Personalised medicine at EU level

LUXCORE Health event

Irene Norstedt
Head of Innovative and Personalised Medicine
DG Research and Innovation
European Commission
Personalised medicine to address significant challenges...

...and benefit from opportunities

- Better outcomes for patients and potential cost savings (as suggested by early studies of stratified approach)
- Europe can lead implementation of personalised medicine thanks to favourable conditions

- Burden of non-communicable diseases (loss of €35 trillion over next 20 years)
- Pressure on healthcare systems
- Gap between EU and global innovation leaders
- Challenges of drug development in Europe
Personalised medicine at activities at EU level

2010: Preparatory workshops
2011: European Perspectives conference
2013: Commission Staff Working Document on "use of '-omics' technologies in the development of personalised medicine"
2015: Council conclusions on Personalised Medicine
2015: Strategic Research and Innovation Agenda of PerMed
2016: Personalised Medicine Conference
2016: Launch of International Consortium of Personalised Medicine

- 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

EU funding - over 2 billion EUR to top research
International Consortium for Personalised Medicine (ICPerMed)

WHAT
Collaboration of research funders and policy makers

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 Action plan based on PerMed Strategic Research Agenda (SRIA)

www.icpermed.eu
Next steps IC PerMed

- Work programme to implement the Action Plan
- ERA-Net Cofund in personalised medicine (ERA PerMed) – first call for proposals 2018 (up to 3 more calls)
- Database of EU wide personalised medicine activities (to inform funding priorities, funding strategies, policies)
- Mapping project – PM related initiatives
Framework for Personalised Medicine

R&D the basics
- "Omics" Technologies
- Data
- Samples
- Statistics

R&D stratifying tools
- Biomarkers Identification
- Qualification
- Validation
- Data modelling tools
- Technical aspects & challenges

R&D test in human
- Clinical trials methodologies
- Patient - recruitment

Towards the market
- Diagnostics & therapies
- Approval processes
- Regulatory aspects

Uptake in healthcare
- Pricing & Reimbursement
- Health economy
- HTA
- Novel models of healthcare organisation

In patients
- Availability & usability in the clinic
- Patient perspective
- Equal treatment
- Social and legal issues
- Education and training

Prediction - Prevention – Treatment - Cure
Rare diseases – a model for PM
Need for a coherent strategy – from bench to bedside

• More efficiently bring the results of research and innovation to the patient
• Programme to implement a research and innovation pipeline, from bench to bedside
• Integrative programme linking major EU and national initiatives – R&D, research infrastructures, registries
• Bridging to ERNs to help implementing research results and taking lessons learned from the clinic back to the bench
Rare diseases activities at EU level

Research and Innovation

Coordination of research

National plans, information, codification, patient registries, access to best care and knowledge
Genomic analysis and gene discovery
Standardized phenotypic data collection
Searchable catalogue of biosamples
Data linkage across resources

Overcoming Silos
Data sharing for research and better data analysis

Disease-causing variant can be identified using the genomics analysis platform
Sample is findable in the Sample Catalogue
Registry data in the ID-Cards directory of registries and biobanks
Pillar 1
Transnational calls for proposals to fund rare diseases research. Joint funding by EC and national funding agencies.

Pillar 2
Virtual platform for coordinated access, data exchange and repository facilities building on existing resources. Standards, analysis tools, links to care data. Pilots to ensure usefulness in clinical setting/ERNs.

Pillar 3
Training and support on data management, product development, translational research etc. for stakeholders including patient organisations. Sharing best practices. Tech transfer facility towards industry.