



# Connecting Europe for Genomic Health

**FEAM Spring Conference 20.05.2016**

**Dr Elmar Nimmesgern, Deputy Head of Unit  
Innovative and Personalised Medicine**

**DG Research & Innovation**

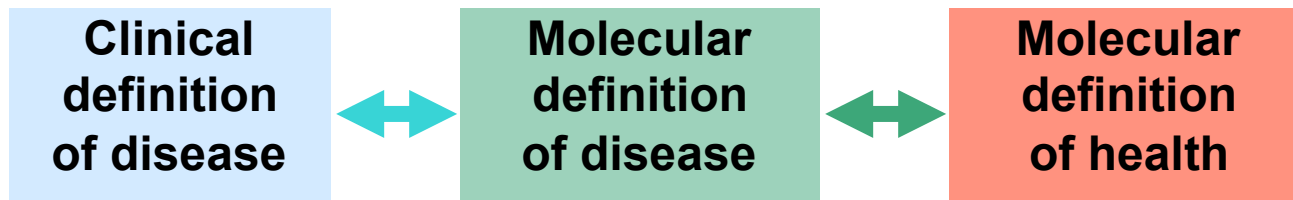
**European Commission**

# Personalised Medicine: Towards a definition ...

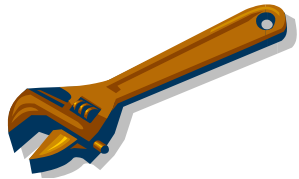
***"Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to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

## ... 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"**



# Clinical development: need to look at the entire innovation ecosystem



## Our EU-level toolbox:

**Funding**

**Policy**

**Regulation**

**Prediction - Prevention – Treatment - Cure**

# 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:*



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)



Maternal and  
child health  
(2016-2017)

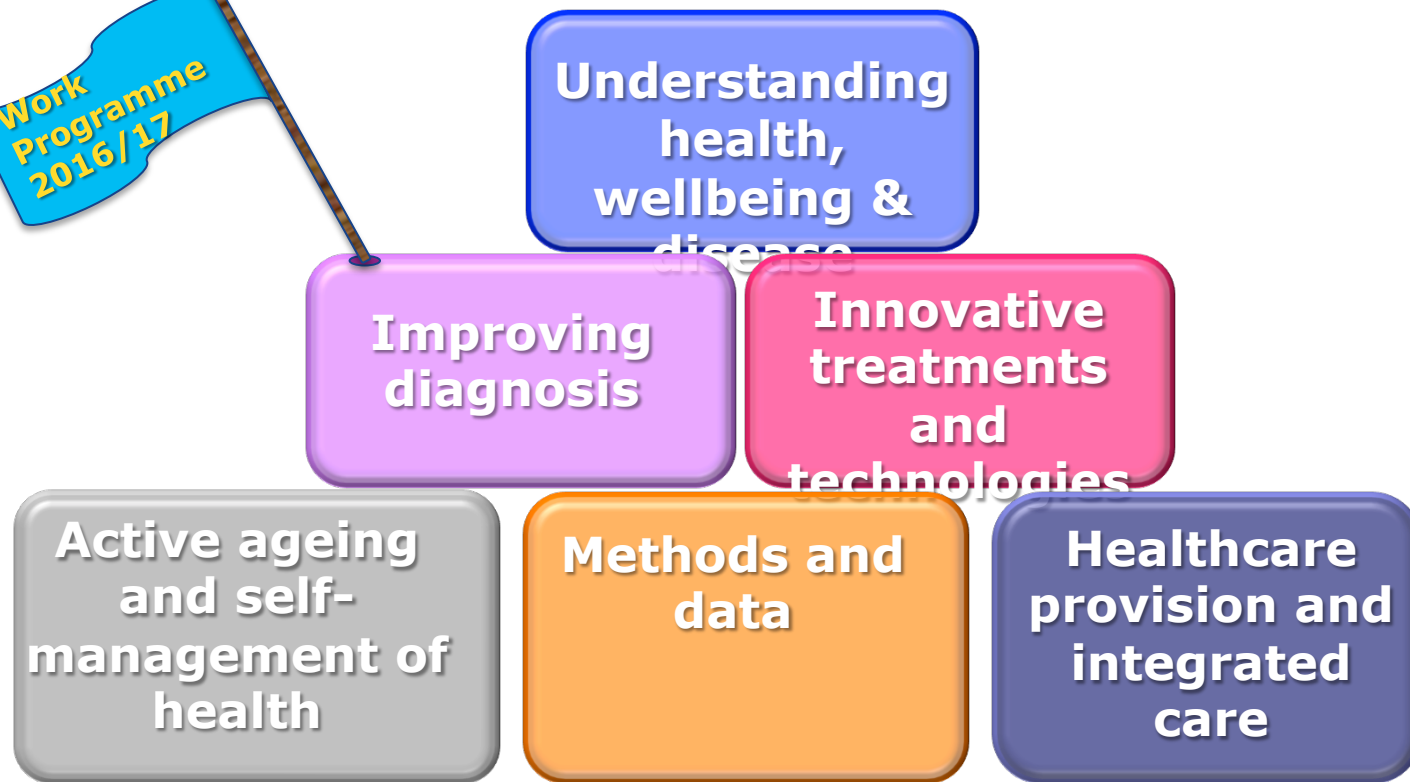
# Rare diseases policy as a testing ground for personalised medicine

