Personalised Medicine

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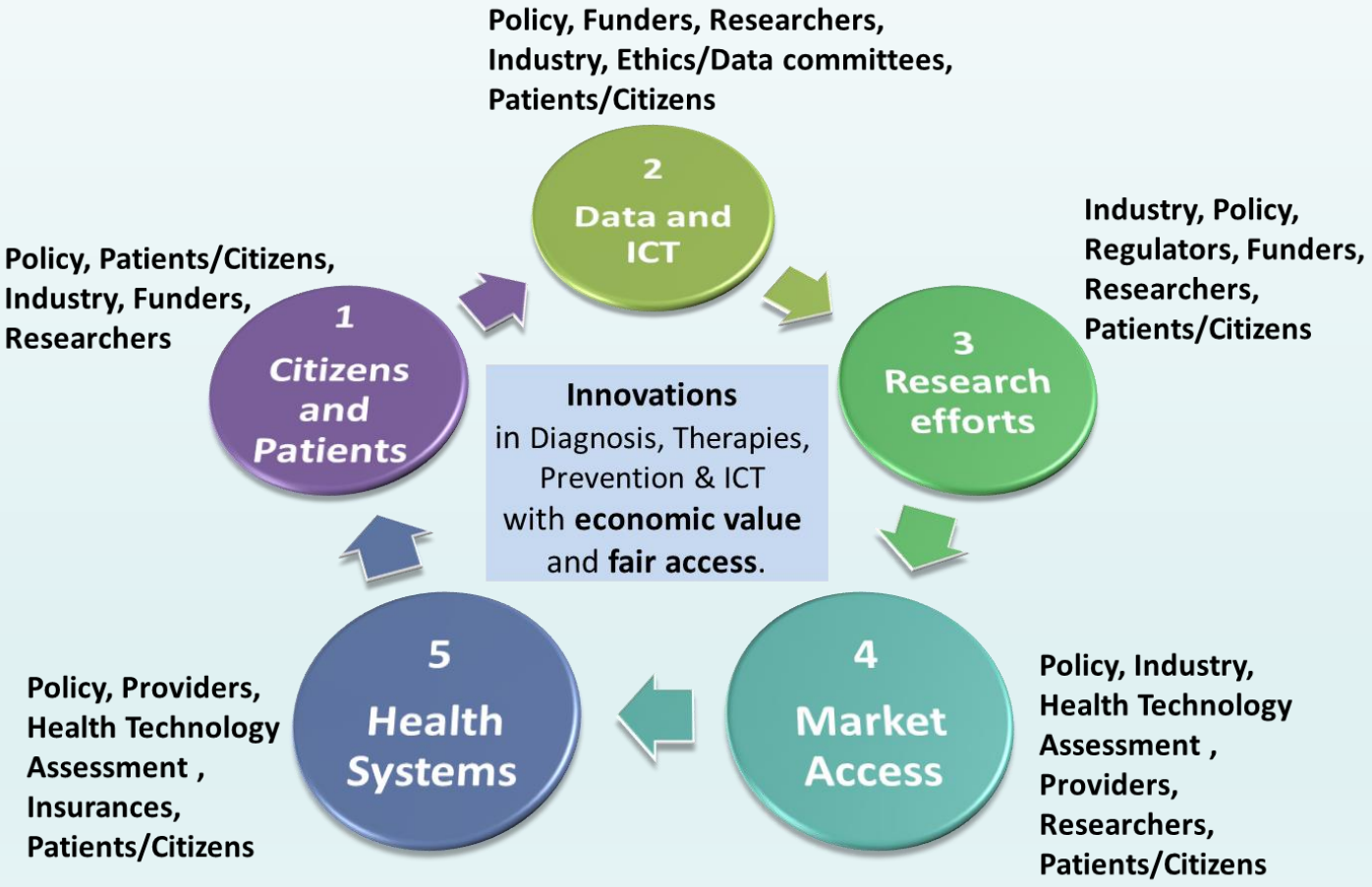
Personalised Medicine

- *Issues at stake:*
  - Need to contain healthcare costs
  - Opportunity to make better use of the accumulating data
  - Increased involvement of citizens in managing their health
  - Improved utilisation of limited resources and capacities
  - Addressing avoidable negative effects

Circle of the five Challenges



One size doesn't fit all

- *Only 25 to 80 % of patients respond to common drugs*
- *5-7 % of all hospital admissions result from adverse drug reactions*

"Take them until further testing shows they really aren't effective."

