
Improving Safety in Polymedication by Managing Drug-Drug-Gene Interactions

Patient involvement in quality and safety research

26 September 2023

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Status Quo

26–40%
of elderly
take >5 drugs
concomitantly¹

197,000
deaths
due to ADRs²

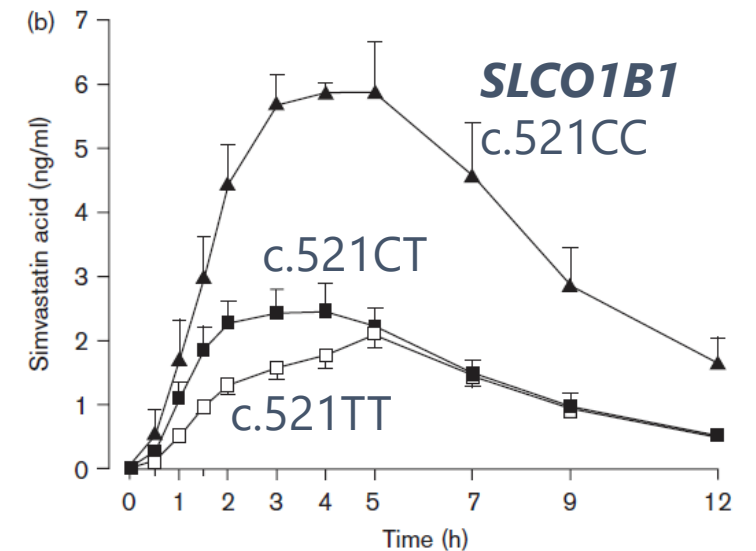
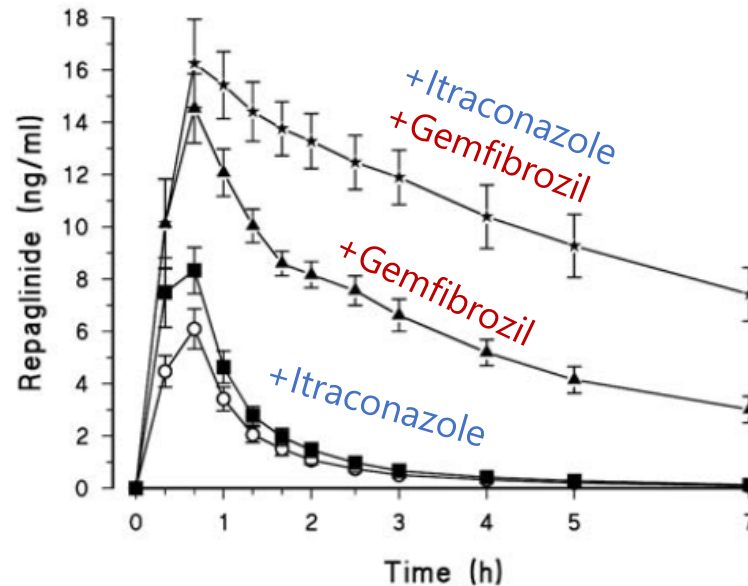
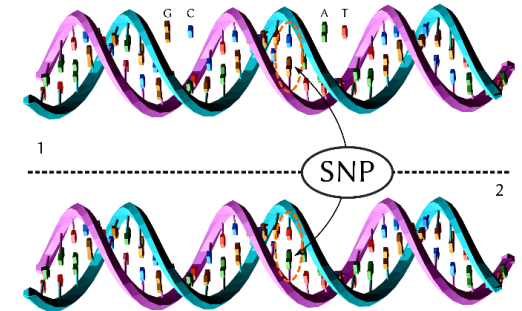
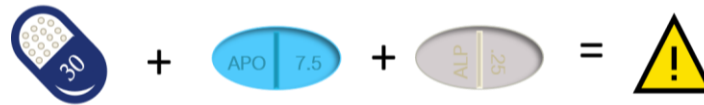
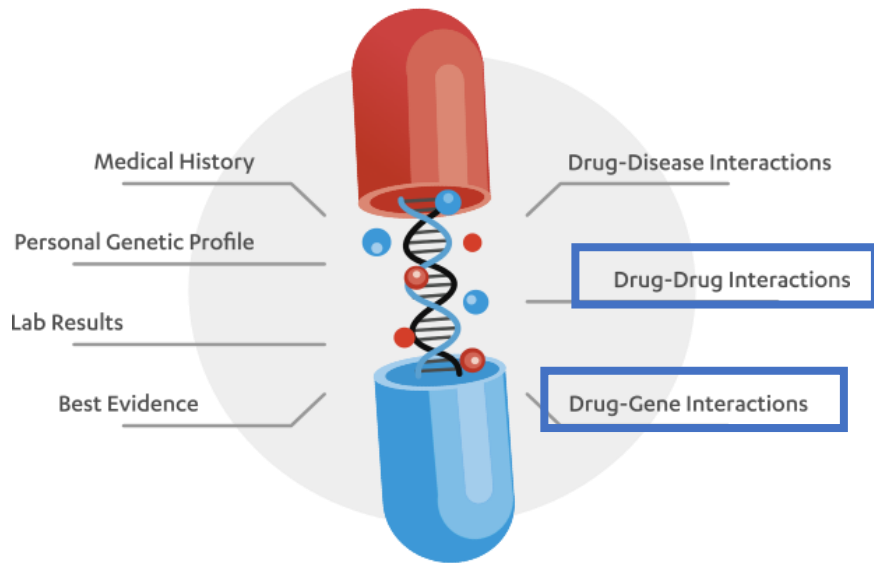
79bn €
HC cost
due to ADRs
annually²

>65%
of ADRs
due to DDIs³

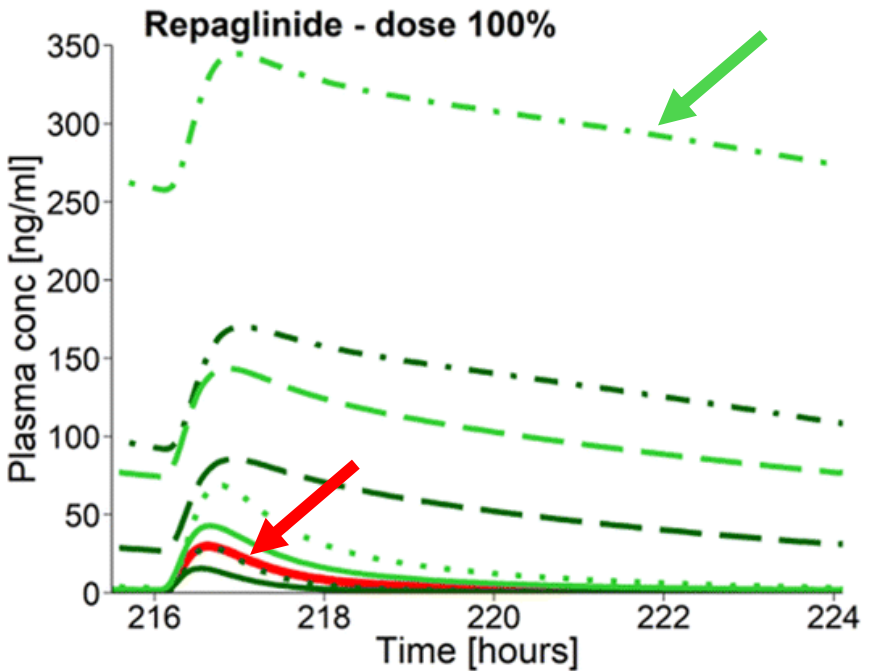
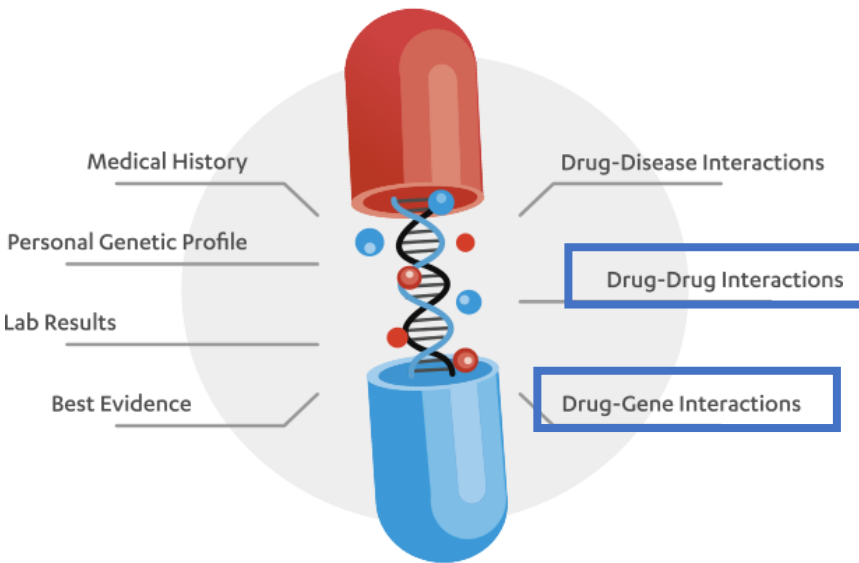
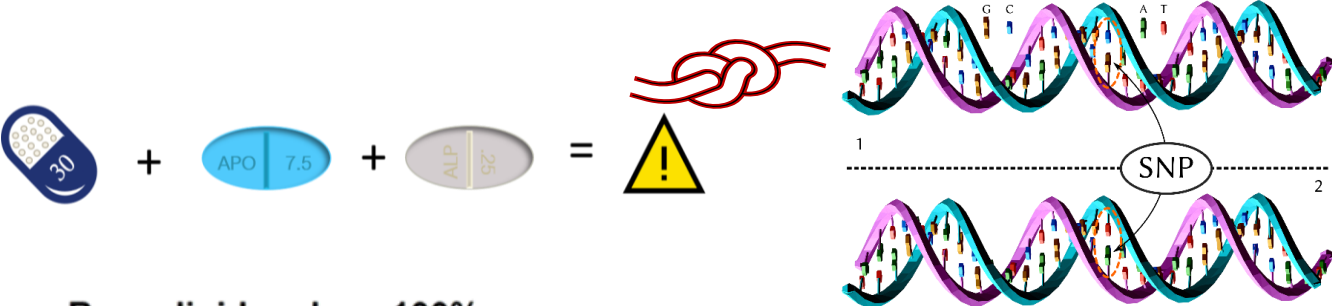
>60%
of ADRs
due to DGIs⁴



