



The societal challenge: health, demographic change and well-being

Work programme 2016-2017

Arnd HOEVELER
Head of unit
DG Research and Innovation

Info-Day
Vienna
22 September 2015

EU Research and Innovation 30 years and €200 billion

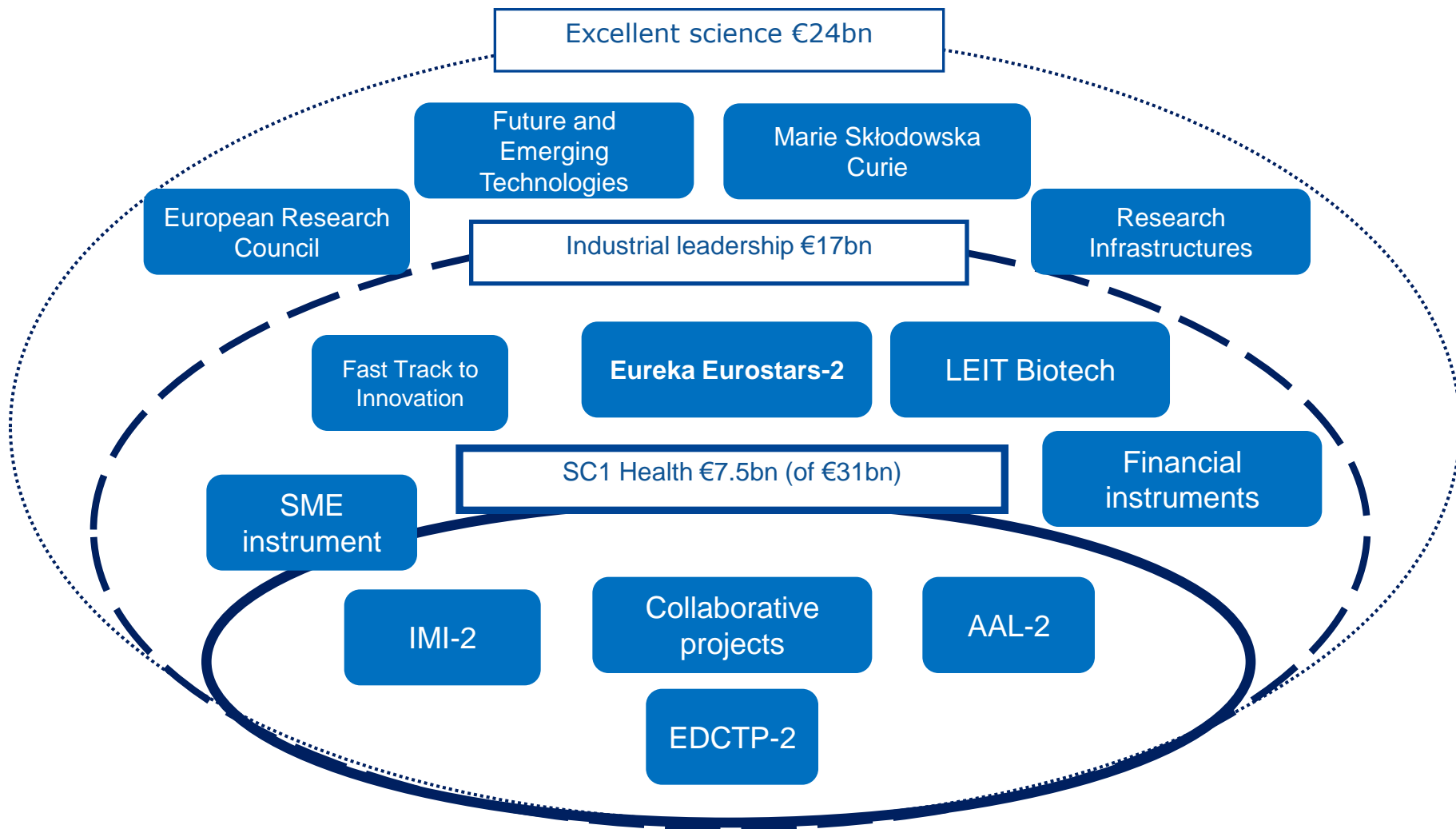


Horizon 2020 - what's up?

