The Medicine Safety Code Initiative

Towards a Global IT System for Personalized Medicine

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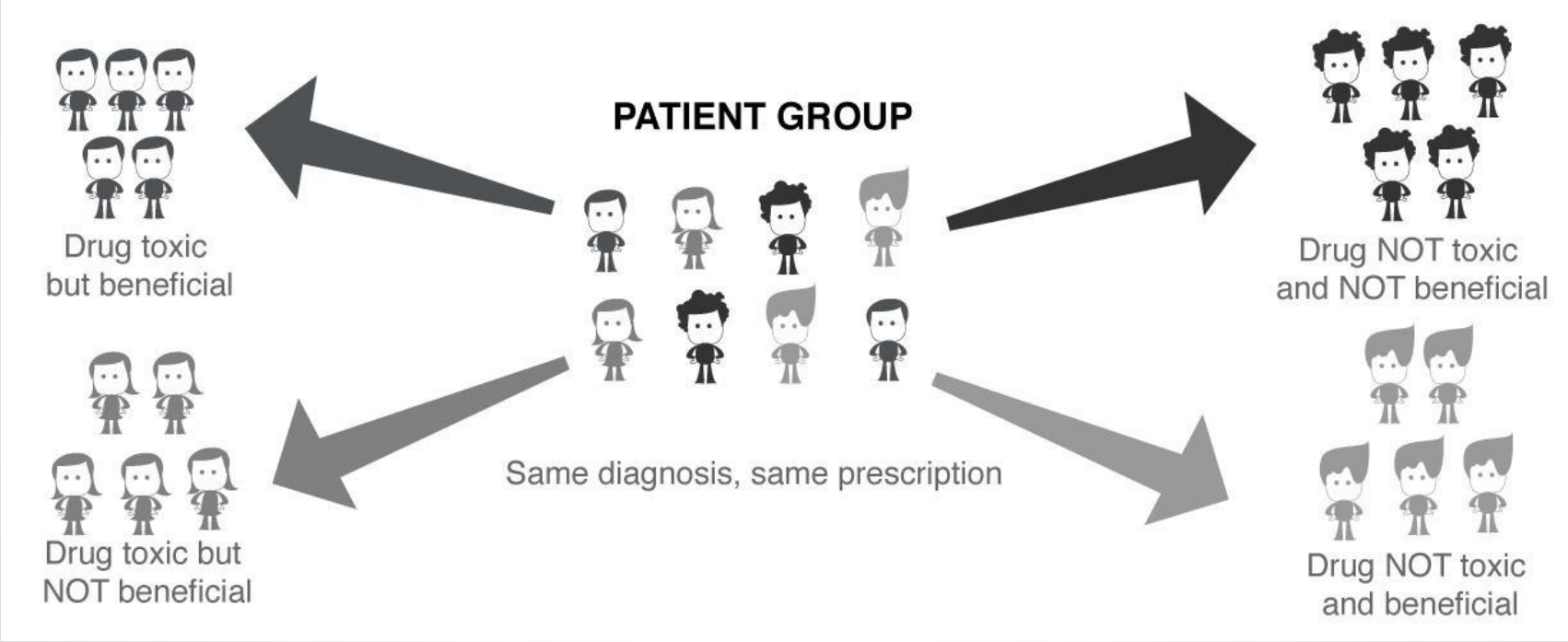
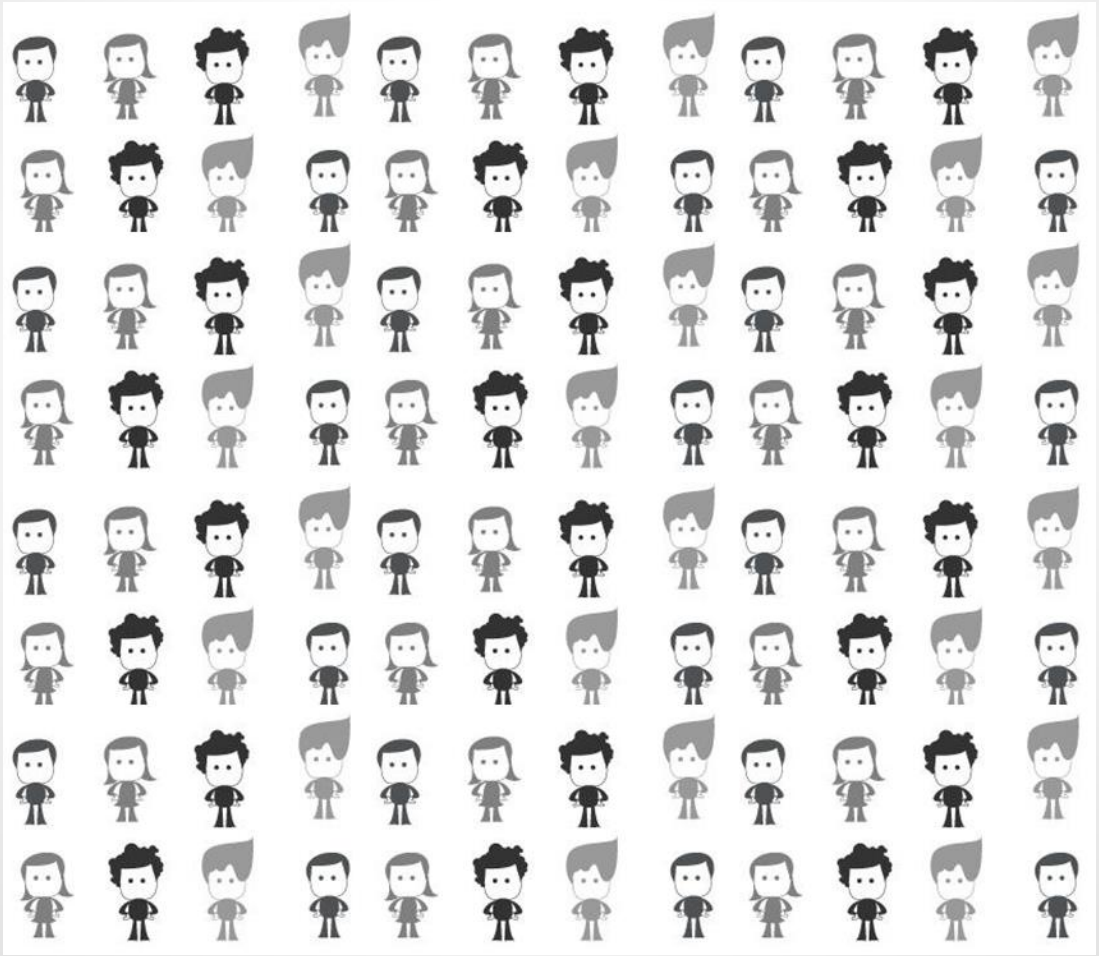
Drug safety and effectiveness vary drastically between patients with different genetic profiles



