PROPHET TOOLBOX FACTSHEET#6

JULY 2026

The Pharmacogenetic Passport: A guide for health professionals

PROPHET

a PeRsOnalized Prevention roadmap for the future HEalThcare

What is Pharmacogenomics?

Pharmacogenomics (PGx) is the study of how inherited genetic variation influences individual responses to medications, affecting both drug efficacy and the risk of adverse drug reactions (ADRs). ADRs account for an estimated 5-15% of adult hospital admissions in Europe, with figures rising above 15% in patients with multiple chronic conditions. Around 90-95% of the general population carries at least one high-risk actionable pharmacogenetic variant, and approximately 25% of people who use medications could benefit from a pharmacogenetic profile.

PGx represents a valuable complement to conventional dosing strategies based on age, body weight, and renal or hepatic function. By identifying patients at increased risk of ADRs or reduced drug efficacy, PGx enables clinicians to prescribe personalized drugs or dosages, maximizing therapeutic benefit and minimizing harm.

PGx testing can be conducted at different time points:

Reactive testing: performed after an ADR or when drug efficacy is lacking, currently the most common approach in routine hospital care;

Pre-therapeutic testing: conducted before prescribing a specific medicine (e.g. DPYD testing before fluoropyrimidine chemotherapy);

Pre-emptive testing: performed without immediate clinical indication, before any target drug is prescribed. This last strategy often relies on analyzing a multigene panel with multiple variants e.g. via a pharmacogenetic passport.

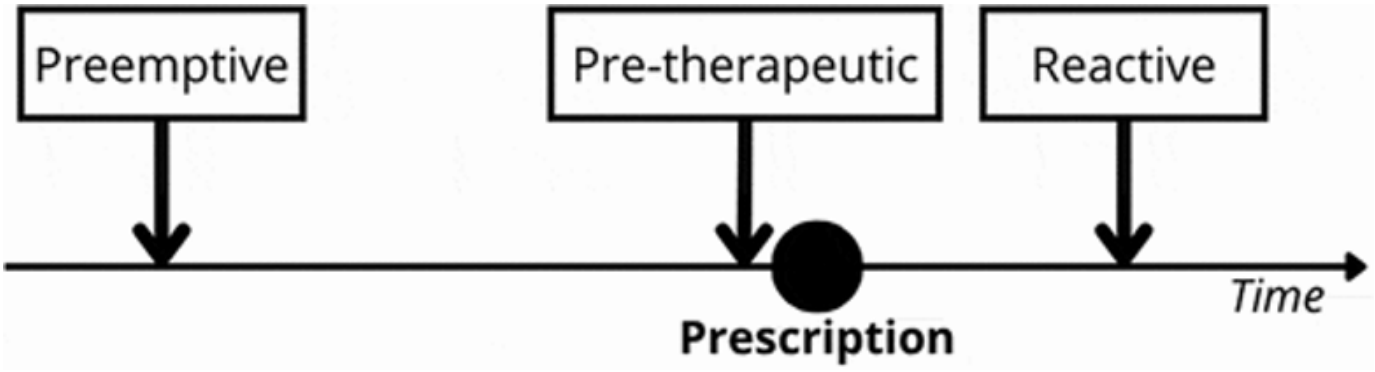

Fig 1. Difference between preemptive testing, pre-therapeutic testing and reactive PGx testing in time related to moment of drug prescription. Figure based on Rigter et al., Front Genet., 2020.

The Pharmacogenetic Passport

A **Pharmacogenetic Passport** is a pre-emptive, multi-gene pharmacogenetic profile providing drug response information that can be used throughout a patient's lifetime, as DNA variants remain stable over time. It includes genes involved in drug metabolism, transport, and mechanism of action, and focuses on clinically actionable pharmacogenetic variants across multiple therapeutic areas, including psychiatry, cardiology, and oncology.

While integration into electronic health records (EHRs) is not yet feasible in most health systems, pharmacogenetic information and tailored prescribing recommendations can be delivered via a physical card (with a QR code) or a secure digital application. In this approach, patients remain in control of their pharmacogenetic information and can share it with healthcare professionals, who can access relevant results and recommendations at the point of prescribing.

One practical example is the "myDNAmedicationpass" piloted at Amsterdam UMC, Leiden UMC and across medical centers in the Netherlands. This tool was generated by reusing whole exome sequencing (WES) data from patients undergoing genetic diagnostics, making it an efficient, low-cost approach to pre-emptive testing.

