Regenerative medicine: from new insights to new applications

Info: SC1-BHC-07-2019
Type of Action: RIA Research and Innovation action
Budget: 50 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary
Regenerative medicine offers hope for untreatable disease and the ageing population, improved quality of life and reduced medical costs. However, so far, regenerative medicine has not yet proved itself in the clinic beyond rare diseases or conditions of limited public health importance. The challenge is to use these to extend the regenerative approach to major diseases and conditions.

Scope:
Regenerative medicine replaces or regenerates human cells, tissue or organs, to restore or establish normal function. Projects should focus on **innovative translational research** to develop regenerative processes towards the ultimate clinical **goal of addressing unmet clinical needs of large patient groups**. Proposals should be based on **new approaches** such as:

- Genome editing or gene therapy
- Trans-differentiation or in vivo reprogramming,
- Cell therapy and transplantation
- 3D bioprinting
- Organoids or use of combined products (non-exhaustive list for illustrative purposes only).

They should **explain in what way their approach is regenerative**. Research on improved methods of tissue and organ transplantation is included on the condition that there is a **clear regenerative step** in the process. The project may **focus on any step(s) on the innovation chain**, from early testing and characterization of regenerative mechanisms to preclinical research, proof of concept or clinical trial. **Sex and gender differences** should be investigated, where relevant. Projects should include a section on the proposed therapy's exploitation potential, regulatory and commercialisation strategy and how it would be made available and delivered to patients.

Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Info: SC1-BHC-10-2019
Type of Action: PCP Pre-Commercial Procurement
Budget: 30 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary:
Progressive shift in routine diagnostics, and more particularly in personalised medicine practice, from a growing number of molecular tests to a next generation sequencing approach (NGS). NGS can **provide insights on a person's genetic susceptibility to disease**, **diagnostic information**, and **predictive indications about treatment outcome**. It also allows to embrace simultaneously different molecular pathways of disease evolution and to identify actionable mutations in a patient for medical decision and further research. It requires less sample material than multiple tests and therefore reduces risk and inconvenience for patients. However, the introduction of NGS in clinical practice is hampered by its **cost**, the **availability of proper NGS tests**, and **diagnostic errors** resulting from insufficient quality assurance, technological bias and complex interpretation of data.

Scope:
The objective is to **implement NGS in routine diagnostics for personalised medicine** and **scale up demand-driven innovation** for healthcare systems. This includes organisational, economical, technical and clinical aspects. It should lead to

- NGS tests,
- Clinically validated procedures (including sex analysis),
- Quality assurance schemes,
- Tools and methods for data collection,
- Management, analysis and interpretation,

with a view to assist clinical decision-making and foster medical research and innovation. Transferability and cloud based NGS data analyses should be considered, as appropriate. Input from initiatives like the EJP Cofund on rare diseases and ERNs should be considered when relevant. Ethical issues should be addressed.

The Commission considers that proposals requesting a contribution from the EU of between **EUR 9 and 11 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 NGS platforms and use of NGS tests in routine diagnostics for personalised medicine.
- Accepted new European standards and quality assurance schemes with respect to NGS.
- Strengthening of implementation of personalised medicine and improved clinical decisions and health outcomes for the benefits of patients.
- Contribution to the sustainability of healthcare systems.
- Growth and benefit to the European industry, in particular SMEs.

Mining big data for early detection of infectious disease threats driven by climate change and other factors

Info: SC1-BHC-13-2019
Type of Action: RIA Research and Innovation action
Budget: 30 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary
A range of factors ARE responsible for the (re-)emergence of infectious disease threats, including antimicrobial resistance, altering the epidemiology and spread of disease in a changing global environment.
At the same time, tools for infectious disease diagnostics and surveillance are evolving rapidly, with more accurate diagnosis in shorter time. The use of next generation sequencing combined with surveillance data, health registries and societal data from informal/non-traditional sources (social media) holds promise for improving health. Current IT technologies offer the opportunity to integrate big data sets and could enable the rapid and personalised treatment of patients, and bolster the detection, tracking and control of infectious disease outbreaks.

