence, future production system engineering requires development of integrated and validated methodologies as basis for an appropriate integrated risk management.

Scope:

The development of new biotechnology-based products needs to be complemented with a scientifically valid identification of the potential hazards from these biomaterials to human health and to the environment, together with the monitoring and reduction of the risk that these new technologies pose. Current knowledge is still incomplete and the established methods may be inappropriate for specific materials. Hence, future production system engineering requires validated methodologies as basis for an appropriate integrated risk management. As relevant, the proposed activities should address sex and gender specific aspects[1].

Projects are expected to initiate and support standardisation of the proposed biomaterials and methods, including methods that will reflect their eventual deployment as part of Advanced Therapy Medicinal Products and/or Medical Devices.

The expected projects should be related to validating, adapting and/or developing a reliable methodology for risk assessment and thorough overarching hazard identification for engineered biomaterials and should address the following areas:

- Comparison and validation of current (and/or development including validation of new) test methods and test schemes, including in vitro and in silico methods, to detect adverse effects from biomaterials to:
  - human health including acute and chronic toxicity (oral, inhalation, dermal);

- modelling toxicity behaviour of engineered Biomaterials, including development of ready-to-use predictive models (web services etc);
- the environment; eco-toxicity tests, bioaccumulation, persistence, bioavailability and life cycle impacts onto all forms of biota.

- Relevant reference and/or certified reference materials;
- Management of accidental risk including explosion and massive release;
- Methods for performance assessment of hazard and exposure monitoring systems and on the field detection systems;
- Methods for evaluation of risk reduction strategies and systems.

The implementation of this topic is intended to start at TRL 4 and target TRL 6.

This topic is particularly suitable for international cooperation.

The Commission considers that proposals requesting a contribution from the EU between EUR 5 and 8 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Development of comprehensive understanding of the properties, interaction and fate of engineered biomaterials in relation to human health and environment;
- Support to policy and decision making concerning biomaterials research in respect to various stakeholders: public authorities, industry, researchers and citizens;
- Validated test methods and schemes for the identification of potential adverse effects from biomaterials and contribution to the future definition of appropriate measures, where needed;
- Support to pre and co-normative activities, such as with reference to the implementation of the REACH regulation[2];
- Support to good governance in biomaterials research following the safe, integrated and responsible approach as laid down in "Nanosciences and Nanotechnologies: An action plan for Europe".

TOPIC : Cross-cutting KETs for diagnostics at the point-of-care

Topic identifier: NMBP-13-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: single-stage
Planned opening date: 20 September 2016 **Deadline:** 19 January 2017 17:00:00

Research and technology development at the interface of key enabling technologies has the potential to provide novel technological Micro-Nano–Bio integrated Systems (MNBS) platforms to enhance the ability to sense, detect, analyse, monitor and act on phenomena from macro (e.g. body, organ, tissues) to nano scale (e.g. molecules, genes). These developments have a high potential for facilitating personalised and preventive healthcare. However, the translation of laboratory proven concepts to the clinical environment involving pre-clinical and clinical testing, prototyping, and small series manufacturing is currently lagging. Business development and market growth are therefore still limited. The challenge is to bring new promising laboratory proven MNBS concepts for addressing priority healthcare needs from the laboratory to the clinic.

Scope:

The focus is on further development into a clinical setting of novel MNBS platforms, techniques and systems that have already been proven in a laboratory setting (laboratory Proof-of-Concept). These must pertain to one or more of the following:

a. In vitro/in vivo diagnostics that are deployed at the point of care;
b. Therapy monitoring at the point of care.

Proposals should pay attention to facilitate clinical data harvesting, e.g. for medical regulatory purposes and/or to enhance epidemiological monitoring of health and disease patterns. As relevant, the proposed activities should address sex and gender specific aspects[1].

Proposals should demonstrate clear compliance with applicable Good Laboratory Practice /Good Clinical Practice /Good Manufacturing Practice, and be consistent with ISO and other regulations (both national and European). The translation from the pre-clinical phase to early clinical testing, including design and pilot manufacturing in appropriate volume for clinical testing (small series), pre-clinical and early clinical testing is a necessary part of the work-up. Attention should be paid to the requirements for Health Technology Assessment (HTA). Standardisation issues have to be taken into account where appropriate.