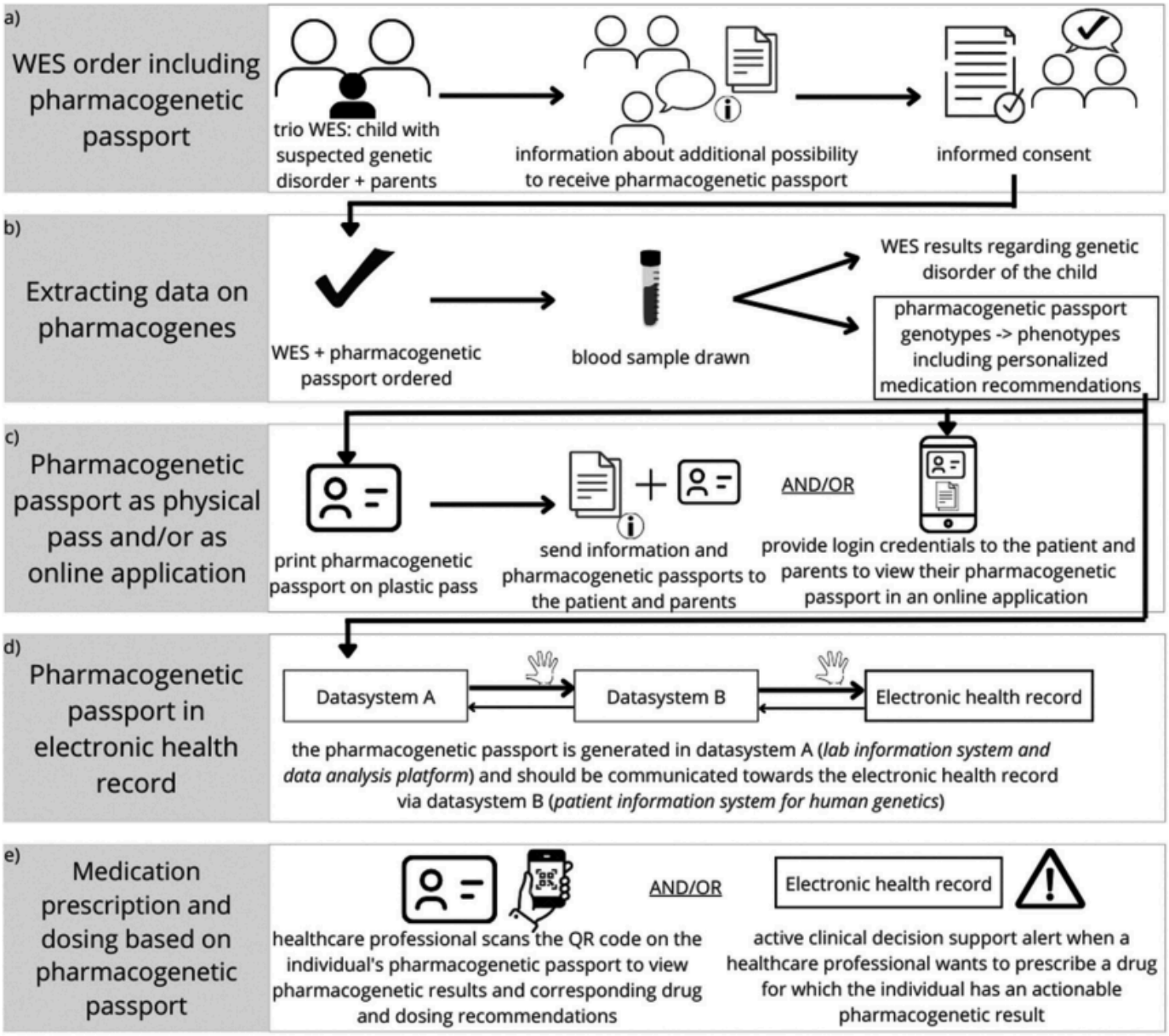

Fig 2. Workflow (a-e) regarding a pharmacogenetic passport in practice, reusing WES data of trios (patient and both biological parents). Figure modified by Roelofsen et al., Pharmacogenomics, 2025.

Key areas for the implementation of pharmacogenetics

The implementation of pharmacogenetics requires action across several interconnected areas. For each area, current barriers should be considered together with the factors that may support adoption and scale-up.

Clinical evidence and target populations

Current barrier: evidence is still limited for some multi-gene panels, particularly in patients with polypharmacy, multimorbidity or complex therapeutic pathways. Enabling factor: growing real-world evidence can support implementation in selected clinical pathways where PGx information can improve medication safety and personalize treatment decisions.