Scope:
It is expected that proposals develop:

- Technology to allow the pooling, access, analysis and sharing of relevant data, including next generation sequencing;
- Innovative bio-informatics & modelling methodologies that enable risk modelling & mapping
- Analytical tools for early warning, risk assessment, monitoring of infectious disease threats

Proposals should

- Demonstrate the feasibility of such extended data mining for the purposes outlined above, as well as its European level added value. The analytical tools and services should be based on an assessment of the needs of potential end, build on and be compatible with existing European initiatives, remain available for public use at the end of the project
- Be transdisciplinary and ensure an integrated One Health approach by linking data from a range of sources depending on the infectious disease threat: including human and animal health surveillance, health registries, microbial and viral genomic data pathogen resistance data, mapping vectors, climate and environmental data, possible sex/gender differences taken into account. Solutions for gaps in existing data should be proposed.

Solutions for interoperability between different data sources should be addressed and integrated. It is expected that quality-controlled data are shared in accordance to the general concepts of the FAIR principles. The technology and tools developed should be functional outside of outbreaks (i.e. in "peace time"), so that all stakeholders involved develop a routine use of them.

The use of advanced IT technologies like high performance computing, or geo-localisation data are anticipated. The use of European health research (e-)infrastructures such as those included under CORBEL is encouraged. The successful proposal(s) should foresee to consult with the end-users at both national (e.g. public health institutes) and European (e.g. ECDC, EFSA) level at key milestones of the project's timeline. The Commission considers that proposals requesting a contribution from the EU of between EUR 12-15 million would allow this specific challenge to be addressed appropriately.

The Human Exposome Project: a toolbox for assessing and addressing the impact of environment on health

Info: SC1-BHC-28-2019
Type of Action: RIA Research and Innovation action
Budget: 50 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary
Despite the general acknowledgement by the scientific community that **'Genetics load the gun but environment pulls the trigger**' when it comes to the causation of major non-communicable diseases, there is persistent **uncertainty as to the global burden of disease attributable to environmental** (life-style and climatic) factors, including healthcare costs and negative economic impact. Deciphering the human exposome is a novel way of addressing the challenge to improve health and reduce burden of disease. This will require **improved knowledge of health risks**, including combinations of risk factors, and the mechanisms by which they affect health at different stages in life. **Effective preventive action** will need to be designed, building on knowledge of various risk factors, including **exposure to pollutants in daily life, individual behaviour and the social contex**t.

Developing a **Human Exposome Project** would present a fundamental shift in looking at health, by moving research away from 'one exposure, one disease' to a more complex picture to build solid, cost-effective preventive actions and policies and respond to the need for more complete and accurate individual-level exposure data to estimate the unknown environmental component of NCDs.

Scope:
Applicants should take advantage of the last decade's rapid technological advances which have opened up new opportunities to collect, combine and analyse large data sets offering new possibilities to understand the contribution of environmental factors to the health burden of chronic diseases. Proposals should use **innovative approaches** to the **systematic and agnostic identification of the most important environmental risk factors** for the development of major NCDs, leading to **preventive interventions** at the **individual, group or population level**. Well-designed retrospective epidemiological studies may be included and envisage the creation of a prospective **Europe-wide exposomics cohort and biobank**, integrating behavioural, socio-economic factors, clinical records.

Innovation and connections with industry are expected in the areas of sensor development (external exposome), omics technology and novel biomarker development (internal exposome), bioinformatics, and data processing and management. Proposals are expected to respond to a persistent or long-standing policy/regulatory need where the exposome approach would be useful to solve a scientific issue to underpin better regulation now or in the future (examples: indoor and outdoor air quality, waste, occupational health, noise).

The Commission considers that a proposal requesting an EU contribution between **EUR 8 to 12 million** would allow this specific challenge to be addressed appropriately.

Pilot actions to build the foundations of a human cell atlas

Info: SC1-BHC-31-2019
Type of Action: RIA Research and Innovation action
Budget: 15 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary:
For better understanding human health as well as improving the diagnosis, monitoring and treatment of diseases, **greater knowledge is needed of the diverse cells** found within the human body. Recent developments in single cell technologies, analytical methods and computational tools allow for unprecedented **characterisation of human cells**. A novel approach to address this challenge is the **international Human Cell Atlas initiative (HCA)** which will create **molecular reference maps** of all human cells. The potential scientific scope and organisation, including the community values to be adhered to by participating researchers, are described in a recent white paper.

European researchers are at the forefront of developments and thus, can make an important contribution to **building a human cell atlas**. It is imperative to **bring together and strengthen expertise** to generate data and develop methods for in-depth, integrated molecular analysis and spatial resolution of single cells from complex biological systems such as human organs.