Activities are expected to commence at Technology Readiness Levels 3/4 and reach 5-6.

A significant participation of SMEs with R&D capacities is encouraged.

The Commission considers that proposals requesting a contribution from the EU between EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

Proposals should address one or more of the following impact criteria and provide metrics to measure and monitor success.

- Address priority needs in healthcare diagnostics and / or therapy monitoring, for the benefit of patients;
- Provide affordable systems with unique features that address specific well identified requirements in healthcare;
- Progress the development of advanced integrated MNBS based diagnostic health platforms, techniques or systems from the laboratory Proof-of-Concept to the clinical setting;
- Establish a world-class European competitive industrial R&D and manufacturing competence in Micro-Nano-Bio Systems integration for healthcare diagnostics applications;
- Strengthening the industrial value chain and progress to marketisation;
- Early involvement of regulatory bodies and patients in the new developments.

Proposals should include a business case and exploitation strategy, as outlined in the Introduction to the LEIT part of this Work Programme.

This topic will be co-funded by LEIT-ICT and LEIT-NMBP within the context of a Cross-KET initiative for Health, for a total budget of EUR 15 000 000.

TOPIC : Regulatory Science Framework for assessment of risk benefit ratio of Nanomedicines and Biomaterials

Topic identifier: NMBP-14-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 11 May 2016
Deadline: 27 October 2016 17:00:00
2nd stage Deadline: 04 May 2017 17:00:00

Specific Challenge:

The application of nanotechnology and nanobiomaterials has great potential to advance medicine for the benefit of citizens. However, the use of these new technologies poses considerable challenges for assessing the quality, safety and efficacy of the novel nanomedicines and medical devices.

Scope:

Proposals should advance the field of medical regulatory science and practice through the development and validation of science based regulatory knowledge and standardisation of innovative technical tools and methods. The intention is to lead to a new and better methodology

for pre-clinical and clinical evaluation and help to take appropriate stock of and to apply innovative scientific advances as and when they occur. As relevant, the proposed activities should address sex and gender specific aspects[1].

Proposals should focus on the development of new regulatory standards and tools that are based on scientific principles that already have a Proof-of-Concept at the laboratory scale.

Where appropriate, proposals should make use of the opportunities for obtaining scientific advice from medical regulatory bodies to support the qualification of innovative development methods.

International cooperation and participation of Member States funding programmes with complementary funding is encouraged to facilitate development of new regulatory science on the global scale.

Established methods, including related equipment, should be brought to Technology Readiness Level 6 and beyond, whereas those based on new concepts are expected to reach TRL 5.

This topic is suitable for international cooperation.

The Commission considers that proposals requesting a contribution from the EU between EUR 5 and 8 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

No more than one action will be funded.

Expected Impact:

- To reduce the cost of pre-clinical and clinical development for new medical products and therapies, that are based on the application of nanotechnology and nanobiomaterials;
- To reduce the time for innovations to reach the patients;
- To provide a set of tools for more informed risk assessment and decision making;
- To improve standardisation of regulatory practice at the European and international level;
- To establish a close collaboration among regulators, industry, science and patients with regard to the knowledge required for appropriate risk management, and create the basis for common approaches, mutually acceptable datasets and risk management practices;
- To establish a European Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicines, involving industrial, medical, academic, regulatory and patient representative stakeholders;
- To identify within the consortium critical issues for innovative products and establishment of an action plan for further studies;
- To establish links with existing European Infrastructures active in the field, along with relevant European Research Networks;
- To elaborate an action plan for a better integration of the European Union with other regions of the world.