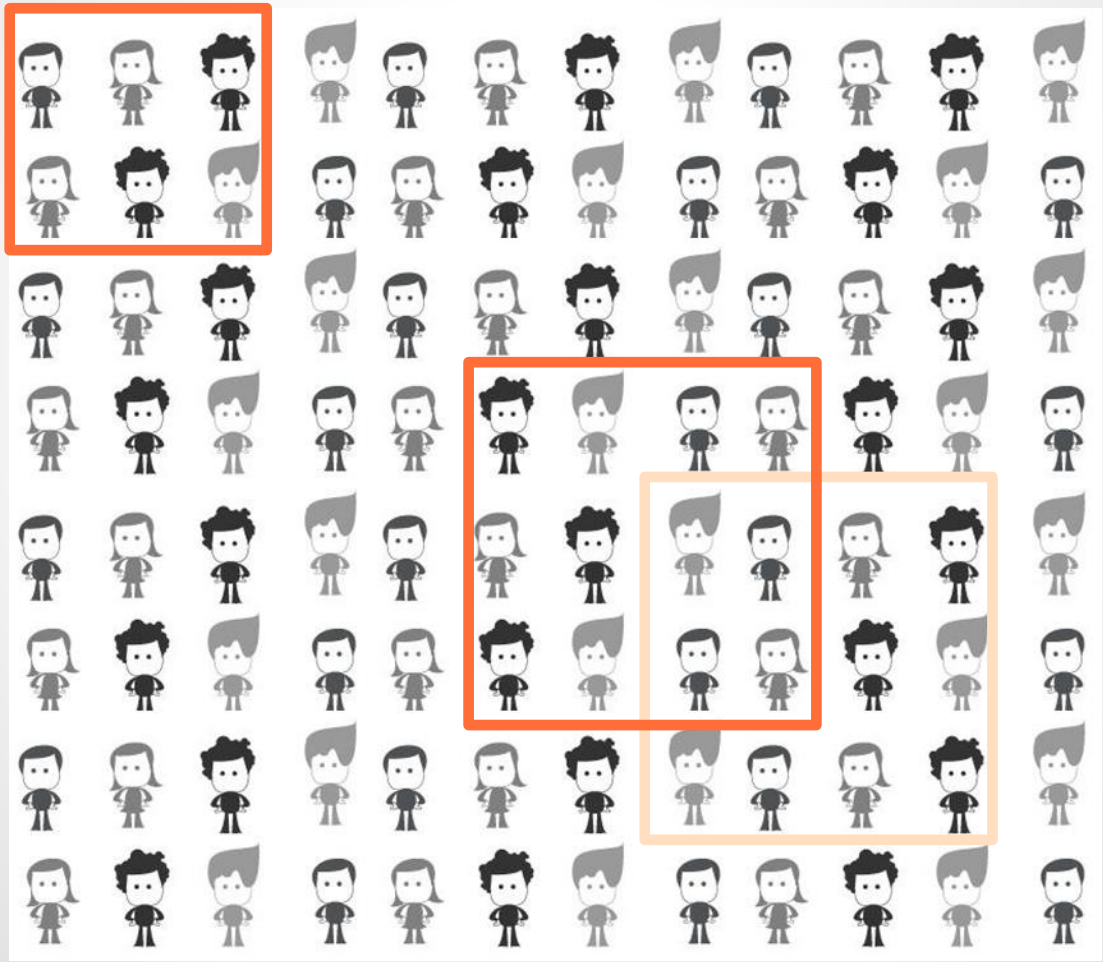
Up to 100,000 deaths and 2 million hospitalisations per year in the United States

