CPIC Update

March 2, 2023

CPIC staff

Michelle Whirl-Carrillo, PhD

Roseann S. Gammal, PharmD, BCPS

Li Gong, PhD

Katrin Sangkuhl, PhD

Ryan Whaley

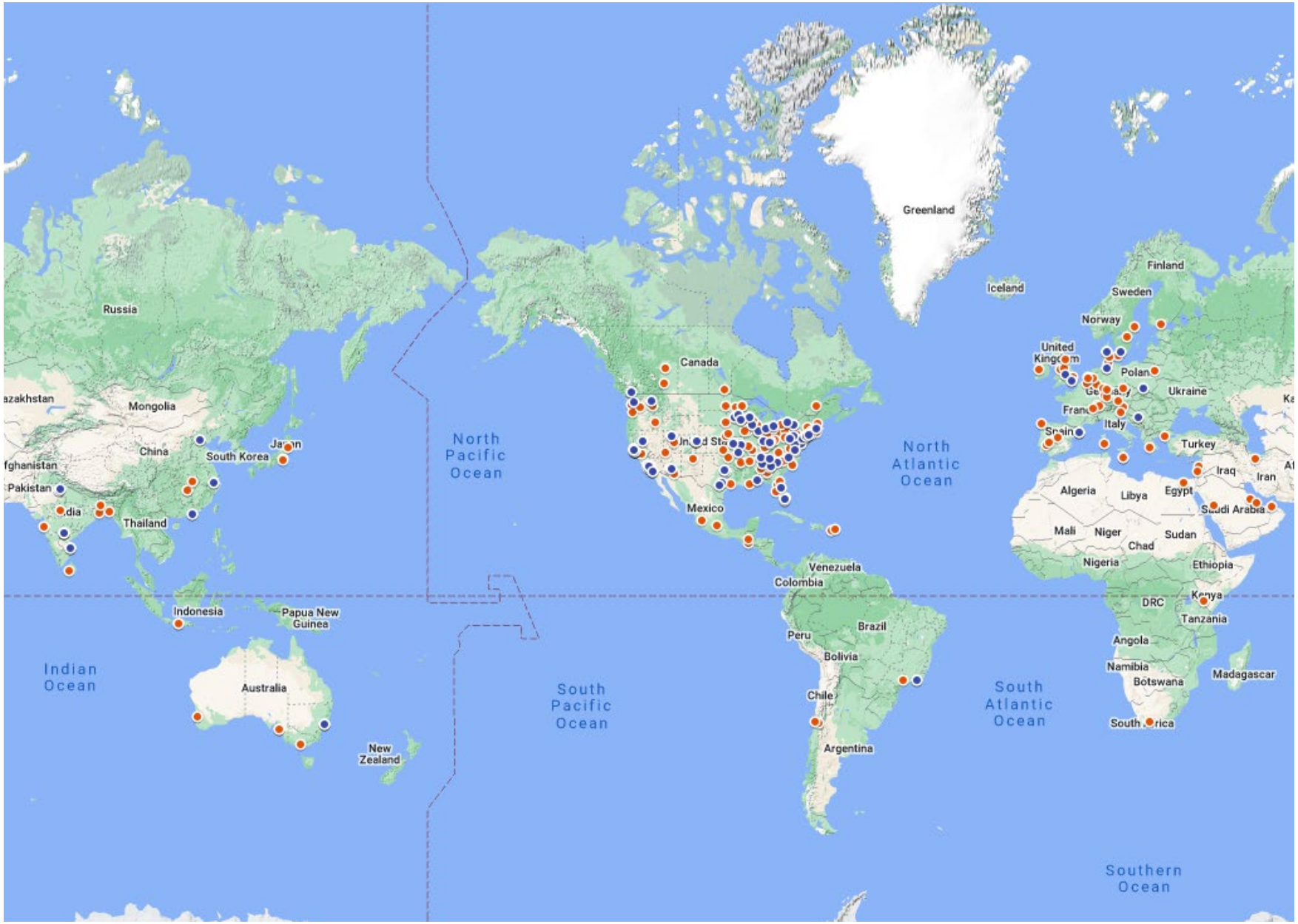
Mark Woon

CPIC membership

As of March 2023:

- 591 current members
  - 437 academia_research
  - 154 industry
  - 443 institutions
  - 49 countries
- 16 observers from FDA and NIH

