



EP PerMed
European Partnership
for **Personalised Medicine**

ICPerMed
INTERNATIONAL CONSORTIUM

ICPerMed & EP PerMed Conference on Personalised Medicine Research
Day 1, 26 November 2025

SESSION 1

Irene Norstedt

Retired/Active Senior | European Commission

European efforts towards personalised
medicine over the last decade



1st ICPeMed & EP PerMed Joint Conference
November 26th, 2025, Prague

EUROPEAN EFFORTS
TOWARDS

Personalised Medicine

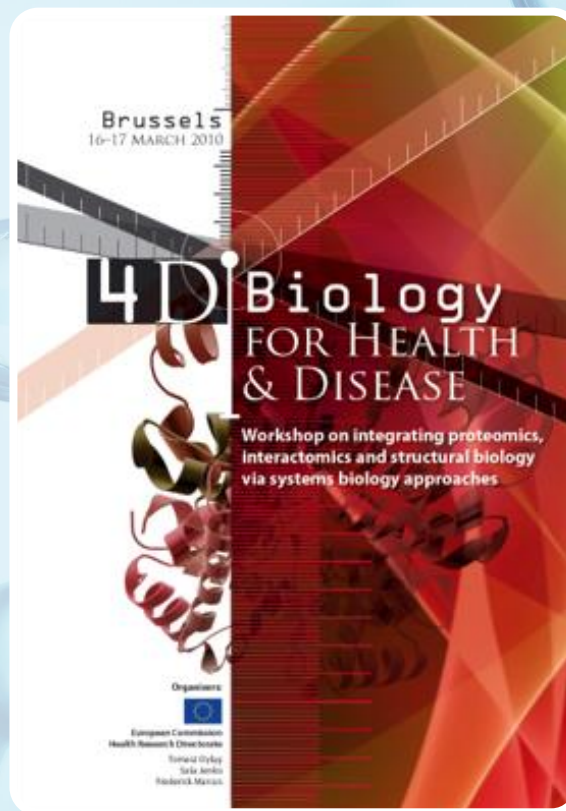
OVER THE LAST DECADE

Irene NORSTEDT

*Active Senior, ex-Director - People, Health and Society Directorate
DG Research and Innovation, European Commission*



How it all started: 2010 workshops



Leading up to: Our first EU wide conference “European Perspectives in Personalised Medicine” 2011



“Personalised medicine can bring significant benefits for both patients and health care providers but challenges across the innovation cycle from basic research through to the uptake in the health care setting need to be overcome.

Due to their nature these challenges will need to be addressed at European, national, regional and local levels.”

Commission Staff Working Document 2013

Use of '-omics' technologies for the
development of personalised medicine



EUROPEAN
COMMISSION

Brussels, 25.10.2013
SWD(2013) 436 final

COMMISSION STAFF WORKING DOCUMENT

Use of '-omics' technologies in the development of personalised medicine



EU support for personalised medicine

POLITICAL PUSH

EU Council conclusions
of 7 December 2015
([15054/15](#))

FUNDING

R&I Framework Programmes
FP7, Horizon 2020,
Horizon Europe, IMI/IMI2/IHI,
EU4Health, Digital Europe, ...

COOPERATION

Facilitation of several new initiatives
and knowledge transfer
(e.g. 1+ Million Genomes,
International Consortium on
Personalised Medicine - ICPeMed),
International Rare Diseases
Research Consortium (IRDiRC))

LEGISLATION

Proposals for new legal acts on data
(EuropeanHealthDataSpace, AI Act,
Data Governance Act, Data Act,
Cybersecurity Act) and review of
existing legal acts (e.g. pharma
package, orphan medicines, HTA)

EU adopted personalised medicine definition 2015



Council of the
European Union

Brussels, 7 December 2015
(OR. en)

15054/15

SAN 428

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
On:	7 December 2015
To:	Delegations
No. prev. doc.:	14393/15
Subject:	Personalised medicine for patients – Council conclusions (7 December 2015)

...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.



