



# **Personalised Medicine in Horizon 2020 Opportunities for biotechnology companies**

**Entrepreneurial Discovery Focus Group  
on biotechnology,  
North-East Region, Iași, Romania,  
6.06.2016**

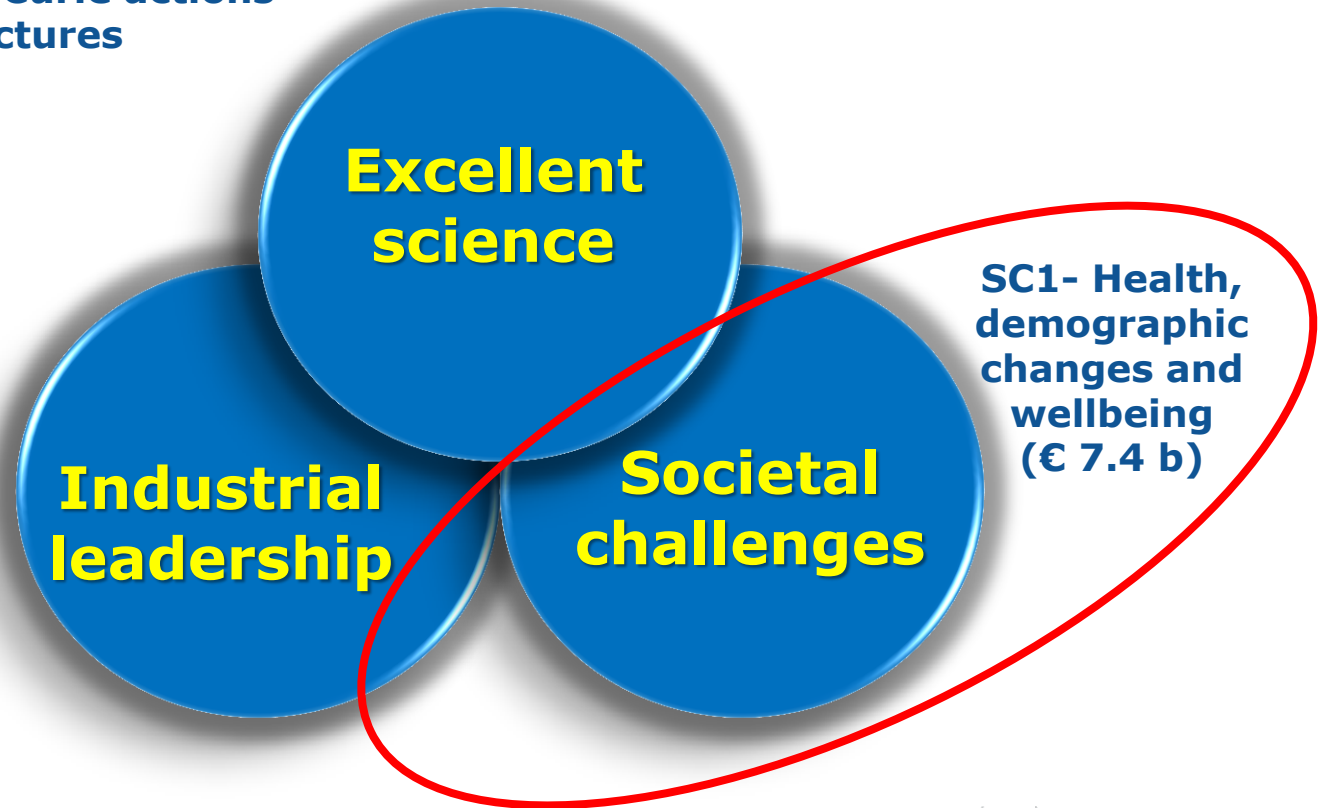


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Innovative and Personalised Medicine  
DG Research & Innovation  
European Commission**

# Horizon 2020 (2014–2020)

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

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



**The new EU programme for research and innovation**

HORIZON 2020

**€ 79 billion (2014-2020)**



European  
Commission

2014-15:  
EUR 1.3 B

2016-17:  
EUR 1.4 B

**PRIORITY**



## Personalised medicine



Healthy ageing  
(2014-2017)



Health ICT  
(2014-2017)



Infectious Diseases  
(2014-2017)

Human  
biomonitoring  
(2016-2017)



Research and  
Innovation



Maternal and  
child health  
(2016-2017)

Towards a definition ...