- **Use of genetic and genomic information in health care**
  - Quality of genetic testing
  - Ethics
  - Data sharing
- **Clinical trials on small populations**
- **Development of clinical guidelines**





# What we are doing in Horizon 2020





# 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

# Project funded from SME Instrument



European  
Commission

Idea



Phase 1

Feasibility  
Assessment

Phase 2

Innovation /  
R&D project

Phase 3

Commercialisation

Market



## ADDIA

**Validation of a fast and simple peripheral blood diagnostic biomarker kit for Alzheimer's disease**  
**Amoneta Diagnostics**

- **Validation** of a blood-based biomarker kit for **diagnostic** of Alzheimer's disease
- **Proof-of-Performance clinical study** in 800 human subjects, including 400 AD patients

**A validated and CE registered IVD biomarker assay will be available and ready for clinical application**



European Commission

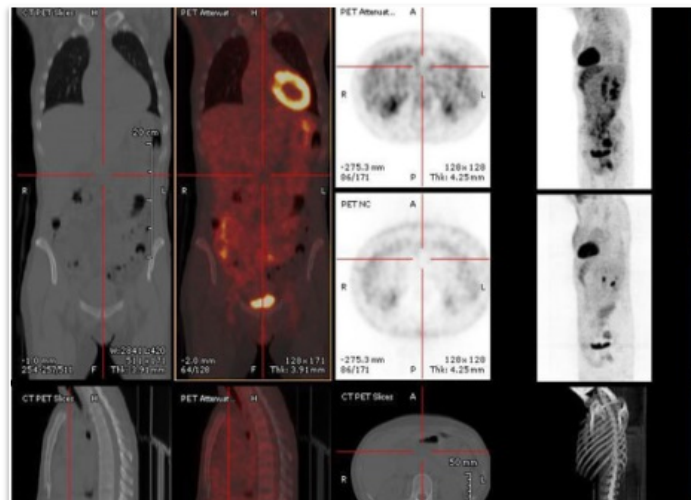


# Example of public-private partnering: Innovative Medicines Initiative

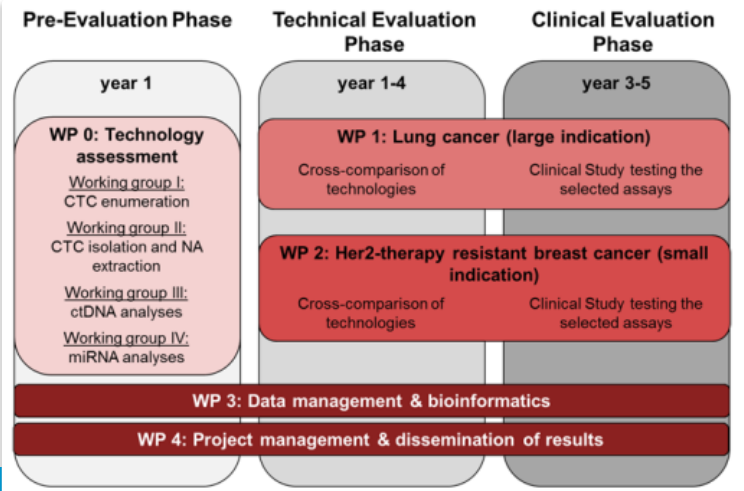
- *Tools for cancer genomic medicine:*
- *QuIC-ConCePT standardises biomarkers for early-stage cancer drug development and advances personalised cancer medicines research*