Scope:
Each pilot action should demonstrate the utility of an interdisciplinary technological/biological platform to generate and integrate standardised molecular, cellular, biochemical and other data sets, characterising single cells or their nuclear components, their interactions and/or spatial location in tissues from one human organ. Platforms supporting analysis of tissues from more than one organ are also in scope. The primary focus should be on healthy tissues, with possible sex, age and ethnicity comparisons. Proposals should provide detailed plans for quality management of tissue procurement and data in compliance with the relevant EU legislation (ethics, data protection).

Proposals must **strictly adhere to the values, standards and practices of the HCA** and provide for coordination with ongoing European and international activities. Plans for building **sustainability** beyond the funding period and **scalability** should be included. Proposals for pilot phase actions under this topic should be ready to **deliver results for the HCA quickly**, with **project duration of two years**. The Commission will ensure an overall coordination mechanism between the projects. Proposals are expected to budget for the attendance of co-ordinators to regular meetings and communicate results and exchange of knowledge gained from each pilot.

The Commission considers proposals requesting a contribution from the EU of between **EUR 3 and 5 million** would allow for the specific challenge to be addressed appropriately.

Towards a next generation influenza vaccine to protect citizens worldwide – an EU-India collaboration

Info: SC1-BHC-32-2019
Type of Action: RIA Research and Innovation action
Budget: 15 000 000
Deadline: 16 April 2019 17:00:00 Brussels time

Summary:
Seasonal influenza is a major health burden, with an estimated **500,000 deaths around the world** each year. A further threat is the non-seasonal emergence of new strains, with potential of major pandemics.

Despite this large danger, vaccines against flu are only moderately effective. In addition, current influenza vaccines need to be developed every year, as they only work against a narrow range of the hugely variable influenza subtypes and are also highly vulnerable to strain mutations. Improved influenza vaccines would ease a significant global health burden and help to better prepare in the event of an influenza pandemic.

The burden of seasonal influenza, and the ever-present threat of a new influenza pandemic, is a high priority for both Europe and India. In recent years, significant progress has been made. To build on this shared recognition of the importance of influenza, as well as significant expertise available in both regions, a renewed effort towards the development of a next generation influenza vaccine is needed. Furthermore, utilisation of the human challenge model of influenza, or improvement of the model may be an important step to progress.

Scope:
Proposals should further the advancement of next generation influenza vaccine candidate(s) with improved efficacy and safety, duration of immunity, and reactivity against different influenza strains. Proposals should make use of new knowledge of structural biology, immunology, genetics and genomics, influenza transmission modelling, vaccine production, formulation, delivery methods.

Proposals should cover at least pre-clinical and/or early clinical research, selecting vaccine candidate(s), supporting their proof of concept, showcasing new pre-clinical or clinical knowledge.

The approach taken should include validation of one or more candidate vaccine(s) in a human challenge model of influenza, and/or work to improve the influenza human challenge model itself. This latter work could include comparative testing of potential human challenge strains, and the responses they elicit in volunteers.

The suitability of the interventions to be developed should be addressed and assessed for different population groups, as should the suitability of the candidate(s) to low- or middle-income settings. The downstream constraints for the uptake of the intervention by national health systems should be taken into account.

The Commission considers that proposals requesting a contribution from the EU of between **EUR 6 and 10 million** would allow this specific challenge to be addressed appropriately

Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

Info: SC1-DTH-01-2019
Type of action: RIA Research and Innovation action
Budget: 35 000 000 / single-stage
Deadline: 24 April 2019 17:00:00 Brussels time

Summary: The use of big data can bring valuable information for monitoring health status and quality of life after the cancer treatment as well as to provide new opportunities to define statistical and clinical significance, but present also challenges as it requires specific analytical approaches.

Scope:

Proposals should **focus and deliver** on how to better acquire, manage, share, model, process and exploit big data using, if appropriate, high performance computing to effectively monitor health status of individual patients, provide overall actionable insights at the point of care and improve quality of life after the cancer treatment. Proposals preferably **address relevant health economic issues**, use patient reported outcome and experience measures (PROMs and PREMs) and take into account the relevant social aspects of health status and quality of life after cancer treatment. Integrated solutions should include suitable approaches **towards security and privacy issues**.

Information can be collected from **traditional sources** of health data (cohorts, comprehensive electronic health records or clinical registries…) from **new sources** of health data (mobile health apps and wearables) and from environmental data.