CPIC members: Over 590



26 guidelines; 25 genes and > 90 drugs

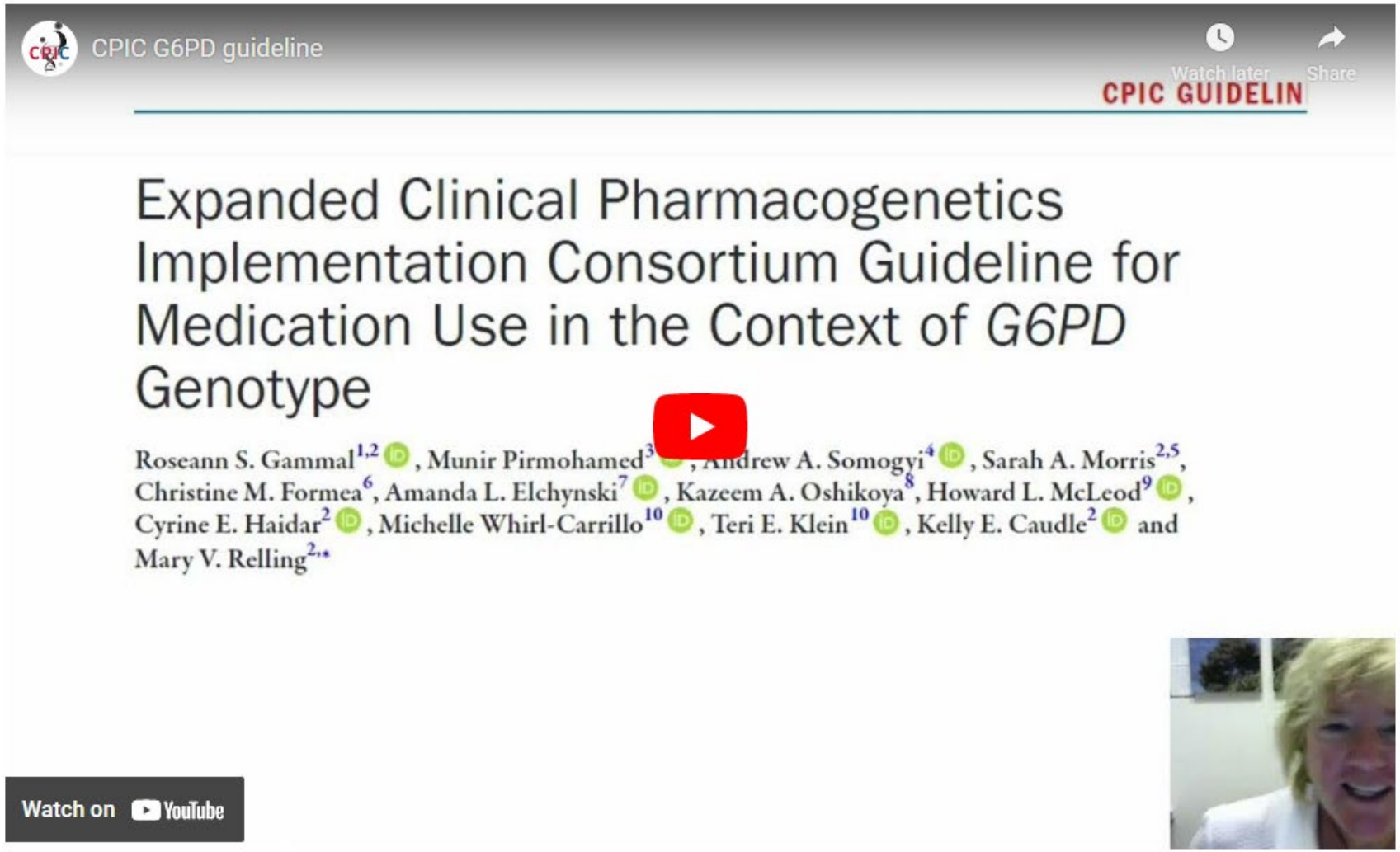
- *TPMT, NUDT15*
  - MP, TG, azathioprine
- *CYP2D6*
  - Codeine, tramadol, hydrocodone, TCAs, tamoxifen, SSRIs, ondansetron, tropisetron, atomoxetine
- *CYP2C19*
  - TCAs, clopidogrel, voriconazole, SSRIs, PPIs
- *VKORC1*
  - Warfarin
- *CYP2C9*
  - Warfarin, phenytoin, NSAIDs, fluvastatin
- *CYP4F2*
  - Warfarin
- CYP2C8
  - NSAIDs
- *HLA-B*
  - Allopurinol, CBZ, Oxcarbazepine, abacavir, phenytoin
- *HLA-A*
  - CBZ
- *CFTR*
  - Ivacaftor
- *DPYD*
  - 5FU, capecitabine, tegafur
- *G6PD*
  - 48 drugs
- *UGT1A1*
  - Atazanavir
- *SLCO1B1*
  - Simvastatin
- *IFNL3 (IL28B)*
  - Interferon
- *CYP3A5*
  - Tacrolimus
- *CYP2B6*
  - Efavirenz, sertraline
- *RYR1, CACNA1S*
  - Inhaled anesthetics
- *mtRNR1*
  - Aminoglycosides
- *ABCG2*
  - Rosuvastatin
- *OPRM1*
  - Opioids (CPIC level C-no recommendation)
- *COMT*
  - Opioids (CPIC level C-no recommendation)
- *HMGCR*
  - Statins (CPIC level C-no recommendation)
- *SLC6A4*
  - SSRIs (CPIC level C-no recommendation)
- *HTR2A*
  - SSRIs (CPIC level C-no recommendation)