Drug-Drug (DDI) and Drug-Gene Interactions (DGI)



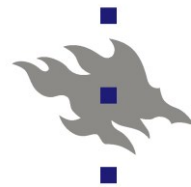
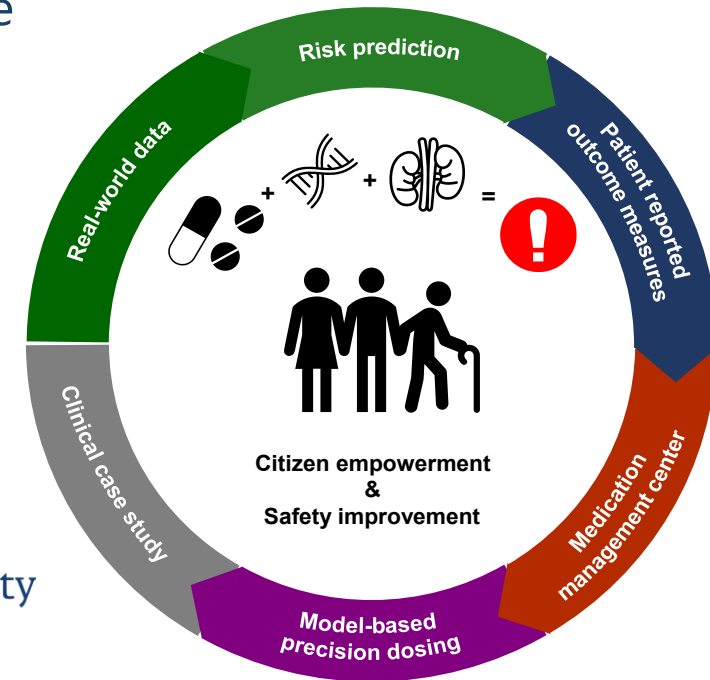
Drug-Drug (DDI) and Drug-Gene Interactions (DGI)



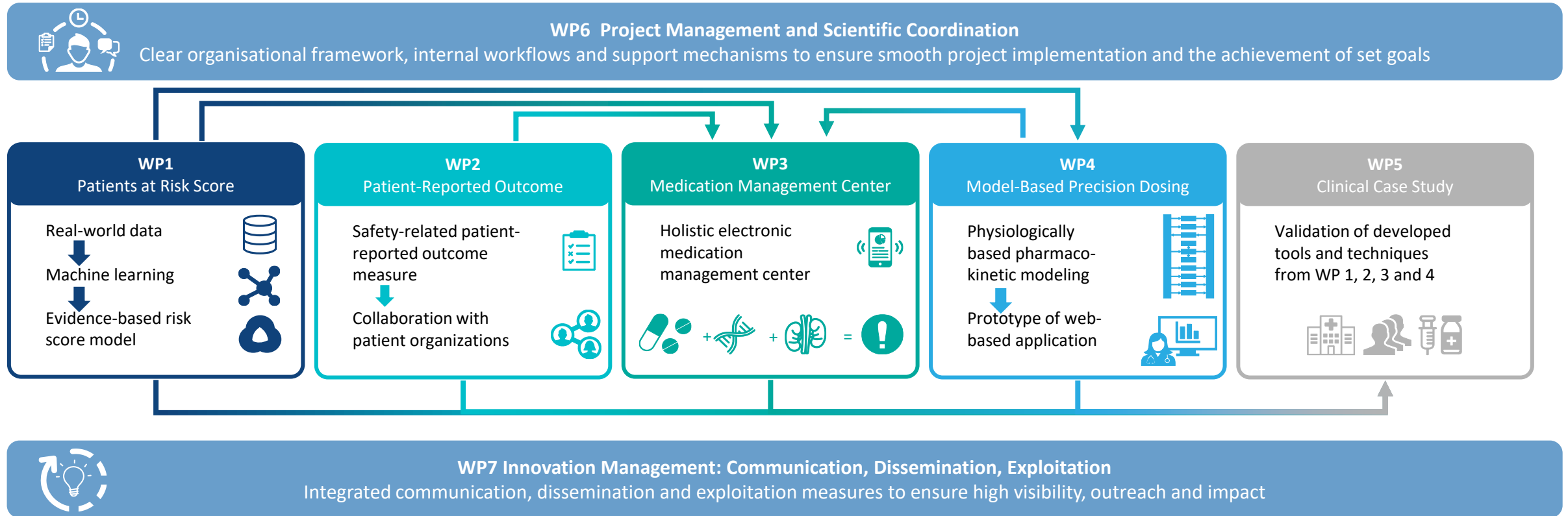
Genotype	Drug-drug interaction			
	<i>CYP2C8</i>	<i>SLCO1B1</i>	Gemfibrozil	Itraconazole
wild type	wild type	-	-	-
*3/*3	wild type	-	-	-
*3/*3	wild type	yes	-	-
*3/*3	wild type	-	-	yes
*3/*3	wild type	yes	yes	yes
wild type	521CC	-	-	-
wild type	521CC	yes	-	-
wild type	521CC	-	-	yes
wild type	521CC	yes	yes	yes

Improve Safety in Polymedication by Managing Drug-Drug-Gene Interactions (SafePolyMed)