Many therapeutics in development eventually fail to reach patients and costs of bringing a new drug to market are now > 1 billion Euros

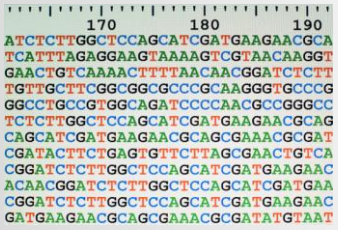
Pharmacogenomic assays and treatment algorithms are becoming more and more numerous



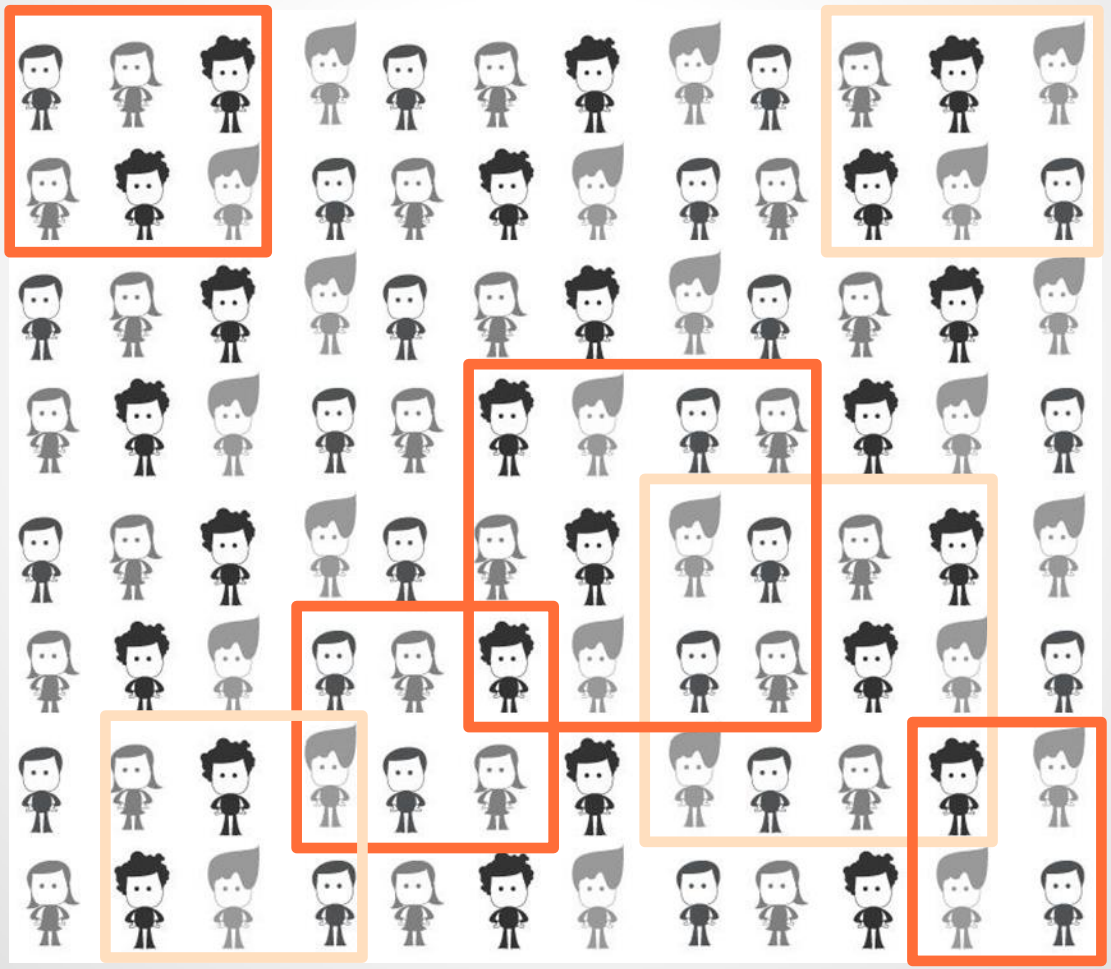
Pharmacogenomic assays and treatment algorithms are becoming more and more numerous

