

Health research and innovation: opportunities for EU-Russia cooperation



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Research and Innovation



Overview

- Introduction to Horizon 2020
- Societal challenge 'Health, demographic change and well-being'
 - Infectious diseases
 - Personalised medicine
 - Regenerative medicine
 - ICT for health
- Innovative Medicines Initiative
- International cooperation
- Towards FP9

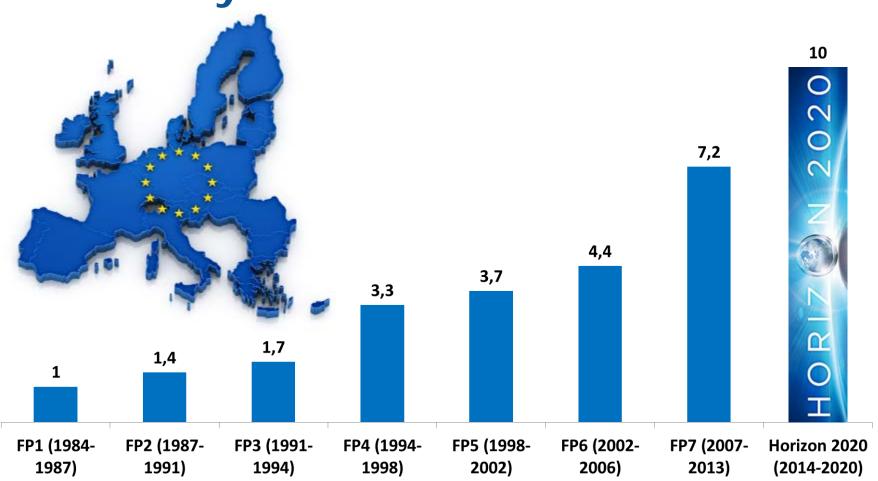








30 years of EU funded R&I



Amount in billions € per year





Research and innovation – a growing priority for the EU



- Jobs, growth and investment
- Digital single market
- Energy Union and Climate
- Stronger Global Actor



- Couple research to innovation
- European industrial leadership and competitiveness
- Provide evidence-base for addressing societal challenges, supporting EU policies and better regulation
- Strengthen research capacities and innovation strategies across all Member States
- Multidisciplinarity and synergies
- Address people's concerns



3 Os of Commissioner Moedas



Carlos Moedas EU Commissioner for Research, Science and Innovation

"As I see it, European success now lies in sharing as soon as possible, (...). The days of open science have arrived."

Speech at "Presidency Conference Open Science", 04 of April, 2016, Amsterdam

Open Innovation
Open Science
Open to the World





H2020: Funding processes

- Overall research priorities defined in the "Framework Programmes" – currently Horizon 2020 (2014-2020). Published work-programmes with list of topics.
- Annual calls for proposals on topics defined jointly by Commission and Member States (PC) upon input from the scientific advisory board and the scientific community regularly consulted
- Evaluation of applications by panels of independent experts (3 evaluation criteria: Science & Technology; Expected Impact, Implementation & Management)
- From call for proposal to grant signature: Max 8 months
- Financial commitments/disbursements: Pre-financing followed by annual disbursements (on costs incurred).
- Monitoring projects activities by EC staff (with addition of independent experts if necessary)



Horizon 2020 pillars

- European Research Council
- Future and Emerging Technologies
- Marie Sklodowska
 Curie Actions
- Research
 Infrastructures

1- Excellent science

7 societal challenges, of which SC1 'Health, demographic change and wellbeing'

- Leadership in enabling and industrial technologies
- Access to risk finance
- Innovation in SMEs

2- Industrial leadership

3- Societal challenges

Research and Innovation











EU health research







One societal challenge, many instruments





Our priorities



Personalised medicine

Call 2014-15: EUR 1.3 B

> Call 2016-17: EUR 1.4 B



Healthy ageing (2014-2017)



Health ICT (2014-2017)



Infectious Diseases (2014-2017)





