PharmVar
Pharmacogene Variation Consortium

The Pharmacogene Variation (PharmVar) Consortium is a central repository for pharmacogene (PGx) variation that focuses on haplotype structure and allelic variation.

The information in this resource facilitates the interpretation of pharmacogenetic test results to guide precision medicine.

Andrea Gaedigk, MS, PhD

Professor

Children's Mercy Research Institute, Kansas City

University of Missouri-Kansas City

Director, PharmVar

Children's Mercy KANSAS CITY | Research Institute

BEST CHILDREN'S HOSPITALS U.S.News RANKED IN 10 SPECIALTIES 2022-23

MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

UMKC School of Medicine

KU SCHOOL OF MEDICINE The University of Kansas

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PharmVar API Services are now available for third party use. For more information, visit the API Service Documentation Page

What's New 3

PharmVar Publications

Articles published by PharmVar are available on the resources page.

What's new on PharmVar

IMPROVEMENT May 20, 2024

Variant Frequencies

- The frequency of a variant displayed in the **Variant Window** is now directly sourced from the latest version of gnomAD
- The frequency provided here represents the global frequency of the variant which may considerably vary across populations
- Information regarding variant frequencies can now also easily be accessed via the external resources link to the PharmGKB SNP page
- Please note that the frequency of a variant does not reflect the frequency of a haplotype (or star allele) if it is part of two or more haplotypes

NEW April 18, 2024

Database Updated to Version 6.1.2

CYP2D6

1. **27.001* now fully characterized; evidence level upgraded to 'Definitive'

2. Addition of wo novel **27* suballeles, **27.002* and **27.003*

3. **27.002* was found as a 'singleton' gene and in an identical **27.002x2* duplication configuration

4. **41.005* was corrected (see Change Log document for details)

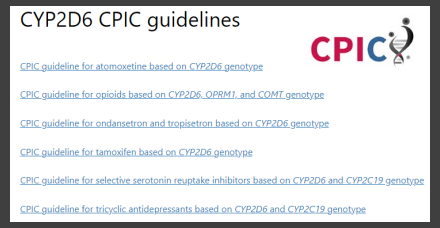
NEW March 11, 2024

Database Updated to Version 6.1

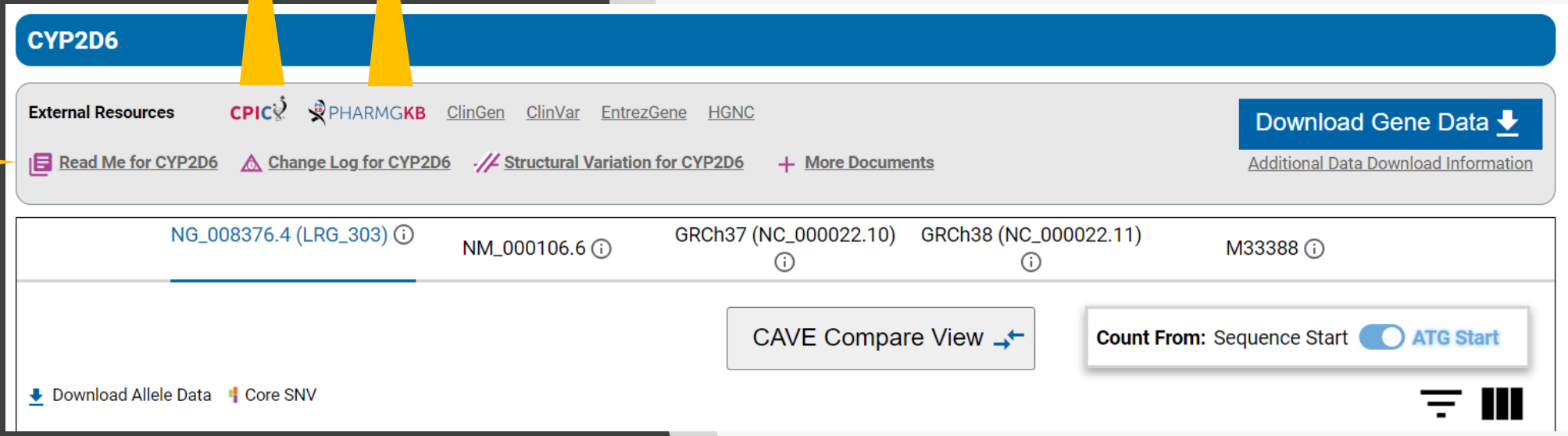
New gene: *NAT2*

NAT2 nomenclature was transferred from from the original Database of Arylamine *N*-Acetyltransferases to PharmVar on March 11, 2024.

PharmVar gene pages



RefSeq	5' limit Counting from the sequence start	5' limit Counting from the ATG translation start	3' limit Counting from the sequence start	3' limit Counting from the ATG translation start
NG_008376.4	3436	-1584	9501	4482
All SNVs within the 5' and 3' limits must be submitted for haplotype (star allele) definitions. This includes 5' flanking sequence, the 5' UTR, exons 1-9, introns 1-8, the 3' UTR, and the 3' flanking sequence.				



PharmVar

deposited by now has “year” the allele was posted

citations

CYP2D6*27		PV00451	CPIC Clinical Function →	
CYP2D6*27.001	CYP2D6*27	PV00130	Def	Marez et al. 1997 Sakuyama et al. 2008 deposited by Gelineau-Morel/PharmVar Team 2024 deposited by Nofziger et al 2024
CYP2D6*27.002		PV02496	Def	deposited by Nofziger et al 2024
CYP2D6*27.003		PV02497	Def	deposited by Nofziger et al 2024

Coming: more info about depositing author(s) in Change Log document

PharmVar
Variant Frequencies

CYP2D6*10 | 100C>T (rs1065852, P34S) | 4181G>C (rs1...