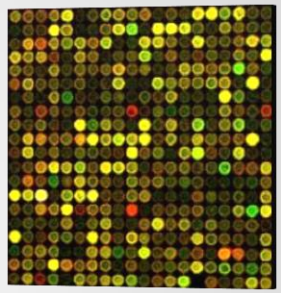


Pharmacogenetic assays and treatment algorithms are becoming more and more numerous



Sequencing-based:
PGRNseq
…

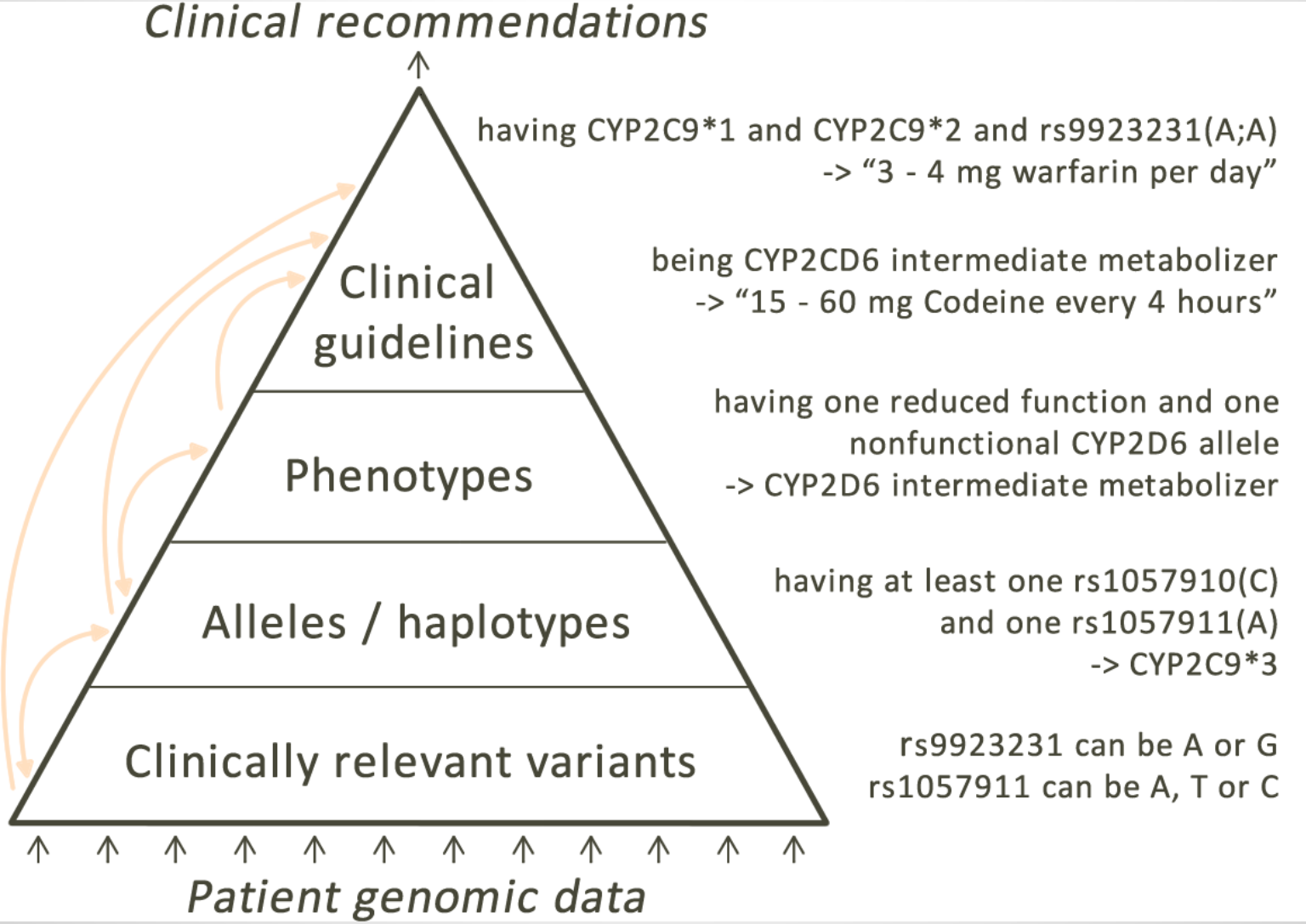




Microarray-based:
23andMe
Affymetrix DMET chip
Florida/Stanford chip
…

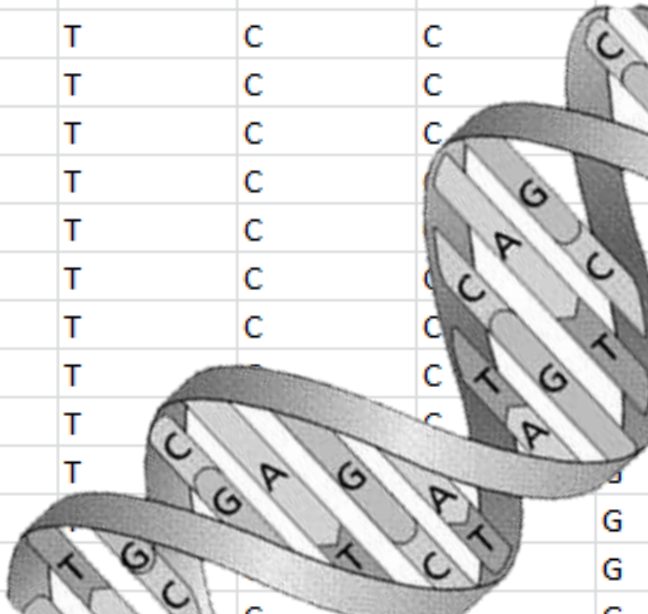
We are creating framework for representing pharmacogenomic knowledge and providing clinical decision support

Matching patients to guidelines while minimizing potential for errors is non-trivial



Matching patients to guidelines while minimizing potential for errors is non-trivial

gene	haplotype	rs1057910	rs1057911	rs1799853	rs2256871	rs28371685	rs28371686	rs56165452	rs57505750	rs67807361	rs7
CYP2C9	*1	A	A	C	A	C	C	T	C	C	G
CYP2C9	*2	A	A	T [tag]	A	C	C	T	C	C	G
CYP2C9	*3	C [tag]	A	C	A	C	C	T	C	C	G
CYP2C9	*4	A	A	C	A	C	C	C [tag]	C	C	G
CYP2C9	*5	A	A	C	A	C	G [tag]	T	C	C	G
CYP2C9	*6	A	A	C	A	C	C	T	C	C	G
CYP2C9	*7	A	A	C	A	C	C	T	C	A [tag]	G
CYP2C9	*9	A	A	C	G [tag]	C	C	T	C	C	G
CYP2C9	*10	A	A	C	A	C	C	T	C	C	G
CYP2C9	*11	A	A	C	A	T [tag]	C	T	C	C	G
CYP2C9	*18	C [tag]	T [tag]	C	A	C	C	T	C	C	
CYP2C9	*19	A	A	C	A	C	C	T	C	C	
