European Commission

#InvestEUresearch

Horizon 2020 Work Programme for Research & Innovation 2018-2020

The societal challenge 'Health, demographic change and well-being'

Philippe Cupers, Deputy Head of Unit
Health research strategy Unit
Health Directorate, European Commission

Research and Innovation

What is Horizon 2020?

HORIZON 2020 is the framework programme for research and innovation of the European Union

28 Member States +
16 Associated Countries pooling resources in one unique R&I programme

What do you need to know about Horizon 2020?

#1

European largest **integrated R&I programme**, from **basic research** to **close-to-market innovation**

Total budget (2014-2020) of ~ **EUR 77 billion** – this represents **~10%** of **public R&I spending** in the EU
~ 3,000 grants signed per year

Horizon 2020 contributes to **~90%** of the total **transnational research** funding in the EU
(~75% of Horizon 2020 funding goes to transnational projects)

What do you need to know about Horizon 2020?

Excellence as guiding principle for selection of projects

A large **toolbox of funding instruments** and actions

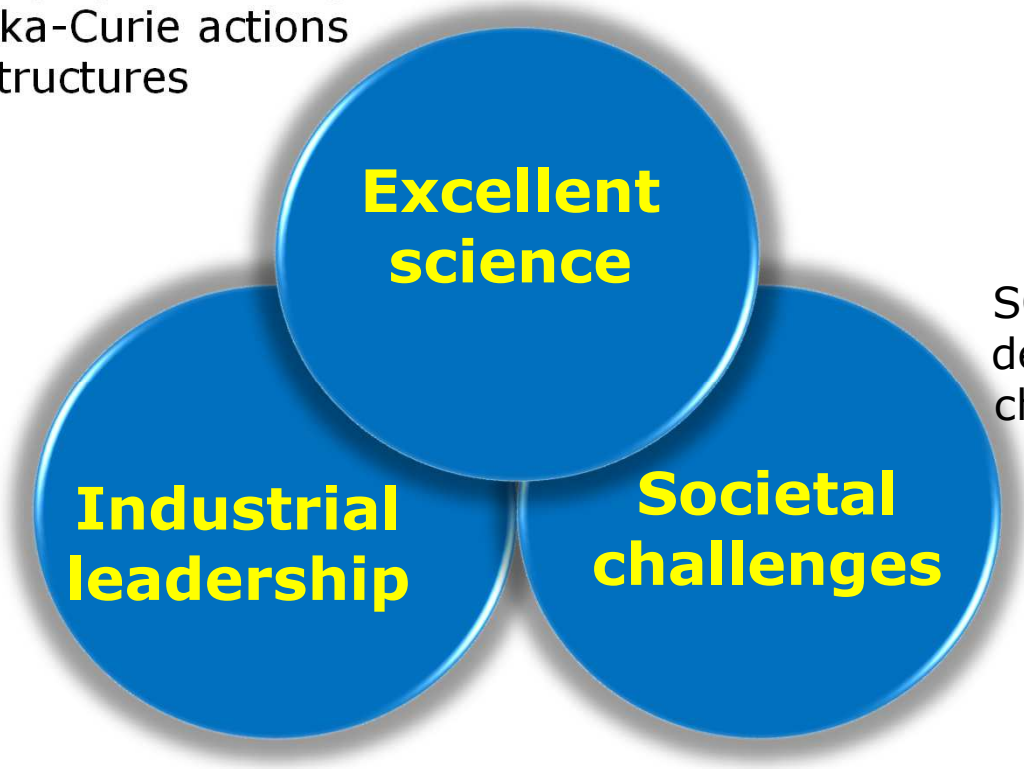
Open to business: from 2014 to 2016, **23.9% of funds go to Small and Mediums Enterprises (SMEs)**

Open to international collaboration: participation of 130 countries

European Commission

EU Horizon 2020: a three-pillar structure

- European Research Council
- Future and Emerging Technologies
- Marie Skłodowska-Curie actions
- Research infrastructures



SC1- Health, demographic changes and wellbeing (€ 7.4 b)

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

Horizon 2020

Work Programmes 2018-2020

Political context

Research and innovation – policy drivers (I)

Contribution to 3 of the 10 Commission priorities

- Jobs, growth & investment
- Digital single market
- EU – a stronger global actor

Research and innovation – policy drivers (II)

SC1 policy drivers

- The 2030 Agenda for Sustainable Development and its Sustainable Development Goals
- Council Conclusions on Personalised Medicine and on Pharmaceuticals
- Digital Single Market
- COP21 and the goals of the Ostrava Declaration on Environment and Health
- The new European One Health Action Plan against Antimicrobial Resistance
- Cross-border healthcare directive (and its support to the European Reference Networks)
- Communication on upgrading the single market (and its proposed health technology assessments initiative)
- Building on the principle of openness – open science, open innovation and open to the world

Key findings from the H2020 INTERIM EVALUATION

KEY STRENGTHS

An attractive, simplified and well-performing programme, highly relevant for stakeholders and societal needs

On track to deliver **value for money** and **to meet its knowledge-creating objectives**

Strong **EU Added Value** through unique opportunities, competition & access to new knowledge

Key findings from the H2020 INTERIM EVALUATION

KEY AREAS FOR IMPROVEMENT

Underfunding

Has lower success rates than FP7, esp. for high quality proposals

Support for market-creating innovation

Demonstrates potential for breakthrough, market-creating innovation, but it should be strengthened substantially