CPIC guideline progress; prioritization based on member feedback

- *G6PD* + ~ 50 drugs
  - Approach for evidence review developed, applied
  - Published August 2022
- SSRI/SNRI
  - Reviewed evidence for *CYP2D6*, *CYP2C19*, *CYP2B6*, *SLC6A4* and *HTR2A*
  - No recommendations for *HTR2A* and *SLC6A4*
  - Expanded recommendations for *CYP2C19* and citalopram, escitalopram, sertraline, *CYP2D6* and fluvoxamine, paroxetine, venlafaxine, and vortioxetine and *CYP2B6* and sertraline
  - No recommendations for fluoxetine
  - In review

CPIC® Guideline for G6PD

Guideline overview presentation



Most recent guideline publication:

CPIC guideline progress; prioritization based on member feedback

- *CYP2D6*/Beta-blockers
  - Drafting manuscript
  - Reviewed evidence for *CYP2D6, ADRB1, ADRB2, GRK4,* and *GRK5*
- *CYP2B6*/methadone
  - Recommendation underway
- *CYP3A5*/tacrolimus
  - Evidence review underway
- *CYP2D6*/antipsychotics
  - First author call yesterday
  - Evidence review underway
- *NAT2*/hydralazine
  - Preliminary evidence review underway
- *UGT1A1*/irinotecan
  - Preliminary evidence review underway (St. Jude resident)

Prioritization based on member feedback 2021

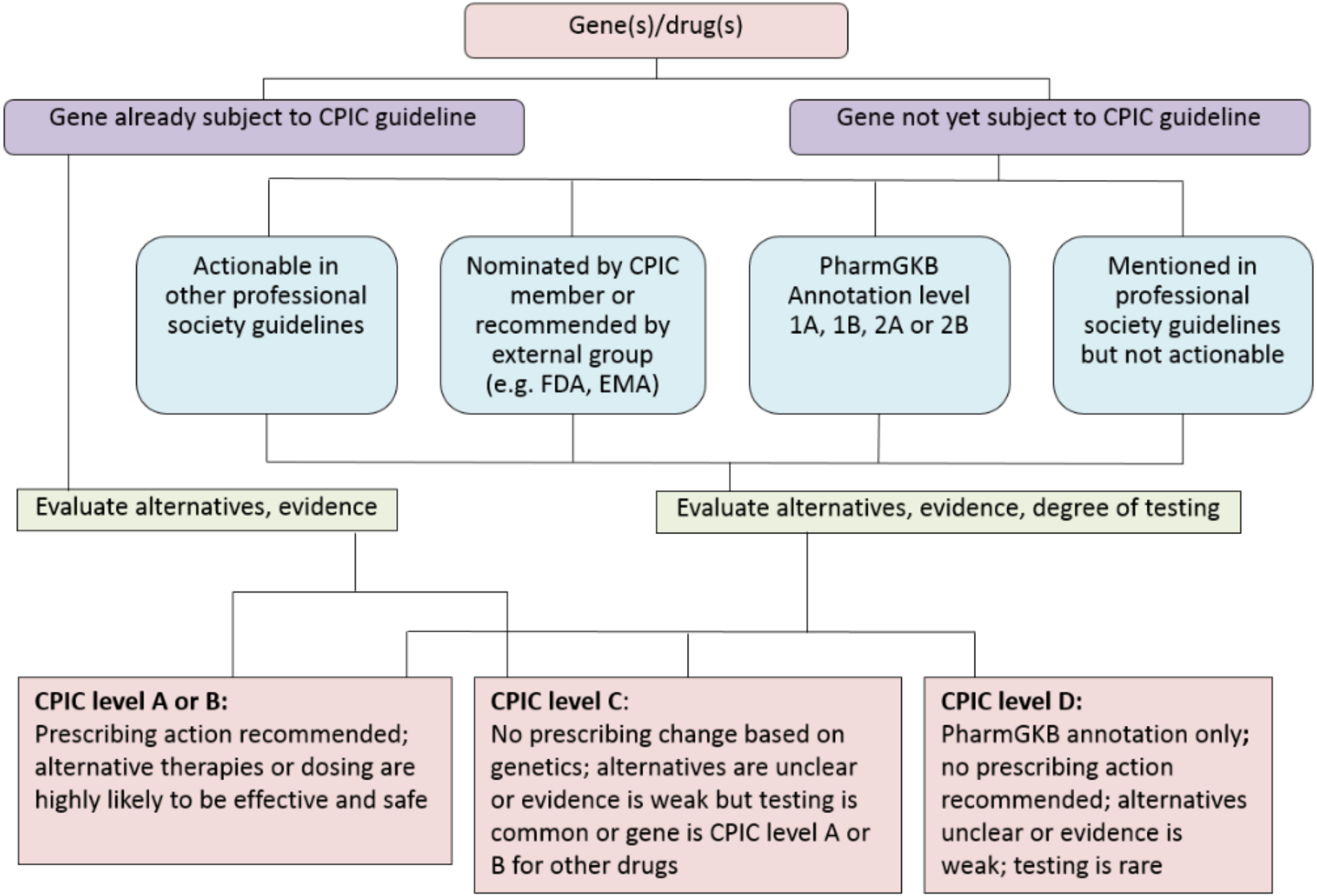
Antipsychotics- CYP2D6/possibly others
CYP2D6 – B-blockers (carvedilol, metoprolol, propranolol, timolol)
UGT1A1 - anticancer drugs (irinotecan. nilotinib, belinostat, others)
CYP2C19 – benzodiazepines (clobazam, diazepam)
CYP2B6 – methadone
CYP2D6 – antiarrhythmics (quinidine, flecainide, propafenone)
MTHFR – methotrexate/others
NAT2 - hydralazine
Factor V Leiden – estrogen
NAT2 – isoniazid
CYP2D6 – pimozide
CYP2D6 – misc. drugs (eliglustat, dextromethorphan, etc)
Genes associated with metabolic disorders (ASL, ASS1, CPS1, NAGS, OTC, GBA, HPRT1, NAGS, POLG, etc) – various drugs (valproic acid, velagluceras alfa, mycophenolic acid, carglumic acid, etc)