It is important to assure **ethical aspects of data**, confidentiality, and anonymity of data transfer and engagement of those who collect / code such data in its analysis and interpretation**. Involvement** of those who work within healthcare systems, patients, family and relatives, and the general public is needed.

The Commission considers that proposals requesting **a contribution from the EU of 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.

The proposal should provide appropriate indicators to measure its progress and specific impact in the following **areas:**

- Mapped comprehensive big data in a reachable and manageable way
- Emerging data driven analytics and advanced simulation methods
- Better knowledge for improved patient counselling as well as to improve follow-up of patients;
- Novel information on health maintenance
- Evidence base for the development of policy strategies
- Improved quality of life after cancer treatment,
- Preventative strategies are established

Large scale implementation of digital innovation for health and care in ageing society

Info: SC1-DTH-05-2019
Type of action: PPI Public Procurement of Innovative solutions
Budget: 10 000 000 single-stage
Deadline: 24 April 2019 17:00:00 Brussels time

Summary:

- To scale up outcome-based innovative digital health and care solutions across EU borders through joining up actions in procurement of innovation.
- An ageing population is increasing demand-side pressures on public health and social care providers across Europe .
- Large-scale deployment of digital health and care solutions across EU borders remains limited
- Lack of collaborative efforts in public purchasing of innovative ICT-based solutions

Scope:
This topic will **contribute to** the Digital Single Market Strategy priorities on digital transformation of health and care (notably to the priority on user-centred integrated care), to the Scaling-Up Strategy of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA). The scope of this PPI is to specify, **purchase and deploy ICT based solutions** (made up of services and ICT products to enable the provision of services) for active and healthy ageing through a common supply and demand side dialogue.

Proposals should:

- Be driven by clearly identified procurement needs of the participating organisations
- Support sustainable deployment of new or improved person-centred and outcome-based services
- Contribute to the creation of scalable markets across Europe in innovative solutions for active and healthy ageing
- Specify measures that will ensure the sustainability of solutions (levels of acceptance with users and professionals, as well as health economics considerations)
- Engage public and/or private procurers from each country participating
- Demonstrate that the implementation phase will reach "large scale"
- Contribute to the use of interoperable solutions based on open platforms
- Contribute to the development of national strategies

The European Commission considers that proposals requesting a contribution from the EU of between **EUR 2 and 5 million** would allow this specific challenge to be addressed appropriately through PPI. This does not preclude submission and selection of proposals requesting other amounts.

Expected Impact: The proposal should **provide appropriate indicators** to measure its progress and specific impact in the following areas: Growing **awareness** and successful use of public procurement,contribution with **data and experiences** to regulatory and legislative process development.Contribution of an open and **comprehensive socio-economic evidence** base for ICT investments in the field that can support the development of sustainable business models, support initiatives on interoperability and standardisation. Creation of **economic boundary conditions**, support **forward-looking**, concerted public-sector investment strategies.Create new opportunities for market uptake and economies of scale for the supply side, Contribute **to inform** policy measures.

Scaling up the univocal Identification of Medicinal Products

Info: SC1-DTH-09-2019
Type of action : IA Innovation action
Budget: 19 000 000 single-stage
Deadline: 24 April 2019 17:00:00 Brussels time

Summary:
Across the European Union, medicinal products display **differences** in names, variations in strength or their package size. Most national **ePrescription** and medicines databases are not currently supporting relevant identification attributes and codes. As the EU-wide implementation of ISO IDMP (identification of medicinal products) standards is currently under way by the European Medicines Agency (EMA) and the EU Regulatory Network to comply with the EU Pharmacovigilance legislation, this action aims at enabling and fostering the use of a common EU medicinal Product repository (ISO IDMP compliant) to fulfil the ePrescription/eDispensation in a cross-border setting use case. .

Scope:
This innovation action is expected to support two goals: (i) **the cross-border mobility** of European patients by offering safer eDispensations across borders, (ii) **the implementation of the IDMP standards** in Member States drug databases (including a possible linkage to the EU SPOR - Substance, Product, Organisation and Referential master data database). **A common approach** and **operating model** needs to be developed, including common processes for validation of contents, error mitigation, linkage of the EU SPOR database with the ePrescription/eDispensing systems, updates and mappings to other systems for at least 5 Member States' organisations.