Research and Innovation



Maternal and child health (2016-2017)

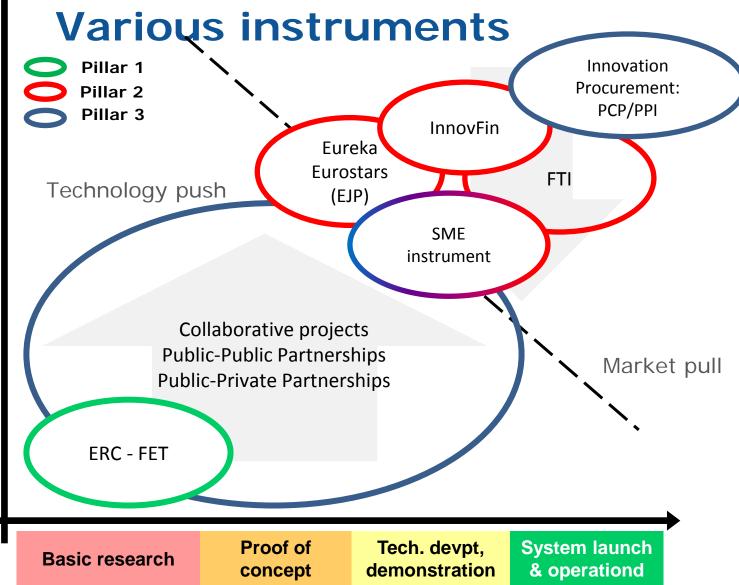


Commercial deployment

Financing pilot, dvlpt, demo, manufact.

Business model and initial financing

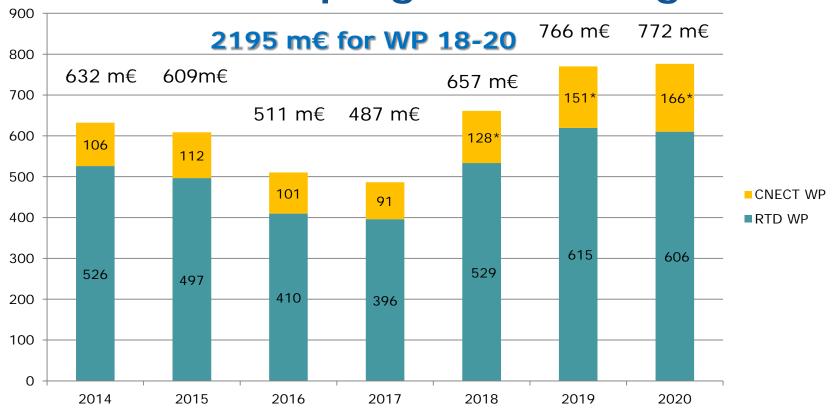
Early
phase/basic
research,
patent
protection



Technological Development



SC1 work programme budgets



Sources: 2014 and 2015 – Committed funds 2016 – 2017 - Published Work Programme 2018 to 2020 – Provisional Budgets





Work programme 2018-2020

Digital
Transformation
in Health
and Care

5 priorities Personalised Medicine €330 million

Innovative
Health and
Care
Industry
€380 million

Infectious
Diseases
and Global
Health
€300 million

Innovative
Health and
Care
Systems
190 million

the role of the environment for health and wellbeing €140 million

Trusted
Digital
Solutions
and
Sybersecurity
in Health
and Care

5 missions Moving towards personalised health and care solutions to benefit citizens

Turning innovative technologies into applications

Tackling infectious diseases and the health of vulnerable groups

Sustainable health interventions and integrated care systems Assessing the impact of environment and climate change on health

key impacts

Improved health outcomes for the citizen Stimulating the healthcare industry Prevent, detect and treat priority diseases worldwide More sustainable and resilient health systems