Member survey scheduled for April/May 2023 and will include questions regarding guidelines to update

Need to update

- *CFTR*/ivacaftor-2014
- *CYP2C19*/voriconazole-2016
- *CYP2D6*/ondansetron and tropisetron-2016
- *CYP2D6-CYP2C19*-TCAs-2016
- *RYR1*/anesthetic agents (will update based on ClinGen assignments)

Considerations for Assignment of CPIC Level for Genes/Drugs



Additional A/B drugs

89	POLG	divalproex sodium	A/B	Provisional		Testing required
90	CYP2D6	eliglustat	A/B	Provisional		Testing required
91	NAT2	hydralazine	A/B	Provisional	3	
92	CYP2D6	oliceridine	A/B	Provisional		Actionable PGx
93	CYP2D6	pimozide	A/B	Provisional		Testing required
94	CYP2D6	tetrabenazine	A/B	Provisional		Testing required
95	POLG	valproic acid	A/B	Provisional	3	Testing required
96	GBA	velaglucerase alfa	A/B	Provisional		Testing required
97	CYP2D6	venlafaxine	A/B	Provisional	1A	Actionable PGx
98	CYP2D6	vortioxetine	A/B	Provisional	3	Actionable PGx

FDA label but no/little published evidence

The FDA-approved drug label for siponimod (MAYZENT) states that it is indicated for treatment of relapsing forms of multiple sclerosis (MS). Siponimod is contraindicated in patients with the CYP2C9*3/*3 genotype. Patients with the CYP2C9*1/*1, *1/*2 or *2/*2 genotypes should be given a daily maintenance dose of 2mg starting on Day 6 of treatment, while patients with the *1/*3 or *2/*3 genotypes should be given a daily maintenance dose of 1mg starting on Day 5 of treatment.

Prescribing

Excerpts from the siponimod drug label:

> MAYZENT is contraindicated in patients who have:
>
> - A CYP2C9*3/*3 genotype (see Use in Specific Populations (8.6) and Clinical Pharmacology (12.5))

> **Recommended Dosage in Patients With CYP2C9 Genotypes *1/*1, *1/*2, or *2/*2** *Maintenance Dosage* After treatment titration (see Treatment Initiation), the recommended maintenance dosage of MAYZENT is 2 mg taken orally once daily starting on Day 6. Dosage adjustment is required in patients with a CYP2C9 *1/*3 or *2/*3 genotype (see Dosage and Administration (2.3)).