Greater outreach to civil society

Should better explain the impacts of R&I, and involve even more the users & citizens in agenda-setting & implementation

Health research expected outputs

More healthy life years

Evidence based policy making

Medicines for children

Health Technology Assessment

ATMP

and many others…

Taking the lead in new areas

Personalised medicine

Responding to emergencies

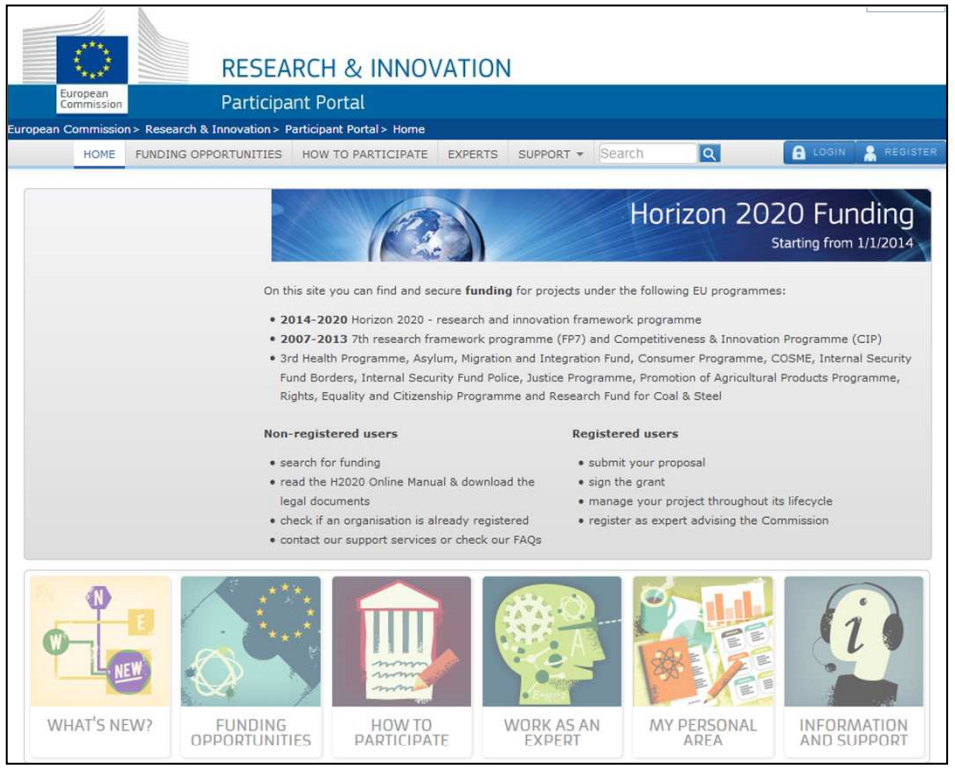
Knowledge creation and exploitation

SME
SMALL & MEDIUM ENTERPRISES

EU Horizon 2020:
supports health research from bench to bedside

Participant portal – one–stop shop

- Call topics + all related documents
- NCPs
- Expert registration
- Legal & guidance documents
- FAQs
- Access to proposal submission system



http://ec.europa.eu/research/participants/portal

Collaborative research – Societal Challenge 1

'Health, demographic change and well-being'

What is health collaborative research?

What are the requirements?

- Biannual work-programmes (with updates) published by EC
- Aims to foster collaboration between
  - ✓ Countries: minimum 3 legal entities from 3 different EU Member States or FP-associated countries
  - ✓ Sectors: pre-clinical, clinical, …
  - ✓ Disciplines: cell biology, genetics, imaging, clinical trial, …

Broad range of topics …

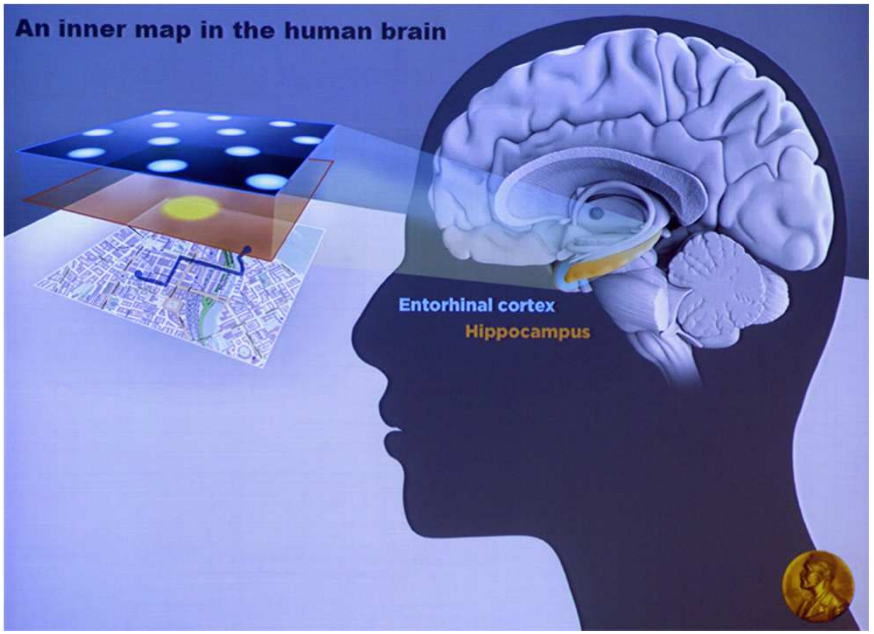
- *From …* BHC-01-2019: Understanding causative mechanisms in co- and multimorbidities
- *To …* HCO-05-2018: Strengthening regulatory sciences and supporting regulatory scientific advice