The **proposal should demonstrate** its ability to: define the additional quality criteria, processes, actors, risk minimisation measures and safety nets, ensure the quality of data, usability of data for national agencies, support integration with existing cross-border ePrescription services, raise awareness and explore benefits for both regulatory and clinical contexts, establish a Working Group of European medicinal products database producers to support the implementation of the IDMP standard…

The **proposal should provide** appropriate indicators to measure its progress and specific impact in the following areas: Design and implementation of an IT solution, better address adverse events/effects and safety issues, Better health data access across Europe, extended healthcare continuum across borders, collection and re-use of a data set that is sufficiently large to detect.

The Commission considers that proposals requesting a contribution from the EU of 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. Synergies with actions and activities supported by different programmes and policy initiatives of the Commission should be encouraged and resources from previous European projects should be considered..

It is **expected** that Members of the Consortium should include a wide range of relevant stakeholders and experts including inter alia Pharmacists, National Competent Authorities, IT Integrators, producers of ePrescribing, clinical record systems.

Large Scale pilots of personalised & outcome based integrated care

Info: SC1-DTH-11-2019
Type of action : IA Innovation action
Budget: 20 000 000 single-stage
Deadline: 24 April 2019 17:00:00 Brussels time

Summary:
Senior people are statistically at greater risk of cognitive impairment, frailty and multiple chronic health conditions with consequences for their independence, their quality of life but also for the sustainability of health and social care systems.
The challenge is now to foster secure, scalable and robust digital solutions for integrated care which will ensure a truly personalized delivery of health,promote a shift towards outcome-based delivery of integrated (health and social) care and ensure trust of users and policy makers,as well as to design flexible but replicable solutions with a potential for financial sustainability, large scale deployment and further business and job creation opportunities.

Scope:
The scope of this topic is to foster the large-scale pilots for deployment of trusted and personalised digital solutions dealing with Integrated Care, with a view to supporting and extending healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities.

Some of expected outcomes:
Efficiency gains in terms of resource utilization and coordination of care, Flexibility and replicability of service delivery patterns to combine personalization and large scale adoption of services with patient and citizen feedback, improvement of quality of life for the patient and his/her family and also of working conditions of all health care and social care providers.

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.

Proposals should provide measurable progress towards:

- A common vision of technical prerequisites and framework to ensure users trust with regard to health and social data and information in IT supported environment,
- An evidence-based minimum data set on key points of the pathway:
  Clerical information: complete definition
  Clinical information: generic definition
- Robust and reliable and replicable business models for IT supported solutions

Supporting for the large scale uptake of open service platforms in the Active and Healthy Ageing

Info:SC1-HCC-02-2019
Type of action : Coordination and support action
Budget: 1 500 000 single-stage
Deadline: 24 April 2019 17:00:00 Brussels time

Summary:
In the past years several open service platforms for Active and Healthy Ageing domains have been developed. These platforms aim at building a common basis for application development, assuring interoperability at the application and service level, and reducing development cost by re-use of components. As these platforms mature more insight is needed, the integration of platforms between different domains will introduce new interoperability issues that need to be tackled.

What is expected from the proposals:

- They should deliver an inventory of the state of the art and analyse the use of open service platforms in the Active and Healthy Ageing domain, covering both open platforms -such as universAAL[1] and FIWARE[2]- and partly-open/proprietary platforms developed by industry. proposals should address interactions between platforms.
- They should elaborate a methodology that monitors open platform development, adoption and spread across Europe,
- They should also address the evolution in the further development and maintenance of the platforms as well as the use and sustainability of relevant open platforms.
- Proposals should elaborate evaluation guidelines aimed at collecting evidence on socio economic costs and benefits of the use of open platforms
- Proposals are expected to include activities aimed at fostering integration efforts and knowledge exchange between the projects and initiatives
- Technical, organisational, financial/business and legal aspects should be taken into account.

The Commission considers that proposals requesting a contribution from the EU of up to **EUR 1.5 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:

- Identification of the critical success factors of open platform development, deployment, and spread;
- Evidence for the socioeconomic benefit of open service platforms
- Increased levels of participation by service platform providers and platform users in networking and knowledge exchange events
- Contribution to the effective implementation of relevant policy initiatives in the field
- Enhanced synergies with other European projects to make joint progress on favourable framework conditions to scaling-up digital innovation for active and healthy ageing across the EU, including standardisation