TOPIC : Nanotechnologies for imaging cellular transplants and regenerative processes in vivo

Topic identifier: NMBP-15-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 11 May 2016
Deadline: 27 October 2016 17:00:00
2nd stage Deadline: 04 May 2017 17:00:00

Specific Challenge:

Detection and monitoring of cell and tissue transplants in vivo is of utmost importance for development of clinical cell therapy. Suitable nanotechnology-based imaging approaches with high sensitivity should allow for monitoring of cell viability, engraftment and distribution, also through the use of nanomaterials for cells marking. Appropriate imaging techniques have been developed for application in small animals, but are not available yet for use in preclinical large animal models and

patients. In particular, such technologies will represent an important safety measure enabling early detection of cell based therapy.

Scope:

Proposals should focus on the following:

- Development of highly sensitive imaging approaches enabling discrimination of living cell and tissue transplants based e.g. on optical imaging, magnetic resonance imaging and / or nuclear medicine techniques;
- Monitoring should be highly sensitive, in best case allowing for detection of single cells and cell morphologies;
- Possibility of non-invasive whole body monitoring (magnetic, optical) in large animals;
- Development of clinically applicable imaging approaches, taking into account medical regulatory aspects;
- Interpretation of the data with theoretical models (to be developed if necessary).

As relevant, the proposed activities should address sex and gender specific aspects[1].

Activities are expected to commence at Technology Readiness Levels 3/4 and reach 5/6.

The Commission considers that proposals requesting a contribution from the EU between EUR 5 and 7 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Availability of novel highly sensitive nanotechnology-based imaging approaches allowing for monitoring of survival, engraftment, proliferation, function and whole body distribution of cellular transplants in preclinical large animal models and patients;
- Imaging technologies facilitating the provision of new regenerative therapies to patients;
- Opening of a new market sector for imaging equipment and supplies, reinforcement of the European healthcare supply chain and improvement of the competitiveness of the European healthcare sector.

Proposals should include a business case and exploitation strategy, as outlined in the Introduction to the LEIT part of this Work Programme.

TOPIC : Mobilising the European nano-biomedical ecosystem

Topic identifier: NMBP-16-2017
Publication date: 14 October 2015

Types of action: CSA Coordination and support action
DeadlineModel: single-stage
Planned opening date: 20 September 2016 **Deadline:** 19 January 2017 17:00:00

Specific Challenge:

Developing innovative nanomedical products for a more personalized, predictive and efficient medicine requires further integration of nanotechnologies aiming at applications in human health notably with further Key Enabling Technologies. It also needs a functioning ecosystem of actors, in which the research, translation, regulation, standardization and take-up of innovative nanomedicines by the different European healthcare systems is stimulated. End-of-life/disposal and recyclability issues should also be addressed as appropriate.

Scope:

Supporting the development of an ecosystem for nanomedicine in Europe, including activities such as coordinating national platforms and regional clusters; developing common training material and services; international cooperation related to community building, road-mapping, regulation, manufacturing, reimbursement and pricing, standardization and recyclability; and reaching out to attract the interest of citizens, young talents and young entrepreneurs. Collaborations with relevant technology platforms or similar initiatives in Europe or worldwide will allow deeper and more

effective cross-KETs activities for innovative integrated solution and well as a consolidated international strategy for the sector.

Attention should be paid to achieve a cross-regional, cross-sectoral and cross-technological approach, based on the analysis of relevant roadmaps, strategic research agendas or smart specialisation strategies which have listed nanomedicine or personalised Medicine as one of their priorities. These different approaches might for instance be united into one “meta” roadmap.

The Commission considers that proposals requesting a contribution from the EU between EUR 1 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Increased take-up of innovative Nanomedicine solutions by industry and SMEs, end-users, regulatory and public authorities, healthcare insurances, doctors and patients, research organisations and academia;
- Improvement of cross-KETs activities to provide better integrated healthcare solutions;
- Increased international networking with new potential market opportunities;
- Improvement of the competitiveness of the European healthcare sector.