Improved risk assessment and mitigation measures



Timetable for WP 2018-20

- 2016: Advisory Group produced a report, which was made public for consultation
- End 2016: EC published 'scoping papers', consulted with Programme Committee
- ❖ 2017: Consultation with Programme Committee; internal consultation; publication around November 2017
- 2018: Update for 2019
- ❖ 2019: Update and financing decision for 2020

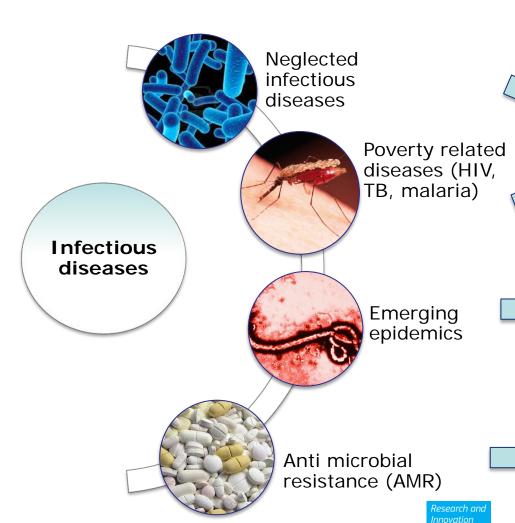








Main initiatives on infectious diseases



European and Developing Countries Clinical Trials partnership (EDCTP2)

> Global Tuberculosis Vaccine Partnership (GTBVP)

Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) Support to Coalition for Epidemic Preparedness Innovations (CEPI)

Joint Programming Initiative on AMR (JPI-AMR) 2nd EU One Health Action Plan against AMR



Some 2018-2020 topics on infectious diseases

- Research on HIV, tuberculosis and/or hepatitis C in patients with mono-, co-infections or comorbidities in the contest of the collaboration between the European Union and the Russian Federation
- New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)
- Horizon Prize on novel solutions to reduce the spread of AMR in the environment









Definition of Personalised Medicine

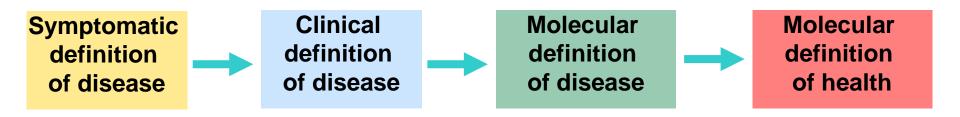
Personalised medicine is a medical model using characterisation of individuals' phenotypes and genotypes for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention

See Council Conclusions (2015/C 421/03)



Personalised Medicine: Moving from 'Sickcare' to genuine Healthcare

Enormous quantity of accumulating data need for translation from basic to clinical research and practice better understanding of health and disease



Changing the focus from isolated treatment and cure to include early diagnosis, prediction and prevention





In a nutshell...

Personalised medicine is about making healthcare **smarter** and **better by**:

- > using multiple information sources about the person, his/her environment and lifestyle
- focusing on prediction and prevention
- shifting from treating disease to managing health





Main past activities on personalised medicine at EU level

- ➤ 2010: Preparatory workshops (-omics, biomarkers, clinical trials/regulatory, uptake)
- ➤ 2011: European Perspectives conference
- ➤ 2013: Commission Staff Working Document on "use of '-omics' technologies in the development of personalised medicine"
- ➤ 2015: Council conclusions on Personalised Medicine
- ➤ 2016: Personalised Medicine Conference (June)
- ≥ 2016: Establishment of ICPerMed (November)



Some 2018-2020 topics on personalised medicine

- International flagship collaboration with Canada for human data storage, integration and sharing for developing personalised medicine approach
- Stratified host-directed approaches to improve prevention and/or treatment of infectious diseases
- Understanding causative mechanisms in co- and multimorbidities