EU-supported research: Brain research

A positioning system in the brain

EU FP5 Life Sciences ('NAPPY') and FP7 Health ('SPACEBRAIN') collaborative research grants

& ERC grants



EU-supported research: Regenerative medicine

Treating leukaemia with designer immune cells

theguardian

Baby girl is first in the world to be treated with 'designer immune cells'

Genetically engineered cells successfully used to treat aggressive form of childhood leukaemia, but landmark treatment had only been tested on mice

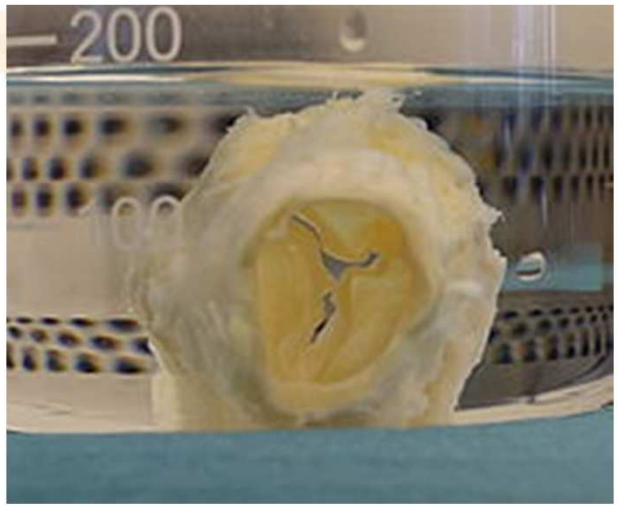
Layla Richards, whose aggressive form of leukaemia was treated with genetically engineered immune cells. Photograph: Great Ormond Street Hospital/PA

A baby girl with aggressive leukaemia has become the first in the world to be treated with designer immune cells that were genetically engineered to wipe out her cancer.

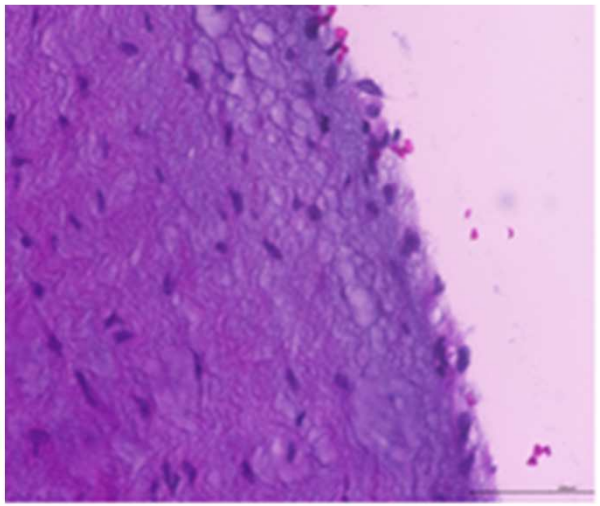
EU-supported research: Regenerative medicine

Project "ESPOIR"

- Heart valve defect (2 in every 100 babies born): valve-replacement surgery very successful BUT limited immune tolerance in young patients, outgrow their valve, re-operations required every 5-10 years
- Implant a **decellularised human donor valve**: does not activate the immune system, and promotes tissue regeneration
- 121 patients treated: zero valve-related mortality - 83 % of patients free from any re-intervention or re-operation
- Obtained regulatory and reimbursement approval for decellularised human heart valves in DE, CH, NL, IT, UK, BE



New tissue growth

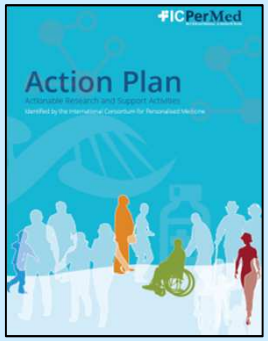


How do we define our research priorities ?

SC1 Advisory Group

Report for 2018-2020 (submitted to a targeted stakeholders' consultation)

advise



Stakeholders
Reports from conferences and workshops, foresight exercises, specific action plans, roadmaps

SC1 Scoping Paper included in the Horizon 2020 Strategic Programming 2018-2020

implementation in topics/calls

Horizon 2020 SC1 Work Programme 2018-2020

Commission
Provides all DGs input

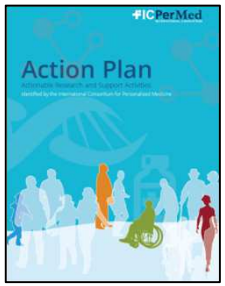
advise, discuss, approve

SC1 Programme Committee
Provides national input

Health collaborative research – 7 priorities for 2018–2020

SUSTAINABLE DEVELOPMENT GOALS

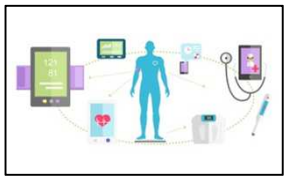
€ 2.0 billion



1. Personalised medicine

2. Innovative health and care industry

3. Infectious diseases and improving global health



4. Innovative health, and care systems – Integration of care

5. Decoding the role of the environment for health and well-being

6. Digital transformation in Health and Care

7. Trusted Big Data solutions and Cybersecurity for Health and Care

European Commission

7 priorities implemented via SC1 Work Programme 2018–2020 through 3 Calls for proposals