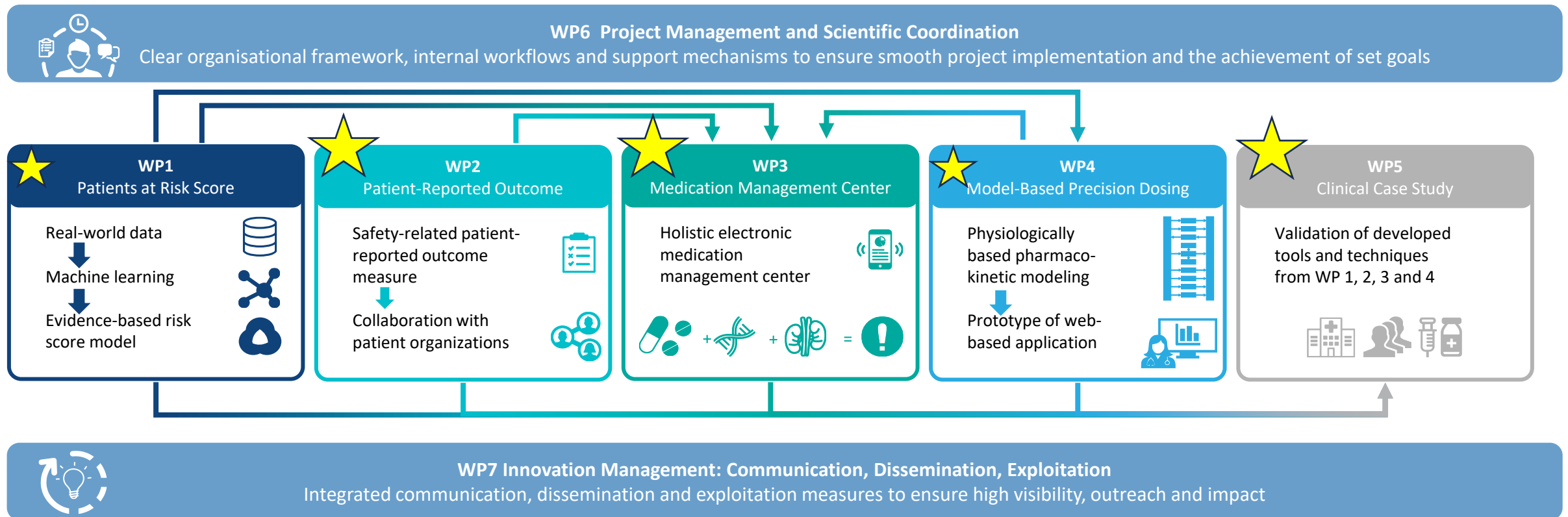
- Increase patient safety and equip health care providers with innovative tools
- Empower patients to proactively manage their own health care by accessible health relevant information
- Increase patient safety towards personalized treatment plans



Work Packages



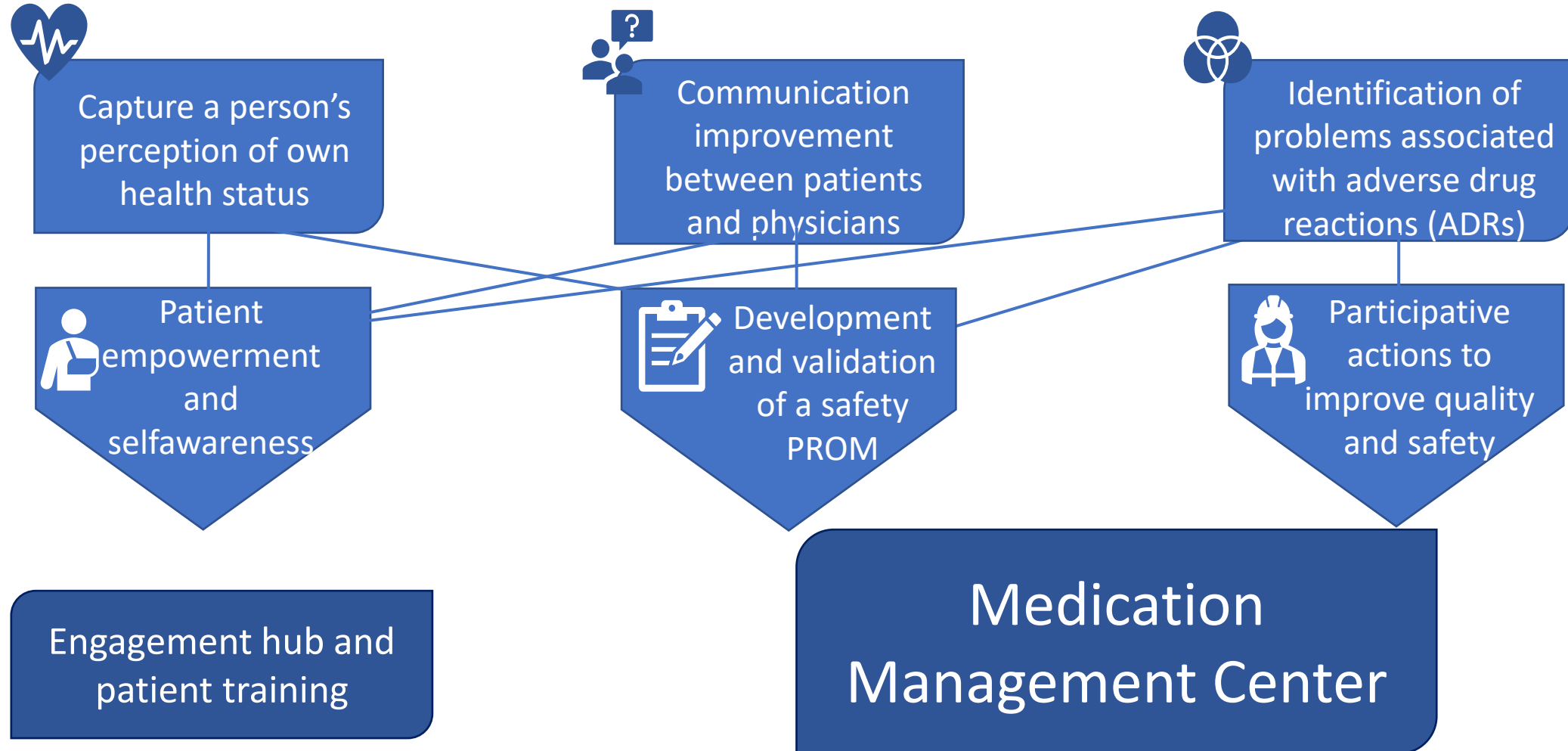
Patient contributions



Patient-Reported Outcome (WP2)

WP lead

UNIKLINIK
RWTHAACHEN



Patient involvement in SafePolyMed




Patient support

Gathering of a group of patient organizations (POs) and patient experts that have the knowledge, experience, and capacity to provide the patient's point of view and knowledgeable insights into:

- The development of the training syllabus for the training courses
- The development of the core set of PROMs via a Delphi Method
- Feedback to the Medication Management Centre
- Input to WP5 with safety PROMs implemented in the medication management system for the clinical pilot study.

Dissemination



Dissemination
Make knowledge and results publicly available free-of-charge

For whom
For those who can learn and benefit from the results, such as: scientists, industry, public authorities, policymakers, civil society

How
Publishing results in:

- ✓ Scientific magazines
- ✓ Scientific and/or targeted conferences
- ✓ Databases

Why

- ✓ Maximise the impact of the action
- ✓ Allow other researchers to go a step forward
- ✓ Contribute to the advancement of world class knowledge
- ✓ Make scientific results a common good

It is a legal obligation!
Article 17 of Horizon Europe Grant Agreement

Scientific Community & Health Care Professionals

- Open-Access Publications
- Conferences & workshops

Patients & Citizens

- Communication and networking via patient engagement hub
- Patient training courses via EUPATI

Communication



Communication
Inform, promote and communicate activities and results

For whom
Citizens, stakeholders and the media

How

- ✓ Having a well-designed strategy
- ✓ Conveying clear messages
- ✓ Using the right channels

Why

- ✓ Engage with stakeholders
- ✓ Attract the best experts
- ✓ Raise awareness of how public money is spent
- ✓ Show the success of European collaboration