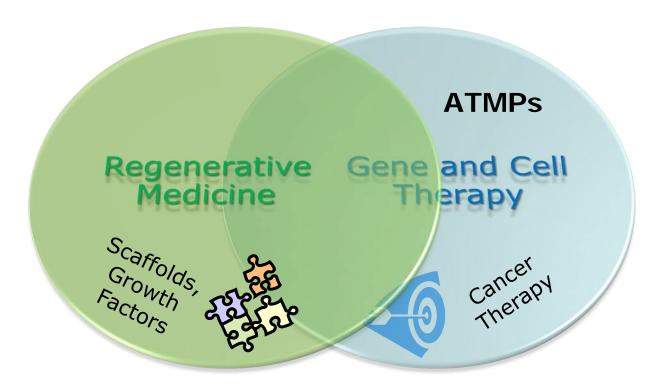






New therapies - overlapping fields vision

(not to scale)







Why is the EU supporting new therapies research?

- Offers hope for untreatable disease and quality of life, ageing population, etc
- Reduce cost of expensive treatments (eg, enzyme replacement therapy – storage disorder, or blood transfusion – thalassemia)
- Collaborative research across borders to:
 - Avoid duplication
 - Share facilities
 - Assemble multi-disciplinary team
 - Access to patient population
 - Obtain more robust results





What are we doing in regenerative so far 24 projects €141 Million medicine?

- Prominent in SC1 decision
- Different parts of the innovation chain, now the clinic
 - Parkinson's, heart, bone, etc. Phase I, II and III
 - Many hurdles: control of differentiation and proliferation, standard product
 - Academic medical centres; big industry largely absent
- Links to
 - 'Disease-in-dish' modelling, understanding development, organ transplantation
- Field moving fast science and therapy, eg cells don't implant
- Hype and hope
 - Stem cell tourism





H2020 Regenerative Medicine clinical research projects - observations

- Most projects severly underestimate time and efforts to obtain cell manufacturing and clinical trial authorisations, and recruiting patients
- Wide range of conditions tackled but few on major degenerative diseases, neuro, muscle, etc.
- Limited innovation; heavy concentration on MSCs
- Mostly Phase II; 2 Phase IIIs
- ➢ If successful, few projects likely to result in commercial products – most likely to be used via Hospital Exemption





H2020 Other gene and cell therapy projects - observations

- Mainly rare diseases and cancer
- More gene therapy/gene modified cells (4 projects)
- Technology projects
- Some clinical trials





Some 2018-2020 topics on regenerative medicine

- New therapies for Non Communicable Diseases
- Regenerative medicine: from new insights to new applications
- Innovation platforms for advanced therapies of the future









ICT: EU Health and Ageing landscape



1. Boosting Jobs, Growth and Investment

Health policy

Long term Care Strategy

Ageing policy



A Connected Digital Single Market

eHealth 2020, mHealth, Silver Economy Strategy

European
Innovation
Partnership on
Active and Healthy
Ageing EIP-AHA

Horizon 2020 Societal Challenge 1 Health, Demographic Change and Wellbeing Active Assisted Living Joint Programme (AAL) European
Institute of
Technology- KIC
on Health and
Ageing

