

PHARMACOGENOMICS TO PRACTICE

Integrating Pharmacogenetic Data into Clinical Decision Support for Hospital Pharmacists

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INTRODUCTION & CLINICAL NEED

Adverse drug reactions (ADRs) are a major cause of preventable harm in hospitals. Individual risk reflects genetics, age, comorbidities, route of administration and drug-drug interactions.

Key European burden estimates:

- ~3.6% of admissions are due to ADRs (median across European studies)
- ~10.1% of inpatients experience an ADR during hospitalization

Pharmacogenomics (PGx) anticipates ineffectiveness and toxicity, enabling proactive drug selection, dose personalization and monitoring - with hospital pharmacists translating evidence into timely bedside decisions.

STATE OF THE ART & REGULATORY BRIDGE

Evidence-based guidance is available and increasingly reflected in labels:

- CPIC and DPWG publish actionable recommendations with graded evidence and phenotype-based dosing rules.
 - FDA maintains the Table of Pharmacogenetic Associations; EMA integrates PGx information in EU product information (SmPC), including contraindications and dose guidance for genetic subgroups.
- Implementation gap: PGx results are often delivered as static reports and remain non-computable at prescribing.

"PGx TO PRACTICE" CONCEPT

To operationalize PGx at the bedside by integrating structured genetic results into the EHR and the Computerized Physician Order Entry (CPOE), enabling real-time CDS alerts, dose suggestions and monitoring pathways - with pharmacist stewardship to maximize benefit and minimize alert fatigue.

From Genome to Bedside in Real Time

Structured reporting + FHIR/LOINC makes PGx results computable for CPOE alerts

Genotyping

Diplotype

Diplotype → Phenotype (CPIC/DPWG mapping)

LOINC-coded phenotype

FHIR Observation / DiagnosticReport

EHR storage (lifetime)

CPOE contextual alert + pharmacist action

Bedside action requires:

- Uniform report structure
- Computable phenotype
- CDS rules embedded in CPOE
- Monitoring pathways

Interoperability building blocks

- HL7 FHIR: Observation + DiagnosticReport (Genomics Reporting IG)
- LOINC: genotype/phenotype + activity score codes
- CPOE context: indication, dose, co-medications → rule trigger

EVIDENCE-BASED CLINICAL RECOMMENDATIONS

CYP2C19 • Clopidogrel (ACS/PCI)

Risk: poor/intermediate metabolizers
CDS: high-severity alert when ACS/PCI
Action: prefer prasugrel or ticagrelor; document rationale if override

HLA-B*57:01 • Abacavir

Risk: immunologically mediated hypersensitivity
CDS: pre-treatment test required; contraindication if positive
Action: alternative antiretroviral

CYP2D6 • Codeine

Risk: ultra-rapid metabolizers → high morphine exposure
CDS: avoid in UM; reinforced warnings in pediatrics and postpartum
Action: use non-prodrug analgesics; plan monitoring pathway

IMPLEMENTATION & OUTLOOK (PHARMACIST-LED)

