Personalised Medicine in Horizon 2020
Opportunities for biotechnology companies

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

Alexandru COSTESCU
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

The new EU programme for research and innovation
€ 79 billion (2014-2020)
**Personalised medicine**

- Infectious Diseases (2014-2017)

**Funding**

- 2014-15: EUR 1.3 B
- 2016-17: EUR 1.4 B
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

Image: © mipan/Fotolia
EU-research funding: the continuum

From enabling to implementing personalised medicine

over 1 billion EUR!

1.3 billion EUR in 2014/15!

1.4 billion EUR in 2016/17!

Additional support from these programmes:
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
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

Diagram:
- GOALS
  - Coordinated approach
    - EU
    - Country W+X+Z FRA-Net
    - Country Y
    - Country X
    - Project A
    - Project E
    - Project C
    - Project D
    - Project F
    - Project G
  - Shared results
- GOALS

Timeline:

PerMed
Shaping Europe's Vision for Personalised Medicine
Strategic Research and Innovation Agenda (SRIA)
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

Funding opportunities for biotechnology SMEs
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

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
  - INNOVFIN Financial Instruments (EC - EIB)
    - INNOVFIN – Infectious Diseases (INNOVFIN-ID)
  - EUREKA - EUROSTARS

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

HORIZON 2020
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

**Phase 1: Feasibility Assessment**
- Feasibility of concept
- Risk assessment
- IP regime
- Partner search
- Design study

**Phase 2: Innovation project**
- Clinical trials
- Development, prototyping, scaling-up
- Miniaturisation, design
- Etc.

**Phase 3: Commercialisation**
- Facilitate access to private finance
- Support via networking, training, coaching, knowledge sharing, dissemination

- €50,000 ~ 6 months
- €1 to 5 million ~36 months
  100% / 70% funding rate
- No direct funding

HORIZON 2020
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)

<table>
<thead>
<tr>
<th></th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut-offs so far</td>
<td>7</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Projects funded</td>
<td>165</td>
<td>31</td>
<td>196</td>
</tr>
<tr>
<td>Success rate</td>
<td>13.5%</td>
<td>4.1%</td>
<td>10%</td>
</tr>
<tr>
<td>SMEs funded</td>
<td>171</td>
<td>36</td>
<td>209</td>
</tr>
<tr>
<td>Success rate</td>
<td>12%</td>
<td>6.6%</td>
<td>13.0%</td>
</tr>
<tr>
<td>Total EU funding</td>
<td>€8.2 m</td>
<td>€102.2 m</td>
<td>€110.4 m</td>
</tr>
<tr>
<td>Average EU funding/project</td>
<td>€50 k</td>
<td>€3.3 m</td>
<td>-</td>
</tr>
<tr>
<td>Remaining cut-offs</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
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**
Birth Day Prize

• 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

FTI (2015–2016): €200 m
What is the Innovative Medicines Initiative?

EU funding goes to:
- universities
- SMEs
- patient groups etc.

EFPIA companies
- receive no funding
- contribute to projects ‘in kind’

Europe’s partnership for health

HORIZON 2020
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](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
- Visit our website www.imi.europa.eu
- Sign up to our newsletter bit.ly/IMInewsletter
- Follow us on Twitter @IMI_JU
- Join our LinkedIn group bit.ly/LinkedInIMI
- E-mail us infodesk@imi.europa.eu
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

http://europa.eu/youreurope/business/funding-grants/access-to-finance/
## InnovFin products

<table>
<thead>
<tr>
<th>SMEs</th>
<th>Midcaps</th>
<th>Large Caps</th>
<th>Thematic Finance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>InnovFin</strong></td>
<td><strong>InnovFin</strong> MidCap Guarantee</td>
<td><strong>InnovFin</strong> Large Projects</td>
<td><strong>InnovFin</strong> Energy Demo Projects</td>
</tr>
<tr>
<td>SME Guarantee</td>
<td>MidCap Growth Finance</td>
<td></td>
<td><strong>InnovFin</strong> Infectious Diseases</td>
</tr>
<tr>
<td>SME Venture Capital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMEs and small Mid-Caps &lt; 500 Employees</td>
<td>Mid-Caps &lt; 3,000 Employees</td>
<td>Large Caps Typically &gt; 3,000 Employees</td>
<td>SPV, Mid-Caps and Large Caps</td>
</tr>
<tr>
<td>Intermediated SME/Mid-Cap Financing</td>
<td>Intermediated and/or direct Corporate lending</td>
<td>Direct Corporate Lending</td>
<td>Project Finance and/or Direct Corporate Lending</td>
</tr>
</tbody>
</table>

**direct products**

**indirect products**

---

**HORIZON 2020**
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

- 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

Practical information & assistance: National Contact Points
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

IP questions and advices: IPR helpdesk
https://www.iprhelpdesk.eu/

SME regulatory one stop shop: EMA SME office

Become evaluator! Select the best projects: Register as Expert

Loan guarantee, equity: Find out financial support available in your country
http://europa.eu/youreurope/business/funding-grants/access-to-finance/
Thank you for your attention

Find out more:
www.ec.europa/research/horizon2020