Horizon2020 and Stratified Medicine

Liverpool Health is Wealth Conference
Forum 4: “Opportunities for European Funding and Partnership”
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One size doesn't fits all / custom made therapy

• Only 25 to 80 % of patients respond to common drugs
• 5-7 % of all hospital admissions result from adverse drug reactions
Personalised medicine: towards a definition

"Personalised medicine refers to a medical model using characterization of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging) 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..."
Personalised Medicine: preparing the ground

• 2010: Preparatory workshops (-omics, biomarkers, clinical trials/regulatory, uptake)

• 2011: European Perspectives conference

• 2013: "Omics report"

• Identify key challenges to be addressed by research

The framework for Personalised Medicine

Prediction - Prevention – Treatment - Cure
Identified key 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

Personalised medicine: A matter of big data?
Various sources of data → Personalised medical decision

Molecular profile
Lifestyle

Health records
Environmental data

Clinical trials
Epidemiology

Diagnostics & monitoring
Pharmacovigilance
Staff Working Document on
Use of '-omics' technologies in the development of personalised medicine

- The potential for, and issues with, the use of '-omics' technologies in personalised medicine, and the related EU research funding
- Recent developments in EU legislation for placing medicinal products and devices on the market
- Factors affecting the uptake of systems


Conclusions

- Horizon 2020 to address research challenges
- Efficient regulatory framework for medicines and in vitro diagnostics
- Robust HTA facilitate re-use of high quality joint work at National/regional level
  -> essential responses from the EU to the current challenges
  -> continued fruitful dialogue with all stakeholders
• The EU’s 2014-20 programme for research & innovation (around €80 billion)
• A core part of Europe 2020, Innovation Union & European Research Area
• Three priorities: Excellent science, Industrial leadership, Societal challenges

Horizon 2020

• Simplification:
  • Simpler programme architecture, a single set of rules
  • Easy to use cost reimbursement model: one project - one funding rate
  • Less paperwork in preparing proposals
  • Reduce time to grant by 100 days

• Inclusive approach:
  • More support for innovation and activities close to the market
  • Strong focus on creating business opportunities
  • New SBIR-like scheme dedicated to SMEs

• Renewed successful partnerships:
  • EDCTP
  • IMI
Funding instruments for health research in the EU funding programme Horizon 2020

**Excellent science**
- European Research Council
- Future and Emerging Technologies
- Marie Skłodowska Curie Actions
- Research Infrastructures

**Industrial leadership**
- Fast Track to Innovation
- Eureka Eurostars 2
- LEIT Biotech
- Financial instruments

**Societal Challenge 1 Health**
- Collaborative projects
- SME instrument
- IMI-2
- EDCTP-2
- AAL-2

Health, demographic change and wellbeing challenge
- Translate science to benefit citizens
- Test and demonstrate new healthcare models, approaches and tools
- Promote healthy and active ageing
- Improve health outcomes, reduce inequalities
- Support a competitive health sector

Over €7 billion to health research
Focus areas of 2014-2015 Work Programme

- Understanding health, ageing & disease
- Improving diagnosis
- Innovative treatments and technologies
- Effective health promotion, disease prevention, preparedness and screening
- Advancing active and healthy ageing
- Integrated, sustainable, citizen-centered care

Implementing personalised medicine in healthcare settings

**PHC 5 – 2014:** Health promotion and disease prevention: translating ‘omics’ into stratified approaches

- Develop and assess a personalized / stratified health promotion or disease prevention programme, taking into account the ‘omics’ characteristics of individuals, complemented by environmental and/or lifestyle factors
PHC 24 – 2015: Piloting personalised medicine in health and care systems

- Pilots of new models of care, based on the concept of personalised medicine
- Proposals should ensure coordination with national, regional or local authorities engaging in health sector reform
- Evidence for a validated model of organisation of care based on the concept of personalised medicine should be produced

PHC 30 – 2015: Digital representation of health data to improve disease diagnosis and treatment

Enable the use of Decision Support Systems by healthcare professionals for personalised prediction and decision in prevention, diagnosis or treatment and should take into account data protection and ethical considerations,..
Horizon 2020

Activities for SMEs

All forms of R&D and all forms of innovation, towards exploitation and commercialisation

- SME participation in collaborative R&D or innovation projects (all three priorities)
- SME instrument (applied in all societal challenges as well as the LEITs)
- Innovation in start-ups, spin-offs and young research-intensive companies (Eurostars and other measures)
- Access to risk finance (debt and equity facility)
- Exchange and mobility of researchers involving SMEs (Marie Curie actions)
- Links for access to procurements...