Food security, sustainable agriculture, marine research and the bio-economy

TOPIC : Co-fund on "One Health" (zoonoses – emerging threats)

Topic identifier: SFS-36-2017
Publication date: 14 October 2015

Types of action: COFUND-EJP COFUND (European Joint Programme)
DeadlineModel: single-stage
Planned opening date: 04 October 2016 **Deadline:** 14 February 2017 17:00:00

Specific Challenge:

Infectious diseases transmitted naturally from animals to humans (zoonoses), constitute major public health risks. In recent years, zoonoses have given rise to a number of human disease problems and anti-microbial resistance is also recognised as a global health threat. Especially when food-borne, zoonoses have significant social and financial impacts in Europe and need to be addressed by all those actors in the farm-to-fork food chain. Coherence in research is needed to better understand processes triggering and propagating zoonoses, their routing in the animal–human-environment triangle and their impact on public health. The means to control these diseases can be improved with a "one health" (i.e. holistic and transdisciplinary) approach involving synergies in various areas of research: human health, animal health food safety and environmental health. Action is needed at European level to identify and characterize risks in the field of food and feed safety, by developing capacity to collect and analyse information, and supporting research on state-of-the-art reference and surveillance tools, taking into account the harmonisation of existing and new diagnostic tests. Action needs to be undertaken in due time to identify the etiological agent. National research programmes in the area need to be further integrated and aligned and related policy activities, including forecasting activities for emerging threats, need further support. This will also add value and should be done in coordination with related European initiatives, bodies and projects and take into account relevant international bodies. There is also a need for research-based recommendations to prevent and control such (especially food-borne) zoonoses, to disseminate these recommendations effectively, to the various stakeholders (e.g. policy-makers, industry, citizens), and measure their impact on human and animal health.

Scope:

The overall objective is to create a European joint programme to deal with zoonoses with an emphasis on zoonotic food-borne microbial infection and intoxication, including natural toxins and the risks associated with domesticated and wild animal reservoirs and their exposure routes towards human infection, including possible illegal imports of animal products, in order to improve preparedness against future 'one health' risks. Related emerging threats such as antimicrobial resistance will be addressed. The aim is to construct a sustainable framework for an integrated

community of research groups including reference laboratories in the fields of life sciences, medicine, veterinary medicine, animal sciences and environmental sciences. This will lead to the joint programming and execution of research and other joint integrative activities such as information dissemination, education and training including knowledge management, access to strain collections, biobanks, experimental facilities and databases, including also harmonisation, standardisation, proficiency tests, training, short-term missions, workshops and summer schools. The work will cover all agents involved, including viruses, bacteria, parasites and nucleotide sequences/genetic material conferring antimicrobial resistance. State-of-the-art technologies taking into account genomics research and modern tools, including biotechnological and epidemiological advances, will be used, also taking into account the harmonisation of diagnostic tests. An appropriate governance structure should be established to ensure effective implementation of the joint programme. Participating legal entities must be nominated by Member States or associated countries and have research funding and/or management responsibilities in the field of zoonoses, in particular for microbiological safety along the food chain. Coherence will be sought between the research activities and public and animal health policies. The acquired knowledge should support informed decision-taking and policy-making in the domain The activities will need to be coordinated with related European research related projects (e.g. EFFORT[1], COMPARE[2]), initiatives (e.g. JPI AMR[3], GloPID-R[4], International Research on animal health, see SFS-12-2016) and entities (e.g. EU reference laboratories, EFSA, ECDC) and take into account relevant international statutory bodies such as OIE, WHO and Codex Alimentarius.

Considering the budget available, the scope covered and the potential entities for this EJP, the Commission considers that an EU contribution to a maximum 50% of the total eligible costs of the action or up to 35 million EUR for the expected 5 year duration of the action would allow this specific challenge to be addressed appropriately. Up to one project will be funded.

Expected Impact:

The project will lead to significant long term alignment of research strategies and activities at national and EU level, thus reducing unnecessary duplication of work on (especially food-borne) zoonoses. It will foster lasting transdisciplinary cooperation in the fields of life sciences, medicine, veterinary medicine, animal sciences and environmental sciences. It will advance understanding of the risks associated with zoonoses, their origin and pathways towards human infections. It will support risk management as regards zoonoses. It will facilitate knowledge dissemination, making beneficiaries aware of the risks and more responsible for their health.