CYP2C9	*20	A	A	C	A	C	C	T	C	C	
CYP2C9	*21	A	A	C	A	C	C	T	C		
CYP2C9	*22	A	A	C	A	C	C	T	C		
CYP2C9	*23	A	A	C	A	C	C	T	C		
CYP2C9	*24	A	A	C/T	A	C	C	T	C	C	
CYP2C9	*25	A	A	C	A	C	C	T		C	
CYP2C9	*26	A	A	C	A	C	C	T			
CYP2C9	*27	A	A	C	A	C	C	T			
CYP2C9	*28	A	A	C	A	C	C				G
CYP2C9	*29	A	A	C	A	C	C				G



We are actively maintaining an ontology-based knowledge base

- Knowledge of approx. 300 decision support rules for 60 drugs, >400 markers associated with 58 genes
- Enabling decision support, KB analysis and consistency checking

- Current side project:
  - Technology assessment and analysis of medical impact, e.g., in Germany, drugs covered by system account for **123 M prescriptions costing 3,7 billion € in private practice per year**

How to anchor pharmacogenomics in clinical routine?

- Data not easily available at point of care
  - Pre-emptive testing for several markers at once is probably more effective than ad-hoc testing [1]
  - Keeping genetic data in patient record might not even be legally allowed!
- Even when data is available, medical practitioners report they do not have enough knowledge to interpret the data!