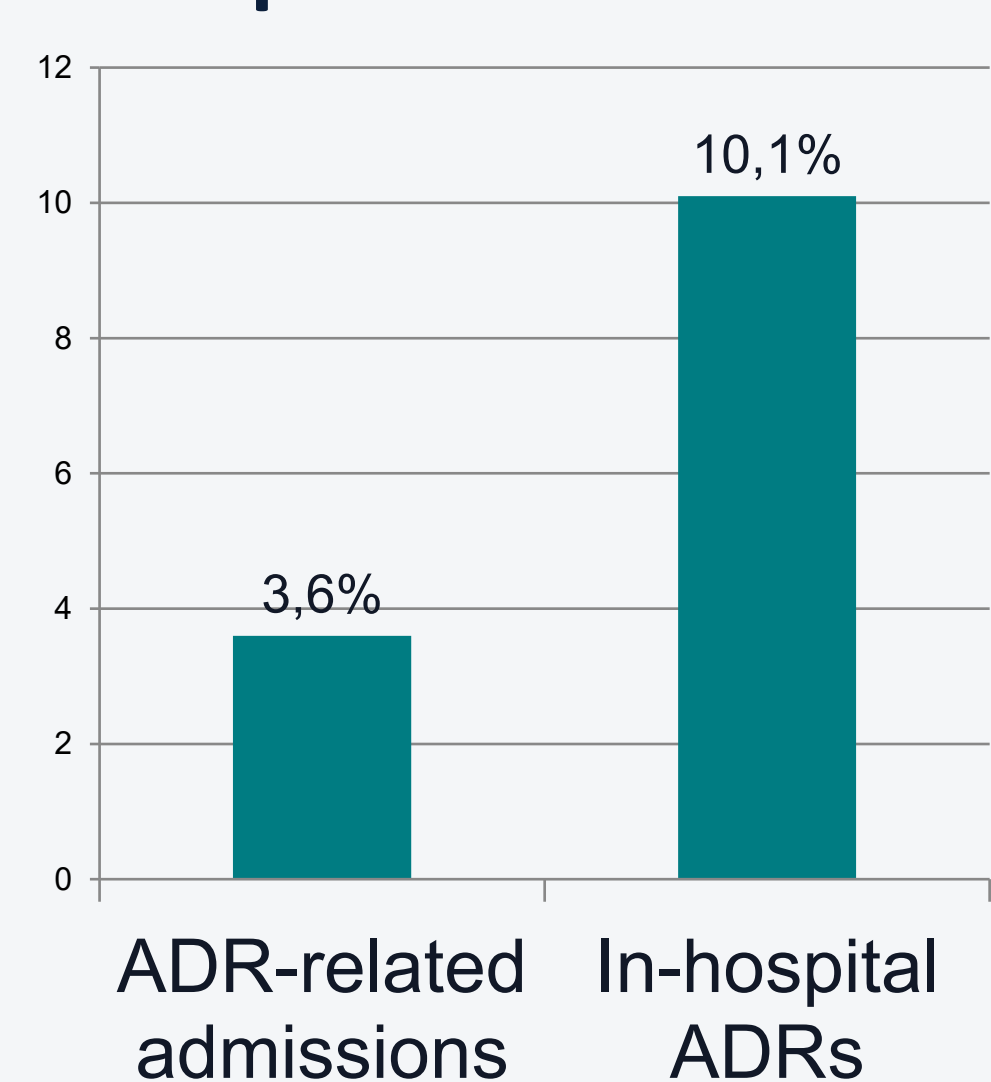
Operational pillars

- Target high-risk units (cardiology/oncology/ID)
- Combine PGx + TDM + clinical context
- ISO 15189-aligned lab quality
- Consent, role-based access, GDPR compliance
- Ongoing training for phenotype interpretation & alert handling
- European priorities (EAHP)**
- Reimbursement routes
- Interoperability standards
- Scalable education to make PGx actionable and improve outcomes

MEASURABLE IMPACT (KPI)