- **A single programme** bringing together three separate former programmes/initiatives*
- **Coupling research to innovation** – from research to retail, all forms of innovation
- **Focus on societal challenges** facing European society e.g. **health and ageing**, clean energy and transport
- **Simplified access**, for all companies, universities, institutes in all EU countries and beyond

* The 7th Research Framework Programme (FP7), innovation aspects of Competitiveness and Innovation Framework Programme (CIP), EU contribution to the European Institute of Innovation and Technology (EIT)

Health Research in H2020



Why health, demographic change and wellbeing?



Healthy life years

Ageing population

Increased disease burden

A fair and high quality health and care sector

Opportunities for European leadership in
global R&I

Our portfolio: Building on experience



2007-13:

6.1 € billion invested

1,050 projects

11,000 teams

3,500 organisations

130 countries

First outcomes (from 370 completed projects)

230 patent applications

12,500 publications

34 spin-offs

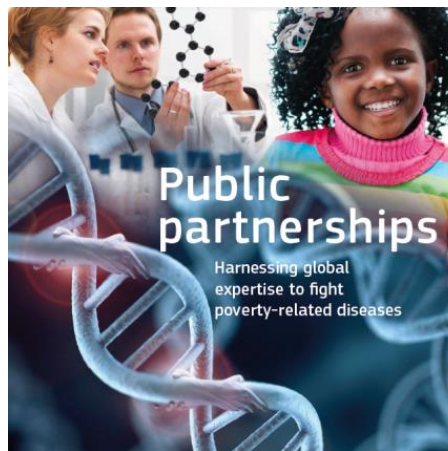
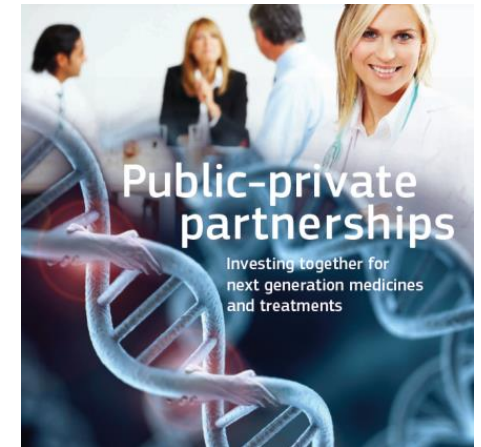
8 average publication
impact factor

HORIZON 2020

SC1 WP16-17, VS.



The right tools to address health challenges – working with the right people in the right way at the right time



Strategic Initiatives



Innovative Medicines Initiative 2
www.imi.europa.eu



**European Innovation Partnership
on Active and Healthy Ageing**
<https://webgate.ec.europa.eu/eipaha>



Active and Assisted Living 2
www.aal-europe.eu



**European & Developing Countries
Clinical Trials Partnership (EDCTP2)**
www.edctp.org

The Work Programme 2016-17 in brief

Call 'Personalised Medecine'

21 topics (32 in '14-'15): 10 in '16, 10 in '17, 1 open in '16 & '17

including 'co-ordination activities'

16 topics (15 in '14-'15): 13 in '16, 3 in '17

- **SME Instrument : 2 Topics**
- **Other Actions: 11 items (incl. InnovFin ID & "Birth Day Prize")**
- **Focus Area Digital Security: 1 Topic**
- **Focus Area Internet of Things: 1 Topic**

**€ 930
million**

From submission to funding: it's fast

- **Single set of** simpler and more coherent participation **rules**
- New **balance between trust & control**
- **Two funding rates** for different beneficiaries and activities (100%, 70%)
- **Single flat rate (25%)** to calculate overhead or «indirect costs»
- **Forthcoming financial regulation** will make things simpler
- **time-to-grant of 8 months (5 + 3)** (exceptions for the ERC and in duly justified cases)



Time to grant: fast

How?

- No detailed negotiations
- Legal entities will be validated in parallel
- No more paper: e-communication & e-signature of grants
- Be prepared !



Participant portal – a one-stop shop

- Call topics
- NCPs !
- Expert registration
- Documents
- Project officers' list for questions
- FAQs
- Rules for participation
- Upload project reports
- Etc.