Call 'Better Health and care, economic growth and sustainable health systems'
5 main priorities & 32 topics

Call 'Digital transformation in Health and Care'
13 topics

Call 'Trusted digital solutions and Cybersecurity in Health and Care'
3 topics

Other Actions 2018–2019
7 items

Priority 1 – Personalised medicine

AIM: Delivering personalised health and care to benefit patients and citizens

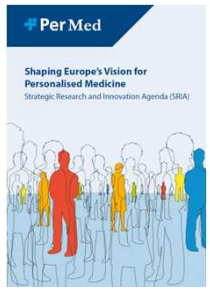
FOCUS: complex disorders, human microbiome, rare diseases and data sharing for enabling personalised medicine, economic models, reinforcing international and regional collaboration

POLICY DRIVERS:

Council conclusions on Personalised Medicine

International Consortium on Personalised Medicine

European Reference Networks



ICPerMed
INTERNATIONAL CONSORTIUM

Personalised Medicine in Work Programme 2018–2019 (I)

- BHC-03-2018: Exploiting research outcomes and application potential of the human microbiome for personalised prediction, prevention and treatment of disease
- BHC-04-2018: Rare Disease European Joint Programme Cofund
- BHC-05-2018: International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches
- BHC-01-2019: Understanding causative mechanisms in co- and multimorbidities
- BHC-02-2019: Systems approaches for the discovery of combinatorial therapies for complex disorders

Personalised Medicine in Work Programme 2018–2019 (II)

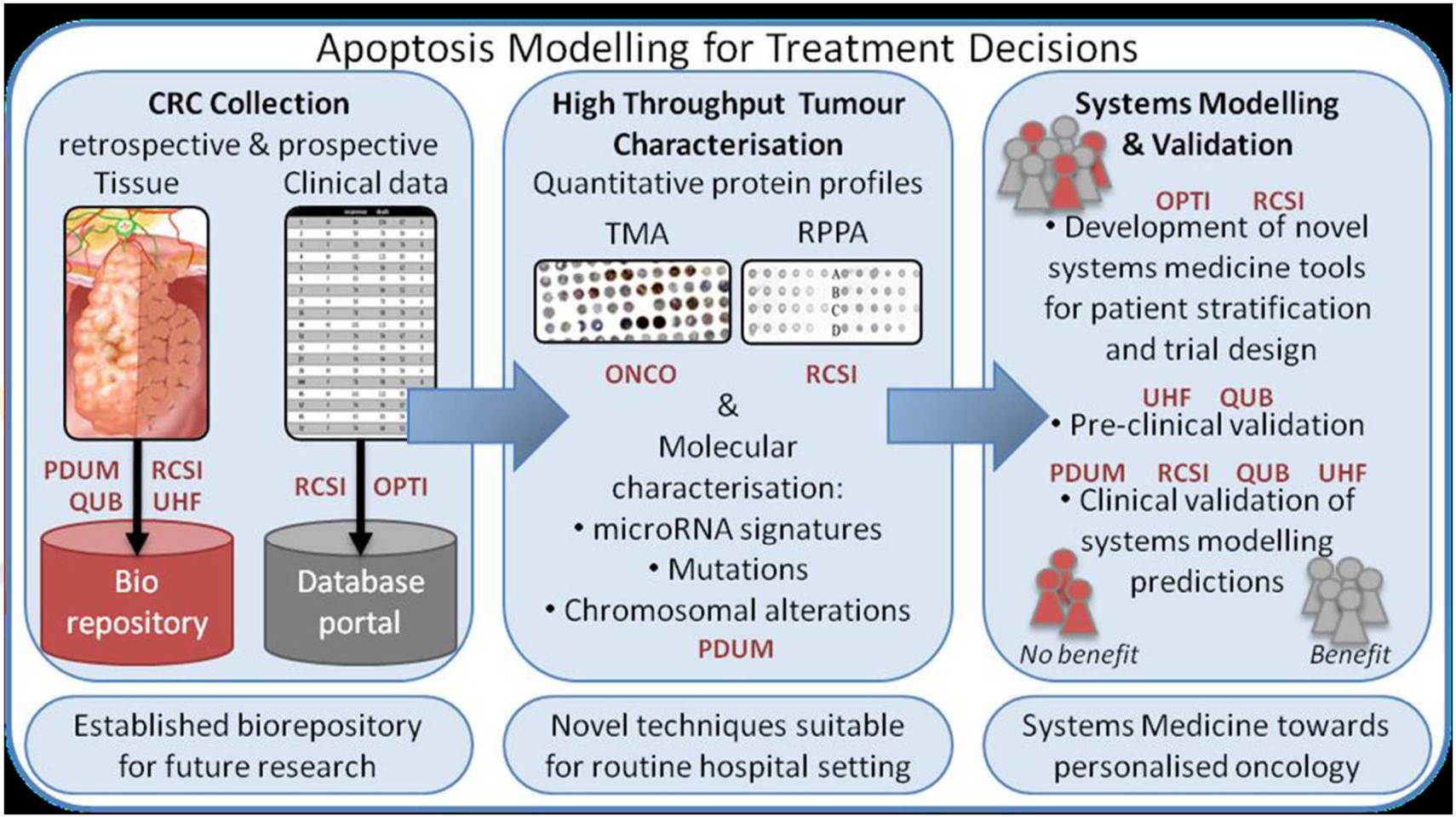
Coordination and support actions

- HCO-02-2018: Data integration and data-driven in-silico models for enabling personalised medicine - a European standardization framework
- HCO-04-2018: ERA-NET to support the Joint Programming in Neurodegenerative Diseases strategic plan (JPND)
- HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine