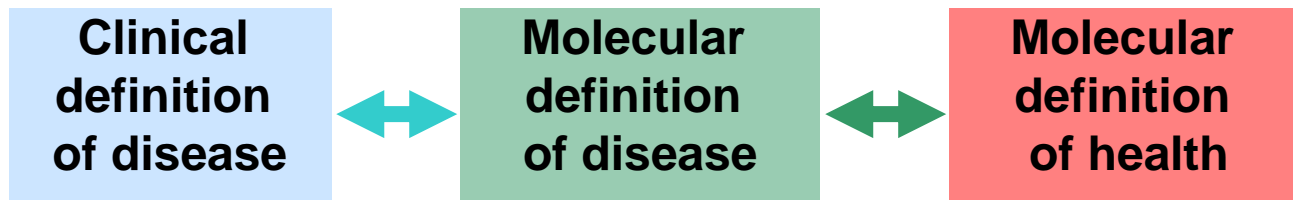
## Council Conclusions on personalised medicine for patients (2015/C 421/03)

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

*Definition developed by the Advisory group for the H2020 Health, demographic change and well-being challenge*

## ... so it's not only about medicines

- **Prediction and prevention are important elements**
- **Diagnostic tools will play a major role**
- **Focus-shift from "treating disease" to "managing care"**



# Main research challenges

**Breaking barriers  
& speaking the same  
language**

**"cross-disciplinarity",  
capacity building,  
education & training**

**Generating knowledge  
& developing the right  
tools**

**standards, clinical  
bioinformatics,  
adaptation of tools**



**Translating knowledge  
to medical applications**

**disease taxonomy,  
biomarker validation,  
clinical trials**

**Understanding the value  
& economic aspects**

**health care pilots, HTA,  
comparative  
effectiveness research,  
value chain**

# EU-research funding: the continuum

*From enabling to implementing personalised medicine*



*Additional support from these programmes:*





Over 2 billion EUR to top research

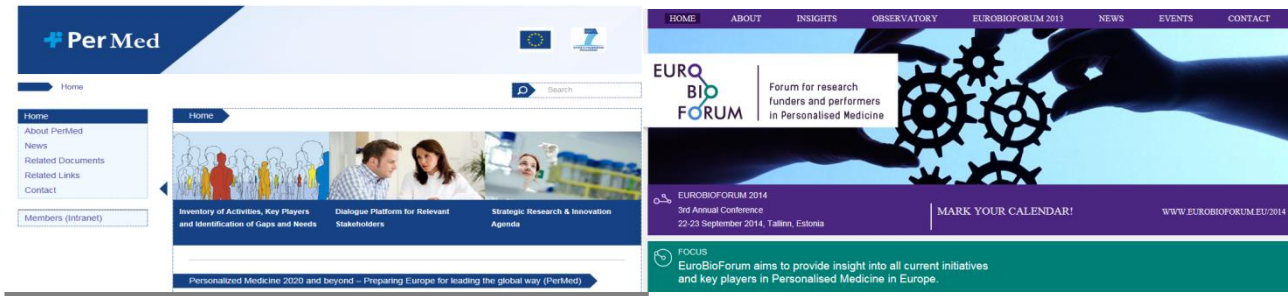
# EU Health Research Programme Enabling personalised medicine 2007-2015



Research areas

- Large scale data gathering and "-omics"*
- Technology development*
- Statistics*
- Diagnostics*
- Biomarkers*
- Clinical trial methodologies*
- Pre-clinical and clinical research*
- Rare diseases: small patient populations*
- Omics for health promotion and disease prevention*
- Piloting personalised medicine in healthcare*

Support and coordination actions







European  
Commission

# What we are doing in Horizon 2020



Understanding  
health, wellbeing  
& disease

Improving  
diagnosis

Innovative  
treatments and  
technologies

Active ageing and  
self-management  
of health

Methods and  
data

Healthcare  
provision and  
integrated care

Implementing personalised medicine in healthcare settings



# What we are doing in Horizon 2020

## *2 examples from first Calls (2014-2015):*

***Omics for prevention:*** € 22 million to 3 projects to develop and assess a personalised/stratified health promotion or disease prevention programme, taking into account the 'omics' characteristics of individuals, complemented by environmental and/or lifestyle factors