Optimising future obesity treatment

Info: IMI2-2019-17-01
Type of action : IMI2-RIA Research and Innovation action
Budget: The indicative in-kind and financial contribution from EFPIA partners and IMI2 JU Associated Partners is EUR 8 301 139. This contribution comprises an indicative EFPIA in-kind contribution of EUR 7 100 000 and an indicative IMI2 JU Associated Partners in-kind contribution of EUR 1 201 139. The latter includes EUR 1 000 000 financial contribution provided by JDRF whose allocation will be decided by the full consortium at stage 2 when preparing the full proposal. The financial contribution from IMI2 JU is a maximum of EUR 8 301 000.
Deadline: 25 April 2019 17:00:00 Brussels time
(2nd stage deadline: 07 November 2019 17:00:00 Brussels time)

Summary:

The prevalence of obesity is increasing and affects more than 650 million people of all ages to become one of the foremost global health threats. Currently we have no way of predicting who will respond to or benefit from what kind of treatment or intervention. There is therefore a need to better understand obesity and define clinically meaningful and relevant subgroups as a premise for optimising future prevention and treatment of obesity and its complications.

Scope:

The overall aim is to identify pathophysiologically and clinically meaningful subgroups of obesity that will allow optimisation of prevention and treatment of obesity and its complications. This will be done by pooling cohorts from observational or interventional studies to establish a federated database with enough clinical phenotyping and multi-omics data for a data-driven stratification of obesity into subgroups. It will also address specifically type 1 diabetes (T1D) and type 2 diabetes (T2D) as examples of conditions in which both clinical phenotype and treatment is influenced by obesity in an intricate manner, including public education about obesity in T1D.

Expected Impact:

This topic should pave the way for an optimised and more personalised future obesity treatment. Deciphering the heterogeneity of obesity and the potentially differential effect of weight loss and weight maintenance should lead for instance to: increased understanding and respect for obesity as a chronic disease entity, increased potential to contribute to the development of more targeted prevention and lifestyle interventions, increased potential to develop targeted delivery of safe and effective treatments,increased understanding of how obesity impacts other diseases as exemplified by impact on incidence, characteristics, treatment, costs, and outcomes

Open access chemogenomics library and chemical probes for the druggable genome

Info: IMI2-2019-17-01
Type of action : IMI2-RIA Research and Innovation action
Budget: The indicative in-kind and financial contribution from EFPIA partners and IMI2 JU Associated Partners is EUR 30 257 000. Topics Text – IMI2 17th Call for proposals Page | 20 This contribution comprises an indicative EFPIA in-kind contribution of EUR 23 800 000, of which EUR 9 930 000 financial contribution to the beneficiaries receiving JU funding in the selected action and an indicative IMI2 JU Associated Partners in-kind contribution of EUR 6 457 000. Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be non-EU/H2020 Associated Countries in-kind contributions. The financial contribution from IMI2 JU is a maximum of EUR 27 935 000.
Deadline: 25 April 2019 17:00:00 Brussels time
(2nd stage deadline: 07 November 2019 17:00:00 Brussels time)

Summary :
Bibliometric evidence shows that pharmacological modulators (chemical and biological probes) have both the greatest scientific citation impact, the greatest sway on exploratory biomedical research, and provide the best mechanism to understand the relevance of a protein as a potential drug target. Indeed, the field of drug discovery and the development of new molecular entities are predicated on the availability of sound mechanistic principles. Unfortunately, our understanding of human disease remains inadequate, and as a result clinical success rates for novel mechanisms remain low.

Scope:
Aim of this project is to establish a framework to assemble an open-access chemogenomics library for the druggable genome – namely a physical library supported by compound meta-data. Further enrich the open access library by inventing new, deeply characterised chemical probes to selected specific protein families. Moreover, to establish sustainable infrastructure, with high priority on accessible platforms and appropriate governance, as well as to develop a communication plan to facilitate the dissemination of the compound sets and to ensure their appropriate use.

Expected impact:
his project will provide the wider academic community with unencumbered access to the highest quality tool compounds for a large number of novel targets, and the expected impact should therefore be transformative. Presently, many companies and organisations are already in the process of setting up their own chemogenomics libraries. This may be a phenomenal resources for the companies, but their utility is also limited. By making a high-quality, broader compound set available, the consortium will seed a massive community target prioritisation and target deconvolution effort. The cell and tissue platform with the high-quality, patient-derived cell assays will provide the opportunity for clinical scientists to undertake translational medical research and biomarker discovery, and will provide the roadmap for other clinical centers to access the libraries and make important translatable discoveries.