Variant Positions

Gene	NG_008376.4:g.5119C>T
Transcript	NM_000106.6:c.100C>T
GRCh37	NC_000022.10:g.42526694G>A
GRCh38	NC_000022.11:g.42130692G>A

Reference Sequence	Position	Reference		Variant
NG_008376.4				
Sequence Start	5119	C	>	T
ATG Start	100	C	>	T
NM_000106.6				
Sequence Start	119	C	>	T
ATG Start	100	C	>	T
GRCh37 (NC_000022.10)				

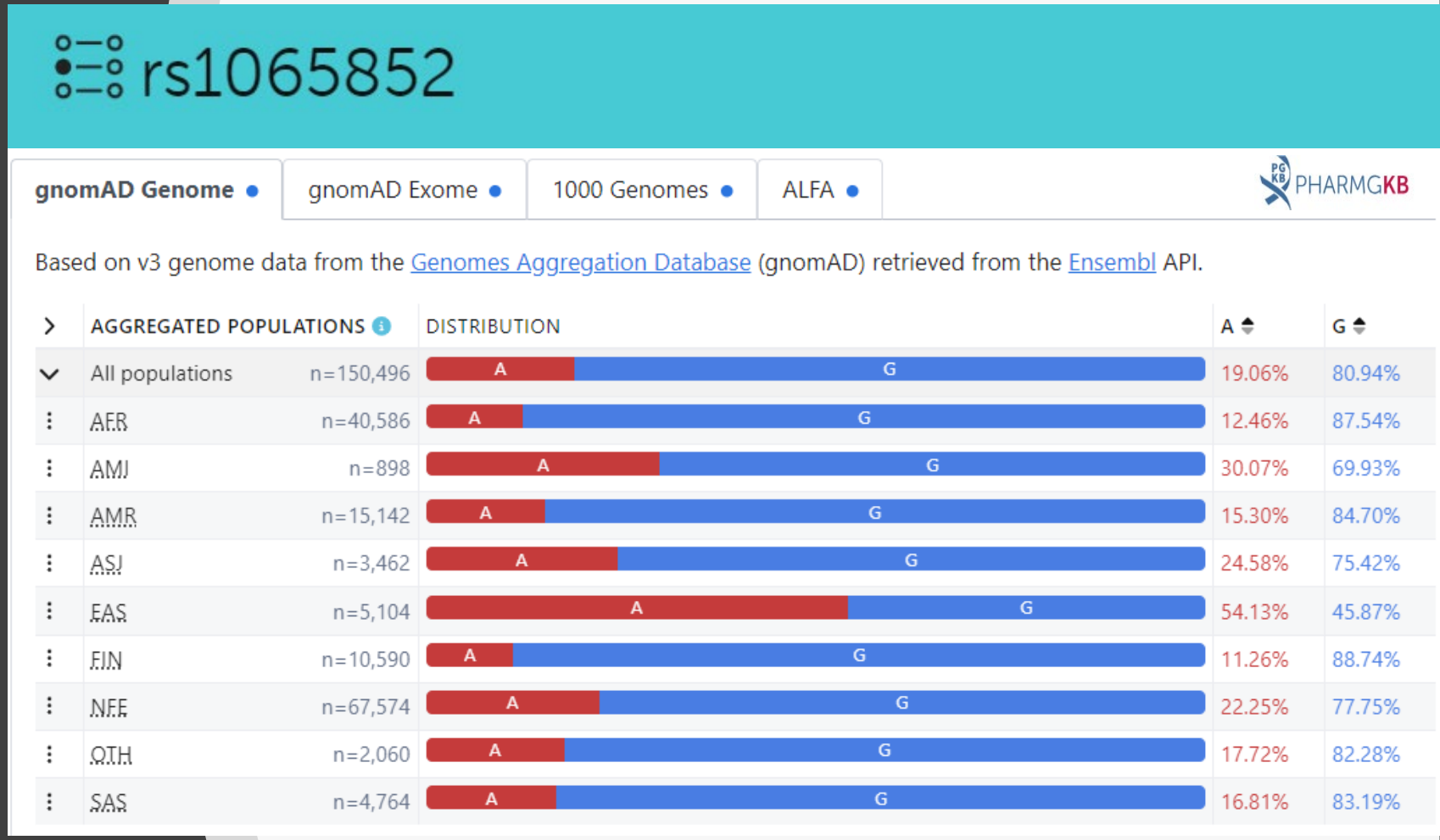
Show Haplotypes With This Variant

External Resources: dbSNP:rs1065852, PharmGKB:PA166156062, GnomAD:rs1065852

Variant Frequency: 0.212157 (GnomAD)

PharmVar Variant Frequencies

link to PharmGKB variant/SNP page



rs1065852

gnomAD Genome • | gnomAD Exome • | 1000 Genomes • | ALFA •

PHARMGKB

Based on v3 genome data from the Genomes Aggregation Database (gnomAD) retrieved from the Ensembl API.