Health & wellbeing

Integrated care

Disease management

In-Silico Modelling Independent living & Active Ageing

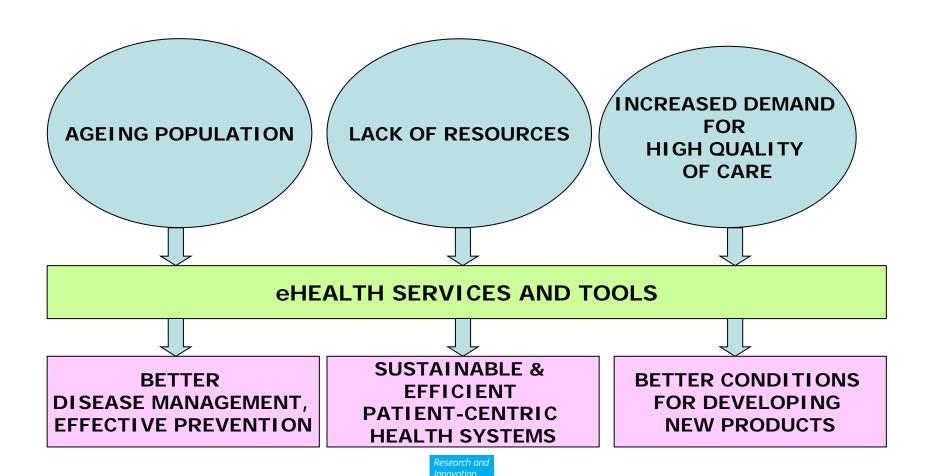
Early Risk Detection & Prevention

Legal & market conditions





Need for changes in Healthcare





H2020, Longer Term Research Areas

- Open Service Platforms for Health & Care (Open Source IoT middleware for service, device, data integration)
- Service robotics within smart living environments
- Early risk detection & intervention
- Advanced ICT for Integrated Care
- ➤ Self-management of health and disease based on predictive computer modelling used by the patient
- Digital representation of health data to improve disease diagnosis and treatment





H2020, Applied Research

- Active and Assisted Living Joint Programme (co-financed with EU Member States)
 - 160+ close to market projects funded until now
 - Transforming proven research ideas into new products and services across Europe
 - Close links with investors



Call 1: Chronic Conditions



Call 3: Self-Serve Society



Call 7: Care of the Future



Call 2: Social Interaction



Call 4: Mobility



Call 5: "Home Care"



Call 6 Occupation in Life



Call 8: Active and independent living

http://www.aal-europe.eu





H2020, Innovation Agenda

Large scale pilot projects

- Piloting ICT solutions for independent living with cognitive impairments (4 pilots starting)
- Piloting Integrated Care solutions (3 pilots running)

European cooperation in innovative public procurement

- Pre-commercial Procurement of service robotics solutions (Silver project) and Patient Empowerment
- Public Procurement of innovative health and care services (Stop and go project)
 - Public procurement of innovative eHealth services



Some 2018-2020 topics on ICT

- Adaptive smart working and living environments supporting active and healthy ageing
- International cooperation in digital solutions and robotics for independent living
- eHealth and care services









IMI - Europe's partnership for health

IMI1: 2008-2013

€2 billion budget 59 projects



IMI2: 2014-2020

€3.3 billion budget
More ambitious
More open
Greater scope





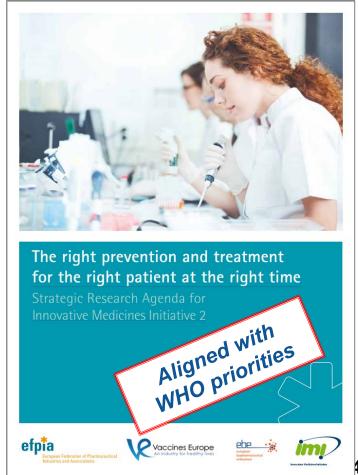


€2.5 bn



IMI2 Strategic agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines





Why do we need IMI? Because drug development is very...

complex risky inefficient
lengthy expensive

Because...

- Biological mechanisms underlying disease are complex
- Clinical trial designs need to be adapted to scientific knowledge
- Regulatory pathways need be adapted in certain cases





How is IMI addressing the challenges in drug development?

Through projects IMI is are trying to...

- put patients at the centre
- share risk (among public & private players)
- increase efficiency (by developing common tools)
- reduce duplication of effort (esp. at early stages)
- reduce timelines (by using a personalised medicine approach)
- integrate the latest science into drug development
- use data and knowledge management to work more effectively

We do this by creating a neutral platform where all involved in drug development – academics, industry, SMEs, patients, regulators, others – can engage in open collaboration on shared challenges.