***Pilot projects:*** € 30 million to 2 projects that will pilot new models of care, based on the concept of personalised medicine in existing health care environments

# International Consortium for Personalised Medicine (IC PerMed)

WHAT

Collaboration of research funders and policy makers from EU Member States and beyond

WHY

- Establish Europe as a global leader in PM research
- Support the PM science base through a coordinated approach to research
- Provide evidence to demonstrate the benefit of PM to citizens and healthcare systems
- Pave the way for PM approaches for citizens

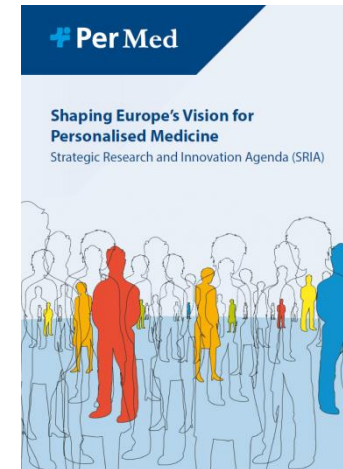
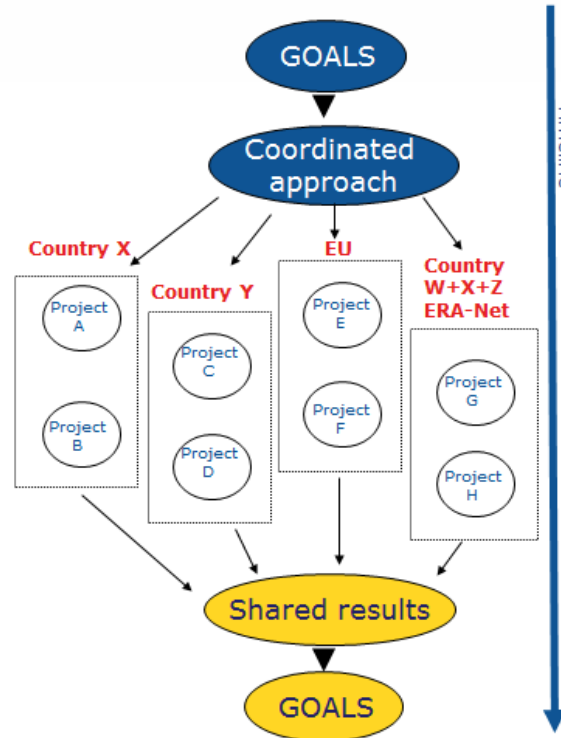
HOW

Implementation of a Roadmap based on PerMed Strategic Research Agenda (SRIA)



# Enabling success through learning and coordination

- Identify common strategic goals
- Agree to share tasks (and costs) for coordination
- Agree on common research policies and standards to speed up research
- Countries fund research according to their funding rules  
(e.g. independent evaluation, selection and funding of projects)
- Results, data and standards are being shared
- Funded projects work towards common goals



# Currently developing a roadmap based on 5 challenges

Developing awareness & Empowerment

Integrating Big Data & ICT solutions

Translating Basic to Clinical Research & Beyond

Bringing Innovation to the Market

Shaping Sustainable Healthcare

## Roadmap

- Actionable research activities
- Mapping of ongoing activities (for proposed actions)
- Proposed means for implementation
- Available in Q4 2016



# **Personalised Medicine Conference 1-2 June 2016**

## ***Charlemagne Building, Brussels***

- **Policy focus with around 600 participants**
- **Official launch of International Consortium for Personalised Medicine (IC PerMed)**
- **5 thematic challenge driven sessions based challenges**

**<http://ec.europa.eu/permed2016>**



# Funding opportunities for biotechnology SMEs

HORIZON 2020



# Small and Medium-sized Enterprise (SME) - EU definition

**Any autonomous entity engaged in an economic activity, irrespective of its legal form, with the following characteristics:**

- < 250 employees
- ≤ €50 million annual turnover
- ≤ €43 million annual balance sheet
- Autonomous entity