- *CANCER-ID establishes standard protocols for blood-based biomarkers, paving the way for personalised medicine for different types of cancer*



## Imaging biomarkers



## Circulating tumour biomarkers



# Enabling success through learning and coordination

Identify common strategic goals

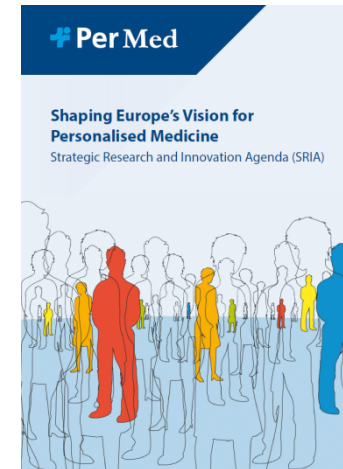
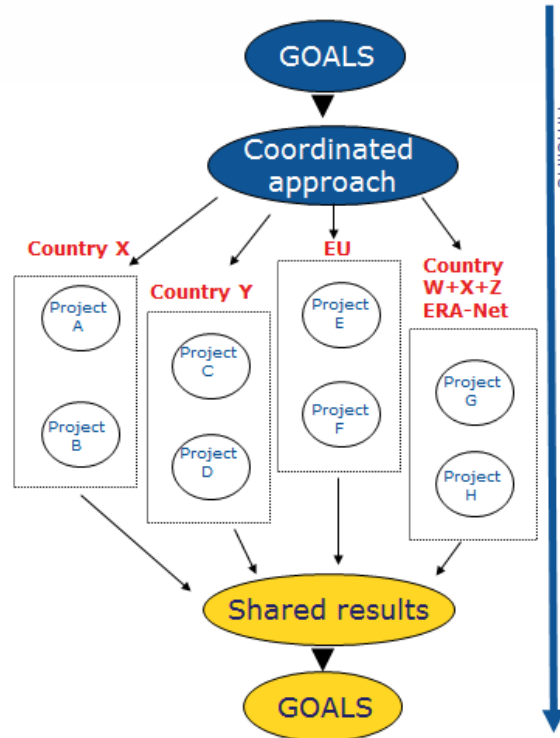
Agree to share tasks (and costs) for coordination

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



# 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)



# 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**

**Last days to register:** <http://ec.europa.eu/permed2016>



# Related policy actions

***Joint action on Comprehensive Cancer control***

***Study on Big data***

***Expert group on Safe and Timely Access to Medicines for Patients***

***Support to HTA cooperation on EU level:  
forthcoming Reflection Paper on Personalised  
medicine and co-dependent technologies***

***Exchange of information on pricing and reimbursement:  
Study on enhanced cross country coordination in the  
area of pharmaceutical product pricing***



**[Elmar.Nimmesgern@ec.europa.eu](mailto:Elmar.Nimmesgern@ec.europa.eu)**

**<http://ec.europa.eu/research/health>**

**<http://ec.europa.eu/programmes/horizon2020>**