> *Treatment Initiation* Initiate MAYZENT with a 5-day titration, as shown in Table 1 (see Warnings and Precautions (5.3)). A starter pack should be used for patients who will be titrated to the 2-mg maintenance dosage (see How Supplied/Storage and Handling (16.1, 16.2)).

> **Recommended Dosage in Patients With CYP2C9 Genotypes *1/*3 or *2/*3** .
> *Maintenance Dosage* In patients with a CYP2C9 *1/*3 or *2/*3 genotype, after treatment titration (see Treatment Initiation), the recommended maintenance dosage of MAYZENT is 1 mg taken orally once daily starting on Day 5.

> *Treatment Initiation* Initiate MAYZENT with a 4-day titration, as shown in Table 2 (see Warnings and Precautions (5.3) and Use in Specific Populations (8.6)). Do not use the starter pack for patients who will be titrated to the 1-mg maintenance dosage.

https://www.pharmgkb.org/labelAnnotation/PA166182738

FDA label but no/little published evidence

Eliglustat (CERDELGA) is a glucosylceramide synthase inhibitor used for the long-term treatment of adult patients with Gaucher disease type 1.

Excerpts from the eliglustat (CERDELGA) drug label:

> CERDELGA is a glucosylceramide synthase inhibitor indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs) or poor metabolizers (PMs) as detected by an FDA-cleared test...**CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect.**

> Select patients with Gaucher disease type 1 based on their CYP2D6 metabolizer status.

> A specific dosage cannot be recommended for CYP2D6 indeterminate metabolizers...**CYP2D6 EMs or IMs: 84 mg orally twice daily...CYP2D6 PMs: 84 mg orally once daily.**

https://www.pharmgkb.org/labelAnnotation/PA166123487

Implementation

https://cpicpgx.org/implementation/
66 large healthcare centers and hospitals
24 industry (labs, educational resources and other)

The following is a list of PGx implementers who are using CPIC guidelines as part of a program to facilitate use of genetic tests to guide prescribing for patients in clinical care settings:

Institution	Website and/or Contact (if available)
AIG Hospitals, Hyderabad, India	AIG Hospitals
Arkansas Children's Hospital	Arkansas Children's Precision Medicine Amanda Elchynski; elchynskia@archildrens.org
Ann and Robert H. Lurie Children's Hospital of Chicago	Nathan Lamb; NLamb@LurieChildrens.org; https://www.luriechildrens.org/
Baptist Health South Florida	Jennifer Miles; jennifermil@baptisthealth.net
BJC Healthcare	
Boston Children's Hospital	Hyun Kim; hyun.kim@childrens.harvard.edu
Brigham and Women's Hospital	Roseann Gammal; roseann.gammal@mcphs.edu
Children's Cancer Hospital Egypt 57357	Mohamed Nagy; mohamed.nagy@57357.com
Children's Minnesota	David Gregornik; david.gregornik@childrensMN.org
Cincinnati Children's Hospital Medical Center	CCHMC Genetic Pharmacology Service
Clalit Health Services, Israel	Naomi Gronich; gronichn@clalit.org.il
Clearview Cancer Institute	Emily K Pauli; emily.pauli@ccihsv.com
Cleveland Clinic	Jennifer Hockings; hockinc@ccf.org