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

Understanding the call topics: example

SC1-PM-02-2017: New concepts in patient stratification

'Specific challenge': Despite the major advances in understanding disease

'Scope': Proposals should deliver novel concepts for

'Expected impact': New models for patient stratification ...
.....

'Type of action': Research and Innovation action

Lessons learned from H2020-PHC-2014/15

- More focus, details on preliminary data with references (concrete outcome of former EU funded projects)
- For clinical trials more toxicity studies data requested
- Proposal evaluated as a "whole": less good parts will not be deleted anymore, no rescue
- More FAQ on participant portal for more transparency and information

Lessons learned from H2020-PHC-2014/15

- No need for many partners: minimum 3!
- No need for long duration: 2–3 years maybe sufficient
- No need for maximum "indicated budget"
- No "fishing expeditions" but focused projects
- No redundancy "blabla"

Main research priorities for 2016-2017



Personalised medicine

Promoting healthy ageing



Human biomonitoring

Health ICT



Infectious Diseases

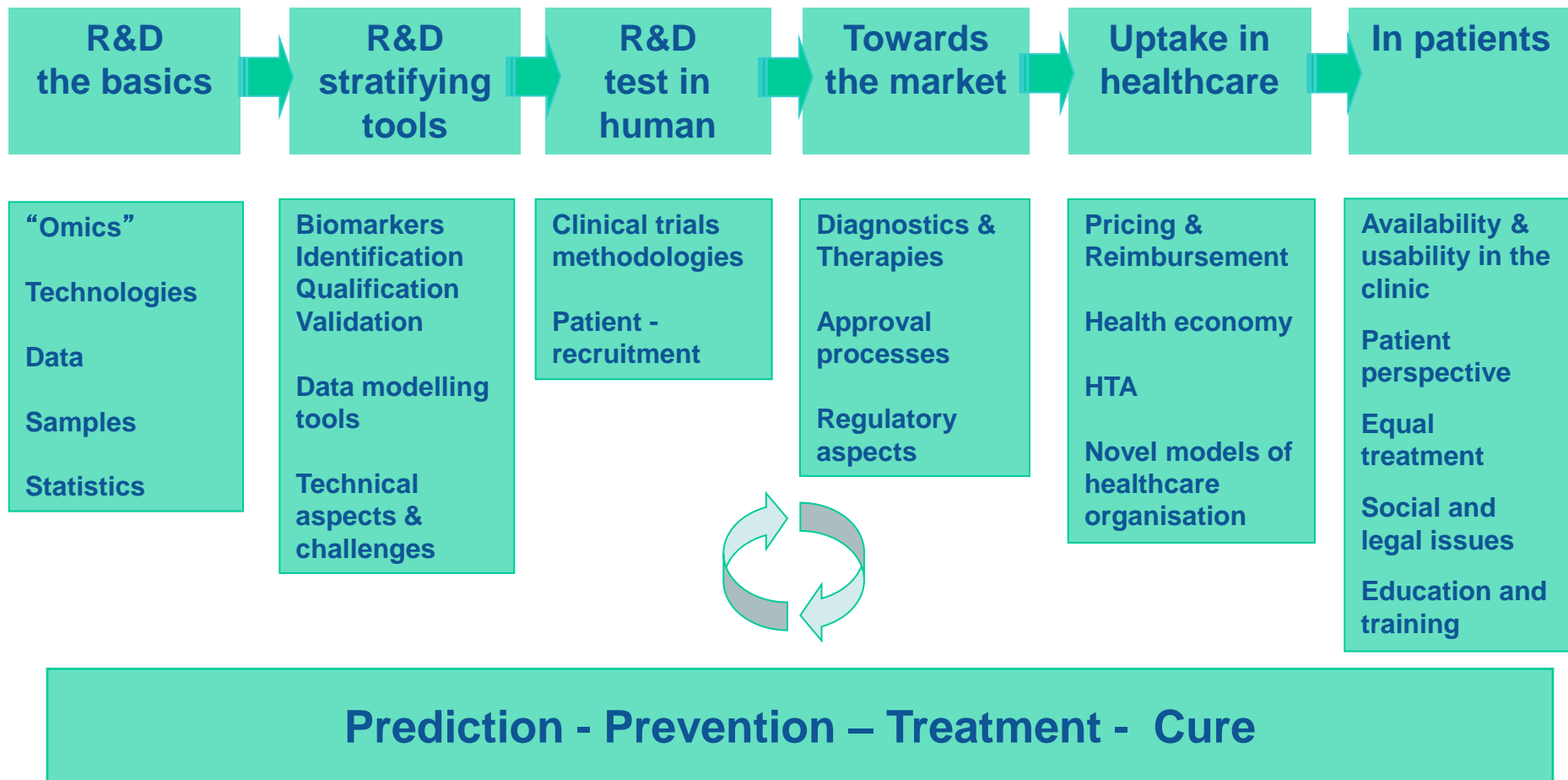
InnovFin

Maternal and child health





Example of implementation: Framework for Personalised Medicine



Personalised medicine in SC1 Work Programme 2016-2017 (I)

Understanding health, well-being and diseases

- SC1-PM-01-2016: Multi omics for personalised therapies addressing diseases of the immune system
- SC1-PM-02-2017: New concepts in patient stratification
- SC1-PM-03–2017: Diagnostic characterisation of rare diseases
- SC1-PM-04–2016: Networking and optimising the use of population and patient cohorts at EU level

Treating and managing diseases

- SC1-PM-08–2017: New therapies for rare diseases
- SC1-PM-09–2016: New therapies for chronic diseases
- SC1-PM-10–2017: Comparing the effectiveness of existing healthcare interventions in the adult population
- SC1-PM-11–2016-2017: Clinical research on regenerative medicine

Personalised medicine in SC1 Work Programme 2016-2017 (II)

Preventing diseases

- SC1-PM-07–2017: Promoting mental health and well-being in the young

Methods and data

- SC1-PM-20-2017: Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector

Health care provision and integrated care