An international, cross-sector community

teams



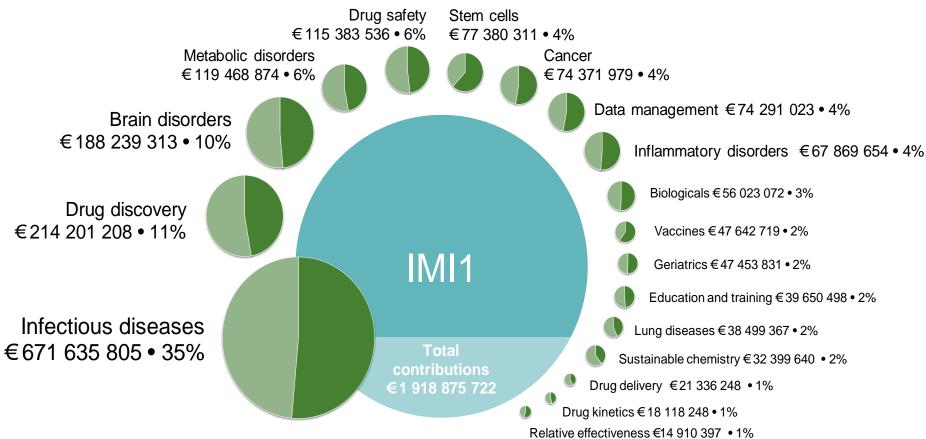
orgs

- Over 9 000
 researchers
 working for:
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Figures from June 2016



Distribution of funding – IMI1









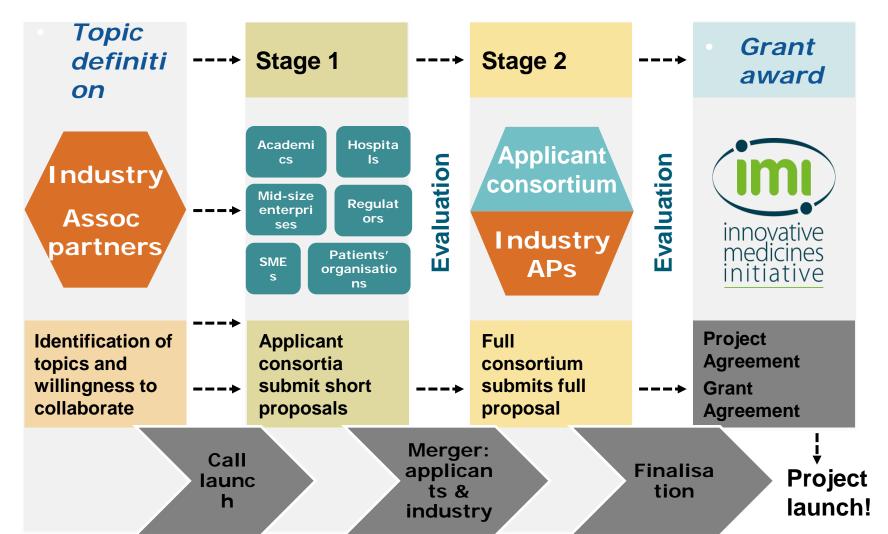
IMI2 and Third countries

- > As BENEFICIARY:
 - IMI2 is open to participation from legal entities in Third countries (Universities, Research centres, SMEs etc.)
 - > Funding possible in *exceptional situations*
- > As IN-KIND CONTRIBUTOR:
 - Either as an EFPIA organisation or as a non-EFPIA organisation, BUT non-EFPIA organisations become Associated Partners to IMI2
 - At IMI2 programme level, the total in-kind incurred by Third countries cannot exceed 30% of the total in-kind





Typical IMI project life cycle





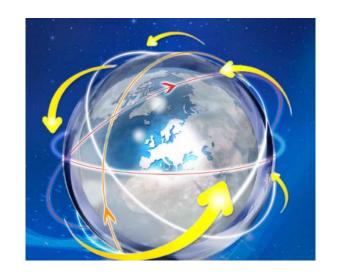




Horizon 2020: open to the world

General opening

Horizon 2020 is fully open to participation of entities from across the globe



Targeted opening

Many topics are flagged as specifically relevant for international cooperation, identifying upfront the targeted area and partner country or region