It is a legal obligation!
Article 17 of Horizon Europe
Grant Agreement

Scientific Community, HC Professionals, Patients & Citizens

- Public events
- Website
- Social Media
- Patient communication via EUPATI

Patient-Oriented Communication

Patients & Caregivers Key Stakeholders

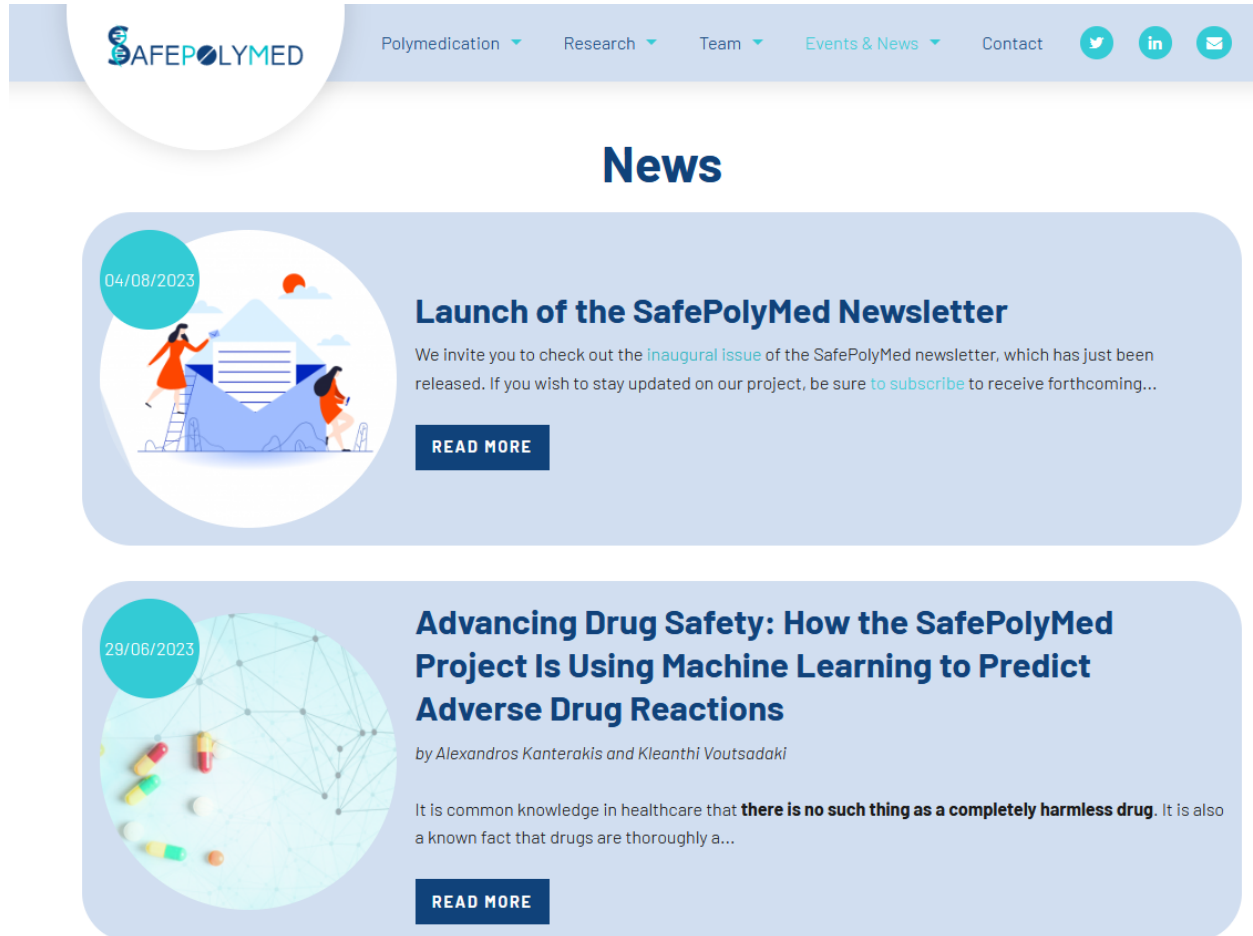
Key Target Groups

- Inform on project & results, also via EUPATI

„Key Players“

- Patients as active partners: project structure & activities

Patient-Oriented Communication



The screenshot shows the top navigation bar of the SafePolyMed website. The logo 'SAFEPOLYMED' is on the left, followed by menu items: Polymedication, Research, Team, Events & News, and Contact. Social media icons for Twitter, LinkedIn, and Email are on the right. Below the navigation is a 'News' section with two articles. The first article, dated 04/08/2023, is titled 'Launch of the SafePolyMed Newsletter' and includes a 'READ MORE' button. The second article, dated 29/06/2023, is titled 'Advancing Drug Safety: How the SafePolyMed Project Is Using Machine Learning to Predict Adverse Drug Reactions' and also includes a 'READ MORE' button. The author of the second article is listed as 'by Alexandros Kanterakis and Kleanthi Voutsadaki'.

SAFEPOLYMED Polymedication Research Team Events & News Contact

News

04/08/2023

Launch of the SafePolyMed Newsletter

We invite you to check out the [inaugural issue](#) of the SafePolyMed newsletter, which has just been released. If you wish to stay updated on our project, be sure [to subscribe](#) to receive forthcoming...

READ MORE

29/06/2023

Advancing Drug Safety: How the SafePolyMed Project Is Using Machine Learning to Predict Adverse Drug Reactions

by *Alexandros Kanterakis and Kleanthi Voutsadaki*

It is common knowledge in healthcare that **there is no such thing as a completely harmless drug**. It is also a known fact that drugs are thoroughly a...

READ MORE



Patient-Oriented Communication

The image shows a screenshot of the SafePolyMed website. At the top, there is a navigation bar with the SafePolyMed logo on the left and menu items: Polymedication, Research, Team, Events & News, and Contact. To the right of the menu are social media icons for Twitter, LinkedIn, and Email. Below the navigation bar is a large banner for World Patient Safety Day 2023. The banner features the SafePolyMed logo, the text 'World Patient Safety Day 2023' in a light blue box, and two dark blue boxes containing the text 'Towards safer drug treatment and' and 'enhanced patient empowerment'. At the bottom of the banner is a colorful graphic of various pills and capsules, and the hashtags #SafePolyMed and #WorldPatientSafetyDay.

SAFEPOLYMED

Polymedication Research Team Events & News Contact

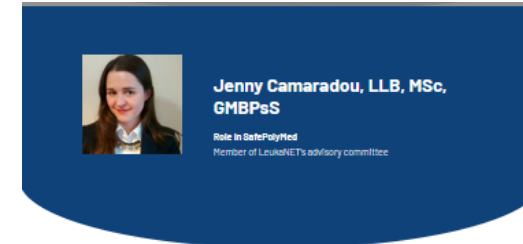
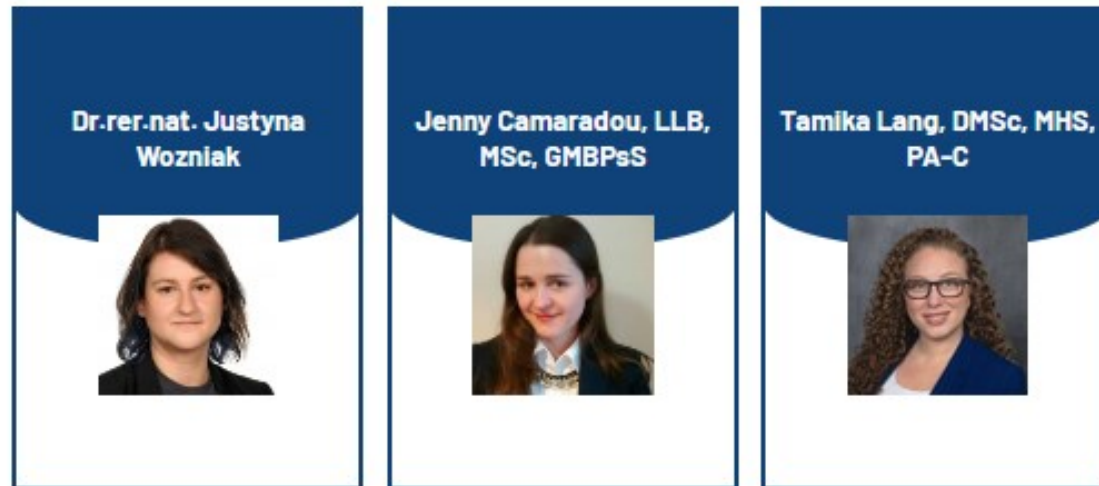
World Patient Safety Day 2023

SAFEPOLYMED

Towards safer drug treatment and
enhanced patient empowerment

#SafePolyMed
#WorldPatientSafetyDay

Patient-Oriented Communication



Can you tell us a bit more about yourself?