EU-supported research: Treating colorectal cancer

Project "APO-decide"

A systems-based modelling of apoptosis signalling pathways to deliver new prognostic and predictive biomarkers for advanced colorectal cancer



EU-supported research: Pharmacogenomics for personalised medicine

EU project "U-PGx"

Patients tested for activity of many genes linked to drug actions

4000 patients + 4000 controls; 18 months

Data collected and embedded into e-records of patients in 7 countries

Doctors e-alerted when a drug is prescribed for a patient with "risky"genotype

Analysis of health outcomes and cost-effectiveness

Higher dose needed for these drugs

Risk of overdosing and harm to patient if prescribed as usual

Priority 2 – Innovative health and care industry

AIM: Turn innovative knowledge and technologies into practical applications benefiting citizens, healthcare systems and businesses

FOCUS: Regenerative medicine, advanced therapeutics and regulatory science

POLICY DRIVERS:

Upgrading the single market

Innovative health and care industry in Work Programme 2018–2019

- BHC-09-2018: Innovation platforms for advanced therapies of the future
- BHC-07-2019: Regenerative medicine: from new insights to new applications
- BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

<u>Coordination and support actions</u>

- HCO-05-2018: Strengthening regulatory sciences and supporting regulatory scientific advice

Priority 3 – Infectious diseases and improving global health

AIM: Fighting infectious diseases and the growing threat of antimicrobial resistance. Addressing the needs of the most vulnerable and the global increase in chronic diseases

FOCUS: Emerging infectious diseases, poverty and neglected diseases, stratified host-directed approaches to communicable diseases, maternal and child health, global collaboration on non-communicable diseases (cohorts, brain research, hypertension, diabetes, cancer

POLICY DRIVERS:

European One Health Action Plan against Antimicrobial Resistance

World Health Organization

Global Action Plan on antimicrobial resistance

Infectious diseases and improving global health in Work Programme 2018–2019 (I)

- BHC-15-2018: New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)
- BHC-16-2018: Global Alliance for Chronic Diseases (GACD) - Scaling-up of evidence-based health interventions at population level for the prevention and management of hypertension and/or diabetes
- BHC-18-2018: Translational collaborative cancer research between Europe and the Community of Latin American and Caribbean States (CELAC)
- BHC-21-2018: Research on HIV, tuberculosis (TB) and/or hepatitis C (HCV) in patients with mono-, co-infections and/or comorbidities in the context of fostering collaboration with the Russian Federation

Infectious diseases and improving global health in Work Programme 2018–2019 (II)

- BHC-13-2019: Mining big data for early detection of infectious disease threats driven by climate change and other factors
- BHC-14-2019: Stratified host-directed approaches to improve prevention, treatment and/or cure of infectious diseases
- BHC-19-2019: Implementation research for maternal and child health

Infectious diseases and improving global health in Work Programme 2018–2019 (III)

Coordination and support actions

- HCO-06-2018: Establishment of an International Network of Social Sciences Research Centres to help address governance and other challenges in the preparedness for and the response to infectious threats
- HCO-08-2018: Creation of a European wide sustainable clinical research network for infectious diseases
- HCO-09-2018: Building international efforts on population and patient cohorts
- HCO-10-2018: Coordinating European brain research and developing global initiatives
- HCO-11-2018: Strategic collaboration in health research and innovation between EU and China

Priority 4 – Innovative health and care systems – Integration of care

AIM: Develop effective, accessible and sustainable health interventions and integrated care systems

FOCUS: Mental health in the workplace, novel approaches for palliative care, implementation of personalised medicine, HTA, innovation in health care

POLICY DRIVERS:

Upgrading the single market

Cross-border healthcare Directive

Innovative health and care systems – Integration of care in Work Programme 2018–2020

- BHC-23-2018: Novel patient-centred approaches for survivorship, palliation and/or end-of-life care
- BHC-26-2018: HTA research to support evidence-based healthcare
- BHC-22-2019: Mental health in the workplace
- BHC-25-2019: Demonstration pilots for implementation of personalised medicine in healthcare

<u>Coordination and support actions</u>

- HCO-12-2018: Innovation in healthcare – a CSA towards using pre-commercial procurement and public procurement of innovative solutions in healthcare systems

Priority 5 – Decoding the role of the environment, including climate change, for health and well-being

AIM: Improving the risk assessment of environment on health and well-being, and the related socio-economic impact and developing mitigation measures

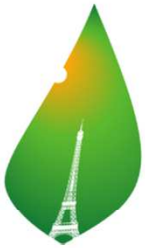
FOCUS: New testing/screening methods to identify endocrine disrupting chemicals, the development of the 'human exposome' (to allow the assessment of lifelong environmental influences on individuals) and to set the priorities for a new research agenda

POLICY DRIVERS:

The 7th Environment Action Programme (EAP)

World Health Organization
REGIONAL OFFICE FOR Europe

WHO Environment and Health Process (since 1989)



The UNFCCC Paris Agreement

REACH and EU related policies

European Commission

Decoding the role of the environment, including climate change, for health and well-being in Work Programme 2018–2019