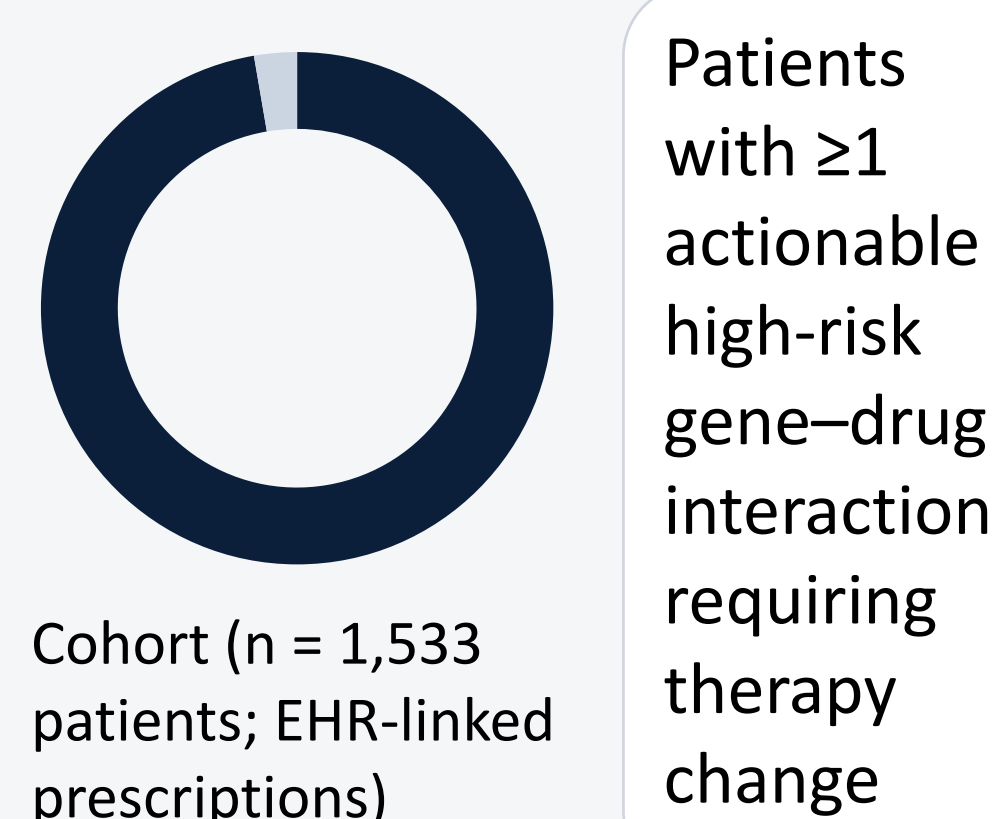
- 50% high-risk gene-drug prescriptions
- 30-40% severe ADRs (target meds)
- 90% guideline-concordant therapy
- <30% alert overrides (documented)
- <24h action on high-severity alerts

European ADR burden



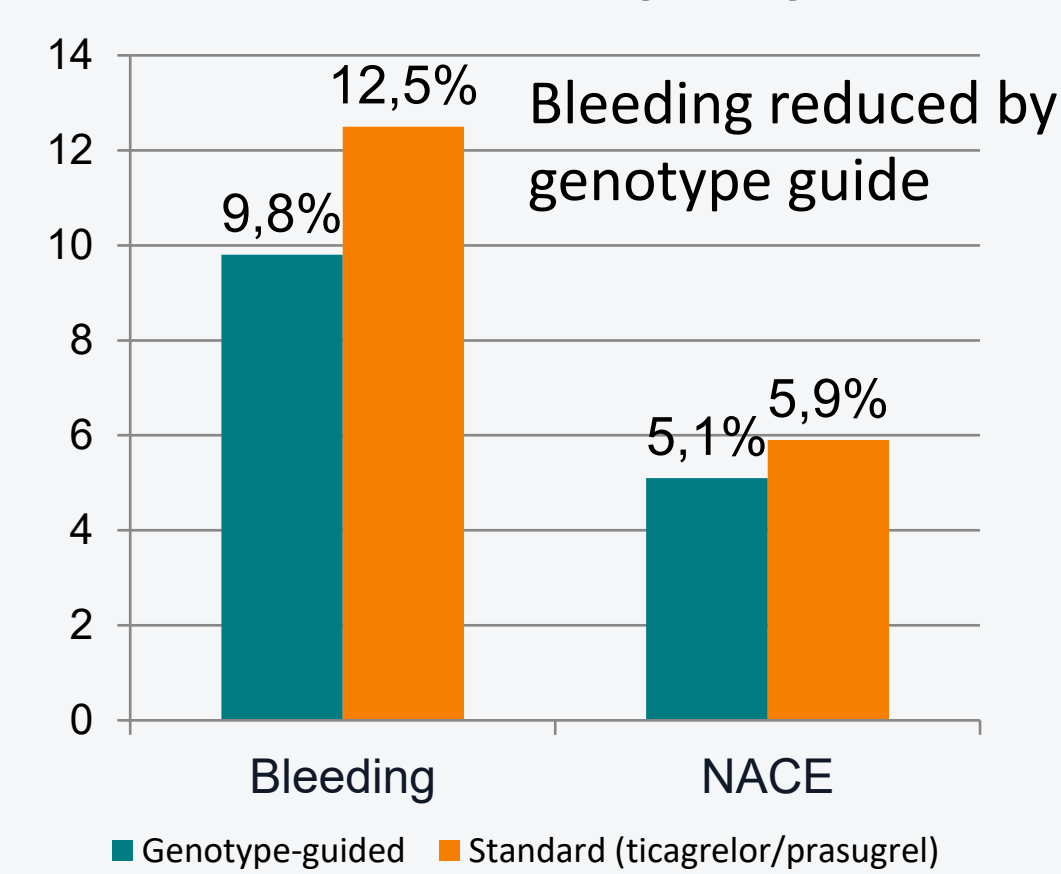
Bouvy JC et al. *Epidemiology of Adverse Drug Reactions in Europe: A Review of Recent Observational Studies.* Drug Safety, 2015