AGGREGATED POPULATIONS		DISTRIBUTION	A	G
All populations	n=150,496	A G	19.06%	80.94%
AFR	n=40,586	A G	12.46%	87.54%
AMJ	n=898	A G	30.07%	69.93%
AMR	n=15,142	A G	15.30%	84.70%
ASJ	n=3,462	A G	24.58%	75.42%
EAS	n=5,104	A G	54.13%	45.87%
FIN	n=10,590	A G	11.26%	88.74%
NFE	n=67,574	A G	22.25%	77.75%
OTH	n=2,060	A G	17.72%	82.28%
SAS	n=4,764	A G	16.81%	83.19%

This SNP is presents the frequency of *ALL* star alleles including **4* and **10*

PharmVar Allele Window

More info coming

- link to PharmGKB haplotype page

CYP2D6*10

CPIC | UK Biobank

Based on CPIC Frequency Tables.

POPULATION	CYP2D6*10 OBSERVED	ALLELES TOTAL	FREQUENCY
African American/Afro-Caribbean	777	20368	3.82%
American	127	8768	1.45%
Central/South Asian	339	4488	7.56%
East Asian	16973	39616	42.84%
European	1750	111390	1.57%
Latino	423	16098	2.63%
Near Eastern	313	4626	6.77%
Oceanian	114	1998	5.71%
Sub-Saharan African	220	4518	4.87%

DPYD

Get-RM study

Reference Materials

AMP

Clinical testing recommendations

Characterization of Reference Materials for *DPYD* – A GeT-RM Collaborative Project

Gaedigk, Turner, Moyer, Zubiaur, Boone, Wang, Broeckel and Kalman

J Mol Diag, in revision

***DPYD* Genotyping Recommendations: A Joint Consensus Recommendation of the AMP, ACMG, CPIC, American Pathologists, DPWG, ESPG, PharmGKV and PharmVar**

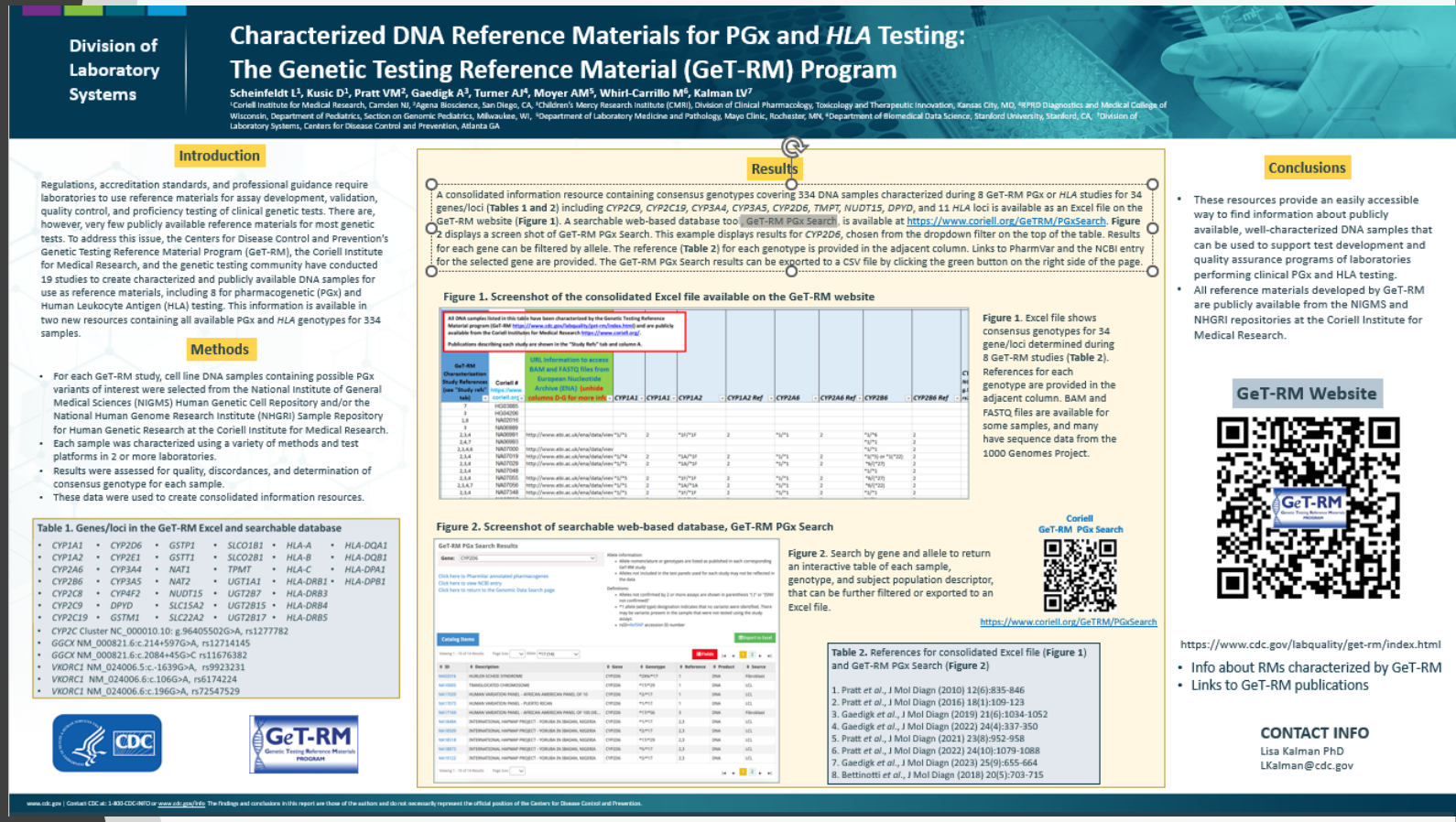
Pratt, Cavallari, Fulmer, Gaedigk, Hachad, Ji, Kalman, Ly, Moyer, Scott, Turner, van Scaik, Whirl-Carrillo and Weck