- SC1-PM-21-2016: Implementation research for scaling-up of evidence based innovations and good practice in Europe and low- and middle-income countries

Personalised medicine in SC1 Work Programme 2016-2017 (III)

Coordination activities

- SC1-HCO-02-2016: Standardisation of pre-analytical and analytical procedures for in vitro diagnostics in personalised medicine
- SC1-HCO-03–2017: Implementing the Strategic Research Agenda on Personalised Medicine
- SC1-HCO-05–2016: Coordinating personalised medicine research
- SC1-HCO-06–2016: Towards an ERA-NET for building sustainable and resilient health system models

European human biomonitoring initiative

Strategic planning & coordination of national initiatives

- Creating a European joint programme for monitoring and scientific assessment of human exposures to chemicals and potential health impacts
- Coordinating HBM initiatives in Europe at national and EU level with special focus on a two way dialogue between policy and science in support of evidence based policy making
- Implementation through a Joint Programme Co-Fund



Preventing diseases

SC1-PM-05-2016: The European Human Biomonitoring Initiative





Infectious diseases



- **Collaborative research** – HIV/AIDS, Malaria and Tuberculosis; Neglected Infectious Diseases (NID); Emerging Epidemics; Antimicrobial drug resistance (AMR)
- **New financial instruments** - InnovFin Infectious Diseases – joint initiative between EC-EIB
- **Inducement prizes** – Horizon 2020 prize for better use of antibiotics
- **Global initiatives** - Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R); Global Tuberculosis Vaccine Partnership (GTBVP)
- **Public-private partnerships** – IMI2
- **Public-public partnerships** – EDCTP2
- **Joint Programming Initiative on AMR** – JPIAMR – ERA-INFECT

Infectious diseases in SC1 WP 16-17 (I)

Understanding health, well-being and diseases

- SC1-PM-02-2017: New concepts in patient stratification
- SC1-PM-04-2016: Networking and optimising the use of population and patient cohorts at EU level

Preventing diseases

- SC1-PM-06-2016: Vaccine development for malaria and/or neglected infectious diseases

Treating and managing diseases

- SC1-PM-09-2016: New therapies for chronic diseases
- SC1-PM-10-2017: Comparing the effectiveness of existing healthcare interventions in the adult population

Coordination activities

- SC1-HCO-04-2016: Towards globalisation of the Joint Programming Initiative on Antimicrobial Resistance