Personalised Medicine Conference 2016

Resulting from strengthened cooperation between EU member states and the European Commission

Five focus areas:

- Developing Awareness and Empowerment
- Integrating Big Data and ICT Solutions.
- Translating Basic to Clinical Research and Beyond
- Bringing Innovation to the Market
- Shaping Sustainable Healthcare

Launch of the International Consortium for Personalised Medicine



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)
- ERA PerMed 2017 for cooperation between funders
- Horizon 2020 complementary funding



Partnerships for co-funding personalised medicine research

ERA PerMed 2017-2023

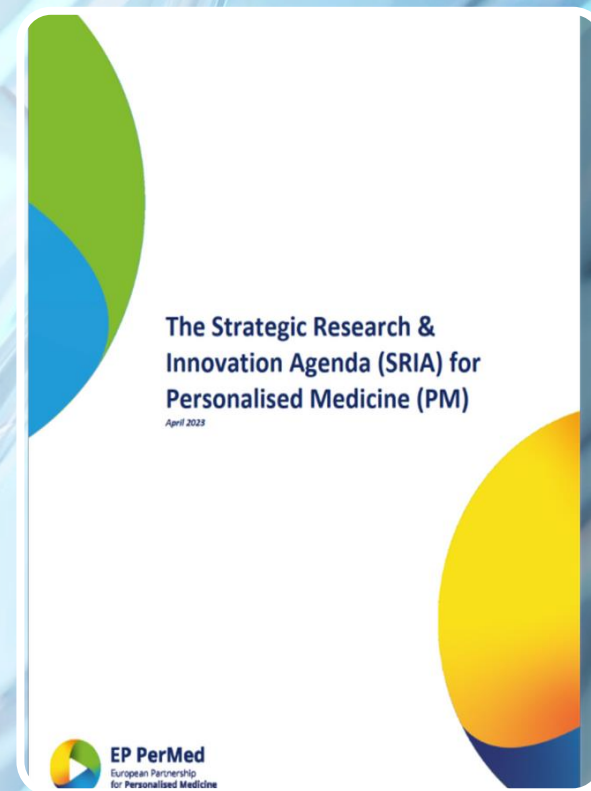
23 partners from 23 countries

>EUR 140 million

EP PerMed 2023 –

>50 partners

>EUR 300 million



Horizon 2020 complementary actions supporting IC PerMed

HEcoPerMed

Healthcare- and pharma-economic models in support of the International Consortium for Personalised Medicine

EULAC-PerMed

Widening EU-CELAC policy and research cooperation in Personalised Medicine

IC2PerMed

Integrating China in the International Consortium for Personalised Medicine

SAPHIRE

Securing Adoption of Personalised Health in REgions

SINO-EU-PerMed

Widening Sino-EU policy and research cooperation in Personalised Medicine

ICPerMed Secretariat

Secretariat for the International Consortium for Personalised Medicine

REGIONS4PERMED

Interregional coordination for a fast and deep uptake of Personalised Health

PERMIT

PERsonalised Medicine Trials

EU-Africa PerMed

Building links between Europe and Africa in Personalised Medicine



Increased political attention – Council presidencies



SWEDISH PRESIDENCY

“Life sciences - The era of
personalised medicine”

Stockholm, 26-27 June
2023



SPANISH PRESIDENCY

“Genomics-based health
strategies: towards
personalised and precision
medicine”

Valencia, 5-6 October 2023



BELGIAN PRESIDENCY

“The convergence of
technologies enabling R&I
for the healthcare of the
future”

Brussels, 28-29 May 2024

National law on personalised medicine

- On May 24, 2023, the Romanian President has promulgated a law **supplementing the earlier Law for patients' rights** no 46/2003
- The bill introduces two new articles, **defining personalised medicine and introducing personalised medicine as the right of every patient**
- Ensuring **fair access of patients to personalised medicine** (to personalised treatments and to personalised prevention services)
- Creating the framework for the **implementation of new technologies** including new drugs

EU-wide funding schemes and research initiatives supporting personalised medicine



1+MillionGenomes



From research project to implementation?

How can we move from interesting research results to practical implementation for better health outcomes?

On example – use of pharmacogenomics in a regulatory context



From research project to implementation?