(1) Van Driest SL, Shi Y, Bowton EA, Schildcrout JS, Peterson JF, Pulley J, et al. Clinically actionable genotypes among 10,000 patients with preemptive pharmacogenomic testing. Clin Pharmacol Ther. 2014 Apr;95(4):423–31.

We are creating a barrier-free system for storing and interpreting personal pharmacogenomic information: The Medicine Safety Code

Current version contains data on ~15 pharmacogenes with clinically actionable variants

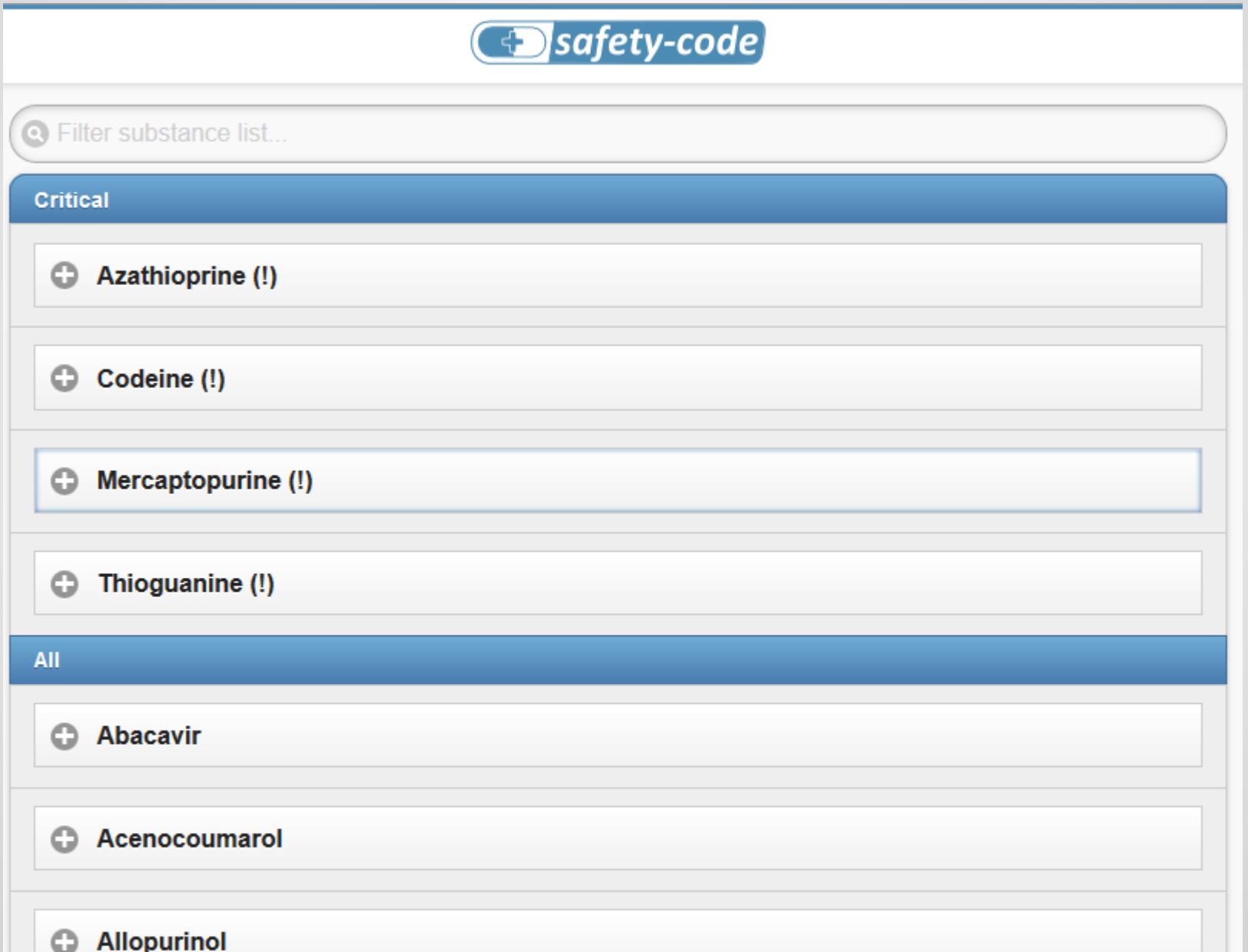
generate
2D barcode

We are creating a barrier-free system for storing and interpreting personal pharmacogenomic information: The Medicine Safety Code