Ubiquitous Pharmacogenomics: Making actionable pharmacogenomic data and effective treatment optimization accessible to every European citizen

Pre-emptive genotyping of multiple pharmacogenes

Data collected prospectively and embedded into the electronic records of patients in NL, ES, UK, IT, AT, EL, SI

Prescribers and pharmacists alerted through electronic clinical decision support systems when a drug is ordered or a patient with an at-risk genotype

Analysis of cost-effectiveness and health outcomes

~ 4000 patients recruited to date

The biggest study of this type in the world

- **Works anywhere in the world (internet access sufficient).**
- **Make PGx data available even in health care systems with no EHRs.**
- **No central patient data storage, GDPR compliant.**

EU contribution: 15M EUR
Duration: 2016-2020
Coordinator: HJ Guchelaar, UMC Leiden

European Commission

Changing breast cancer clinical practice

FP6, 2002-2006

Horizon 2020, 2014-2020

€ 7 million

Validation of the 70-gene signature

€ 4 million

2015: MammaPrint final clinical utility

TRANSBIG

2002: 70-gene signature published

2007: FDA approves Mammaprint

2007 → **2011**

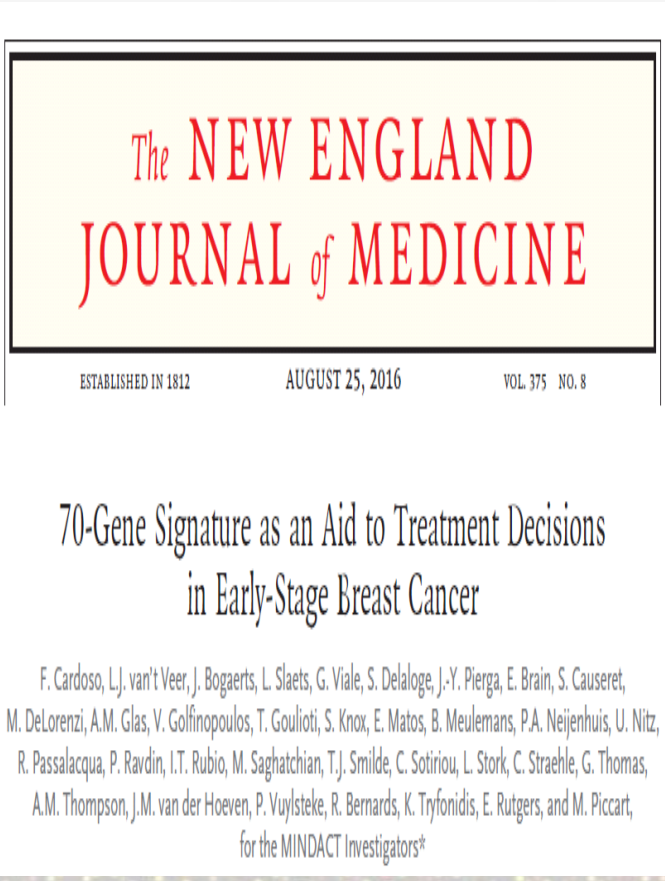
MINDACT trial : Microarray In Node negative Disease may Avoid ChemoTherapy

MINDACT

Leveraged funds: € 43 million

Mammaprint may reduce chemotherapy prescription post-surgery by 46% in high-risk group

Phase III CT 6693 women enrolled


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 25, 2016 VOL. 375 NO. 8

70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer

F. Cardoso, L.J. van't Veer, J. Bogaerts, L. Slaets, G. Viale, S. Delaloge, J.-Y. Pierga, E. Brain, S. Causeret, M. DeLorenzi, A.M. Glas, V. Golfinopoulos, T. Goulioti, S. Knox, E. Matos, B. Meulemans, P.A. Neijenhuis, U. Nitz, R. Passalacqua, P. Ravdin, I.T. Rubio, M. Saghatchian, T.J. Smilde, C. Sotiriou, L. Stork, C. Straehle, G. Thomas, A.M. Thompson, J.M. van der Hoeven, P. Vuylsteke, R. Bernards, K. Tryfonidis, E. Rutgers, and M. Piccart, for the MINDACT Investigators*

THE MINDACT TRIAL

EUROPEAN JOINT PROGRAMME ON RARE DISEASES EJP RD

- *Research and innovation pipeline for rapid translation of research results into clinical applications and uptake in healthcare for the benefit of patients*
- *Research funders, universities, research institutes, research infrastructures, hospitals from ERNs and patient organisations from 35 countries (including 27 EU Member States, 7 Associated Countries and Canada)*
- *Joint Transnational Calls for rare diseases research projects: JTC 2019 launched*
- *Virtual platform for rare diseases research data, information and tools*
- *Capacity building, training, facilitation of partnerships, validation of new methods for clinical trials*

