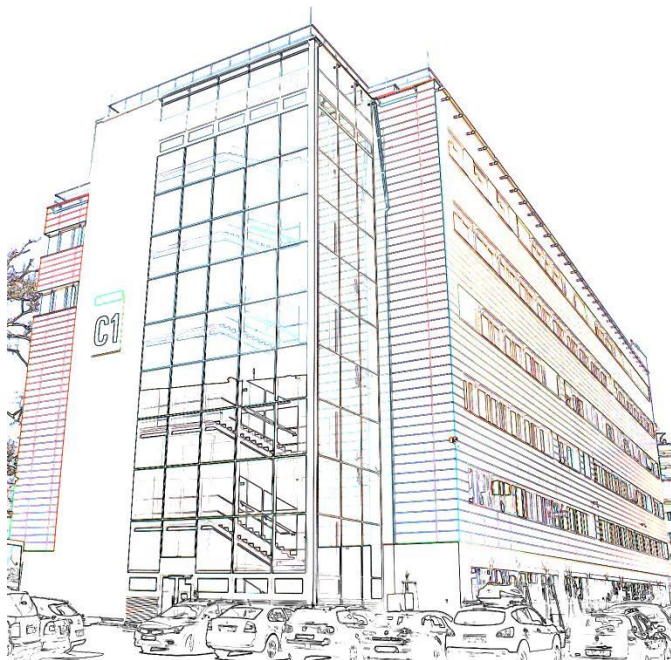


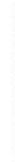
Academic Clinical Trials: Funding Options

Martin Bartos
Project manager

III rd. PharmAround Conference
25. 3. 2015



EUROPEAN UNION
EUROPEAN REGIONAL DEVELOPMENT FUND
INVESTING IN YOUR FUTURE



OP Research and
Development for Innovation

Horizon 2020

Horizon 2020 - General information

Horizon 2020 – Pillar III: Tackling Societal Challenges

Horizon 2020 – Where to find information

Innovative Medicines Initiative (IMI 2)

IMI 2 – General information

IMI 2 – Recent topics

IMI 2 - Where to find information

Proposal preparation

Proposal preparation – Budget

Proposal preparation – Time planning

Proposal preparation – How to success

Horizon 2020 – General information



- Horizon 2020 is the biggest EU Research and Innovation programme ever
- Nearly €80 billion budget
- Funding available over 7 years (2014 to 2020)

HORIZON 2020

the Framework Programme for Research and Innovation (2014 -2020)

Pillar 1: Excellent science

European Research
Centre (ERC)

Future and Emerging
Technologies (FET)

Marie Curie Actions
Research (MCA)

Infrastructures

Pillar 2: Industrial Leadership & Competitive Frameworks

Leadership in Enabling and
Industrial Technologies

- Information & communication technologies (ICT)
- Nanotechnologies
- Advances materials
- Biotechnology
- Advanced manufacturing & processing
- Space

Access to Risk Finance

Innovation in SMEs

Pillar 3: Tackling Societal Challenges

Health, demographics changes and well
being

Food security, sustainable agriculture
marine and maritime research & bio-
economy