**Learn more:**

[http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index\\_en.htm](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm)



# EU Research opportunities for SMEs

## Funded and implemented by the European Commission

- Collaborative research
- SME instrument
- Horizon prize – Better Use of Antibiotics
- Fast Track to Innovation (FTI)



## Funded and implemented jointly with others

- Public–Private partnership (EC - EFPIA): Innovative Medicines Initiative 
- Public–Public partnerships
  - European and Developing Countries Clinical Trial Partnership 
  - Joint Programming Initiative  Joint Programming Initiative in Antimicrobial Resistance
  - INNOVFIN Financial Instruments (EC - EIB)  
INNOVFIN – Infectious Diseases (INNOVFIN-ID) 
  - EUREKA - EUROSTARS

## Cooperation with other funders (BMGF, TATFAR, GACD etc.)

# Collaborative research

- Biannual workprogrammes (with updates) published by EC
- Aims to foster collaboration between
  - Countries
  - Sectors
  - Disciplines
- Open for the participation of the world but
- Minimum: 3 legal entities from 3 different EU Member States or FP-associated countries

## Broad range of topics

e.g. (SME-relevant, both open on 29.07.2016):

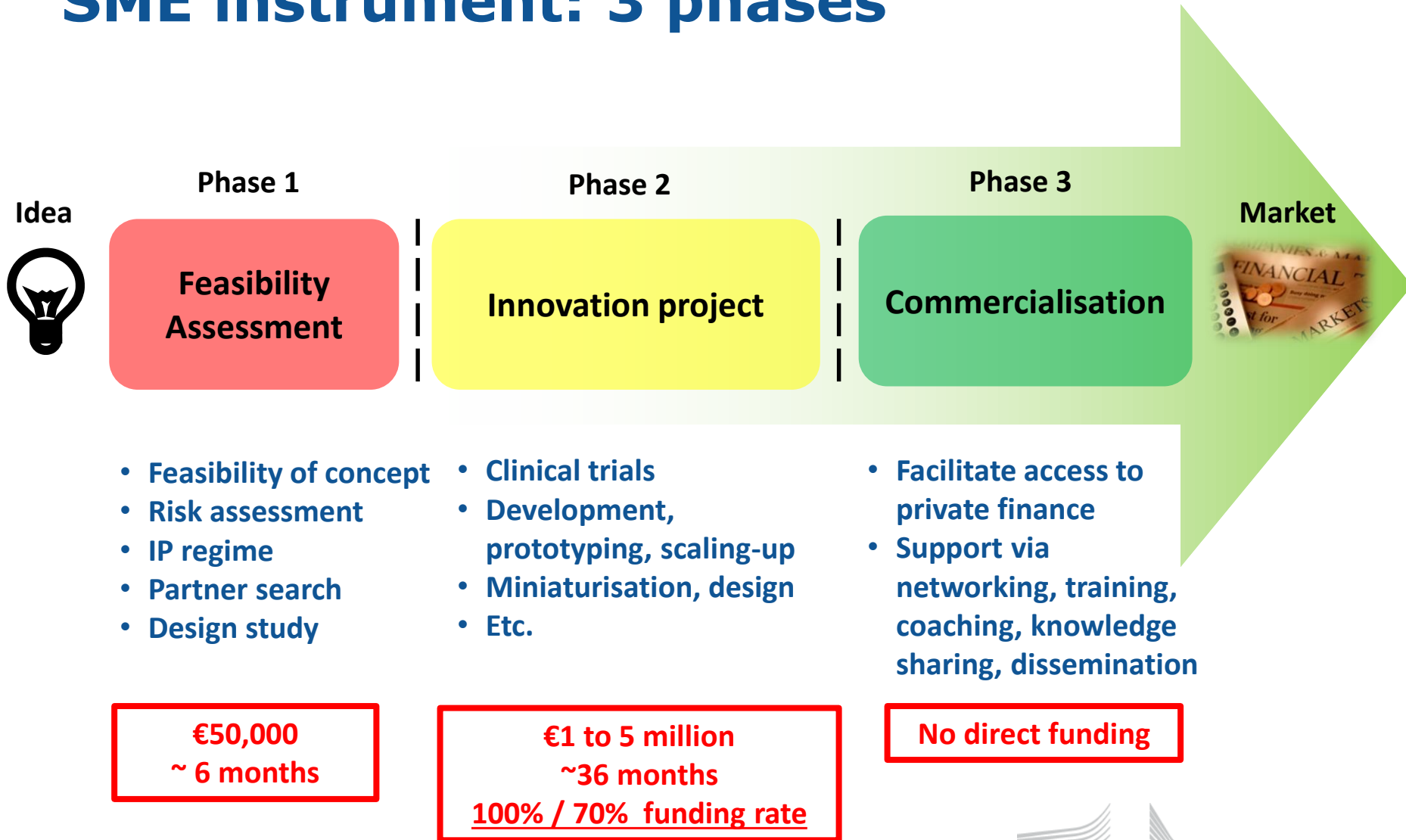
SC1-PM-02-2017 – New concepts in patient stratification