J Mol Diag, accepted

GeT-RM PGx Search Tool

coriell.org/GetRM/PGxSearch

Consensus genotypes covering
- 334 Coriell DNA samples
- 8 GeT-RM studies
- 34 genes/loci



Division of Laboratory Systems

Characterized DNA Reference Materials for PGx and *HLA* Testing: The Genetic Testing Reference Material (GeT-RM) Program

Scheinfeldt L[1], Kusic D[1], Pratt VM[2], Gaedigk A[3], Turner AJ[4], Moyer AM[5], Whirl-Carrillo M[6], Kalman LV[7]
[1]Coriell Institute for Medical Research, Camden NJ, [2]Agena Bioscience, San Diego, CA, [3]Children's Mercy Research Institute (CMRI), Division of Clinical Pharmacology, Toxicology and Therapeutic Innovation, Kansas City, MO, [4]PRPD Diagnostics and Medical College of Wisconsin, Department of Pediatrics, Section on Genomic Pediatrics, Milwaukee, WI, [5]Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN, [6]Department of Biomedical Data Science, Stanford University, Stanford, CA, [7]Division of Laboratory Systems, Centers for Disease Control and Prevention, Atlanta GA

Introduction

Regulations, accreditation standards, and professional guidance require laboratories to use reference materials for assay development, validation, quality control, and proficiency testing of clinical genetic tests. There are, however, very few publicly available reference materials for most genetic tests. To address this issue, the Centers for Disease Control and Prevention's Genetic Testing Reference Material Program (GeT-RM), the Coriell Institute for Medical Research, and the genetic testing community have conducted 19 studies to create characterized and publicly available DNA samples for use as reference materials, including 8 for pharmacogenetic (PGx) and Human Leukocyte Antigen (HLA) testing. This information is available in two new resources containing all available PGx and *HLA* genotypes for 334 samples.

Methods

- For each GeT-RM study, cell line DNA samples containing possible PGx variants of interest were selected from the National Institute of General Medical Sciences (NIGMS) Human Genetic Cell Repository and/or the National Human Genome Research Institute (NHGRI) Sample Repository for Human Genetic Research at the Coriell Institute for Medical Research.
- Each sample was characterized using a variety of methods and test platforms in 2 or more laboratories.
- Results were assessed for quality, discordances, and determination of consensus genotype for each sample.
- These data were used to create consolidated information resources.

Table 1. Genes/loci in the GeT-RM Excel and searchable database

CYP1A1	*CYP2D6*	*GSTP1*	*SLCO1B1*	*HLA-A*	*HLA-DQA1*
CYP1A2	*CYP2E1*	*GSTT1*	*SLCO2B1*	*HLA-B*	*HLA-DQB1*
CYP2A6	*CYP3A4*	*NAT1*	*TPMT*	*HLA-C*	*HLA-DPA1*
CYP2B6	*CYP3A5*	*NAT2*	*UGT1A1*	*HLA-DRB1*	*HLA-DPB1*
CYP2C8	*CYP4F2*	*NUDT15*	*UGT2B7*	*HLA-DRB3*	
CYP2C9	*DPYD*	*SLC15A2*	*UGT2B15*	*HLA-DRB4*	
CYP2C19	*GSTM1*	*SLC22A2*	*UGT2B17*	*HLA-DRB5*	

- *CYP2C* Cluster NC_000010.10: g.96405502G>A, rs1277782
- *GGCX* NM_000821.6:c.214+597G>A, rs12714145
- *GGCX* NM_000821.6:c.2084+45G>C rs11676382
- *VKORC1* NM_024006.5:c.-1639G>A, rs9923231
- *VKORC1* NM_024006.6:c.106G>A, rs6174224
- *VKORC1* NM_024006.6:c.196G>A, rs72547529

Results

A consolidated information resource containing consensus genotypes covering 334 DNA samples characterized during 8 GeT-RM PGx or *HLA* studies for 34 genes/loci (**Tables 1 and 2**) including *CYP2C9, CYP2C19, CYP3A4, CYP3A5, CYP2D6, TMPT, NUDT15, DPYD,* and 11 *HLA* loci is available as an Excel file on the GeT-RM website (**Figure 1**). A searchable web-based database tool, GeT-RM PGx Search, is available at https://www.coriell.org/GeTRM/PGxSearch. **Figure 2** displays a screen shot of GeT-RM PGx Search. This example displays results for *CYP2D6*, chosen from the dropdown filter on the top of the table. Results for each gene can be filtered by allele. The reference (**Table 2**) for each genotype is provided in the adjacent column. Links to PharmVar and the NCBI entry for the selected gene are provided. The GeT-RM PGx Search results can be exported to a CSV file by clicking the green button on the right side of the page.

Figure 1. Screenshot of the consolidated Excel file available on the GeT-RM website

Figure 1. Excel file shows consensus genotypes for 34 gene/loci determined during 8 GeT-RM studies (**Table 2**). References for each genotype are provided in the adjacent column. BAM and FASTQ files are available for some samples, and many have sequence data from the 1000 Genomes Project.

Figure 2. Screenshot of searchable web-based database, GeT-RM PGx Search

Figure 2. Search by gene and allele to return an interactive table of each sample, genotype, and subject population descriptor, that can be further filtered or exported to an Excel file.