Guidance and clinical recommendations

Current barrier: existing recommendations often explain how PGx results should be used once available, but may not clearly define whether, when and in which patients PGx testing should be performed. Enabling factor: clear, practical, and actionable guidelines can help healthcare professionals identify eligible patients, interpret PGx results and apply them in prescribing decisions

Economic sustainability and reimbursement

Current barrier: large-scale economic evaluations of pre-emptive multi-gene PGx approaches are still limited, and the lack of standardized reimbursement frameworks may restrict uptake. Enabling factor: evidence that several PGx tests can be cost-effective or cost-saving may support reimbursement decisions and broader implementation.

Equity of access and service availability

Current barrier: access to PGx testing may vary across regions, healthcare settings and patient groups, depending on laboratory capacity, available expertise, reimbursement mechanisms and local resources. Enabling factor: standardized implementation pathways, equitable reimbursement models and integration into routine care can help reduce regional and socioeconomic disparities in access.

Digital infrastructure and data interoperability

Current barrier: PGx results need to be stored, updated and shared across healthcare platforms, but many healthcare systems still lack interoperable IT systems.
Enabling factor: integration into electronic health records, prescribing platforms and clinical decision support systems can make PGx information available at the point of care through automated alerts and clear prescribing recommendations.

Education, training and professional confidence

Current barrier: many healthcare professionals recognize the value of PGx but report limited confidence in interpreting test results and applying them to prescribing decisions. Enabling factor: targeted training for physicians, pharmacists, nurses and general practitioners can increase confidence and support the appropriate use of PGx in clinical practice.

Roles, responsibilities and clinical workflows

Current barrier: unclear task division among pharmacists, medical specialists and general practitioners may hinder the translation of PGx results into clinical action.

Enabling factor: clearly defined roles, shared care pathways and multidisciplinary workflows can support the use of PGx results across different care settings.

Patient awareness, trust and engagement

Current barrier: patients may have limited awareness of PGx and may have concerns about privacy, data misuse or unequal access.

Enabling factor: providing patients with accessible information and direct control over their PGx data, for example through a physical card or secure digital application, can strengthen trust, empowerment and continuity of care.

Use of existing genomic data

Current barrier: PGx implementation may require additional testing infrastructure and resources when testing is performed separately from other genomic analyses. Enabling factor: reusing already available genomic data, such as whole-exome sequencing data, may make pharmacogenetic passports more efficient and affordable once data systems are connected.

Implementation leadership and institutional readiness
Current barrier: lack of institutional commitment, limited awareness and fragmented implementation strategies can slow down adoption. Enabling factor: early adopters, clinical champions and motivated institutions can raise awareness, promote local implementation and support the scale-up of PGx innovations.

Key priorities

A European multidisciplinary expert workshop, held in Amsterdam in January 2025, brought together 55 participants from 10 European countries. Based on expert presentations and structured discussions around three pillars (evidence, acceptance, and integration), five key priorities were identified for advancing PGx across European healthcare systems.

1. **Robust clinical and health economic evidence:** generate policy-relevant evidence on clinical utility and cost-effectiveness of multi-gene PGx panels, including data from diverse populations and long-term outcomes, to support funding and reimbursement decisions.

2. **Education, training and public awareness:** train healthcare professionals to apply and interpret PGx tests; increase public awareness via campaigns, multiple communication channels and digital tools; engage patient organizations and policymakers to build trust and demonstrate value.

3. **IT infrastructure and interoperability:** build interoperable digital infrastructure to integrate PGx data into EHRs and clinical decision support systems; standardize data formats and ensure that results are accessible at the point of care across the healthcare chain.

4 **Harmonized regulatory and reimbursement policies:** define clear reimbursement models, align EU and national policies, and develop national PGx implementation roadmaps; include PGx counselling in reimbursement frameworks.

5 **Equitable access:** reduce financial and geographic barriers to PGx testing; standardize indicators to monitor equitable uptake; invest in laboratory infrastructure in underserved regions and expand research on underrepresented populations.

Moving from evidence to practice

Pre-emptive pharmacogenetic testing holds a strong potential to improve patient outcomes, enhance medication safety, and support healthcare sustainability. Although the evidence base is still evolving, current data already support the clinical utility and economic value of targeted PGx testing for several gene-drug pairs. Real-world studies, such as the PREPARE trial, show meaningful reductions in ADRs when PGx-guided prescribing is implemented.

Translating this potential into routine clinical practice requires coordinated action across governance, evidence generation, professional training, laboratory capacity, and information systems.

Many of the barriers identified are common across European countries, highlighting the importance of collaborative research and structured exchange of best practices. The European Health Data Space offers a timely opportunity to embed PGx within a secure, interoperable digital infrastructure, advancing its role as a standard component of personalized medicine.

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