SC1-PM-08-2017 – New therapies for rare diseases

# SME instrument

- Inspired by the US Small Business Innovation Research (SBIR) program
- Piloted by the Health Directorate in 2012/13
- Single company support
- Only EU SMEs allowed to apply for funding
- Competitive, market-oriented, EU dimension
- Several cut-off dates i.e. submission deadlines per year
- Resubmission is possible

# SME instrument: 3 phases



# SME instrument topics (I)

## **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 (previously topic PHC 12 in the Work programme 2014/15)
  - 18/01/2017: phase 2 only cut-off
- 2) Cell technologies in medical applications
  - 2016: 4 cut-offs in phase 1 & 2 (Feb., April, June, October)
  - 2017: 4 cut-offs in phase 1(?) & 2 (Idem)

**Overall budget: €80 million**

**Funding rate: 100%**

# SME instrument topics (II)

## **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 (Idem)
- 2017: 4 cut-offs in phase 1 & 2 (Idem)

**Overall budget: €30.5 million**

**Funding rate: 70%**

# 2014-15: Key figures from the biomarker topic (topic PHC 12)

	Phase 1	Phase 2	Total
Cut-offs so far	7	6	13
Projects funded	165	31	196
Success rate	13,5%	4,1%	10%
SMEs funded	171	36	209
Success rate	12%	6.6%	13.0%
Total EU funding	€8.2 m	€102.2 m	€110.4 m
Average EU funding/project	€50 k	€3.3 m	-
Remaining cut-offs	0	1	1



## BETTER USE OF ANTIBIOTICS

#HorizonPrize

- The European Commission has launched the Horizon Prize for Better use of Antibiotics
- This challenge prize is offering a cash reward of **€ 1 million**
- To the person/team meeting the following challenge:  
*Develop a rapid test that will allow healthcare providers to distinguish, at the point-of-care, between patients with upper respiratory tract infections that require antibiotics and those that can be treated safely without them.*
- **Timeline**  
Deadline for submissions: 17/08/2016  
Award decision at the end of 2016
- [www.ec.europa.eu/horizonprize/antibiotics](http://www.ec.europa.eu/horizonprize/antibiotics)



# Birth Day Prize

#HorizonPrize



- Joint initiative between the European Commission and Bill & Melinda Gates Foundation (possible additional fundings with MSD for Mothers)
- Funding: **€ 2 million**
- Scope: a novel solution to improve the outcome of facility-based deliveries (of a clinical, technological or managerial nature, or a combination of these)
- Impact: demonstrated reduction in maternal and/or new-born morbidity and mortality and/or stillbirth during facility-based deliveries,
- Launch: 28 April 2016
- End date: 6 September 2017
- <http://ec.europa.eu/research/horizonprize/index.cfm?prize=birthday>

# Fast Track to Innovation 2015-2016

Topic: FTIPilot-01-2016



## • Pilot call - rules & conditions:

- Eligibility: 60% of the overall project budget allocated to industry participants in the consortium or majority of industry participants (defined as 'private for-profit organisation')
- Restricted to Member States and Associated Countries
- 3 to 5 partners maximum, max. €3 million EU contribution
- Fully bottom-up, close-to-market activities, 70% funding rate
- Market uptake no later than 3 to 4 years after the start of the project
- Next cut-off: 25 October

# What is the Innovative Medicines Initiative?

## EU funding goes to:

- universities
- SMEs
- patient groups etc.