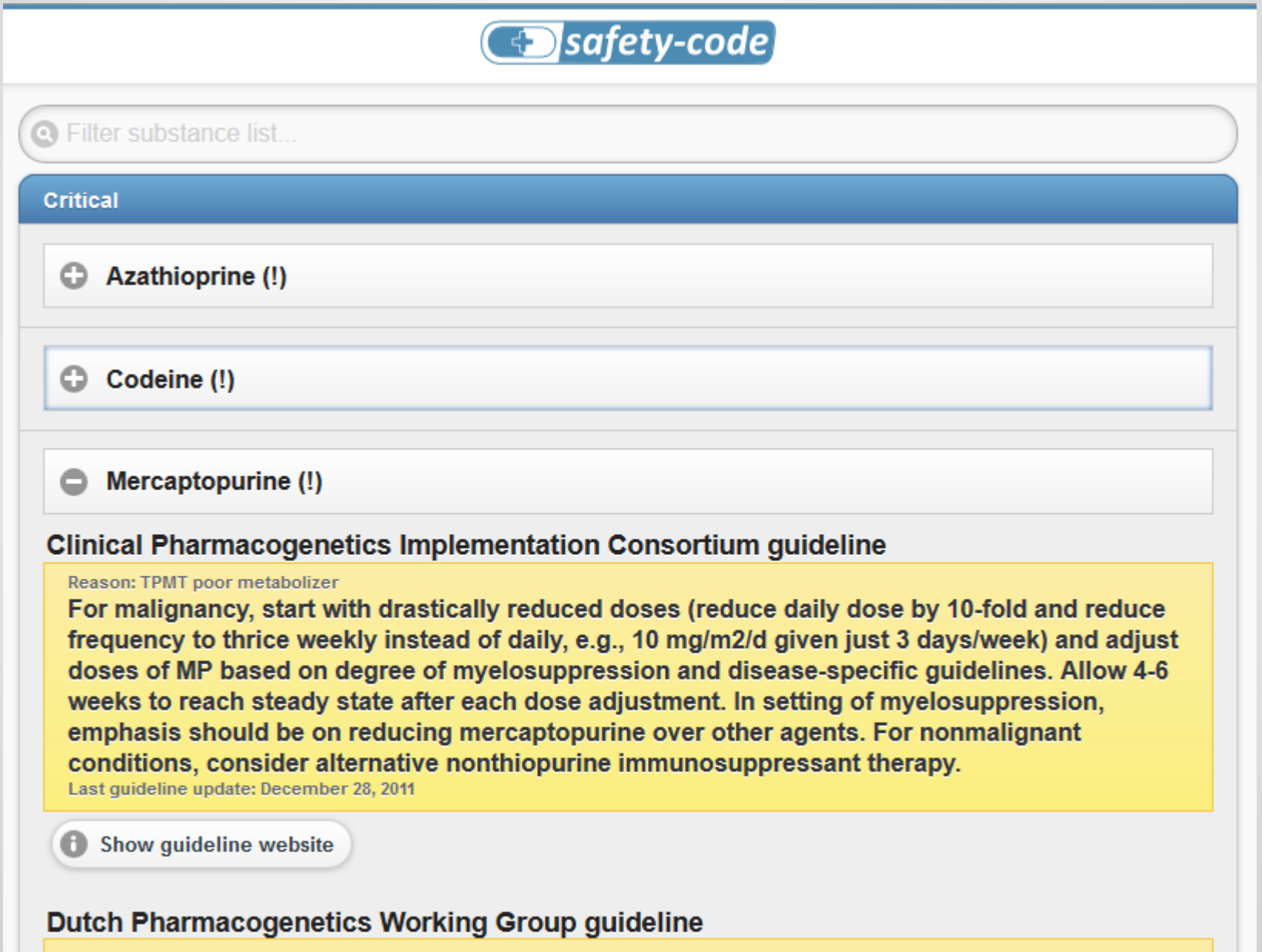
Technology

- **Compressed pharmacogenomic data in QR codes**
- **Can be readily decoded and interpreted with common mobile devices**
  - QR code readers come pre-installed on most devices; installation of dedicated apps not required
  - Web-based decision support service gives dosing recommendations based on up-to-date clinical guidelines
- **All data are inside the QR code**
  - No central database required
    (patients have full control over their data)
  - Optionally, client-side decoding without web access possible
- **Data remains anonymous**
- **Backed by a sophisticated knowledge base we created**