Infectious diseases in SC1 WP 16-17 (II)

Other Actions: InnovFin Infectious Diseases (InnovFin ID) Pilot

A New Financial Instrument for Infectious Diseases R&D:

- Jointly developed by the European Commission and European Investment Bank
- Launched on 15 June 2015 in Riga during 'The First Innovative Enterprise Week'
- Established under InnovFin - EU Finance for Innovators
- Provides loans between EUR 7.5m and EUR 75m to innovative players active in developing vaccines, drugs, medical and diagnostic devices, and research infrastructures for combatting infectious diseases

<http://www.eib.org/innovfin>

New Financial Instrument for Infectious Disease R&D



InnovFin
Infectious Diseases

- Jointly developed by the European Commission and European Investment Bank.
- Established under InnovFin - EU Finance for Innovators.
- Investing in the development of innovative **drugs**, **vaccines**, medical and diagnostic **devices**, and **infrastructures for Infectious Diseases**, including those with uncertain commercial outcome but high public health impact.
- Use risk-sharing loans where the repayment depends on success.
- Launched 15 June 2015 in Riga during 'The First Innovative Enterprise Week'.

How does InnovFin Infectious Diseases work?



- Broad range of products - standard debt instruments to risk sharing instruments with forgiveness options.
- < 50% of project costs, co-funding required.
- Comprehensive due diligence (legal, financial, technical, etc.).

Which projects can be supported?

InnovFin
Infectious Diseases

Eligible Projects

Infectious diseases

Innovative

Vaccines, drugs

**Medical and
diagnostic devices**

R&D Infrastructures

- Projects that passed pre-clinical and for which clinical validation is needed for further development.
- Loan amount: min € 7.5 million, max € 75 million.
- Loan maturity: up to 7 years.
- Projects with proven public health impact and market potential.

Example

InnovFin
Infectious Diseases

caVIDI

- €10 million loan from EIB, backed by H2020
- Low-cost HIV viral load testing device was proven to work in simplified, less sophisticated laboratories, in FP7 EU project
- Loan will allow CavidI to develop an automated, high-throughput version of the device, and launch it in January 2016.



Promoting healthy ageing



Health ICT



A large number of research and innovation topics, and coordination topics in the SC1 Work Programme 2016 - 2017

Promoting healthy ageing & Health ICT in SC1 Work Programme 2016-2017 (I)

Active ageing and self-management of health

- SC1-PM-12–2016: PCP - eHealth innovation in empowering the patient
- SC1-PM-13–2016: PPI for deployment and scaling up of ICT solutions for active and healthy ageing
- SC1-PM-14–2016: EU-Japan cooperation on Novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities

Methods and data

- SC1-PM-16–2017: In-silico trials for developing and assessing biomedical products
- SC1-PM-17–2017: Personalised computer models and in-silico systems for well-being
- SC1-PM-18–2016: Big Data supporting Public Health policies
- SC1-PM-19–2017: PPI for uptake of standards for the exchange of digitalised healthcare records
- SC1-PM-20-2017: Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector

Promoting healthy ageing & Health ICT in SC1 Work Programme 2016-2017 (II)

Coordination activities

- SC1-HCO-09–2016: EU m-Health hub including evidence for the integration of mHealth in the healthcare systems
- SC1-HCO-10–2016: Support for Europe's leading Health ICT SMEs
- SC1-HCO-11–2016: Coordinated action to support the recognition of Silver Economy opportunities arising from demographic change
- SC1-HCO-12–2016: Digital health literacy
- SC1-HCO-13-2016: Healthcare Workforce IT skills
- SC1-HCO-14–2016: EU-US interoperability roadmap
- SC1-HCO-15-2016: EU eHealth Interoperability conformity assessment
- SC1-HCO-16-2016: Standardisation needs in the field of ICT for Active and Healthy Ageing



Horizon 2020 – SC1

SME instrument

SME Instrument (1)

- Implemented via EASMEagency
- Bottom-up approach
- Several call deadlines per year
- Only SMEs are eligible

PHC 12 – 2014/2015: Clinical research for the validation of biomarkers and/or diagnostic medical devices

Specific challenge: Biomarkers are used in clinical practice to describe both normal and pathological conditions. They can also have a prognostic or a predictive power. They are therefore increasingly used in medicine and many potential biomarkers are proposed every year.