Horizon 2020

**Phase 1: Concept and feasibility assessment**

- Feasibility of concept
- Risk assessment
- IP regime
- Partner search
- Design study
- Pilot application intention
- Business plan II

  Lump sum: around 50,000 to 100,000 €
  ~ 6 months

**Phase 2: R&D, demonstration, market replication**

- Development, prototyping, testing
- Piloting innovative processes, products and services
- Miniaturisation/design of products
- Planning & developing scaling-up (market segments, process etc.)
- Market replication
- Business plan III

  Cost reimbursement: 1 to 3 MC EC funding
  12 to 24 months

**Phase 3: Commercialisation**

- Quality label for successful projects
- Facilitate access to private finance
- Support via networking, training, coaching, information, addressing i.a. IP management, knowledge sharing, dissemination
- SME window in the EU financial facilities (debt facility and equity facility)

No direct funding
**Topic of the SME instrument**

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

**Scope**

- All existing potential biomarkers are eligible.
- € 50 000 and 6 months – Phase 1
- Between € 1 and 5 million – Phase 2
- Duly justified duration (time for samples, patient follow up, etc.) – Phase 2

**Expected impact**

- Clinical availability and exploitation of biomarkers
- New diagnostic devices
- Improved diagnostics in the clinic and the market
- Enhancing profitability and/or growth performance of SMEs
- Support to revised IVD regulation...

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**Check list for participating in H2020**

- Find a topic (call for proposals) and find partners
- Check status register and provide documents for validation of legal entity (Appoint a LEAR; financial viability check in some cases)
- Address rules for participations (minimum number of participants, etc.) and check specific requirements in the work programme
- Read the provision of the standard Grant Agreement
- Plan exploitation and dissemination aspects, and address IPR issues (in the proposal and later in a consortium agreement)
- Address ethics issues (in particular if clinical trials)
Participant Portal— your one-stop shop

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

Innovative Medicines Initiative

- Up to €3.3 billion, shared equally between EU and industry
- Breakthrough vaccines, medicines and treatments
- For top quality research and innovation with great public health benefits and commercial possibilities
- Compared to IMI: more budget, broader scope and objectives, open to other industry partners
IMI 2 Priorities

Priority Themes
1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Enablers
Patient access to innovative solutions:
- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

Support Technologies
1. Imaging
2. ICT
3. Medical devices...

Overview of IMI's Calls for Proposals

two calls launched simultaneously in December 2014

IMI 2 - Call 3 (Stage 1 deadline - 24 March 2015)
- Remote assessment of disease and relapse (RADAR) - CNS
- Towards a quantitative biological approach for neuropsychiatry
- Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification
- The consistency approach to quality control in vaccine manufacture
- Pertussis vaccination research
- Knowledge repository to enable patient focused medicine development

IMI 2 - Call 4 (Stage 1 deadline - 11 Feb. 2015)
- Enabling Platform on Medicines Adaptive Pathways to Patients
How to take part in IMI projects

**Apply for funding**
- Look out for new IMI Calls
  - [www.imi.europa.eu](http://www.imi.europa.eu)
  - IMI newsletter
  - Twitter, LinkedIn
- Link up with other experts
- Read and understand the Call documents
  - Info sessions / webinars
  - Contact the IMI Programme Office
- Submit your proposal

**Contribute to IMI as an Associated Partner**
*Your contribution is matched by the EU*
- Read the IMI Strategic Research Agenda
- Identify points that match your priorities
- Contact the IMI Programme Office

Information about IMI2 funding opportunities

**EU Research Participants portal**

**Stay up to date about IMI2**

**Website:** [www.imi.europa.eu](http://www.imi.europa.eu)

**Twitter:** @IMI_JU
**Who are we looking for?**

- Consortia of a limited size: min. 3, max. 5 partners
- All of the partners should be legally established in the EU or in a Horizon 2020 associated country*, and partners must be from at least three different eligible countries
- Consortia must be industry-intensive:
  - *either* 2 out of 3/4 partners = private-for-profit
  - *or* 3 out of 5 partners = private-for-profit
  - *or* 60% of the budget of the proposal (=total estimated eligible costs) must be allocated to private-for-profit entities
- ... but can be composed of partners of any type of legal entity (industry, SMEs, first-time applicants...)
- EU funding cannot exceed EUR 3 million; 70% of funding for private-for-profit entities
- And last but not least...

* A list of Horizon 2020 associated countries is available via [this link](#).
Learn more & take part!

http://ec.europa.eu/programmes/horizon2020

Thank you

www.ec.europa.eu/research/health
www.ec.europa.eu/research/horizon2020