My name is Jenny Camaradou, and I am a dual UK/EU (Greek) national. I am a trained Patient Expert, a fellow of EUPATI, the European Patients' Academy, and an alumna of EURORDIS, representing patients across the EU. I serve as a patient advocate in various areas, including the EAN (European Academy of Neurology) Working Group on Autonomic Nervous System Disorders, and I am a patient ambassador for the EU region in the OneNeurology Global Partnership Initiative, which encompasses more than 400 neurological and neurodegenerative conditions. Additionally, I hold the role of being an assigned lay member on the UK NICE Covid-19 expert panel and have contributed to the COVID-19 evidence synthesis to aid decision-makers network, a Q&A partner to the WHO looking at the full spectrum of pandemic management. I work as a freelance grant writer for a Dutch social not-for-profit organisation that is actively engaged in EU R&D health innovation projects, as well as in knowledge exchange. I am contemplating the possibility of pursuing my own doctoral study in the future!

What is your role in SafePolyMed?

Within SafePolyMed, I am supporting the team of clinicians and researchers in the consortium by providing consultancy to better embed patient concerns around the development of the core set of PROs for the project. I am also identifying and modifying the research questions for the development of the Delphi analysis itself, as well as practical issues around the implementation and delivery of the medication management centre and training materials. Members of my family have sustained life-threatening anaphylactic shock from different medications over the last 30 years on multiple occasions due to having systemic mast cell disease. I recognise the importance of working together with doctors, patients, and other stakeholders to support good, safe patient care and ensure a shared understanding of mutual issues and goals. This project provides a great opportunity to utilise some of the training I have undertaken so far to improve the research itself from a patient's point of view and enhance engagement.

This year, the theme of World Patient Safety Day is 'Engaging Patients for Patient Safety.' Why do you think it is essential to involve patients in current research endeavors and clinical practices?

Involvement and engagement are terms often used interchangeably in various contexts, sometimes carrying country-specific interpretations. It is crucial to engage patients in research to ensure that the right questions are asked when identifying and prioritising research topics. Models such as the James Lind Alliance Priority Setting Partnership in the UK, with a tradition dating back to the 18th century, highlight the importance of involving citizens in research. Initiatives like EUPATI provide training for patients to become experts, contributing to the design and delivery of trials and healthcare system reforms.

Patient-Oriented Communication



World Patient Safety Day 17 September 2023

The days of paternalistic medicine are by and large over. As clinicians and researchers who strongly desire to keep our patients as healthy and safe as can be, we need to recognise and **support our patients as they take the lead.**



Tamika Lang
DMSc, MHS, PA-C
Member of LeukaNET's advisory committee in SafePolyMed





SafePolyMed.eu

Improving Safety in Polymedication by Managing Drug-Drug-Gene Interactions

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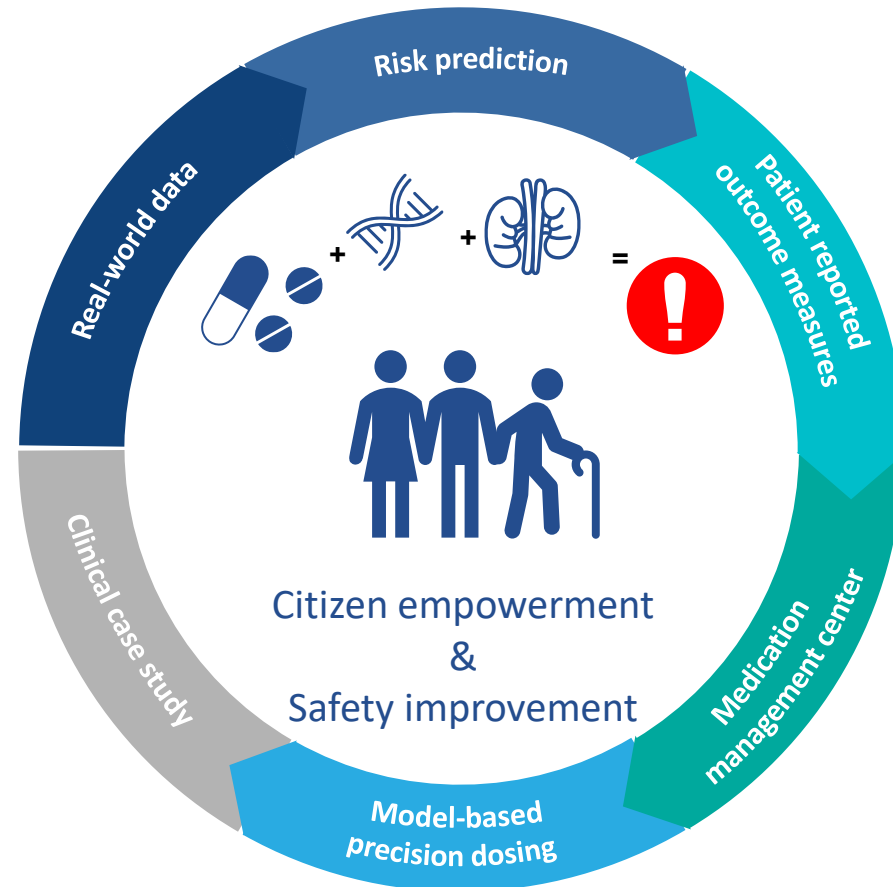
Towards Safer Drug Treatment and Enhanced Patient Empowerment

#SafePolyMed
#FromEuropeForAll
#HealthForAll



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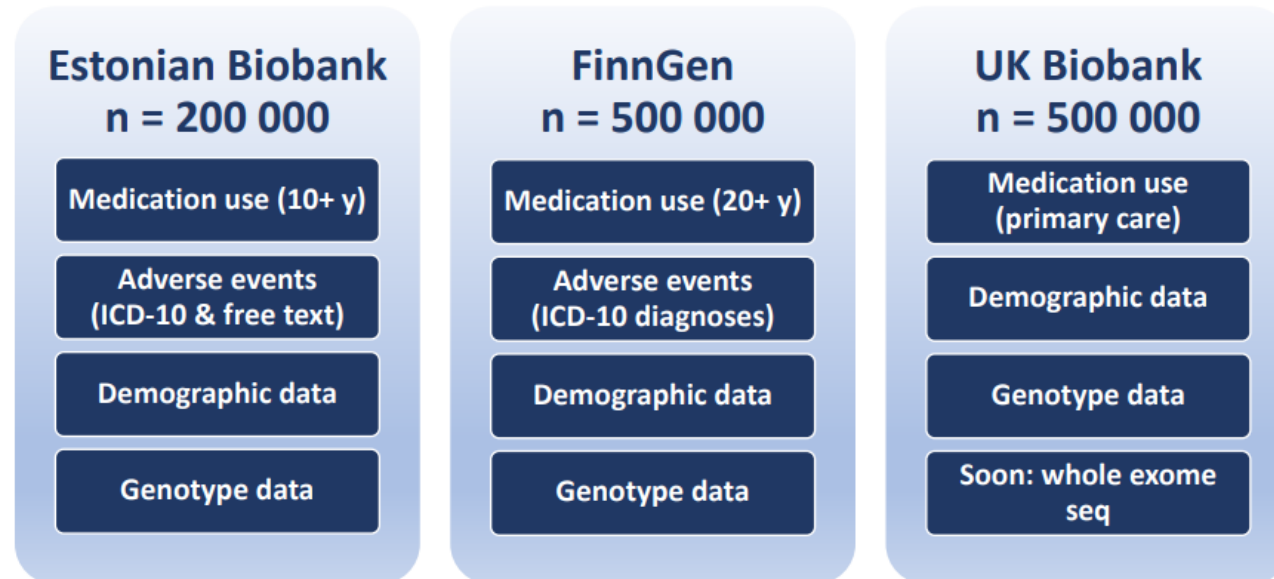
Project Overview and Objectives





Patients at Risk Score (WP1)