CPIC guidelines are highly cited and downloaded

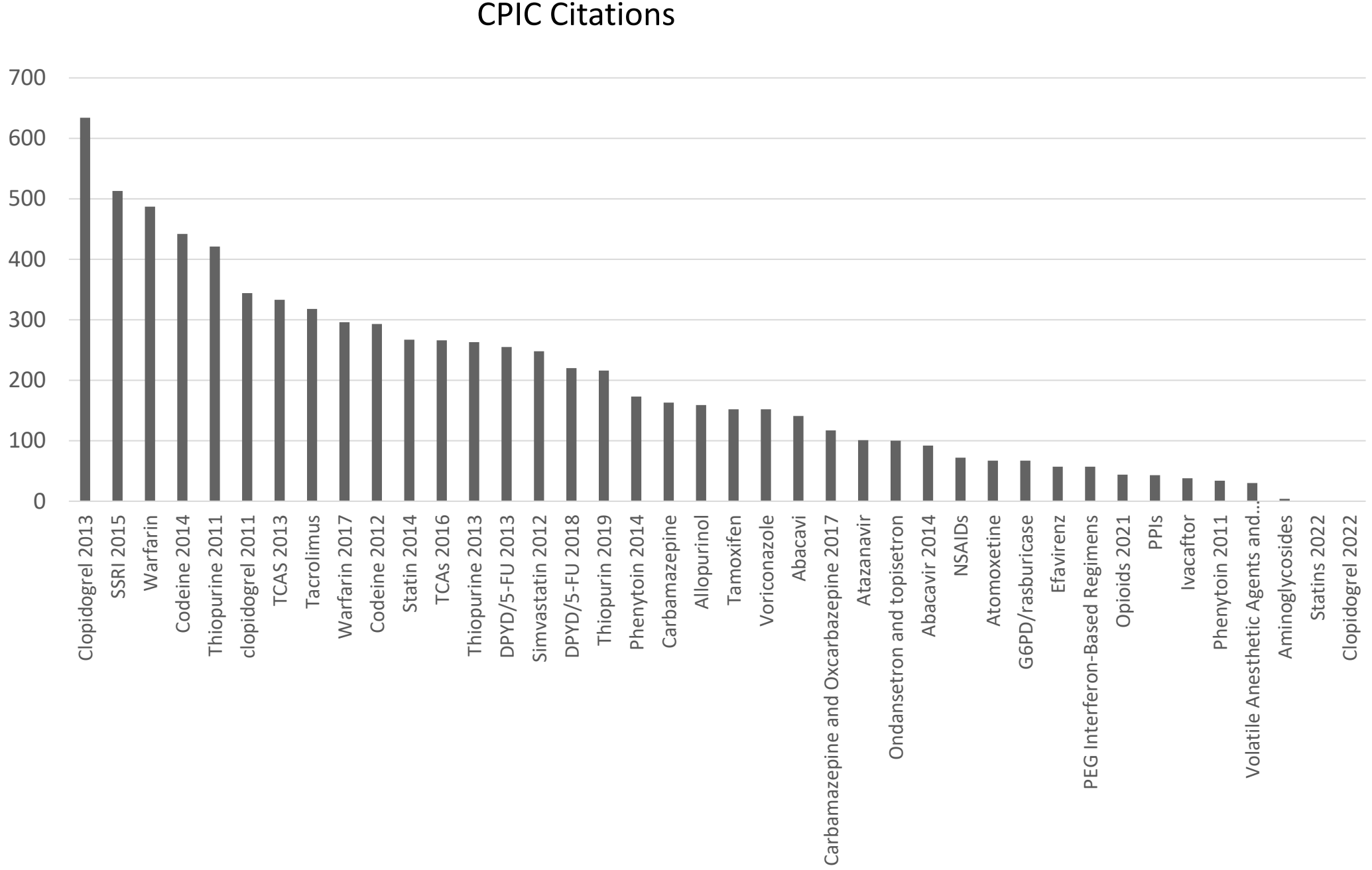
- #2 cited article: Clinical Pharmacogenetics Implementation Consortium Guideline for CYP2D6, OPRM1, and COMT Genotypes and Select Opioid Therapy (61 cites in 2022)

- #4 cited article: Clinical Pharmacogenetics Implementation Consortium Guideline (CPIC) for CYP2C9 and Nonsteroidal Anti-Inflammatory Drugs (46 cites in 2022)

- #5 cited article: Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline forCYP2C19 and Proton Pump Inhibitor Dosing (40 cites in 2022)

- #2 most downloaded article: Clinical Pharmacogenetics Implementation Consortium Guideline for CYP2C19 Genotype and Clopidogrel Therapy: 2022 Update (6,088 downloads)

- #4 The Clinical Pharmacogenetics Implementation Consortium Guideline for SLCO1B1, ABCG2, and CYP2C9 genotypes and Statin-Associated Musculoskeletal Symptoms (4,953 downloads)


CPIC Citations
700
600
500
400
300
200
100
0
Clopidogrel 2013
SSRI 2015
Warfarin
Codeine 2014
Thiopurine 2011
clopidogrel 2011
TCAS 2013
Tacrolimus
Warfarin 2017
Codeine 2012
Statin 2014
TCAs 2016
Thiopurine 2013
DPYD/5-FU 2013
Simvastatin 2012
DPYD/5-FU 2018
Thiopurin 2019
Phenytoin 2014
Carbamazepine
Allopurinol
Tamoxifen
Voriconazole
Abacavi
Carbamazepine and Oxcarbazepine 2017
Atazanavir
Ondansetron and topisetron
Abacavir 2014
NSAIDs
Atomoxetine
G6PD/rasburicase
Efavirenz
PEG Interferon-Based Regimens
Opioids 2021
PPIs
Ivacaftor
Phenytoin 2011
Volatile Anesthetic Agents and...
Aminoglycosides
Statins 2022
Clopidogrel 2022