[1]http://www.effort-against-amr.eu/

[2]http://www.compare-europe.eu/

[3]http://www.jpiamr.eu/

[4] http://www.glopid-r.org/

TOPIC : How to tackle the childhood obesity epidemic?

Topic identifier: SFS-39-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 04 October 2016
Deadline: 14 February 2017 17:00:00
2nd stage Deadline: 13 September 2017 17:00:00

Specific Challenge:

Childhood obesity is one of the most serious public health challenges of the 21st century and its prevalence has increased at an alarming rate in the last decades. The main problem is that overweight and obese children are likely to remain obese in adulthood and more likely to develop noncommunicable diseases like diabetes and cardiovascular diseases at a younger age. An integrated EU approach to help reduce the impact on health of poor nutrition, excess weight and obesity is a political objective. A wide range of factors interacting at various levels are known to be

associated with obesity. Overweight and obesity, as well as their related diseases, are largely preventable. Starting from an early age, diet and lifestyle have a strong impact on health throughout life. Therefore, the prevention of childhood obesity needs to be given a high priority.

Scope:

Within the context of improving the health of citizens and promoting sustainable economic growth, the main objective is to reduce childhood obesity and its comorbidities effectively. Proposals should focus primarily on specific target groups in the young (e.g., during pregnancy and foetal development, in infants, toddlers, most vulnerable groups in children, adolescents). To better understand the complex interactions between the factors influencing obesity in individuals and populations, it is necessary to combine the approaches and expertise from different disciplines (e.g. (epi)genetics, molecular biology, microbiome, gut-brain signalling, physiology, nutrition, physical activity sciences, information and communication technology, social sciences and humanities, education, environment, architectural and urban design, psychology). Proposals should consider a range of geographic, socio-economic, behavioural and cultural factors. Proposals should aim at innovative and efficient strategies, tools and/or programmes for promoting sustainable and healthy dietary behaviours and lifestyles. Proposals should reflect and build on existing initiatives and platforms and should provide a robust science-based impact assessment of the tools, strategies and/or programmes delivered for further consideration by policy makers. Tackling this societal challenge requires both interdisciplinary and multi-actor approaches engaging academics, policy makers, civil society and relevant industry and market actors. The gender dimension in the research content shall also be taken in account. In line with the strategy for EU international cooperation in research and innovation, international cooperation is encouraged, in particular with the US, Australia, New Zealand and Canada. Proposals should fall under the concept of the 'multi-actor approach'[1].

The Commission considers that proposals requesting a contribution from the EU of up to EUR 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude the submission and selection of proposals requesting other amounts.

Expected Impact:

In the effort to tackle the childhood obesity epidemic, proposals should show how some, or all, of the following impacts will be achieved:

- Provide an understanding of which factors are involved and how they influence the childhood obesity epidemic.
- Provide innovative, efficient, effective, scientific evidence-based and ready-to-use tools, strategies and/or programmes to improve sustainable and healthy dietary behaviour and lifestyles in children.
- Transfer the generated knowledge and innovation to relevant stakeholders.
- Strengthen interdisciplinary research approaches and foster participatory and inclusive multi-actor approaches for long-lasting implementation of the results obtained.

[1]See definition of the 'multi-actor approach' in the introduction of this Work Programme part.

TOPIC : Sweeteners and sweetness enhancers

Topic identifier: SFS-40-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 04 October 2016
Deadline: 14 February 2017 17:00:00
2nd stage Deadline: 13 September 2017 17:00:00

Specific Challenge:

In recent decades, sweeteners and sweetness (flavour) enhancers (S&SEs) have become key ingredients in food produced and consumed in the EU, and exported to and from it. Because of their diversity (natural/artificial, geographical origin, processing, caloric content, etc.), S&SEs are

used in different foodstuffs and food processes and in different dosages. However, information is lacking about new and emerging S&SEs throughout the agri-food chain, (e.g. their potential use in single or multiple food (ingredient) production chains, traceability, production and/or processing (cost) efficiency, safety and quality risks/benefits (for single or combined use), allergenicity and sustainability). The interaction of all these factors influences the role of S&SEs in a healthy diet and the fight against obesity. In addition, the toxicological impact of high doses, combined effects and the prolonged use of S&SEs are still unknown and the health-related aspects need further investigation.