> €5 bn

## EFPIA companies

- receive no funding
- contribute to projects 'in kind'



€2.5 bn

Partnership  
2008 - 2024



€2.5 bn

## Europe's partnership for health

# How is the IMI addressing the challenges in drug development?

Through IMI's projects we are trying to...

- **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
- **put patients at the centre**

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.

# Why should an SME participate in an IMI project?

- Unique collaborative partnerships in pharmaceutical research and development
- IMI projects are focused on translating excellent research into real world outcomes – an opportunity for SMEs
- Collaboration with large pharmaceutical companies on key challenges for the industry
- Build research and business networks
- Funding opportunities
- Flexibility in IPR e.g., ELF and ENABLE projects
  
- IMI projects vary in their scope and approach therefore not all IMI projects are suitable for all SMEs
  - Check the call topic text carefully
  - Contact the IMI Programme office

# IMI Call 8

## Single Stage RIA Call

Ebola and other filoviral haemorrhagic fevers (Ebola+) programme:  
future outbreaks

This call for proposals is continuously open for a period of two years with the following cut-off dates for submission of proposals:

- **15 September 2016**
- **16 March 2017**
- **14 September 2017**
- **15 March 2018**

<http://www.imi.europa.eu/content/imi-2-call-8>

# Ongoing calls

The following topics are part of IMI 2 - Call 9, open 27.04 – 26.07.2016

- Addressing the clinical burden of Clostridium difficile infection (CDI): evaluation of the burden, current practices and set up of a European research platform  
*Note: topic forms part of the IMI New Drugs for Bad Bugs (ND4BB) programme*
- Development of immune tolerance therapies for the treatment of rheumatic diseases
- Data quality in preclinical research and development
- Next generation of electronic translational safety
- Identification and validation of biomarkers for non-alcoholic steatohepatitis (NASH) and across the spectrum of nonalcoholic fatty liver disease (NAFLD)
- Joint influenza vaccine effectiveness studies

Webinars for applicants, held between 11-29 April, are still available at:  
<http://www.imi.europa.eu/events/2016/03/18/webinars-imi2-call-9>

# Stay in touch

- Dedicated SME contact  
[colm.carroll@imi.europa.eu](mailto:colm.carroll@imi.europa.eu)

- Visit our website  
[www.imi.europa.eu](http://www.imi.europa.eu)

- Sign up to our newsletter  
[bit.ly/IMInewsletter](http://bit.ly/IMInewsletter)

- Follow us on Twitter  
[@IMI\\_JU](https://twitter.com/IMI_JU)

- Join our LinkedIn group  
[bit.ly/LinkedInIMI](http://bit.ly/LinkedInIMI)

- E-mail us  
[infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu)

- Fiction vs. facts

[http://www.imi.europa.eu/sites/default/files/uploads/IMI\\_fiction\\_vs\\_facts.pdf](http://www.imi.europa.eu/sites/default/files/uploads/IMI_fiction_vs_facts.pdf)

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The image shows a composite of the IMI website and social media content. At the top is the IMI website header with the logo and navigation links (Contact, Newsletter, Links). Below is a sidebar menu with links to Home, About IMI, Ongoing projects, Calls for proposals, News, Events & Media, and Reference documents. The main content area features a search bar, a section titled 'THE INNOVATIVE MEDICINES INITIATIVE' with a description and the EFPIA logo, and a 'PARTNER SEARCH' section with categories like Education & Training, Small & Medium-Sized Enterprises, and Intellectual Property. A 'Members area' lists the Governing Board, States Representatives Group, and Scientific Committee. Other sections include 'IMLAUNCHES EBOLA+ PROGRAMME', 'ONGOING PROJECTS' (A life-saving technology), and 'FUTURE CALLS'. A 'NEWSLETTER' section offers a 'Read & subscribe' link. At the bottom, two tweets from @IMI\_JU are shown, discussing Ebola diagnostic tests and vaccine distribution.