- BHC-27-2018: New testing and screening methods to identify endocrine disrupting chemicals
- BHC-28-2019: The Human Exposome Project: a toolbox for assessing and addressing the impact of environment on health

Coordination and support actions

- HCO-13-2018: Setting the priorities for a European environment, climate and health research agenda

Other actions for 2018–2019

- Subscription fee: Human Frontier Science Programme Organisation
- Studies, activities of the Scientific Panel for Health, conferences, events and outreach activities
- External expertise
- Grant to the Global Alliance for Chronic Diseases
- Expert group for the impact assessment of the planned Commission communication on infectious diseases
- Subscription fee: World RePORT international health research database
- Mobilisation of research funds in case of Public Health Emergencies

Call deadlines

Better Health and care, economic growth and sustainable health systems

BHC + HCO call topics
Calls open: 7 November 2017
Calls close: 18 April 2018

Exception
BHC-15-2018
Lump Sum Funding: a pilot topic
Calls open: 7 November 2017
First stage: 6 February 2018
Second stage: 4 September 2018

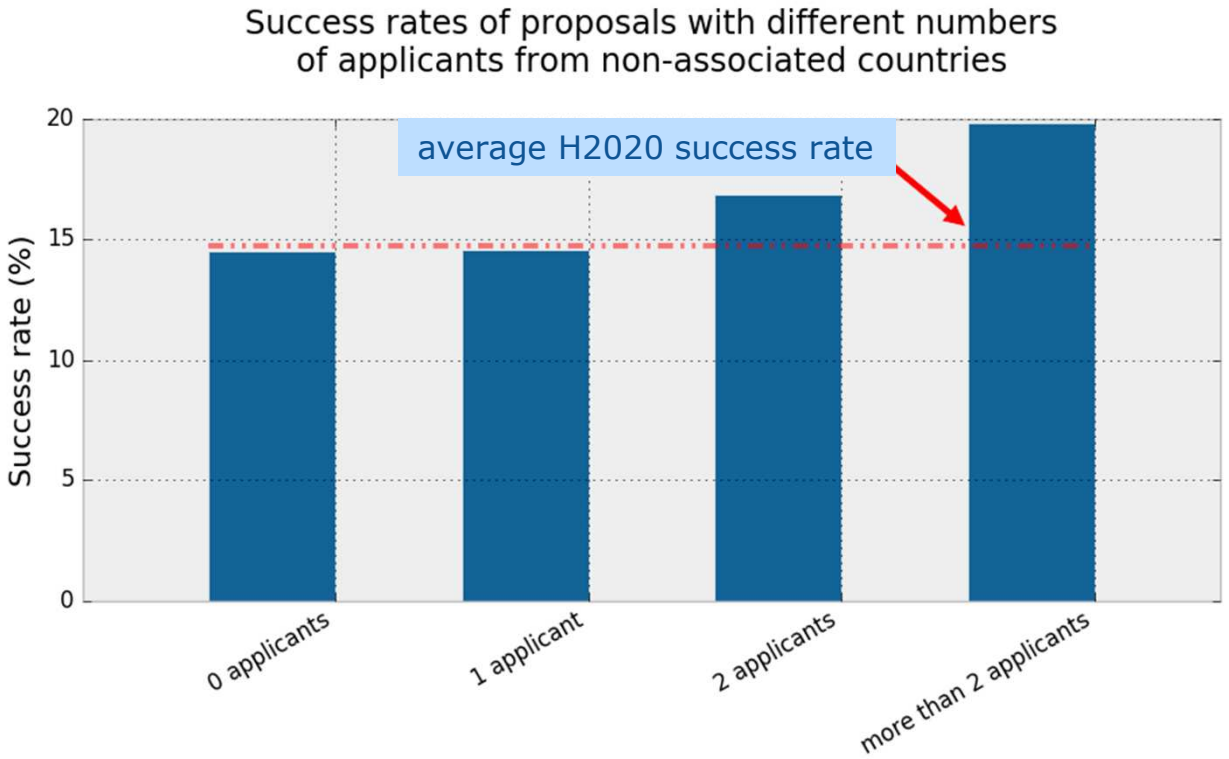
Digital transformation in Health and Care

Trusted digital solutions and Cybersecurity in Health and Care

DTH, HCC, and SU-TDS call topics
Calls open: 7 November 2017
Calls close: 24 April 2018

International cooperation

Why International Collaboration?



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 (JRC, EIT & art.185 not included), extraction date: 17/10/2017

In the SC1 Work Programme 2018-2020 (I)

- **All SC1 topics are open to international cooperation**
- **EC financial contribution**:
  - ✓ **Yes** to 28 Member States, 16 Associated Countries and 124 Third countries (General Annexes A)