Coriell GeT-RM PGx Search

https://www.coriell.org/GeTRM/PGxSearch

Table 2. References for consolidated Excel file (**Figure 1**) and GeT-RM PGx Search (**Figure 2**)

1. Pratt *et al.*, J Mol Diagn (2010) 12(6):835-846
2. Pratt *et al.*, J Mol Diagn (2016) 18(1):109-123
3. Gaedigk *et al.*, J Mol Diagn (2019) 21(6):1034-1052
4. Gaedigk *et al.*, J Mol Diagn (2022) 24(4):337-350
5. Pratt *et al.*, J Mol Diagn (2021) 23(8):952-958
6. Pratt *et al.*, J Mol Diagn (2022) 24(10):1079-1088
7. Gaedigk *et al.*, J Mol Diagn (2023) 25(9):655-664
8. Bettinotti *et al.*, J Mol Diagn (2018) 20(5):703-715

Conclusions

- These resources provide an easily accessible way to find information about publicly available, well-characterized DNA samples that can be used to support test development and quality assurance programs of laboratories performing clinical PGx and HLA testing.
- All reference materials developed by GeT-RM are publicly available from the NIGMS and NHGRI repositories at the Coriell Institute for Medical Research.

GeT-RM Website

https://www.cdc.gov/labquality/get-rm/index.html

- Info about RMs characterized by GeT-RM
- Links to GeT-RM publications

CONTACT INFO
Lisa Kalman PhD
LKalman@cdc.gov

Poster #16

PharmVar publications

Pharmacogene Variation Consortium: A Global Resource and Repository for Pharmacogene Variation

Andrea Gaedigk[1,2,*], Scott T. Casey[3], Michelle Whirl-Carrillo[4], Neil A. Miller[3] and Teri E. Klein[4,5]

2021

Please cite!

2023

PharmVar Tutorial on *CYP2D6* Structural Variation Testing and Recommendations on Reporting

Amy J. Turner[1,2], Charity Nofziger[3], Bronwyn E. Ramey[4], Reynold C. Ly[5], Chad A. Bousman[6], José A. G. Agúndez[7,8], Katrin Sangkuhl[9], Michelle Whirl-Carrillo[9], Simone Vanoni[3], Henry M. Dunnenberger[10], Gualberto Ruaño[11,12], Martin A. Kennedy[13], Michael S. Phillips[14], Houda Hachad[15], Teri E. Klein[16], Ann M. Moyer[17] and Andrea Gaedigk[18,19,*]

Coming

PharmVar GeneFocus: *CYP2A6* (in revision)

PharmVar GeneFocus: *CYP4F2* (submitted)

PharmVar GeneFocus: *NAT2* (initiated)

CYP2D6
this panel keeps busy…

- New star alleles, suballeles and structural variants keep coming
- "Clean-up" efforts
  - Looking into alleles with limited evidence that were first defined using methods we would not accept today
    - Confirmed **27*, there are now three suballeles, one found as **27.002x2*
    - *Need to confirm *20, *23, *24, *25, *26, *30, *34, *37* and some **2, *3, *4, *6, *12, *19* suballeles
  - Concerns that some of these alleles do not exist as defined
    - Retire some alleles if no evidence can be found in the literature or databases supporting the allele in question?
  - Can we identify samples with SNV(s) of interest for reanalysis?

If you have data for alleles with a "Limited" or "Moderate" evidence level, please consider submitting to PharmVar

CYP2D6 Gene Expert Panel

Role	Name	Institution	Country
Chair	Andrea Gaedigk	Children's Mercy/PharmVar	USA
Vice Chair	Houda Hachad	AccessDx	USA
PharmVar Representative	Michael Phillips	Precision Medicine Advisers	Canada
PharmGKB/CPIC Representative	Teri Klein	Stanford, PharmGKB	USA
PharmGKB/CPIC Representative	Katrin Sangkuhl	Stanford, PharmGKB	USA
PharmGKB/CPIC Representative	Michelle Whirl-Carrillo	Stanford, PharmGKB	USA
Member	Jose Agundez	Universidad de Extremadura	Spain
Member	Chad Bousman	University of Calgary	Canada
Member	Mark Dunnenberger	NorthShore University HealthSystem	USA
Member	Martin Kennedy	University of Otago	New Zealand
Member	Reynold Ly	Nationwide Children's Hospital	USA
Member	Ann Moyer	Mayo Clinic	USA
Member	Charity Nofziger	PharmGenetix GmbH	Austria
Member	Bronwyn Ramey	Let's Get Checked	USA
Member	Gualberto Ruano	Institute of Living at Hartford Hospital	USA
Member	Amy Turner	Medical College of Wisconsin; RPRD Diagnostics, LLC	USA

***CYP2D6* expert panel**

CYP1A2 curation underway

CYP1A2 Gene Expert Panel

Role	Name	Institution	Country
Chair	Andrea Gaedigk	Children's Mercy Research Institute	USA
Vice Chair	Pablo Zubiaur	Universidad Autonoma de Madrid	Spain
PharmGKB/CPIC Representative	Michelle Whirl-Carrillo	Stanford, PharmGKB	USA
PharmGKB/CPIC Representative	Teri Klein	Stanford, PharmGKB	USA
Member	Solomon Adams	Base5	USA
Member	Matthias König	Humboldt University	Germany
Member	Dora Koller	University of Barcelona	Spain
Member	Volker Lauschke	Karolinska Institutet and Institute of Clinical Pharmacology	Sweden, Germany
Member	Martin Lewis	South Australia Health & Medical Research Institute, Adelaide	Australia
Member	Katalin Monostory	HUN-REN Research Centre for Natural Sciences	Hungary
Member	Mohamed Nagy	Children's Cancer Hospital	Egypt
Member	Amy Turner	Medical College of Wisconsin; RPRD Diagnostics, LLC	USA
Member	David Twesigomwe	Brenner Institute, University of the Witwatersrand	South Africa
Trainee	Gonzalo Villapalos-Garcia	Hospital Universitario de La Princesa and Children's Mercy Research Institute	Spain, USA
Data Specialist	Erin Boone	Children's Mercy Research Institute	USA
Ad Hoc Member	Chad Bousman	University of Calgary	Canada