EU-funded project demonstrates the clinical utility of pre-emptive pharmacogenetic testing

Setup

- Clinical study to test personalised drug prescribing and dosing, based on DNA sequencing data
- Analysis of 39 drugs, against the panel of 12 genes and 50 types of genetic variants
- Almost 7000 patients sequenced and tested in real-life healthcare
- Piloted in seven countries: Austria, Greece, Italy, the Netherlands, Slovenia, Spain, UK
- Several therapeutic areas: general medicine, oncology, cardiology, psychiatry...
- Project coordination: Leiden University Medical Center (prof. Henk-Jan Guchelaar)

Findings

- Patients experience **30% fewer side effects when drug dosing is tailored to patient's DNA sequence**
- Drug prescription based on DNA sequencing is feasible across European healthcare systems
- Need for wide-scale implementation in healthcare



safety-code
The Medication Safety Code initiative

What is it?
The Medication Safety Code on the left represents a patient-specific genetic profile regarding important pharmacogenes.

How does it work?
After scanning the QR code (e.g. with a smartphone), you are led to a website that displays patient-specific drug dosing recommendations.

www.safety-code.org

Laboratory contact
+0123456789
Some lab name
Some street name 123/45
1234 Some city name

U-PGx | Ubiquitous Pharmacogenomics

safety-code
The Medication Safety Code initiative

Name: Jane Doe
Date of birth: 01.02.1934

Gene, status	Critical drug substances (modification recommended!)
CYP2C19 Poor metabolizer	Clopidogrel, Sertraline
CYP2D6 Ultrarapid metabolizer	Amitriptyline, Aripiprazole, Clomipramine, Codeine, Doxepin, Haloperidol, Imipramine, Metoprolol, Nortriptyline, Paroxetine, Propafenone, Risperidone, Tamoxifen, Tramadol, Venlafaxine
TPMT Poor metabolizer	Azathioprine, Mercaptopurine, Thioguanine
Other genes Not actionable	ABCB1, ADRB1, BRCA1, COMT, CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP3A4, CYP3A5, DPYD, G6PD, HMGCR, P2RY12, SULT1A1, UGT1A1, VKORC1

Date printed: 15.03.2016 Card number: 0000001



15 million EUR budget



2016-2021



22 partners



A 12-gene pharmacogenetic panel to prevent adverse drug reactions: an open-label, multicentre, controlled, cluster-randomised crossover implementation study



Jesse J Swen, Cathelijne H van der Wouden, Lianne EN Manson*, Heshu Abdullah-Koolmees, Kathrin Blagec, Tanja Blagus, Stefan Böhringer, Anne Cambon-Thomsen, Erika Cecchin, Ka-Chun Cheung, Vera HM Deneer, Mathilde Dupui, Magnus Ingelman-Sundberg, Siv Jonsson, Candace Joefield-Roka, Katja S Just, Mats O Karlsson, Lidija Konta, Rudolf Koopmann, Marjolein Kriek, Thorsten Lehr, Christina Mitropoulou, Emmanuelle Rial-Sebbag, Victoria Rollinson, Rossana Roncato, Matthias Samwald, Elke Schaeffeler, Maria Skokou, Matthias Schwab, Daniela Steinberger, Julia C Stingl, Roman Tremmel, Richard M Turner, Mandy H van Rhenen, Cristina L Dávila Fajardo, Vita Dolžan, George P Patrinos, Munir Pirmohamed, Gere Sunder-Plassmann, Giuseppe Toffoli, Henk-Jan Guchelaar, on behalf of the Ubiquitous Pharmacogenomics Consortium†*



**Lancet February 2023; 401: p. 347–56
+ Comment p. 320**



Next steps in pharmacogenomics?