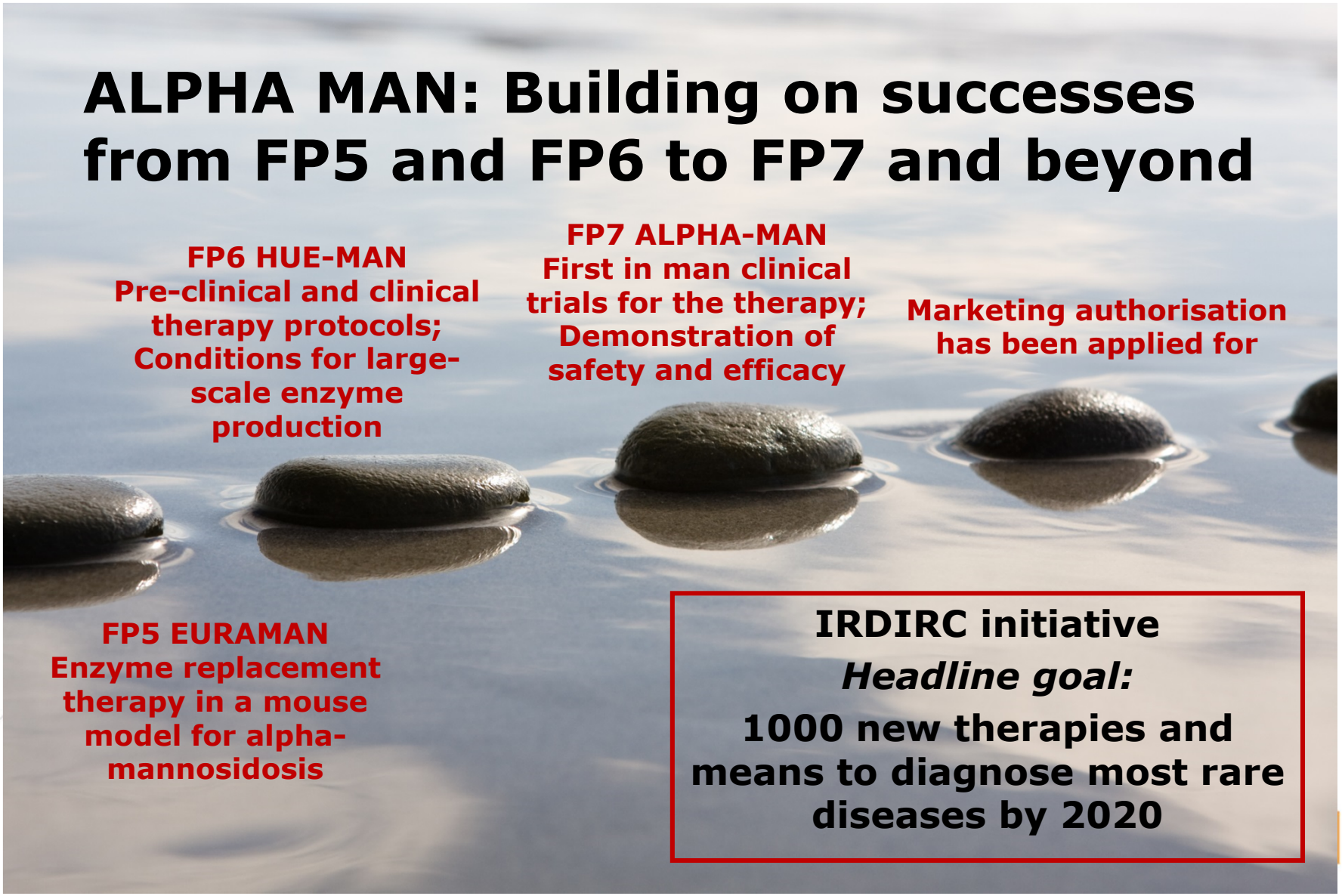
    + United States of America (mutual opening with NIH)
  - ✓ **No** to other Third Countries, but some of those set up a co-funding mechanism (CFM): Australia, Brazil, Canada, China, Hong Kong & Macau, India, Japan, Republic of Korea, Mexico, Russia, Taiwan

In the SC1 Work Programme 2018-2020 (II)

Topics targeting specific countries /regions (e.g. CELAC, Russian Federation, Canada, etc.)

- Lower overall participation of TC in WPs 2014-2016 if compared to FP7
- Need to get higher and more visible participation of TC in the last WP
- Stimulate cooperation on targeted areas that represent a burden for EU and TC (e.g. cancer for CELAC)
- Give a politically visible 'sign' of cooperation (science diplomacy)

International Rare Diseases Research Consortium (IRDiRC)



International Human Epigenome Consortium (IHEC)

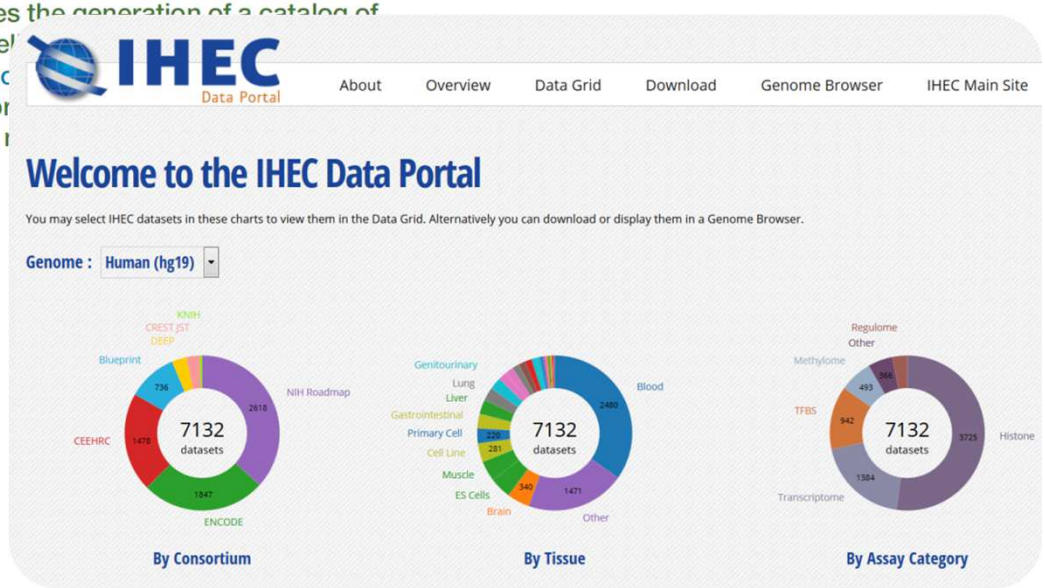
Leading Edge
Essay

Cell

The International Human Epigenome Consortium: A Blueprint for Scientific Collaboration and Discovery