***CYP1a2* expert panel**

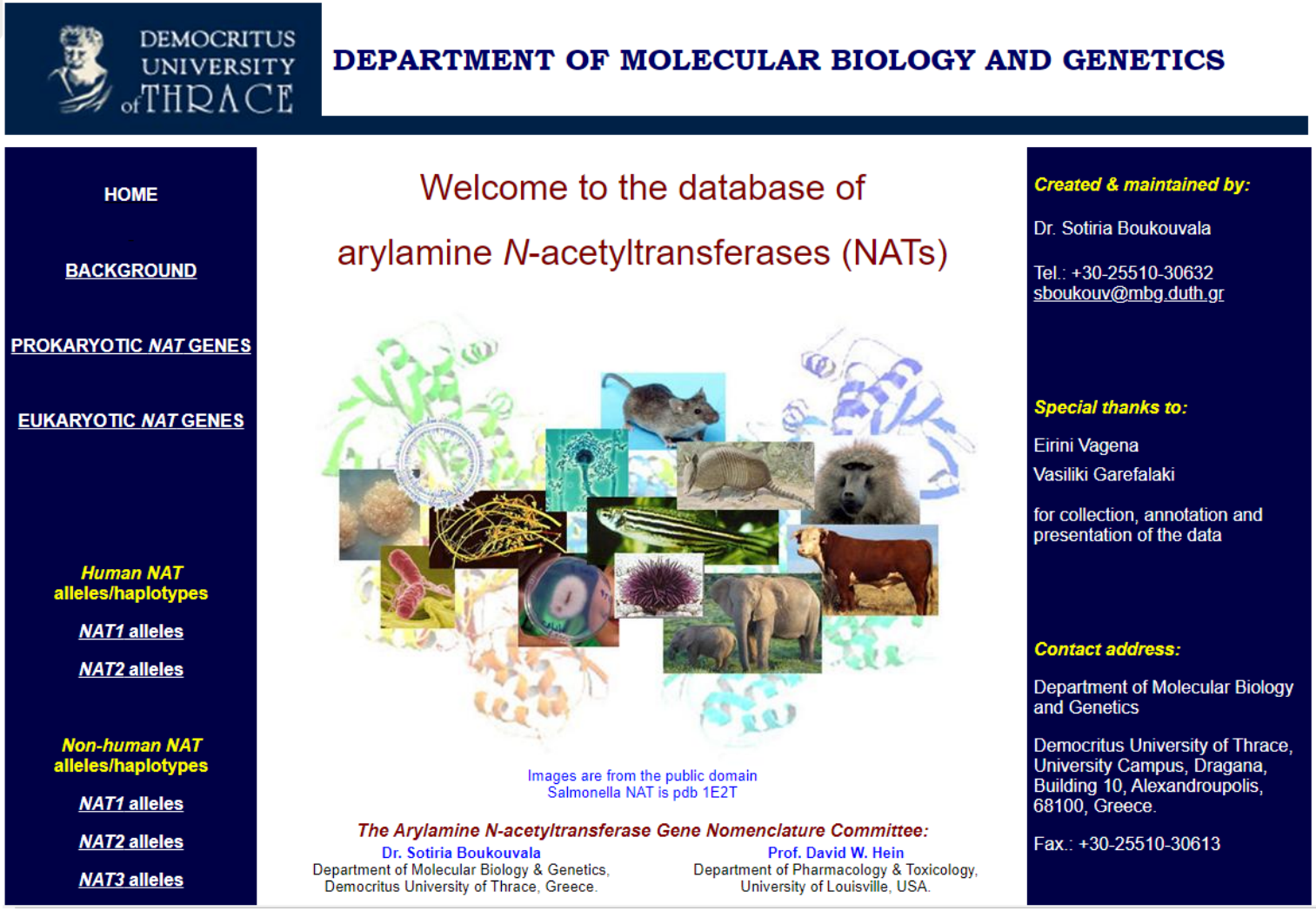
- No CPIC or DPWG guidelines
  - PharmGKB PharmGKB level 3/4
  - PharmVar Priority Level low
- Tested by many PGx panels
- Many star alleles poorly characterized
- Many common haplotypes not defined

Major changes are coming

- Fall 2024

NAT2 transferred from the NAT database to PharmVar!