Secure, clean and efficient energy

Smart, green and integrated transport

Climate action and resource efficiency
including raw materials

Inclusive, Innovative and Reflective
Societies

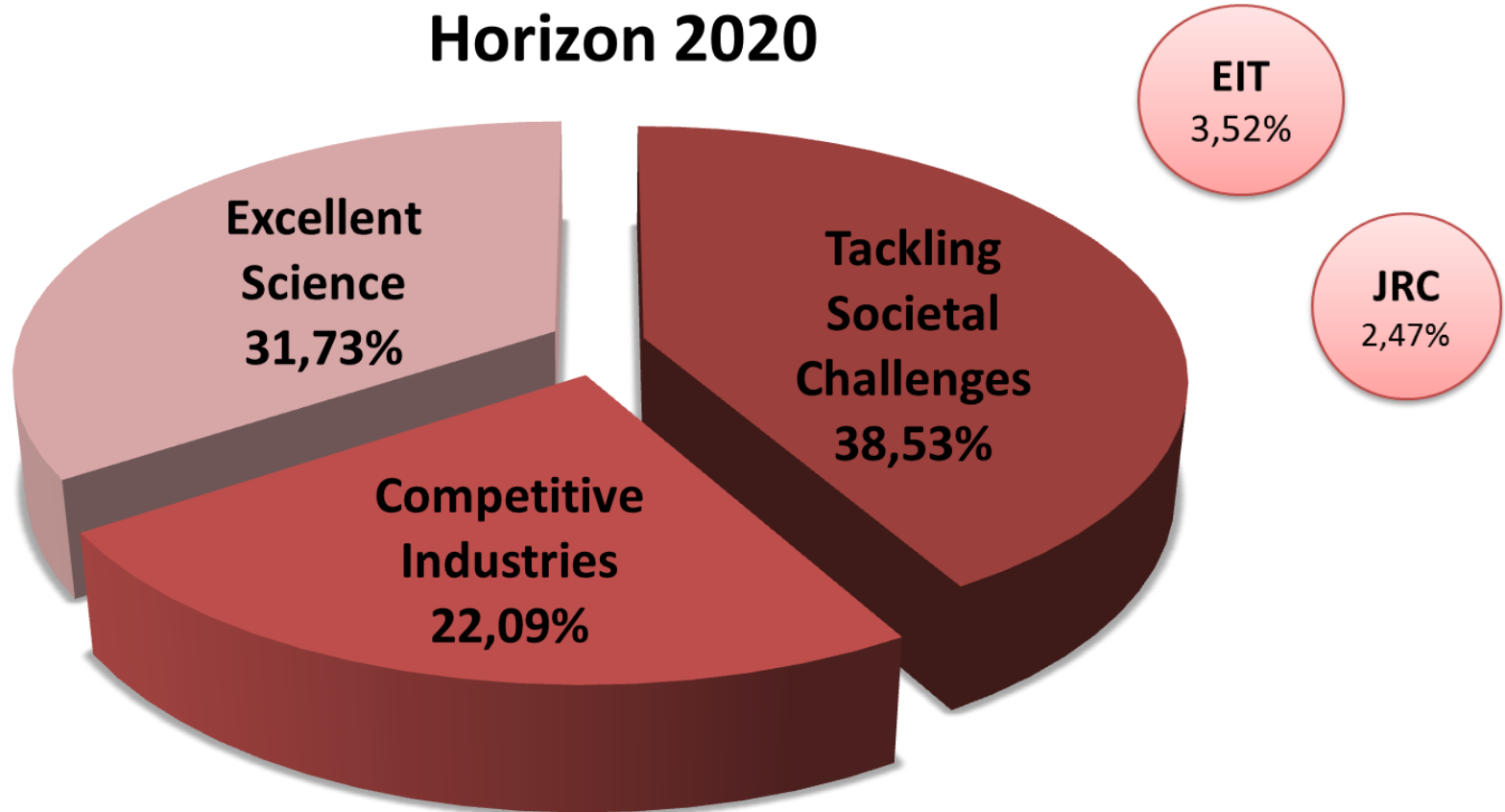
Secure societies: protecting freedom and
security of Europe and its citizens

JOINT RESEARCH CENTRE (JRC)

EUROPEAN INSTITUTE OF TECHNOLOGY (EIT)

Horizon 2020 – 3 Pillars = 3 Priorities

Horizon 2020



- Budget for Pillar III: **29.901.591.800 EUR**

Horizon 2020 – Pillar III: Tackling Societal Challenges



- **Support of a broad range of activities:**
 - Basic research
 - Knowledge transfer
 - Large-scale clinical studies
 - And other ...

Horizon 2020 – Pillar III: Tackling Societal Challenges



- This pillar consist of many topics – for the Clinical Trials, the most important one is this priority:
- **Health, demographic changes and wellbeing**
- **Goal** of research and innovation in this priority **is to find a solution** for:
 - Ageing society
 - Civilization diseases (cardiovascular, neurological, diabetes, obesity...)
 - Other topics: personalized medicine, electronical healthcare

Horizon 2020 – Pillar III: Tackling Societal Challenges



Broadly defined, the goal is to:

- **ensure the good health** of the European population throughout life and particularly in old age
- **ensure optimal living conditions**
- **develop effective prevention, early diagnosis and effective treatment** to create conditions for the full life of citizens with various disabilities.