Scope:

Proposals should focus on health, obesity and safety aspects (including combined/prolonged use, metabolic effects and gut brain signalling, neuro-behaviour, and effects on the microbiota) associated with S&SEs. Activities indicated in the proposals should explore the sustainability of the whole value chain (ingredient sourcing, production/processing, market opportunities for new and emerging S&SEs). They should investigate consumer perceptions and preferences giving proper consideration to the underlying physiological, psychological and socio-economic drivers. The approach should be interdisciplinary and should give careful and detailed consideration to the regulatory framework. Proposals should also include dissemination to all stakeholders as well as the food industry, including small and medium-sized enterprises (SMEs). Where relevant, proposals should address gender-specific aspects and the gender dimension in the research content shall be taken into account.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 9 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude the submission and selection of proposals requesting other amounts.

Expected Impact:

With the objective of combating obesity, while improving sustainable food security in the EU, proposals should show how some, or all, of the following impacts will be achieved:

- Promote healthy diets and contribute to combating obesity while improving sustainable food security in the EU.
- Stimulate market uptake (with a specific focus on small and medium-sized enterprises) of new, healthy and sustainable S&SEs.
- Strengthen the EU economy with a move towards more sustainable and future-oriented business practices.
- Dissemination to EU food, health and food ingredient stakeholders, especially to food-related SMEs.
- Evidence-based policy inputs on health, environmental and food safety issues.

TOPIC : Alternative production system to address anti-microbial drug usage, animal welfare and the impact on health

Topic identifier: SFS-46-2017
Publication date: 14 October 2015

Types of action: RIA Research and Innovation action
DeadlineModel: two-stage
Planned opening date: 04 October 2016
Deadline:
2nd stage Deadline: 14 February 2017 17:00:00

Specific Challenge:

Confined systems dominate in modern livestock production worldwide, in particular as regards monogastric species. These systems often constrain natural animal behaviour and may result in health problems and product quality issues. The EU and China are facing a similar challenge, though not to the same extent. Efforts to maximise production and ensure product safety often involve overuse of anti-microbial drugs in farm animals either in veterinary treatment, or for growth-promoting purposes in those countries where they are allowed. Drug residues may accumulate in animal products and the environment, lead to food quality issues and constitute a risk for consumers. Welfare and environmentally-friendly production systems may improve animals'

immunity and health conditions, and reduce veterinary drug use, in combination with other measures such as good husbandry practices and biosecurity. The EU has an increasingly active policy on improving animal welfare and fighting the threat of anti-microbial resistance. As China is seeing high levels of veterinary drug use in increasingly intensive production systems, it has an interest in cooperating with the EU on strategies to make those systems more sustainable.

Scope:

Focusing on monogastric species in confined intensive systems, the proposed research activities should assess the links between livestock welfare and health, the underlying factors, the related use of anti-microbial drugs and the subsequent presence of residues in products and their spread into the environment. They should in particular address immunity and health, biosecurity measures and residue detection. The activities should develop possible means, including tools, methods and schemes, by which more welfare-friendly production systems can help improve health and reduce the use of veterinary drugs. The proposed activities should, where possible, measure the potential impact of the proposed measures, including the socio-economic aspects and the scope for establishing schemes (standard-setting, management, policy, monitoring and verification components).

The Commission considers that proposals requesting a contribution from the EU of up to EUR 5 million would allow this specific challenge to be addressed properly. Nonetheless, this does not preclude the submission and selection of proposals requesting other amounts. Contributions for Chinese participants will come in addition and will be made available by China.

Expected Impact:

- welfare-friendly production systems (housing, equipment, technology) to improve farm animal immunity, health and welfare effectively;
- reduced veterinary drug use at farm level and reduced residue in animal products in order to improve food safety;
- improved biosecurity at farm level; and
- contribution to the development of common legislation and standard-setting in the EU and China