- PharmVar *NAT2* gene page launched in March 2024
- *NAT2* "legacy" content still available at the DUTH site
- *NAT1* and non-human *NATs* will continue to be hosted by DUTH



Big "Thank You" to all who provided *NAT2* nomenclature in the past and/or served on the PharmVar expert panel to make the transition happen

NAT2
New nomenclature

used for the CPIC guideline on *NAT2* and hydralazine

- Allele definitions include the 5’ and 3’ untranslated regions
- Star allele definitions use NG_012246.1
- The “new” *NAT2*1* allele matches NG_012246.1 and GRCh38 (and the “old” *12A)
- Used 1000 Genomes 30X WGS data to confirm existing allele definitions (and discover some new ones)
- Not all previously defined star alleles were transferred to PharmVar
- Many were assigned a new star allele number to conform with PharmVar rules

NAT2 Gene Expert Panel

Role	Name	Institution	Country
Chair	Andrea Gaedigk	Children's Mercy Research Institute	USA
Chair	Sotiria (Rea) Boukouvala	Democritus University of Thrace	Greece
PharmGKB/CPIC Representative	Michelle Whirl-Carrillo	Stanford, PharmGKB	USA
PharmGKB/CPIC Representative	Katrin Sangkuhl	Stanford, PharmGKB	USA
PharmGKB/CPIC Representative	Teri Klein	Stanford, PharmGKB	USA
Member	Jose Agundez	Universidad de Extremadura	Spain
Member	Giannoulis Fakis	Democritus University of Thrace	Greece
Member	Mariam Habil	University of Louisville	USA
Member	David Hein	University of Louisville	USA
Member	Rod Minchin	University of Queensland	Australia
Trainee	Georgia Papanikolaou	Democritus University of Thrace	Greece
Member	Estella Poloni	University of Geneva	Switzerland
Member	Adalberto Rezende Santos	Oswaldo Cruz Foundation	Brazil
Member	Raquel Teixeira	Laboratório de Biologia Molecular Aplicada a Micobactérias	Brazil
Data Specialist	Erin Boone	Children's Mercy Research Institute	USA

***NAT2* expert panel**

NAT2

Alleles not transferred

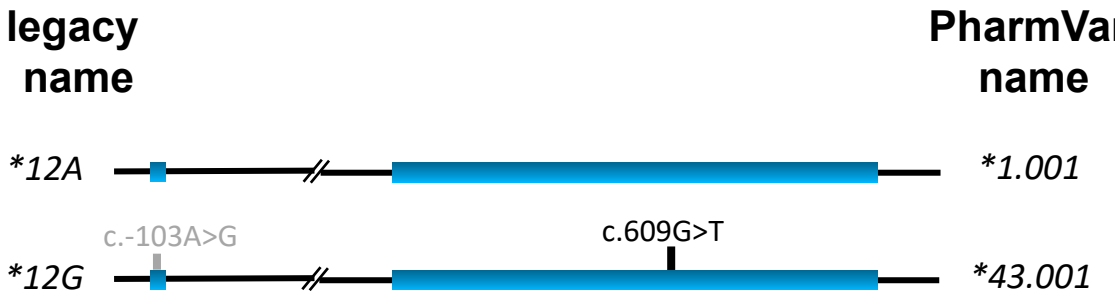
to PharmVar

- Numerous alleles defined based on computational inference
- Papers provide limited/no information about
  - about method
  - SNPs present in subjects(s) with “new” haplotype
  - Possible/alternate diplotype
  - Inferred to be present in one/few subjects
- Concerns about whether these exist
- Efforts underway by panel experts to reanalyze samples, if available
- Experts concurred that experimental validation is needed before transfer to PharmVar to ensure high-quality content of *NAT2* star alleles in PharmVar

NAT2

Renamed alleles

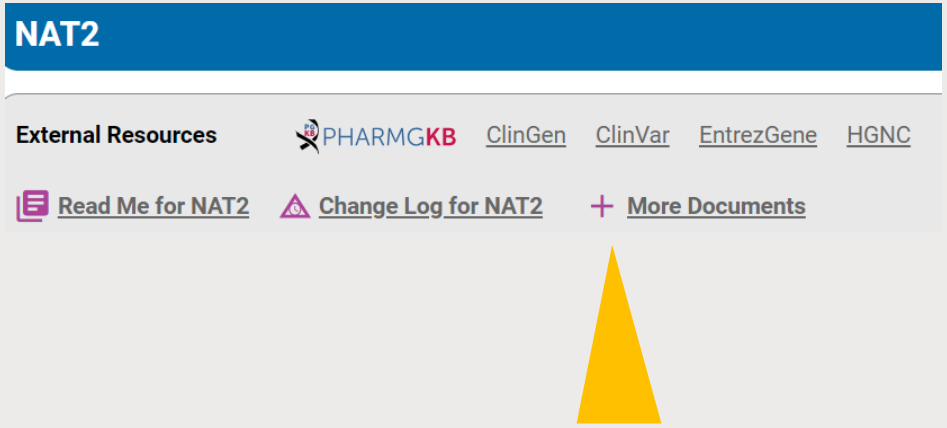
to conform to PharmVar rules



NAT2

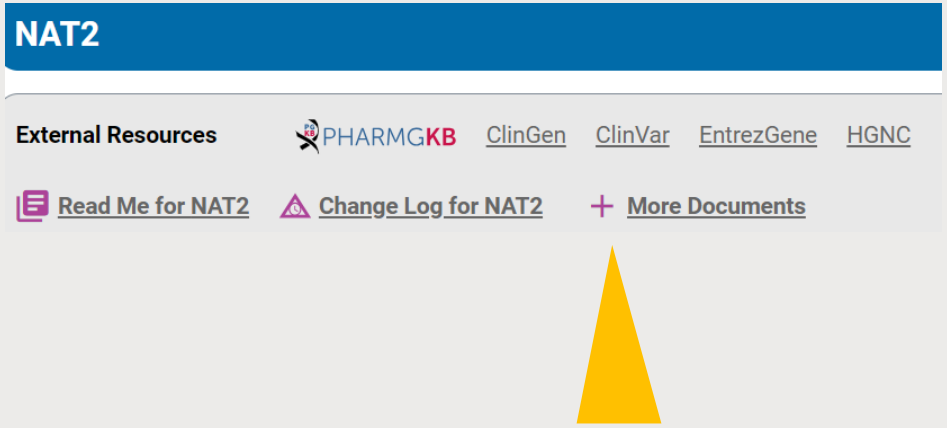
New nomenclature

Look it up!