Hospital opportunity



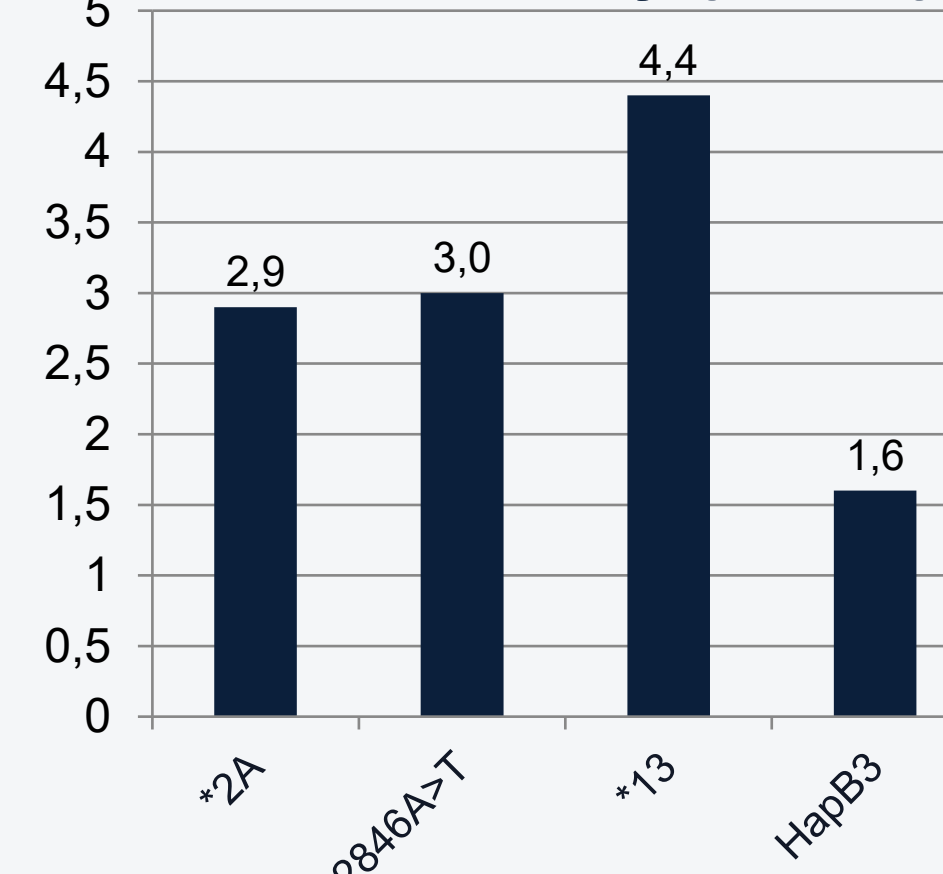
Hodel EM et al. *Prevalence of actionable pharmacogenetic variants and high-risk drug prescriptions: A Swiss hospital-based cohort study.* Clin Transl Sci, 2024

CYP2C19-guided P2Y12 selection (PCI)



POPular Genetics trial, NEJM 2019

DPYD variants: RR severe toxicity (G3-5)



Meulendijks D et al. *Lancet Oncol.* 2015

TAKE-HOME MESSAGE: Pharmacogenomics becomes clinically valuable only when genetic data are structured, computable, and delivered as real-time CDS at the point of prescribing. Hospital pharmacists are the translational bridge between evidence, interoperability and patient safety.