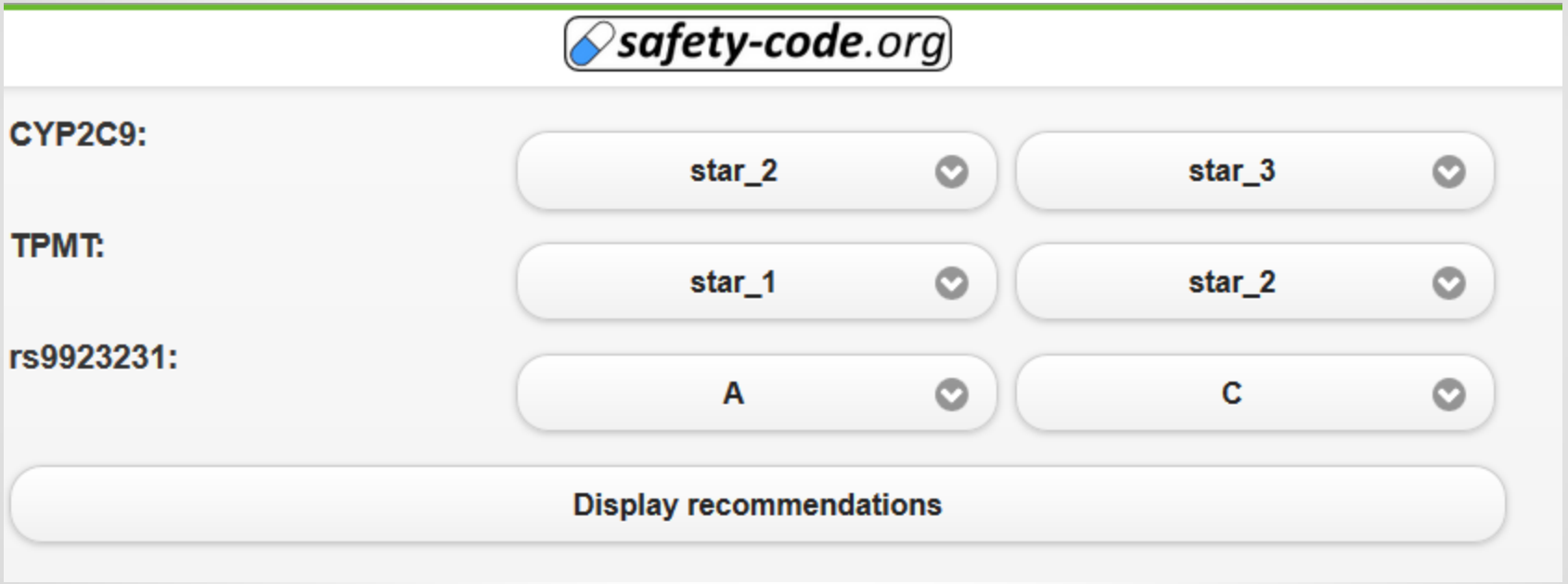
Matching treatment recommendations are displayed



Matching treatment recommendations are displayed



Alternatively, you can select drugs for which treatment recommendations are required and enter data manually



Goal

- **Creating a barrier-free system for putting personalized medicine into the pockets of patients**
- **Making pharmacotherapy safer, more effective and less costly**
- **Cooperation of stakeholders**
  - Clinical institutions and medical professionals
  - Health insurance providers
  - Pharmaceutical companies
  - Genetic testing providers
  - Health IT companies
  - Patient organisations
- **Enable bringing stratified/personalized therapeutics to market**

safety-code
The Medicine Safety Code initiative

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LET'S MAKE DATA ON ESSENTIAL PHARMACOGENES AVAILABLE FOR EVERY PATIENT EVERYWHERE!

The MSC is a technologically-simple and intuitive system that could address many of the barriers that limit the ability to share and utilize pharmacogenetic test results in clinical practice, but the true potential of this project will not be realized until the MSC is tested in different scenarios. Partnerships with clinical institutions, researchers, pharmaceutical companies, genetic testing providers, health IT companies and governmental organizations are needed. If you are interested in making personalized medicine a reality, please visit the contact page on this website.

COORDINATOR

- **Matthias Samwald** (Medical University of Vienna, Vienna, Austria)

ACTIVE PARTICIPANTS

- **Robert R. Freimuth** (Mayo Clinic, Rochester, MN, USA)
- **Richard D. Boyce** (University of Pittsburgh, Pittsburgh, PA, USA)
- **Michel Dumontier** (Stanford University, Stanford, CA, USA)

Join us on
http://safety-code.org/

Next steps / Important discussion points

- Evaluate in clinical settings, incorporate feedback
  - Preliminary evaluations currently conducted by participants at the University of Pittsburgh, USA
- Integrate with guidelines for drug-drug interactions

Next steps / Important discussion points

Food for discussion:
How could super-institutional IT systems for clinical pharmacogenomics be established in Austria?

- Safety Code system a viable option?
- Practical considerations?
- Legal considerations?
- (Pharmaco-)genetic data in ELGA??

Thanks!

Local team (Medical University of Vienna)

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Simon Lin (Marshfield Clinic)

Web

http://safety-code.org/

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