Global challenges for global responses



- ✓ Engaging in international cooperation is essential to attract talent, access knowledge and markets, thus increasing EU competitiveness
- ✓ Horizon 2020 is a vehicle to work together with the best worldwide

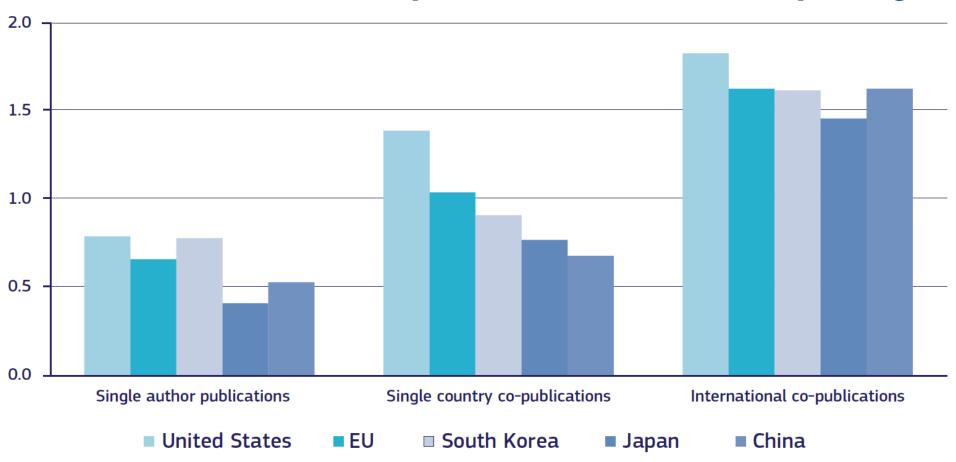


enhancing and focusing EU international cooperation in research and innovation





International cooperation increases quality

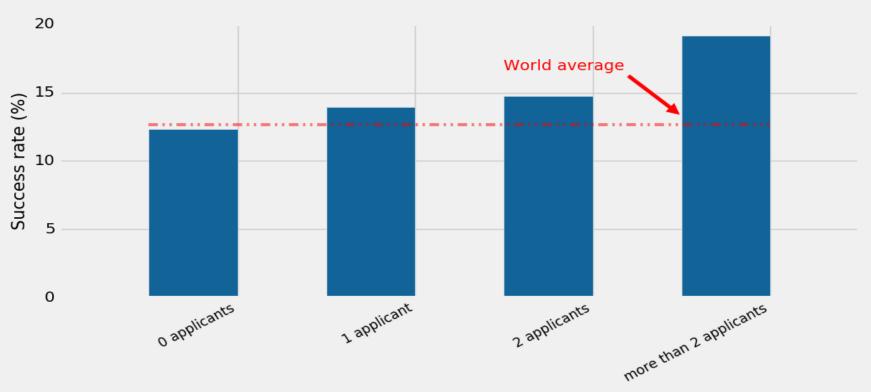


Average Relative Citations (ARC) of publications by type of co-operation, 2010



International participation increases H2020 success rate

Success Rates for different numbers of Non-Associated Third Country applicants

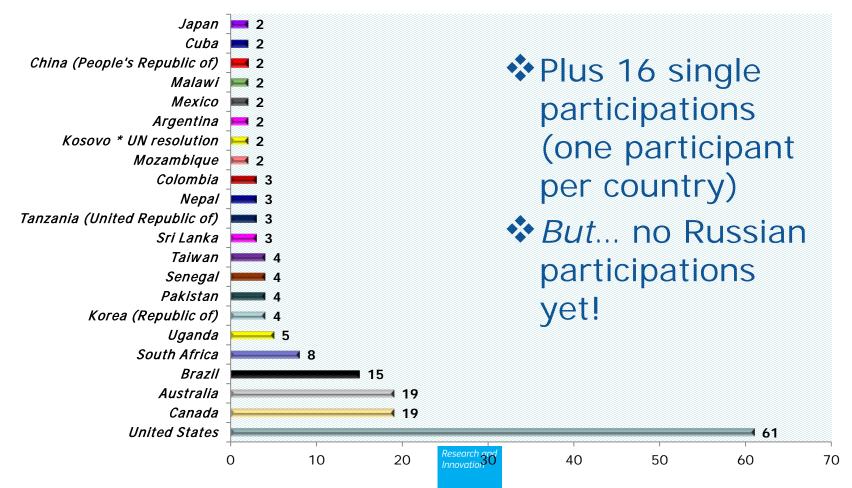


Note: Data for collaborative projects of Horizon 2020. Success rate is the ratio of mainlisted over eligible proposals.

Source: DG RTD - International Cooperation Data: CORDA, extraction date: 28/09/2016



Participation of Third countries in SC1: collaborative projects





Open to the world Multi-lateral health research activities















Global Research Collaboration for Infectious Disease Preparedness

http://www.glopid-r.org/







Global Research Collaboration for Infectious Diseases Preparedness (GloPID-R): Objectives

- Facilitate exchange of information in outbreak situations
- Establish a response plan and a strategic agenda for a coordinated and rapid research response
- Address scientific, legal, ethical and financial challenges to a rapid response
- Connect infectious disease research networks
- Supports public health decision-making
- Is NOT a new funding organisation





GloPID-R Members



Observer Status: World Health Organization (WHO)





GloPID-R Priorities 2017

- Links with antimicrobial resistance
- Creating network of social science researchers
- Establishment of an Industry Stakeholder Group
- Forming a long-term scientific research agenda
- New working group of clinical research networks
- Continuing work on Zika and data sharing



Flagships for international cooperation in WP 2018-2020

- Objective: bring international cooperation to at least FP7 level
- > Topics should be:
 - specifically devoted to international cooperation