Only a few of them are however validated for use in a clinical research setting. Such validation implies the demonstration of a link to a pertinent clinical endpoint or process, as well as a robust and appropriate analytical method.

The clinical validation of biomarkers will be increasingly important for the development of new diagnostics, and this is a research area where many small European companies are active.

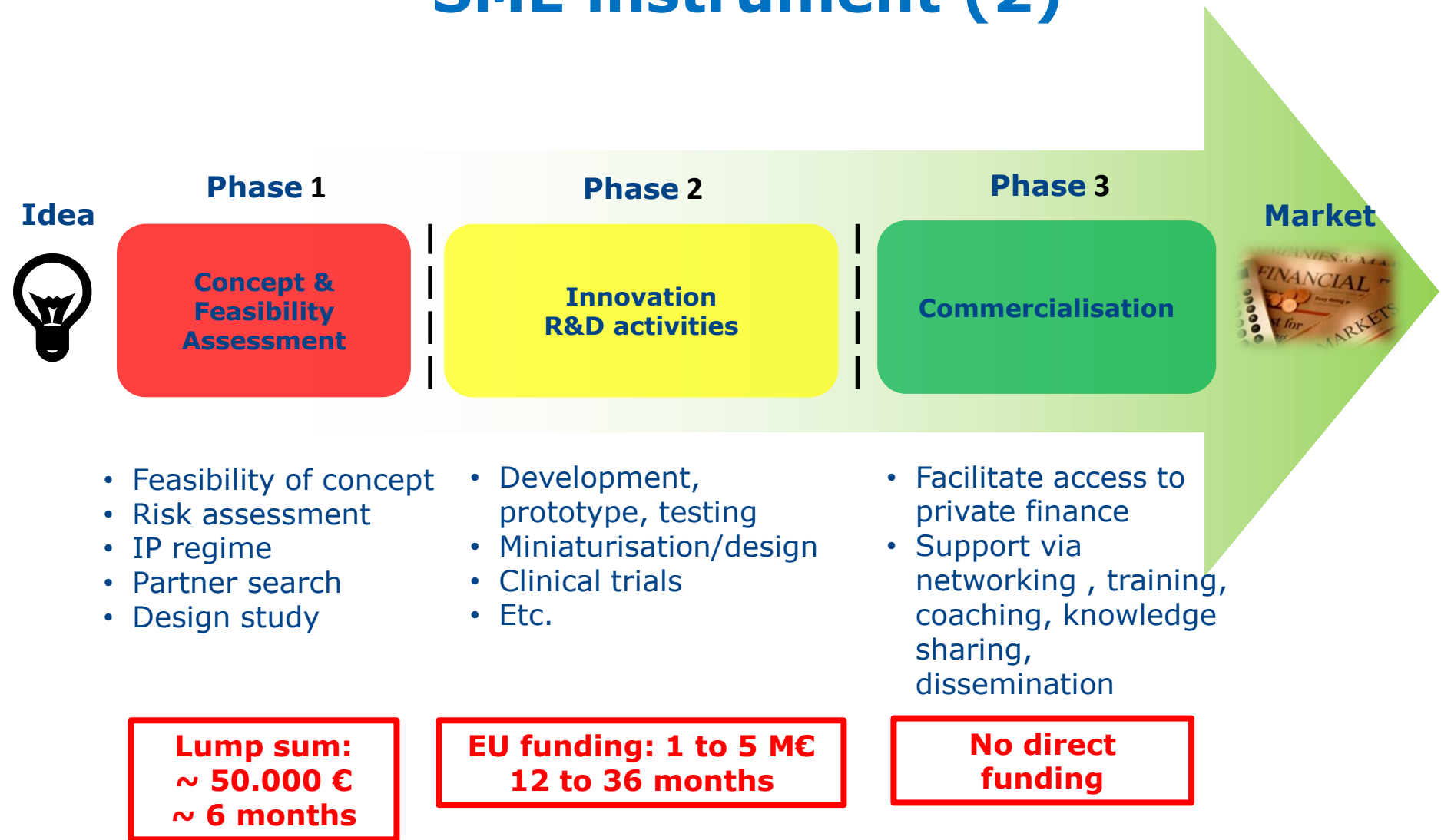
Improved clinical decisions should lead to better health outcomes while contributing to the sustainability of the health care system.