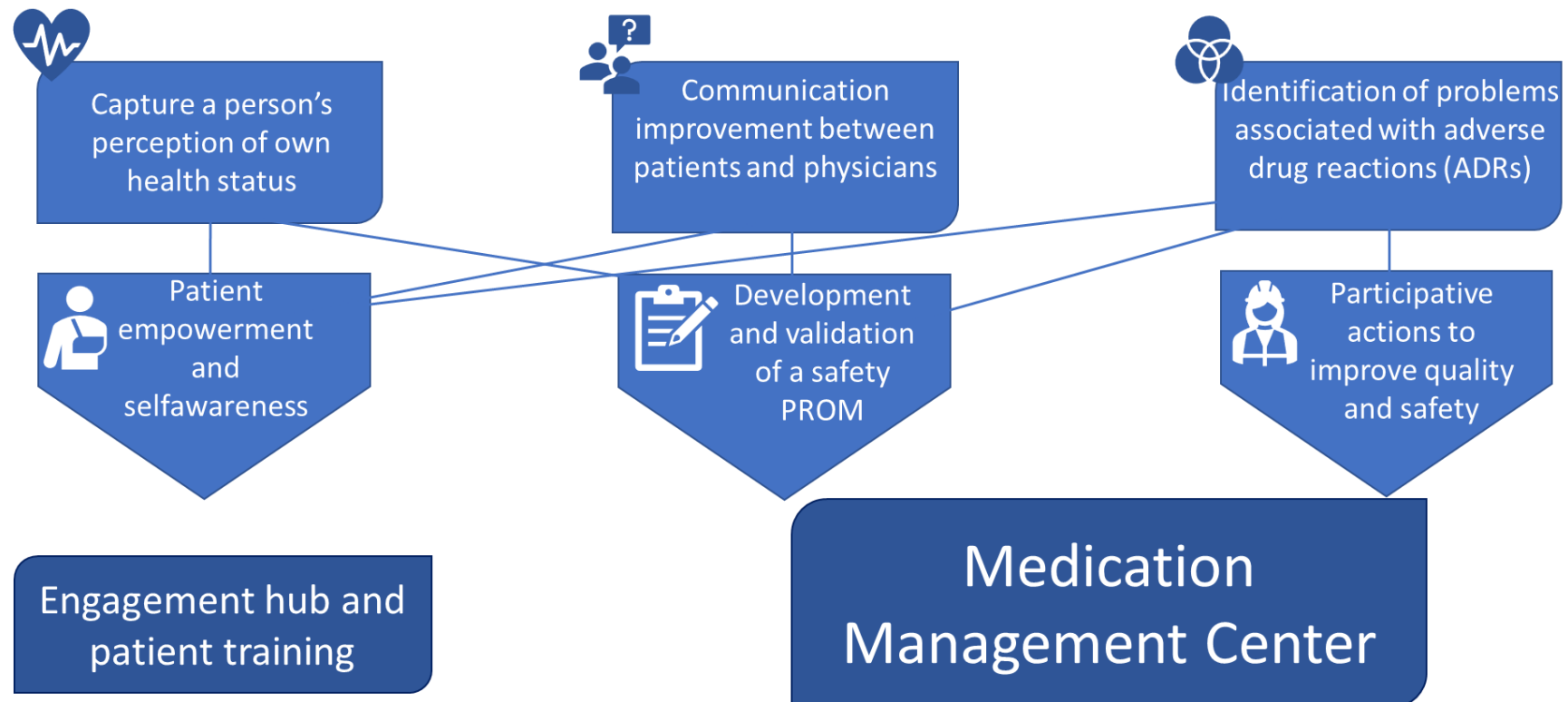
Development of a novel, evidence-based risk score model for individual patients with machine learning based on the analysis of large real-world dataset



Genome-wide association studies → novel genetic variants → polygenic hazard scores
 Pharmacogenetic star alleles + novel hazard scores
 Machine learning models integrating different layers of data → novel models

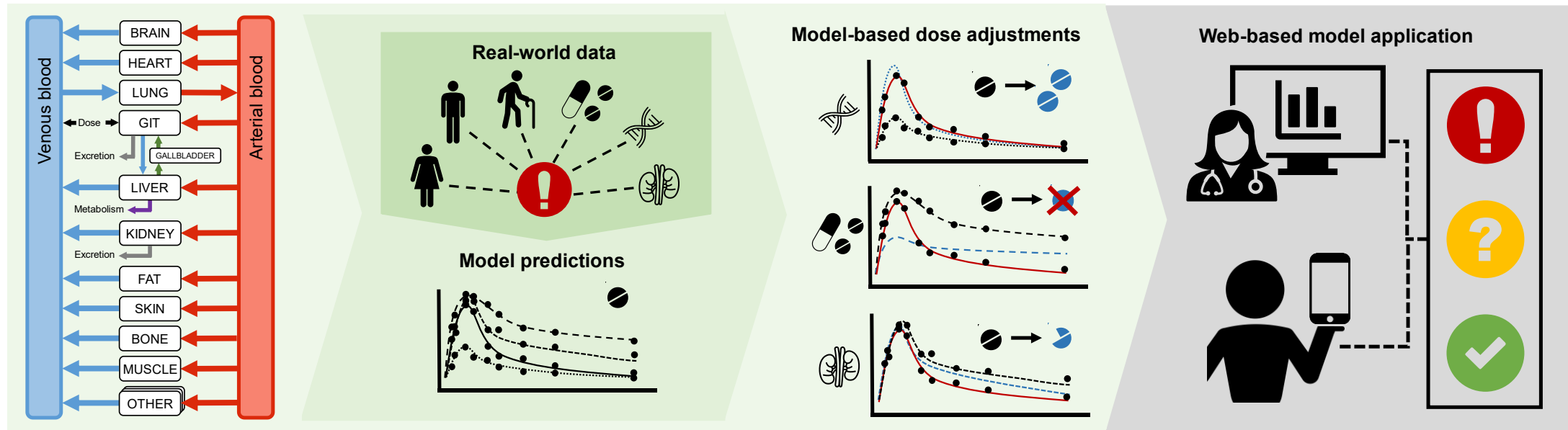
Patient-Reported Outcome (WP2)

Improving adherence, patient satisfaction and safety by empowering patients to assess and report ADRs through PROMS



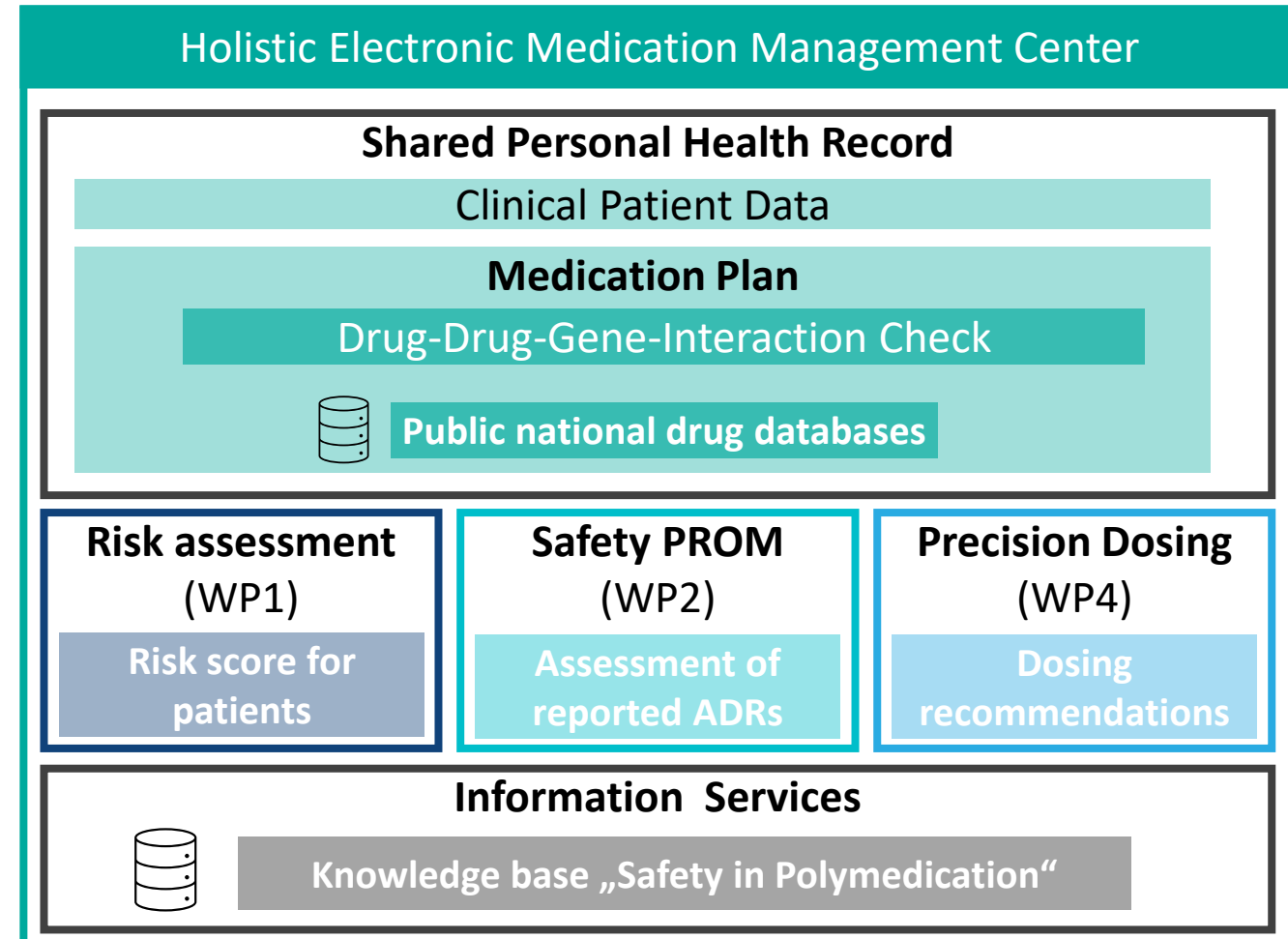
Model-Based Precision Dosing (WP4)