- **Regulatory & uptake:**

First briefing meeting of U-PGx at the EMA
Innovation Task Force (May 2023)

- **Scientific:**

Polypharmacy & multi-drug adverse reactions



<https://www.safepolymed.eu/>

Improve Safety in Poly medication
by Managing Drug-Drug-Gene Interactions



5.6 million EUR budget



2022-2025



13 partners



Pharmacogenomics - multistakeholder workshop



Recommendations and next steps:

- additional regulatory action
- facilitating uptake in health care
- leverage genomic and real world data
- increase impact of project results

Summary and presentations at EMA homepage and
**Article in Nature Reviews Drug Discovery 21
Nov 2025:**

[Joint EC/HMA/EMA multi-stakeholder workshop on
pharmacogenomics | European Medicines Agency \(EMA\)](#)

[Advancing pharmacogenomics in medicines regulation and
clinical practice: a call for collaborative action](#)



A driver for personalised medicine development - cancer

EU Cancer mission's unique approach: connect R&I and care, engage with citizens in projects and other activities, create project clusters, focus on end-users, work across sectors

PANCAID

Develop a composite blood multi-marker panel that is sensitive and specific enough to detect **Pancreatic Ductal Adenocarcinoma** via a blood draw at earlier stages than current diagnostic measures – patients benefit from more personalized screening

ONCOSCREEN

Personalised **Risk Stratification** methodology for colorectal cancer

SANGUINE

A minimally-invasive, fast, cost-effective, patient centric, highly sensitive screening and monitoring tool for blood cancers using detection technology that combines several types of epigenetic biomarkers

17 Pragmatic Clinical Trial Projects Testing Better Diagnostic and Treatment Interventions (and more to come)

● SAGITTARIUS

Liquid biopsy (LB), a new innovative assay for detecting the circulating tumor DNA (ctDNA) in the blood, to **personalize the post-surgical care** of patients with loco-regional **stage III and high-risk stage II colon cancer (LRCC)**

● PRIME-ROSE

Access to affordable Precision Cancer Medicine (PCM) that prolongs life at the best quality possible for all cancer patients

● MONALISA

A SIOPEX pragmatic clinical trial to **MONitor NeuroblastomA relapse with Liquid biopsy Sensitive Analysis**



Personalised medicine with rare diseases as a model for clinical trials

- Clinical trials for small populations

*“...In certain areas such as rare diseases, including rare cancers, where **target populations of new medicines are often very small**, a proportion of marketing authorisation applications are submitted to EMA with **clinical data from single-arm trials as pivotal evidence**.”*

- Patient-centric adaptive platform trials: Integrated Research Platforms (rare disease neurofibromatosis as one of case studies)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<https://www.ema.europa.eu/en/news/single-arm-trials-pivotal-evidence-authorisation-medicines-eu>



EU-PEARL
EU PATIENT-CENTRIC
CLINICAL TRIAL PLATFORMS



Personalised medicine – equalities in clinical research

Rethinking the actual approach to clinical studies holistically (READI)

Clinical research should actively include population groups facing health disparities, such as ethnic, sexual and gender, as well as age diversity or socioeconomically disadvantaged groups identified as **underserved and underrepresented communities**.



<https://ihi-readi.org/>

READI project aims to promote a less fragmented, and more democratic ecosystem around clinical studies in Europe by engaging critical stakeholders in the process of inclusion of underserved and underrepresented populations in clinical studies



66 million EUR budget



2025-2030



>70 partners



Pre-commercial procurement: Instand-NGS4P



<https://www.instandngs4p.eu/>

Integrated and Standardized NGS
Workflows for Personalised Therapy
Bringing together the demand and supply
in healthcare

Personalised Medicine and Women's Health

- Cardiovascular risk assessment in menopausal women via multimodal data analysis enabling personalized prevention strategies
- CVD remains underdiagnosed and undertreated in women
- Integrate clinical records, medical imaging, wearable sensor data, lifestyle information...
- Develop AI models to assess risk and tailor personalised prevention plans



<https://www.caramel-project.eu/>



				
5	25	11	6	6.000
Years	Partners	Countries	Clinical sites	Women involved



A developing area: personalised prevention

- A **Personalised Prevention Roadmap for healthcare**, to support the definition and implementation of innovative, sustainable personalised strategies to prevent chronic diseases
- A **mapping** of the **existing predictive biomarkers** for chronic diseases with major burden in the EU:
 - in terms of analytical and clinical validity
 - but also in terms of clinical utility
- SRIA available on the project website



<https://www.prophetproject.eu/>



Thank you!

#HorizonEU

<https://ec.europa.eu/horizon-europe>



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