Scope: The SME instrument consists of three separate phases and a coaching and mentoring service for beneficiaries. Participants may apply to phase 1 with a view to applying to phase 2 at a later date, or directly to phase 2.

(S.1-9/15



SME instrument (2)



SME instrument topics (1/2)

SMEInst-05-2016-2017: Supporting innovative SMEs in the healthcare biotechnology sector

1) Clinical research for the validation of biomarkers and/or diagnostic medical devices (PHC 12)

- 25/11/2015: phase 1 & 2 cut-off
- 18/01/2017: phase 2 only cut-off

2) Cell technologies in medical applications

- 2016: 4 cut-offs in phase 1 & 2
- 2017: 4 cut-offs in phase 1 & 2

Overall budget: €80 million

Funding rate: 100%

PM 11 – '16+'17 - Cell technology in medical applications technologies [SME Instrument] [phase 1 and 2]

Challenge: Overcome stability, scale-up & automation barriers to harness the power of cells. Address regulatory issues & business models

Scope: Topic covers all cell technologies, from cell manufacturing to GMP compliance, and all areas of applications. Application must be to human medicine. There are no limitations to the TRL degree.

Expected Impact:

- Stimulate growth & competitiveness of EU cell technology based medical applications
- Strengthen EU SMEs and industry operating in the sector
- Foster development of innovative therapeutic approaches

SME instrument topics (2/2)

SMEInst-06-2016-2017: Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well

- 2016: 4 cut-offs in phase 1 & 2
- 2017: 4 cut-offs in phase 1 & 2

Overall budget: €30.5 million
Funding rate: 70%

Learn more

Search:

Portfolio

- **Health Research – European Commission**
- **Innovative Medicines Initiative**
- **European and Developing Countries Clinical Trials Partnership**

Funding opportunities and support

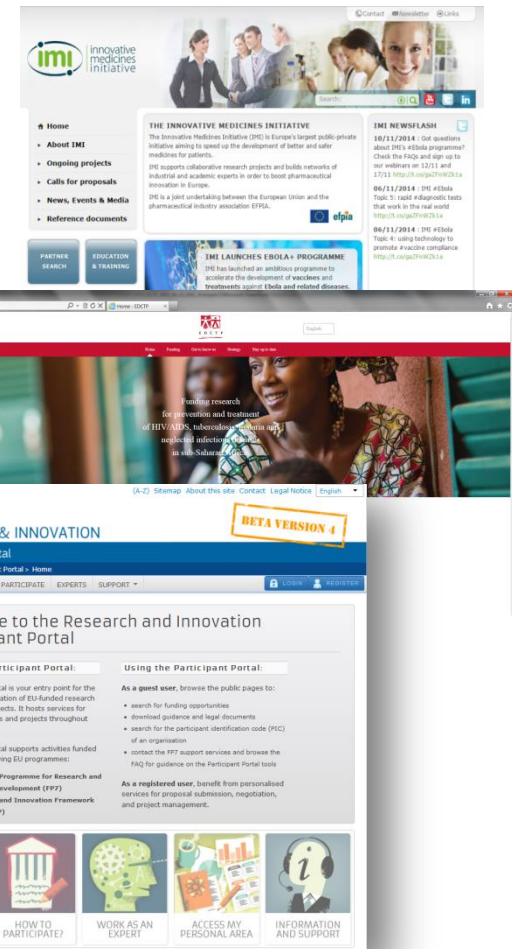
- **Research and Innovation participant portal**
- **Health, demographic change and wellbeing**
- **National contact points**
- **Fit for health 2.0**
- **EMA SME office**
- **IPR helpdesk**

Help us with evaluations of proposals

- **Experts: research participant portal**

HORIZON 2020

SC1 WP16-17, VS.1-9/15





HORIZON 2020

Thank you!

Find out more:

www.ec.europa.eu/research/horizon2020

<http://ec.europa.eu/research/participants/portal/desktop/en/home.html>