Development of precision dosing models with help of PBPK modeling and extension to web-based decision support systems



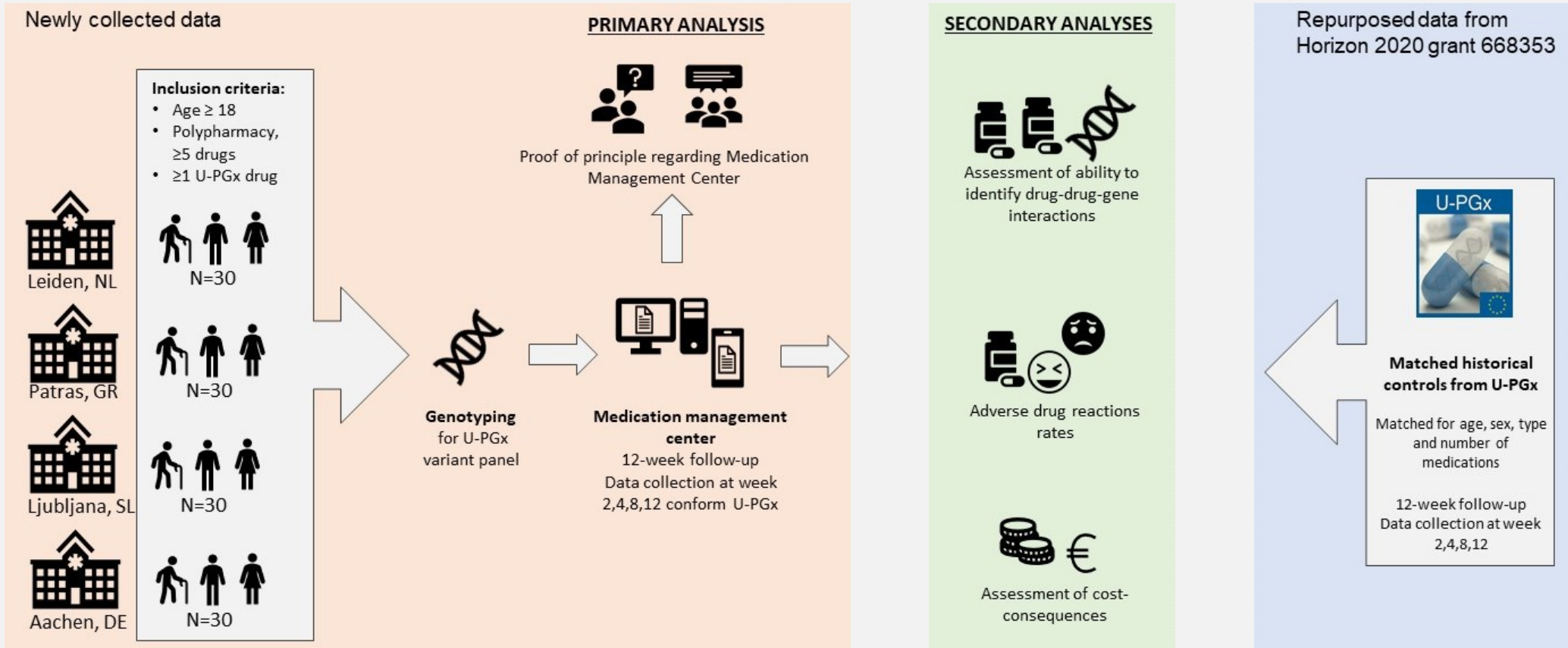
Medication Management Center (WP3)

- Integrate, harmonise and standardise medication data
- Comprehensive, sustainable knowledge base concerning polymedication
- Increasing access to health relevant information
- Ensure quality and comparability of health data according to ethical, legal and regulatory guidelines



Clinical Case Study (EmPaSafe) (WP5)

EmPaSafe Study – Empowering Patients to Improve Safety in Polymedication



Key Results of SafePolyMed



Pharmacology and drug safety training in EUPATI



Medication Management Center



Patient engagement hub for patient organizations



Risk score model to identify patients at risk



Set of PROMs to assess drug safety



Web-based precision models

Results from the proof of principle study EmPaSafe to validate developed tools

Supporting citizens in managing their own health care

innovative tools for health care professionals to manage polypharmacy

Dissemination and Communication

➤ **Dissemination**

❖ Scientific community

- Open science principle
- Participation in scientific conferences
- Organisation of SafePolyMed satellite event

❖ Patients and citizens

- Communication and networking via patient engagement hub
- Patient training courses via EUPATI

➤ **Exploitation**

❖ Exploitation Strategy and Activity Planning Workshops

➤ **Communication**

❖ Project website as information hub

❖ Communication and networking via social media

❖ Patient communication via close link to European Patient Academy

- Information on project objectives and background for health care professionals and citizens
 - Updates on project progress and recent publications