Guidelines	Page views on CPIC site (3/25/2021-3/25/2022)
Fluoropyrimidines and DPYD	23562
Clopidogrel and CYP2C19	22813
Selective Serotonin Reuptake Inhibitors and CYP2D6 and CYP2C19	22514
Opioids and CYP2D6, OPRM1, and COMT	20020
Tricyclic Antidepressants and CYP2D6 and CYP2C19	14023
Thiopurines and TPMT and NUDT15	13123
Warfarin and CYP2C9 and VKORC1	12266
NSAIDs and CYP2C9	11754
Proton Pump Inhibitors and CYP2C19	9512
Simvastatin and SLCO1B1	8767
Phenytoin and CYP2C9 and HLA-B	6913
Carbamazepine and Oxcarbazepine and HLA-A and HLA-B	6568
Tacrolimus and CYP3A5	6369
Atomoxetine and CYP2D6	5655
Tamoxifen and CYP2D6	5580
Voriconazole and CYP2C19	5479
Abacavir and HLA-B	5243
Efavirenz and CYP2B6	5117
Allopurinol and HLA-B	5105
Atazanavir and UGT1A1	4738
Ondansetron and Tropisetron and CYP2D6	3536
Ivacaftor and CFTR	3523
Rasburicase and G6PD	3298
Potent Volatile Anesthetic Agents and Succinylcholine and RYR1 and CACNA1S	3091
Aminoglycosides and MT-RNR1	2808
Statins and SLCO1B1, ABCG2 and CYP2C9	2797*
PEG Interferon-Alpha-Based Regimens and IFNL3	1605

PRINCIPLES OF PHARMACOGENETICS

- Patients may respond differently to the same drug given at the same dose for the same indication often as a result of inherent differences in drug disposition due to genetic alterations that impact drug metabolism. These differences may lead to little or no analgesic response or significant adverse effects.
- Genetic factors can influence the analgesic response to opioids via pharmacokinetic (metabolic enzymes, ie, CYP P450) or pharmacodynamic (receptors and signal transduction) pathways.[1]
- Pharmacogenomic testing may be considered prior to initiation or during analgesic pharmacologic treatment when concerns of toxicity or lack of analgesic response are demonstrated or suspected.
- Many commonly prescribed analgesics are metabolized via P450 (CYP) such as CYP2D6, CYP2C19, or CYP2C9.
- Opioid-mediated analgesia can be influenced by the Catechol-O-methyltransferase (*COMT*) gene and the μ-opioid receptor (OPRM1) A118G single-nucleotide polymorphism; however, the clinical importance of these are unclear.
- FDA-approved pharmacogenetic tests for *CYP2D6, CYP2C19 and CYP2C9* are currently available; however, insurance reimbursement and availability of approved laboratories may be limited.
- Consider consulting a clinical pharmacist or clinical pharmacogenomics specialist to aid in drug selection and dose adjustments based on the interpretation and evaluation of pharmacogenomic test results.
  - CYP2D6: Codeine, Tramadol[1]
    - Avoid codeine and tramadol in patients who are known CYP2D6 ultrarapid metabolizers (UM) due to the risk of increased toxicity. If a patient is determined to be a CYP2D6 UM, rotate to another opioid (morphine, oxymorphone, or hydromorphone) and/or consider non-opioid analgesic alternatives.
    - Avoid codeine and tramadol in patients who are known poor metabolizers (PM) due to the lack of analgesic effect. If a patient is determined to be CYP2D6 PM, rotate to another opioid (morphine, oxymorphone, or hydromorphone). Tramadol is not recommended as an alternative to codeine.
    - Monitor codeine and tramadol use in patients who are intermediate metabolizers (IM) for less than optimal response and offer an alternative analgesic if warranted.
  - CYP2C19 & CYP2D6: Amitriptyline, Doxepin[2,3]
    - CYP2C19 PM and UM consider alternatives to doxepin and amitriptyline such as nortriptyline or desipramine
    - CYP2D6 UM consider alternatives to amitriptyline. CYP2D6 PM consider lower starting doses of amitriptyline or a 50% dose reduction.
  - CYP2C9: Celecoxib, Meloxicam, Ibuprofen[4]
    - CYP2C9 PM, consider alternatives to celecoxib or ibuprofen, or initiate therapy with 25%–50% of the lowest recommended starting dose (ie, 50%–75% dose reduction), and careful dose titration to effect.
    - CYP2C9 IM or PM consider alternatives to meloxicam.