EU contribution 55M EUR for 2019-2023

RESEARCH FUNDING	COORDINATED ACCESS TO DATA & SERVICES FOR RESEARCH	CAPACITY BUIDLING & EMPOWERMENT	ACCELERATING TRANSLATION OF RESEARCH & THERAPY DEVELOPMENT

www.ejprarediseases.org

European Commission

Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

- *Pre-Commercial Procurement – 16 April 2019*
- *Aims is to implement NGS in routine diagnosis for personalised medicine and scale up demand-driven innovation for health care systems*
- *Two proposals selected (ca 10M€ each) currently under grant agreement preparation*

Nomen est omen

Whether we talk about Individualised Medicine, Precision Medicine, Personalised Health, Stratified Medicine or …

The importance is that we know what we are talking about

Since 2015 the EU has used the term "Personalised Medicine" with a very wide definition

European Council conclusions on Personalised Medicine (PM) for patients (2015/C 421/03)

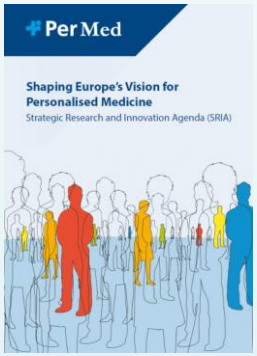
"Personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease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

Definition developed by the Advisory group for the H2020 Health, demographic change and well-being challenge

International Consortium for Personalised Medicine

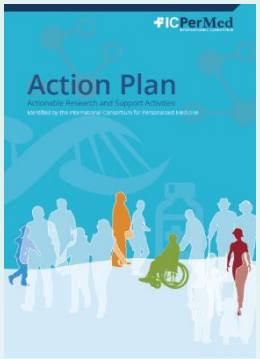
WHAT

- 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)

Members active in the IC PerMed

·28 countries and 4 regions
· 11 Health Ministries
· 6 Science and Education Ministries

- Austria
- Brazil
- Canada + *British Columbia Region*
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- EU as observer
- Finland
- France
- Germany
- Hungary
- Ireland
- Israel
- Italy + *Lombardy Region*
- Lithuania
- Luxembourg
- Moldova
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovenia
- Spain + *Regions Basque Country & Navarre*
- Sweden
- Switzerland
- Turkey

Research and Innovation

EC projects are helping to drive the area forward and structure it:

- *Setting up the cooperation: PERMED (2013-2015)*
- *Running the secretariat: ICPerMed (from 2016)*
- *Funding an ERA-Net: ERA PerMed (from 2017)*
- *Supporting regional cooperation*
- *International outreach; CELAC, China, Africa*
- *Addressing health economy; HEcoPerMed*
- *New clinical trials models*
- *PM demonstration pilots*
- *A multitude of research and innovation projects*