Intelligent prediction and identification of environmental risks posed by human medicinal products

Info: IMI2-2019-17-03
Type of action : Research and Innovation action
Budget: The indicative in-kind and financial contribution from EFPIA partners is EUR 4 550 000. Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be non-EU/H2020 Associated Countries in kind contributions. The financial contribution from IMI2 JU is a maximum of EUR 4 550 000.
Deadline: 25 April 2019 17:00:00 Brussels time
(2nd stage deadline: 07 November 2019 17:00:00 Brussels time)

Summary:
Pharmaceuticals are present in the environment as a consequence of patient use, manufacture, and improper disposal. They predominantly enter the aquatic environment via patient use. In the European Union (EU) an environmental risk assessment (ERA) is required as part of the marketing application and approval for new drugs. Currently the ERA is conducted late in drug development and often parallel to Phase III clinical trials and after significant investment.

The growing regulatory and scientific concerns regarding pharmaceuticals in the environment have reached the point where some stakeholders are advocating for the inclusion of environmental hazard and risk within the patient-benefit evaluation that underpins the marketing authorisation of a drug, a catch-up scheme for medicines authorised for use prior to 2006 that lack comprehensive environmental assessments, increased transparency of environmental data as well as increased consideration of environmental properties in drug development (i.e. greener drug design).

However, without validated tools to predict environmental risk earlier in drug development these stakeholder expectations could impact the availability of life-changing medicines to patients within Europe and impact the competitiveness of the industry.

Scope:
The overall aim of this project is to apply innovative approaches to ensure the environmental safety of human medicinal products such that both (i) environmental concerns do not become a barrier to patient access to medicines, and (ii) the intended use of medicines does not pose an unacceptable risk to the environment.

Expected impact:
This project aims to develop an **EU-wide pharmaceutical ecotoxicology database** which will help all stakeholders better understand the risks posed to the environment by human medicinal products, allow environmental chemists to present their monitoring work in the context of risk and reduce duplication of environmental testing across the industry. The database will also enable the environmental risks of a human medicinal product to be actively managed across its product life cycle and help facilitate the industry extended environmental risk assessment (eERA) model. The availability of tools and models has the potential to deliver significant animal welfare benefits and cost savings without compromising environmental protection, for example, the pharmaceutical industry could save more than EUR 500 million.

A CALL FOR MULTINATIONAL RESEARCH PROJECTS ON PERSONALISED MEDICINE FOR NEURODEGENERATIVE DISEASES (Co-funded with the European Commission)

Info

Funding: The total made available for this call is **24 million euros** (from all participating countries) with a top-up funding by the European Commission that could increase the total funding up to **30 million euros**. Under this call, each country funds their own national participants in successful collaborative proposals, according to their national budget allocation.
Deadline: pre-proposal 15:00h C.E.T on **March 12, 2019**, via the electronic subimission tool
Full proposal 15:00h C.E.S.T. **on June 25, 2019**

Summary:
With the ageing of the world population, the incidence of neurodegenerative diseases is on the rise. At present, an estimated 47 million people are suffering from Alzheimer's disease and related disorders, the most prevalent class of neurodegenerative diseases. This figure shows no signs of abating, and is expected to double every 20 years as the population ages.
One of the greatest challenges for neurodegenerative diseases treatment is the deciphering of the large variability – in origins, mechanisms and clinical expression – that these debilitating diseases are characterised by. With this in mind, The EU Joint Programme – Neurodegenerative Disease Research (JPND) has launched a new cohesive action with the European Commission – **a call for "Multinational research projects on Personalised Medicine for Neurodegenerative Diseases"**. More than €30 million have already been earmarked by JPND member countries and the European Commission for this action.

The aim of the call is to establish a number of ambitious, innovative, multi-national and multidisciplinary collaborative research projects that will add value to the respective research areas.

Proposals can apply when focussing on one or several of the following neurodegenerative diseases: 1) Alzheimer's disease and other dementias, 2) Parkinson's disease and PD-related disorders , 3) Prion diseases • Motor neuron diseases, 4) Huntington's disease, 5) Spinocerebellar ataxia (SCA), 6) Spinal muscular atrophy (SMA).
Proposals submitted under this call will have to include one or several of the following research areas: **diagnosis, prevention, care**. JPND is committed to patient and public involvement and proposals are expected to engage patients, carers and the public.

List of participating JPND countries is available here.