 - be of large scale
 - be recognised in political dialogues
- Russia, Canada and CELAC









Towards FP9: learning from the past & benefitting of co-design

H2020 Interim Evaluation Political drivers:

EU budget under intense scrutiny: return on investment, impact on the ground, output-based funding, flexibility ...

Foresight

High Level Group chaired by Pascal Lamy

Impact Assessment Proposal for the successor Framework Programme

Challenging political climate: EU added value; UK; EP elections

Programme drivers:

Strong steer from Juncker priorities and objectives of Commissioner Moedas (3 Os, EIC); simplification...

Economic case of R&I

Research an Innovation



Horizon 2020 Interim Evaluation - timeline

2016	
December	High Level Group in the context of the Interim Evaluation (chair: Pascal Lamy)
20/10-15/01	Public stakeholder consultation
2017	
May	Publication of EC Staff Working Document (evidence base)
June	Publication of HLG report (vision for maximising impact of FPs) Stakeholder conference on Horizon 2020 Interim Evaluation
October	Publication of Commission Communication
2018	
	Impact Assessment and proposal for FP9





Stakeholder consultation First inputs received

- Continuity with Horizon 2020: "an evolution and not a revolution"
- Continue with the societal challenge-based approach
- Support both research and innovation
- Continue with simplification



Some key questions for shaping FP9

Excellence vs. cohesion

Continuity vs. breaking with the past

Top-down vs. bottom-up

Output-based vs. cost-based

Grants vs. loans

International vs. European only

Incremental vs. disruptive

Single beneficiaries vs. collaborative

All businesses eligible vs. focus predominantly on SMEs

Include defence vs. only civil / dual research







More info @

- Participant portal
 - http://ec.europa.eu/research/participants/portal/desktop/en/home.html
- Societal challenge 1
 - http://ec.europa.eu/programmes/horizon2020/en/h2020section/health-demographic-change-and-wellbeing
- Research & Innovation shaping our future: 7 July 2017
 - http://ec.europa.eu/research/index.cfm?pg=events&eventcode = 032132EF-D4BD-39B3-6C981F6EB7F3D7C4