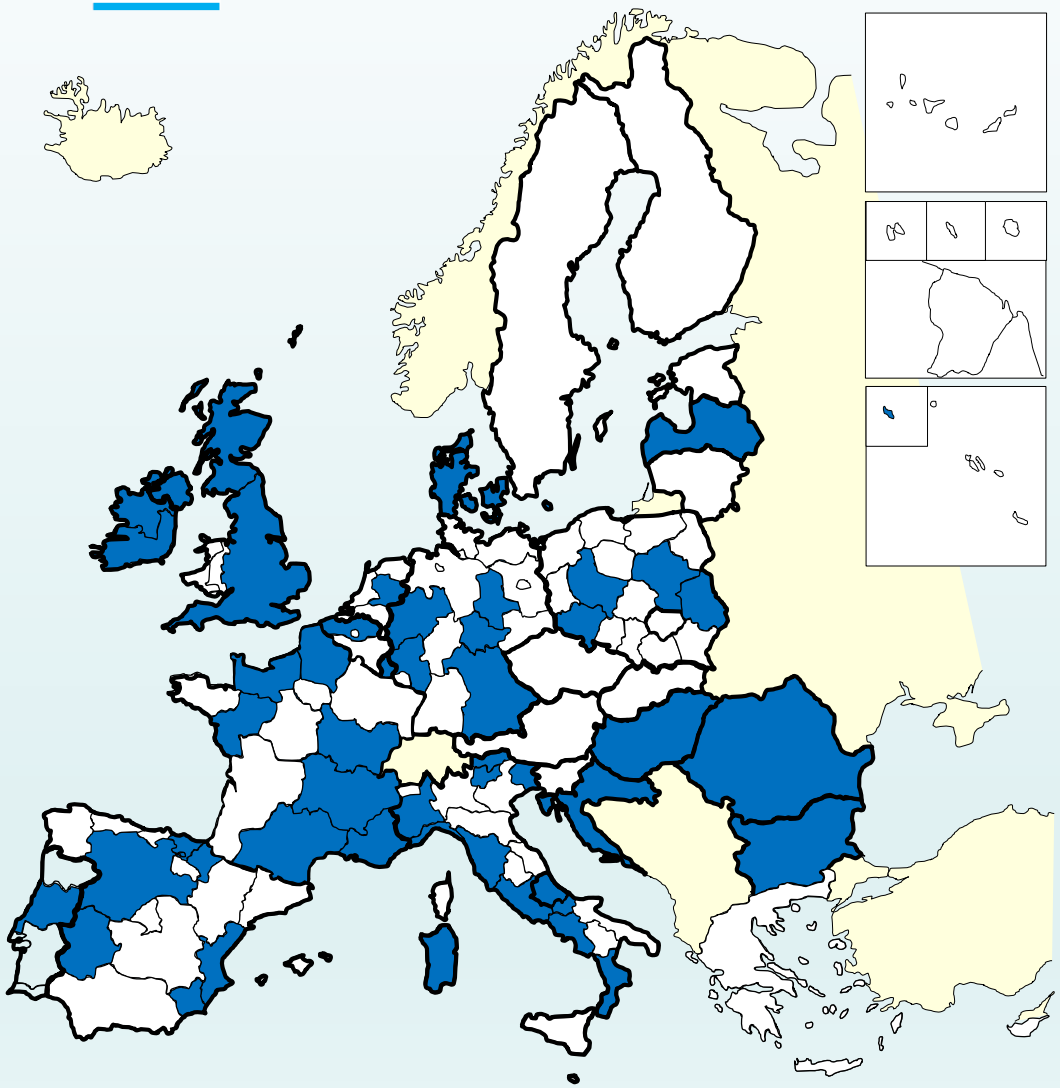
European Commission

Personalised Medicine in the RIS3 priorities

53 RIS3 out of the 135 analysed, explicitly prioritise **Personalised Medicine (38%)**

No Personalised Medicine priority

Personalised/stratified/precision Medicine priority



Research and Innovation

Three pillars in digital health and care

- ***Electronic health records:*** *secure access, possibility to share across borders; and the use of e-prescriptions*
- ***Data infrastructure****: to advance research, disease prevention and personalised health and care in key areas including rare, infectious and complex diseases*
- ***Feedback and interaction between patients and healthcare providers****: to support prevention, citizen empowerment, quality and patient-centred care; focus on chronic diseases and outcomes of healthcare systems*

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% agree — To access their own health data (requiring interoperable and quality health data)

80% agree — To share their health data (if privacy and security are ensured)

80% agree — To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data

Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

#DigitalSingleMarket #DigitalHealth @eHealth_EU @EU_Health

Declaration "Towards access to at least 1 million genomes in the EU by 2022"

The EC supports Member States in setting up a voluntary coordination mechanism of public authorities to link ongoing genomic medicine initiatives. The coordination mechanism will:

- Define a governance model of the cooperation, particularly concerning the terms and conditions for distributed access to genomic data across-borders, usage of the data and others;
- Support the development of technical specifications for secure access and cross-border exchange of genomic datasets within the internal market; and
- Facilitate interoperability of relevant registries and databases to support personalised medicine research

Articles and videos on our activities

- Perspective for the Journal Personalised Medicine: ***'Enabling personalised medicine in Europe by the European Commission's funding activities'*** www.futuremedicine.com/doi/full/10.2217/pme-2017-0003

- Clinical and Translational Sciences: ***'Personalised Medicine in Europe'*** http://onlinelibrary.wiley.com/doi/10.1111/cts.12446/full

- Video ***'How co-operation paves the way for personalised medicine'***, issued by the American Society for Human Genetics (ASHG) for the ASHG conference in Orlando, October 2017: https://youtu.be/vSpSwLZ54nY

Personalising healthcare: Focusing on citizens' health - European Commission

WebsEdgeHealth • 2K views • 1 year ago

How co-operation paves the way for **personalised medicine**. Innovative and **Personalised Medicine** Unit Directorate E - **Health** ...