Other key topics:

- **personalized medicine** and **personalised approach**
- **ICT** (e-Health, m-Health)
 - **imaging methods**
 - **techniques for the prevention, early and accurate diagnosis and monitoring treatment.**

Horizon 2020 – Pillar III: Tackling Societal Challenges



16 thematic directions:

- Understanding the determinants of health, health promotion and disease prevention
- The development of screening programs and evaluation susceptibility to diseases
- Improving surveillance and preparedness of health services
- Understanding the disease
- The development of effective vaccines
- The development of diagnostic methods
- Computer modeling and prediction of treatment of diseases
- Transfer research knowledge for routine use in clinical practice
- Treatment with specific groups
- Better use of health data
- Development of scientific tools and methods for creating health policy
- Active aging, an independent and assisted living
- Strengthening the individual care of their own health
- Promotion of integrated care
- Optimizing the efficiency and effectiveness of health care, reduction of inequalities using evidence-based medicine (evidence based medicine), dissemination of good clinical practice
- Special aspects

Horizon 2020 – Where to find information



- European Commission
 - <http://ec.europa.eu/research/horizon2020>
- Technology center AV ČR
 - <http://www.fp7.cz/cs/horizon-2020>
 - <http://www.h2020.cz>
- Participant portal (proposals, etc.)
 - <http://ec.europa.eu/research/participants/portal>
- CORDIS (searching for partners for consortiums, etc.)
 - <http://cordis.europa.eu/>

Horizon 2020

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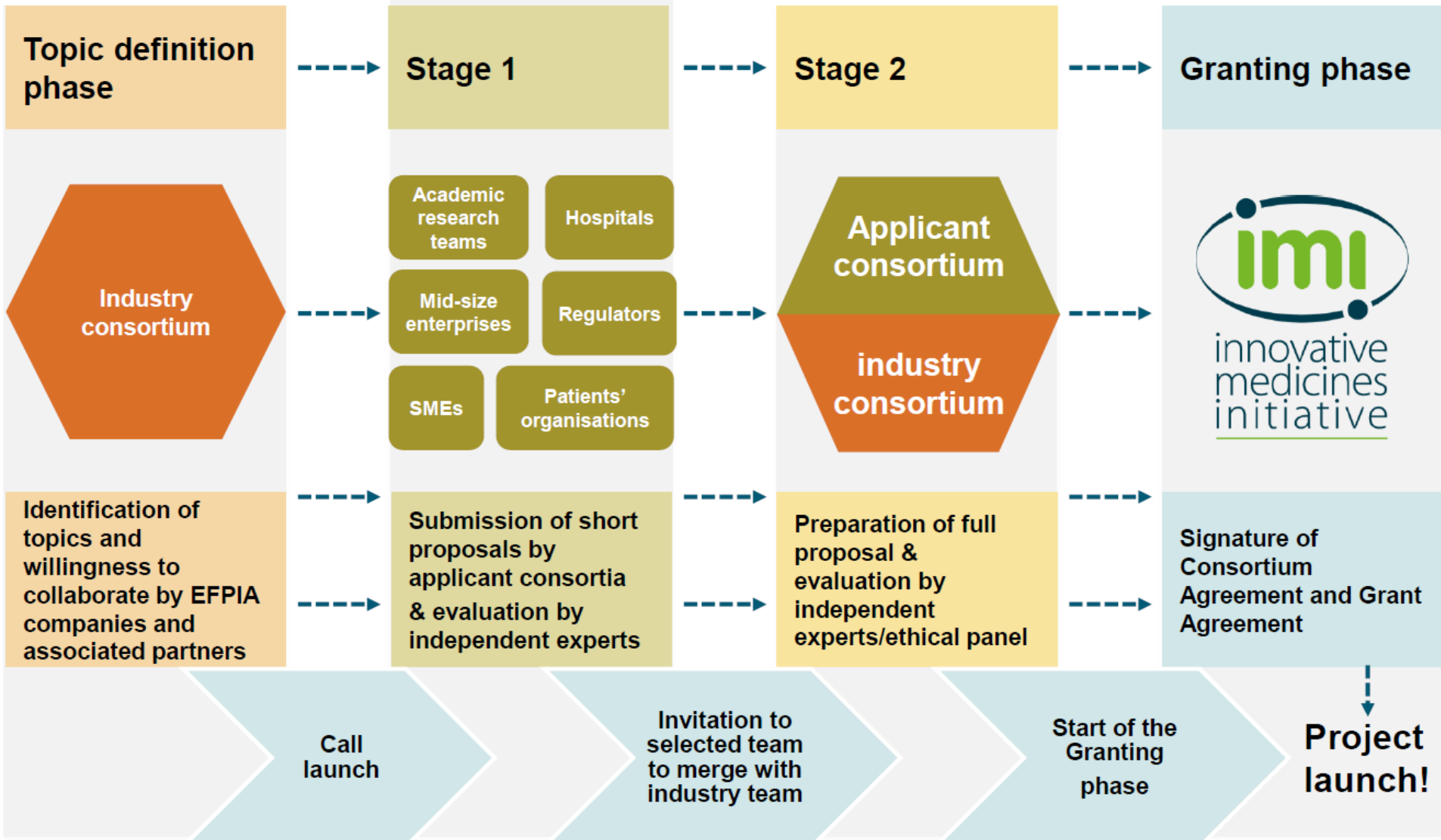
Proposal preparation – How to success