SAFEPOLYMED

01 JUNE 2022
START DATE



24-25 NOV 2022
1st FACE-2-FACE



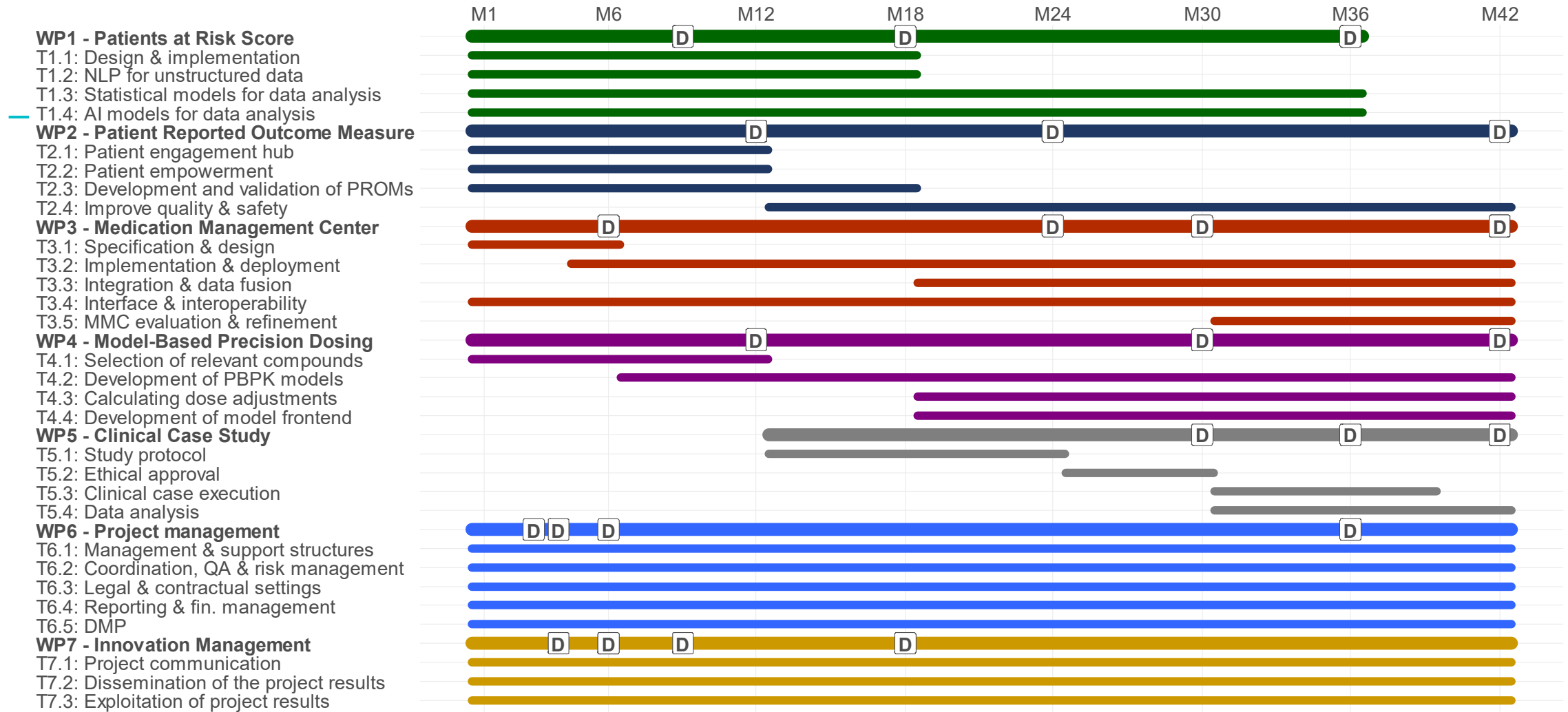
42 MONTHS
OF DURATION



Thank you for your attention!

Back Up

Project timeline



SafePolyMed as
part of Horizon
HLTH 2021
alongside
BE-SAFE,
DELIVER and
SAFEST

Project Duration:
42 months
(June 1, 2022 –
November 30, 2025)
Funding: € 5,650,442.81



Impact

197,000
deaths
due to ADRs¹

79bn €
HC cost
due to ADRs
annually¹

>60%
of ADRs
due to DGIs⁴

26–40%
of elderly
take >5 drugs
concomitantly²

>65%
of ADRs
due to DDIs³

~38%
of ADRs
assumed to be
preventable⁵

20-30%
of patients
show poor
adherence⁶

400m €
savings
annually

~25%
of ADRs
expected to be
reduced

~10%
increase
in adherence



Impact



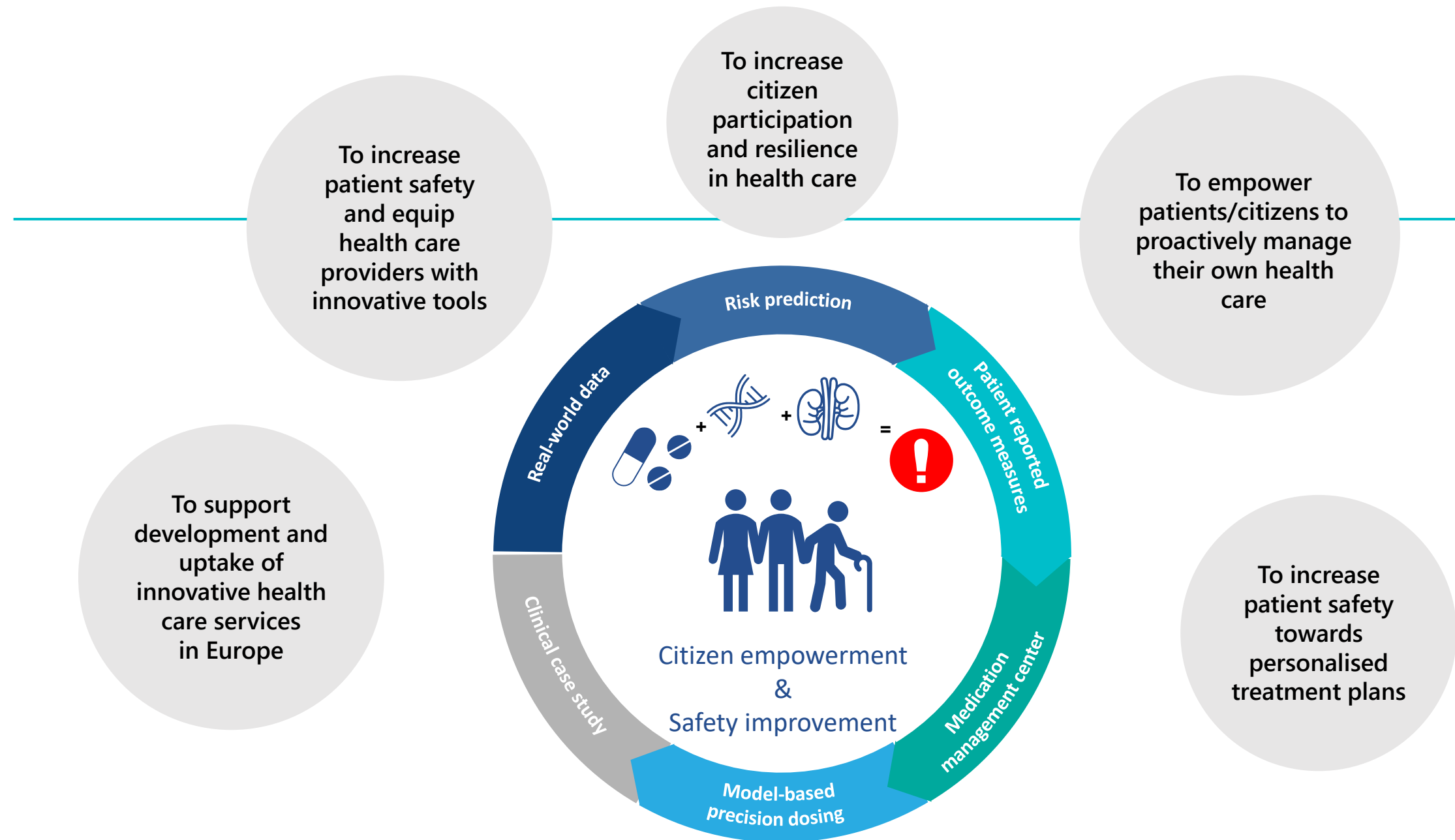
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A controlled prospective real-world implementation study of a 12-gene pharmacogenetic panel to prevent adverse drug reactions in 6,944 patients in seven European countries.

J. Swen, ..., T. Lehr, ..., HJ Guchelaar
Lancet, 2022, accepted

Interpretation: Genotype-guided treatment using a 12-gene pharmacogenetic panel significantly reduced the incidence of clinically relevant adverse drug reactions (OR 0.70; 95% CI 0.61 – 0.79; $p < 0.0001$)



SafePolyMed Consortium

Participant	Participant organisation name	Principal Investigator	Country
Experts in Precision Dosing and Modeling (Project Coordinator)			
USAAR	Saarland University	Thorsten Lehr	DE
Clinical Partners			
LUMC	Leiden University Medical Center	Jesse Swen	NL
UKA	University Hospital of RWTH Aachen	Julia Stingl	DE
UL	University of Ljubljana	Vita Dolzan	SI
UPAT	University of Patras	George P. Patrinos	GR
Patient Organisation			
LeNET	LeukaNET	Jan Geißler	DE
Experts in AI and Machine Learning			
FORTH	Foundation for Research and Technology - Hellas	Manolis Tsiknakis	GR
UTARTU	University of Tartu	Lili Milani	EE
UH-FIMM	University of Helsinki	Samuli Ripatti	FI
Experts in Health Information Systems			
FhG-IBMT	Fraunhofer Institute for Biomedical Engineering IBMT	Sabine Müller	DE
GOZ	Gospodar zdravja d.o.o.	Gorazd Hladnik	SI
Experts in Project Management, IP & Innovation Management			
EURICE	EURICE – European Research and Project Office GmbH	Christina Eder	DE