Hendrik G. Stunnenberg,[1,*] The International Human Epigenome Consortium,[4] and Martin Hirst[2,3,*]
[1]Department of Molecular Biology, Faculties of Science and Medicine, Radboud University, Nijmegen, 6525AG, the Netherlands
[2]Department of Microbiology and Immunology, Michael Smith Laboratories, University of British Columbia, Vancouver, BC V6T 1Z4, Canada
[3]Canada's Michael Smith Genome Sciences Centre, BC Cancer Agency, Vancouver, BC V5Z 4S6, Canada
[4]http://ihec-epigenomes.org/
*Correspondence: h.stunnenberg@ncmls.ru.nl (H.G.S.), mhirst@bcgsc.ca (M.H.)
http://dx.doi.org/10.1016/j.cell.2016.11.007

The International Human Epigenome Consortium (IHEC) coordinates the generation of a catalog of high-resolution reference epigenomes of major primary human cel
sented (see the Cell Press IHEC web portal at http://www.cell.cc
the coordinated achievements of IHEC teams to gather and interpr
datasets to gain insights in the epigenetic control of cell states
disease.



More than 1,000 epigenomes mapped through IHEC initiative, special issue in Cell, success of 'BluePrint' EU project

Clinical studies

Template
Essential information about clinical studies

PURPOSE

- Providing structured information to experts for evaluation
- Giving applicants the chance to provide detailed information about clinical studies without page limitations
  Reasons: - detailed but important information, e.g. about Scientific Advice Meetings, relevant (regulatory) guidelines, in- / exclusion- criteria, etc.
  - potentially high number of studies
- Providing necessary information to request 'unit costs'

Available under 'call documents'[1] and in submission system

[1]http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

Template
Essential information about clinical studies |

APPLICABILITY

- Use of template mandatory for certain single-stage and second-stage topics, **if** a clinical study is included
  - But: no eligibility criterion, no disadvantage when information provided in other part of proposal
  - Rather: more and more appreciated (applicants, evaluators) as an opportunity for structured information
- These topics are listed in the template itself

Template
Essential information about clinical studies | SCOPE

- Ethical considerations have to be addressed in the respective separate section
- Risks and contingency plans have to be addressed in the respective section of the proposal (part B.3.2 and table 3.2.a) … If contingency plans are not outlined in the proposal (and the grant agreement), your grant agreement might be terminated and/or the EU contribution significantly reduced if a study cannot proceed as planned

"Extensions of project duration can generally not be granted in H2020. Significantly delayed key study milestones (e.g. 'first patient/first visit') might lead to the termination of the grant agreement"

Open research data pilot

Open Research Data Pilot

- **Introduced** with H2020 as part of Open Science and Open Access policies of DG RTD.
- **Legal basis**: Art. 29.3 of the H2020 MGA
- A **default** as of 01 January 2017 for SC1 projects
- **'Opt-out' option** only for specific and well justified reasons
- **Principle**: 'As open as possible, as closed as necessary'
- **Type of Data concerned**
  - Data underlying scientific publications (raw/individual patient data (IPD) not concerned)
  - Additional data defined and agreed by the consortium in the data management plan (DMP) (avoiding potential IP and confidentiality infringements)

Open Research Data Pilot

- 'Opt-out' possible at any stage (but rarely justified):
  - during the application phase
  - during the grant agreement preparation (GAP) phase and
  - after the signature of the grant agreement
- **Costs** associated with open access to research data, can be claimed as eligible costs of any Horizon 2020 grant
- Participation in the ORD pilot is **not part of the evaluation of proposals**
- **First version of the DMP** (as a deliverable) must be submitted within the first 6 months of the project
- General DMP template* is available online, draft annotations specific for health research will be available in the near future
- The DMP needs to be updated over the course of the project whenever significant changes arise

*http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Research Infrastructures

Health-related ESFRIs: covers the whole spectrum

Target identification

Hit/Lead/ Optimisation & Preclinic

Clinical research

Biological Resource Centres

- **BBMRI** - Biobanks and Biomolecular Resources
- **EMBRC** - Marine biology resources
- **EU-OPENSCREEN** - Chemical libraries
- **INFRAFRONTIER** - Mouse archives and clinics
- **MIRRI** – Microbial resources

Genomics and proteomics facilities

- **INSTRUCT** - Structural biology facilities

Bioinformatics resources

- **ELIXIR** – Data repositories
- **ISBE** – Infrastructure for systems biology

Imaging facilities

- **EUROBIOIMAGING** – Imaging facilities

Medical research facilities

- **EATRIS** - Translational research facilities
- **ECRIN** - Clinical trial platform
- **ERINHA** - High-security labs

Thank you!

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#EUHealthResearch

http://ec.europa.eu/research/health

http://ec.europa.eu/research/participants/portal

European Commission