NAT2

New nomenclature

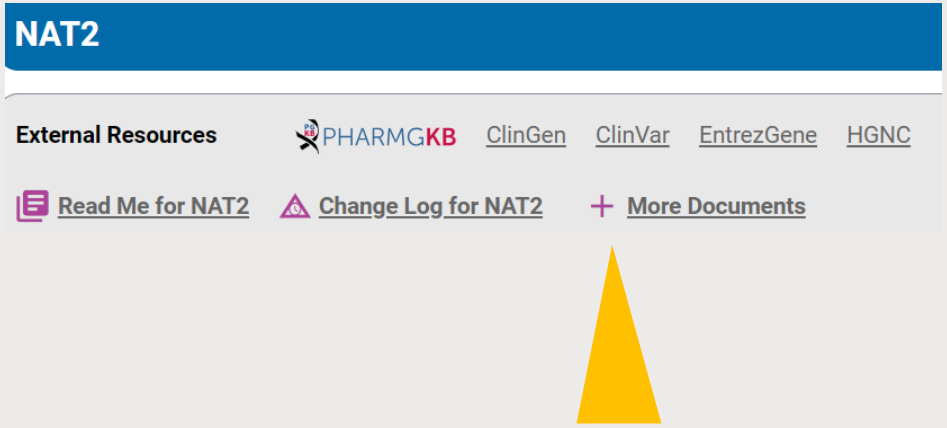


Look-up table

Legacy name	PharmVar Name[1]	Transferred Yes/No	PharmVar data base version if transferred OR why allele was not transferred
**10*	**10.001*	yes	6.1 (March 11, 2024)
**11A*	**4.002*	yes	6.1 (March 11, 2024)
**12A*	**1.001*	yes	6.1 (March 11, 2024)
**12B*	**1.002*	yes	6.1 (March 11, 2024)
**12C*	**1.003*	yes	6.1 (March 11, 2024)
**12D*	**48.001*	yes	6.1 (March 11, 2024)
**12E*	**41.001*	yes	6.1 (March 11, 2024)
**11B*	n/a	no	allele retired from NAT nomenclature site
**12K*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12L*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12M*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**13B*	**13* reserved	no	evidence review in progress; if transferred, allele will keep its original star number
**13C*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar

NAT2

New nomenclature



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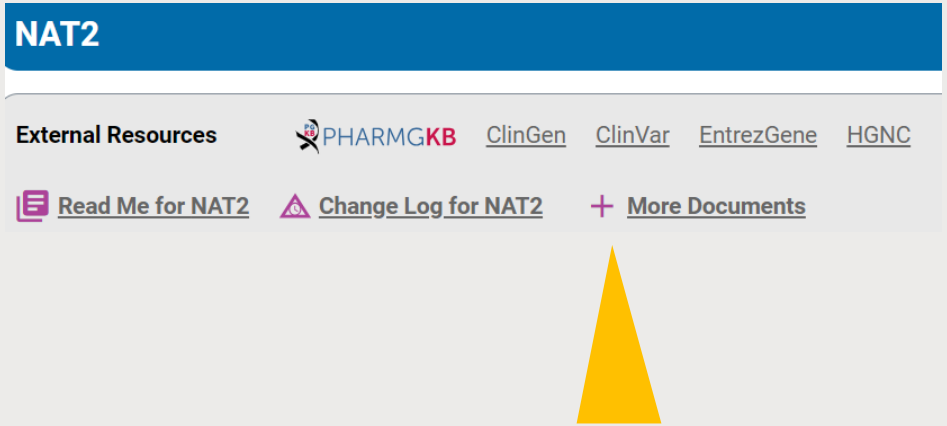
**12A*	**1.001*	yes	6.1 (March 11, 2024)
**12B*	**1.002*	yes	6.1 (March 11, 2024)
**12C*	**1.003*	yes	6.1 (March 11, 2024)
**12D*	**48.001*	yes	6.1 (March 11, 2024)
**12E*	**41.001*	yes	6.1 (March 11, 2024)
**11B*	n/a	no	allele retired from NAT nomenclature site
**12K*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12L*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12M*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**13B*	**13* reserved	no	evidence review in progress; if transferred, allele will keep its original star number
**13C*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar

NAT2

New nomenclature



Look-up table

Legacy name	PharmVar Name[1]	Transferred Yes/No	PharmVar data base version if transferred OR why allele was not transferred
**10*	**10.001*	yes	6.1 (March 11, 2024)
**11A*	**4.002*	yes	6.1 (March 11, 2024)
**12A*	**1.001*	yes	6.1 (March 11, 2024)
**12B*	**1.002*	yes	6.1 (March 11, 2024)
**12C*	**1.003*	yes	6.1 (March 11, 2024)
**12D*	**48.001*	yes	6.1 (March 11, 2024)
**12E*	**41.001*	yes	6.1 (March 11, 2024)
**11B*	n/a	no	allele retired from NAT nomenclature site
**12K*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12L*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**12M*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar
**13B*	**13* reserved	no	evidence review in progress; if transferred, allele will keep its original star number
**13C*	n/a	no	computationally inferred; experimental evidence needed to confirm haplotype and transfer to PharmVar

TPMT?
ABCG2?
VCORC1?
UGT1A1?
Other?

Can’t do this without

Gene Champions and Experts

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PharmVar

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