IMI 2 – General information



- The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.
- IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.
- IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.
- €3.3 billion budget
- Funding available from 2014 to 2024

IMI 2 – Life cycle



IMI 2 – Recent topics



Call 1 – April 2014

- Type 1 Diabetes Mellitus (T1DM)
- Dry age-related macular degeneration and diabetic retinopathy

Call 2 – December 2014

- Ebola and other filoviral haemorrhagic fevers

Call 3 and 4 – December 2014

- Remote assessment of disease and relapse (RADAR) - CNS
- Prediabetes and type 2 diabetes
- Linking clinical neuropsychiatry and quantitative neurobiology
- The consistency approach to quality control in vaccine manufacture
- Pertussis vaccination research
- Knowledge repository to enable patient focused medicine development
- Enabling Platform on Medicines Adaptive Pathways to Patients

IMI 2 – Where to find information



- Innovative medicine initiative
 - <http://www.imi.europa.eu/>
- Submitting a proposal
 - <https://sofia.imi.europa.eu/Pages/Login>
- IMI Partnersearch tool
 - <http://www.imi.europa.eu/content/partner-search>
- IMI Partnersearch tool (supported by German Federal Ministry of Education and Research)
 - <http://www.imi-partnering.eu/>

Horizon 2020

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Proposal preparation – How to success

- **Horizon 2020 is supposed to have simpler rules and structure**
- Simple evaluation criteria:
 - Excellence
 - Impact
 - Implementation
- Successful applicants will get **finances quickly**
 - „time-to-grant“: 8 months.

- **Financial information**

- total **eligible direct costs**:

- up to **100% funding**

- **indirect costs**:

- flat-rate financing 25%** of the total eligible direct costs

Proposal preparation - Budget



– Direct eligible costs are:

- Personnel Costs; Equipment Costs; Consumables; Travel and Subsistence Costs; Publication Costs (page charges and related fees for publication of results).

– Non-eligible costs cannot be reimbursed through the grant,

- Examples: indirect taxes, including VAT or duties; interest owed; provisions for possible future losses or charges; exchange losses

– Indirect cost are:

- those which cannot be identified as directly attributable to the project, but incurred in direct relationship with the project's direct eligible costs
- Examples: costs related to general administration and management; costs of office or laboratory space and related expenditure such as water, heating, electricity; maintenance, postal charges... etc.

– It is necessary to specify carefully and include ALL needs!

Proposal preparation - Budget



Direct costs of clinical studies*:

- **Personnel** (doctors and other medical and technical personnel)
- **Consumables**
- **Medical equipment** (*depreciation and costs of service contracts necessary for their functioning*)
- Other **specific service contracts** necessary for the clinical study

* *Travel and subsistence costs of patients are not included (will be reimbursed on the basis of eligible costs actually incurred under the cost category “other direct costs”)*

Proposal preparation - Time planning



Don't be over ambitious!

Experience has shown that almost 50% of all FP7 projects were not finished in the originally planned time. Proper time planning is even more of a challenge for clinical trials activities:

- Project start date \neq start of the study... esp if ethical approval still needs to be obtained (which is usually the case if a new/additional approval is needed for work under the project)
- Include enough time for protocol development (proposal includes draft protocol only.. development of final protocol may take some time, esp if initiated after start of the project as part of the workplan)
- Estimate recruitment speed carefully and realistically!

Proposal preparation – How to success



- **start working early**
- **good researchers** in the team
- **high research performance** (publications, patents, previous grants)
- **partners** (foreign institutions with good results and experience) – you must be in contact with them
- your time and ability to prepare a **good research proposal**
- **good project structure and high quality of the project application**

Thank you for your attention!

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