# Financial instruments for SMEs in H2020

Part of the Horizon 2020 budget (~2.7 bn) will not be provided through grant funding but in the form of risk-sharing and risk finance:

- A **debt facility** providing loans, guarantees and other forms of debt finance to entities of all forms and sizes, notably research and innovation-driven SMEs: InnovFin SME Guarantee
- An **equity facility** providing finance for mainly early-stage investments, with focus on early-stage SMEs with the potential to carry out innovation and grow rapidly: InnovFin SME Venture Capital

# Browse financial support available in your country

The screenshot shows the 'Your Europe' website interface. At the top, there is a navigation bar with links for 'Contact', 'Sitemap', 'About this site', 'Legal notice', and a language selector set to 'English (en)'. The main header features the 'Your Europe' logo and a search bar. Below the header is a breadcrumb trail: 'EUROPA > Your Europe > Business > Funding > Access to finance'. A horizontal menu contains several categories: 'Start & grow', 'VAT & customs', 'Selling abroad', 'Staff', 'Product requirements', 'Funding' (highlighted in red), 'Public contracts', and 'Environment'. The main content area is titled 'Access to finance' and includes a sub-section 'Access to EU finance'. A text block explains that the site helps users apply for finance supported by the European Union. Below this is a map of Europe with a 'Select a country' button overlaid. A yellow banner at the bottom of the screenshot contains the URL: <http://europa.eu/youreurope/business/funding-grants/access-to-finance/>. The footer of the page includes a 'Help & advice' button and a 'Living and moving in Europe' section.

# InnovFin products

SMEs	Midcaps	Large Caps	Thematic Finance
InnovFin SME Guarantee	InnovFin MidCap Guarantee	InnovFin Large Projects	InnovFin Energy Demo Projects
InnovFin SME Venture Capital	InnovFin MidCap Growth Finance		<b>InnovFin Infectious Diseases</b>
SMEs and small Mid-Caps < 500 Employees	Mid-Caps < 3,000 Employees	Large Caps Typically > 3,000 Employees	SPV, Mid-Caps and Large Caps
Intermediated SME/Mid-Cap Financing	Intermediated and/or direct Corporate lending	Direct Corporate Lending	Project Finance and/or Direct Corporate Lending

 direct products

 indirect products

# How does InnovFin Infectious Diseases work?



- Broad range of products - standard debt instruments (i.e. senior, subordinated, and mezzanine) to risk sharing instruments (RSL) with forgiveness options
- Amount: **min EUR 7.5m, max EUR 75m**
- EIB can only finance 50% of project costs
- Pricing : **commensurate to the risk incurred**

# Eureka Eurostars 2 2014-2020

**Eurostars2:**  
~€1.1 billion  
EC: €0.3b – 34 countries:  
€0.8b

- Programme funded jointly by several countries and the EU via H2020 budget (art. 185)
- Focus: stimulate growth and research and innovation in SMEs
- Budget: +200% increase compared to Eurostars 1
- SME-targeted programme:
  - Minimum participation: two organisations from two participating countries (34 countries)
  - Bottom-up i.e. no topics, 25% success rate
  - Typical project budget: 2 m€
  - Market-oriented, 70% of participants are SMEs
  - All organisations can join

# Get prepared - free of charge services to assist you

Call text, guide for applicants, FAQ: Participant portal

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

Practical information & assistance: National Contact Points

[http://ec.europa.eu/research/participants/portal/desktop/en/support/national\\_contact\\_points.html](http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html)

Find partners, training, brokerage: Fit for Health 2.0

<http://www.fitforhealth.eu/>

Find out what projects are or have been funded: EU Health projects database

[http://cordis.europa.eu/projects/home\\_en.html](http://cordis.europa.eu/projects/home_en.html)

IP questions and advices: IPR helpdesk

<https://www.iprhelpdesk.eu/>

SME regulatory one stop shop: EMA SME office

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000059.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000059.jsp)

Become evaluator! Select the best projects: Register as Expert

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

Loan guarantee, equity: Find out financial support available in your country

<http://europa.eu/youreurope/business/funding-grants/access-to-finance/>



# HORIZON 2020

**Thank you  
for your attention**

***Find out more:***

[www.ec.europa.eu/research/horizon2020](http://www.ec.europa.eu/research/horizon2020)

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