[1] Crews KR, et al. Clin Pharmacol Ther 2021;110:888-896.
[2] Hicks JK, et al. Clin Pharmacol Ther 2013;93:402-408.
[3] Hicks JK, et al. Clin Pharmacol Ther 2017;102:37-44.
[4] Theken KN, et al. Clin Pharmacol Ther 2020;108:191-200.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

ClinGen, CPIC and PharmGKB Partnership

ClinGen, CPIC and PharmGKB Partnership

I. Introduction

ClinGen, CPIC and PharmGKB, all NIH-based efforts, have formed a critical partnership to expand ClinGen's valuable clinical genetics resource to include pharmacogenetics (PGx). CPIC and PharmGKB are two main resources for the PGx research and implementation communities. This partnership provides the opportunity to characterize and disseminate the clinical relevance of pharmacogenetic variation based on expert, manually curated information created through transparent, documented Standard Operating Procedures (SOPs).

II. The ClinGen-CPIC-PharmGKB Partnership

ClinGen's Expert Panels review gene-disease relationships, but do not include gene-drug relationships, while CPIC and PharmGKB focus on gene-drug and variant-drug associations. CPIC provides evidence-based clinical practice guidelines for pharmacogenetics implementation, and assigns clinical actionability to gene/drug pairs. PharmGKB provides expertly curated variant-drug phenotype summaries based on peer-reviewed publications, including associations for which the level of evidence may not yet reach the requirement for an implementation guideline.

ClinGen has partnered with CPIC and PharmGKB to bring pharmacogenetics knowledge to ClinGen. This knowledge is represented at the gene level on the ClinGen website, displaying PGx relationships alongside validation, dosage and actionability curations. PharmGKB also represents disease phenotypes using standardized vocabularies (e.g. SNOMED) linked to genes and variants, and will represent ClinGen's clinical relevance for genes and variants associated with disease on the PharmGKB website for dissemination to the PGx community.

ClinGen, CPIC and PharmGKB are aligned and play a critical role in the growing data sharing movement within the clinical genetics community, with CPIC and PharmGKB focusing on pharmacogenetics, an area not previously included in the ClinGen effort. ClinGen relies on CPIC and PharmGKB as sources for expertly curated pharmacogenetic knowledge.

III. Details about ClinGen, CPIC and PharmGKB

CYP2C19

View Gene Facts

0	0	0	0	21 / 15	
Gene-Disease Validity Classifications	Dosage Sensitivity Classifications	Clinical Actionability Assertions	Variant Pathogenicity Assertions	CPIC / PharmGKB High Level Records	Follow Gene

Curation Summaries | Status and Future Work (0) | External Genomic Resources | ClinVar Variants

Group By Activity

Pharmacogenomics - CPIC

Gene	Drug	CPIC Level	Date Accessed	CPIC Clinical Guidelines
CYP2C19	lansoprazole	Level A	03/01/2023	Guideline
	omeprazole	Level A		
	pantoprazole	Level A		
	dexlansoprazole	Level B		
	esomeprazole	Level C		
	rabeprazole	Level C		
CYP2C19	clopidogrel	Level A	03/01/2023	Guideline
CYP2C19	citalopram	Level A	03/01/2023	Guideline

Pharmacogenomics

The Pharmacogenomics (PGx) Working Group is a multi-disciplinary team of researchers and professionals with expertise in pharmacogenomics, clinical pharmacology, medical genetics, and molecular diagnosis.

Membership

Mission:

Our mission is to develop a framework of tiered standard terminology and definitions that reflect clinical significance for genomic variants implicated in drug response variability (efficacy, dosing, or adverse event risk), and to facilitate incorporating pharmacogenomics knowledge into ClinGen.

Chairs

Teri Klein, PhD

Stuart Scott, PhD, FACMG

Michelle Whirl-Carrillo, PhD

Coordinators

Please contact a coordinator if you have questions.

Li Gong, PhD
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Clarissa Klein
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CPIC/PGRN in-person meeting

- 2 ½ days in Colorado
- Over 300 in attendance
- Over 80 posters

Pharmacogenomics
GLOBAL RESEARCH NETWORK

Back

Add to my calendar

PGRN 2023 Annual Scientific Meeting

Start	***Mon, June 12, 2023***
End	*Tue, June 13, 2023*
Location	Memphis, Tennesee, USA

PGRN will once again bring together the best of the best in pharmacogenetics and pharmacogenomics with a program showcasing the latest research from the top minds in the field.

Event details and registration coming soon.

Informatics Working Group

- Meets now for meetings on a as needed basis
- Writing paper on how to utilize CPIC implementation resources
- Upcoming presentations:
  - Adapting to a new EHR while expanding the pharmacogenomics informatics structure
    - Cyrine Haidar, St. Jude Children's Research Hospital
    - March 27th 4pm ET
  - Cerner implementation (title TBD)
    - Emili Leary, Marshfield Clinic
    - May 15th 4pm ET

CYP2D6 allele function

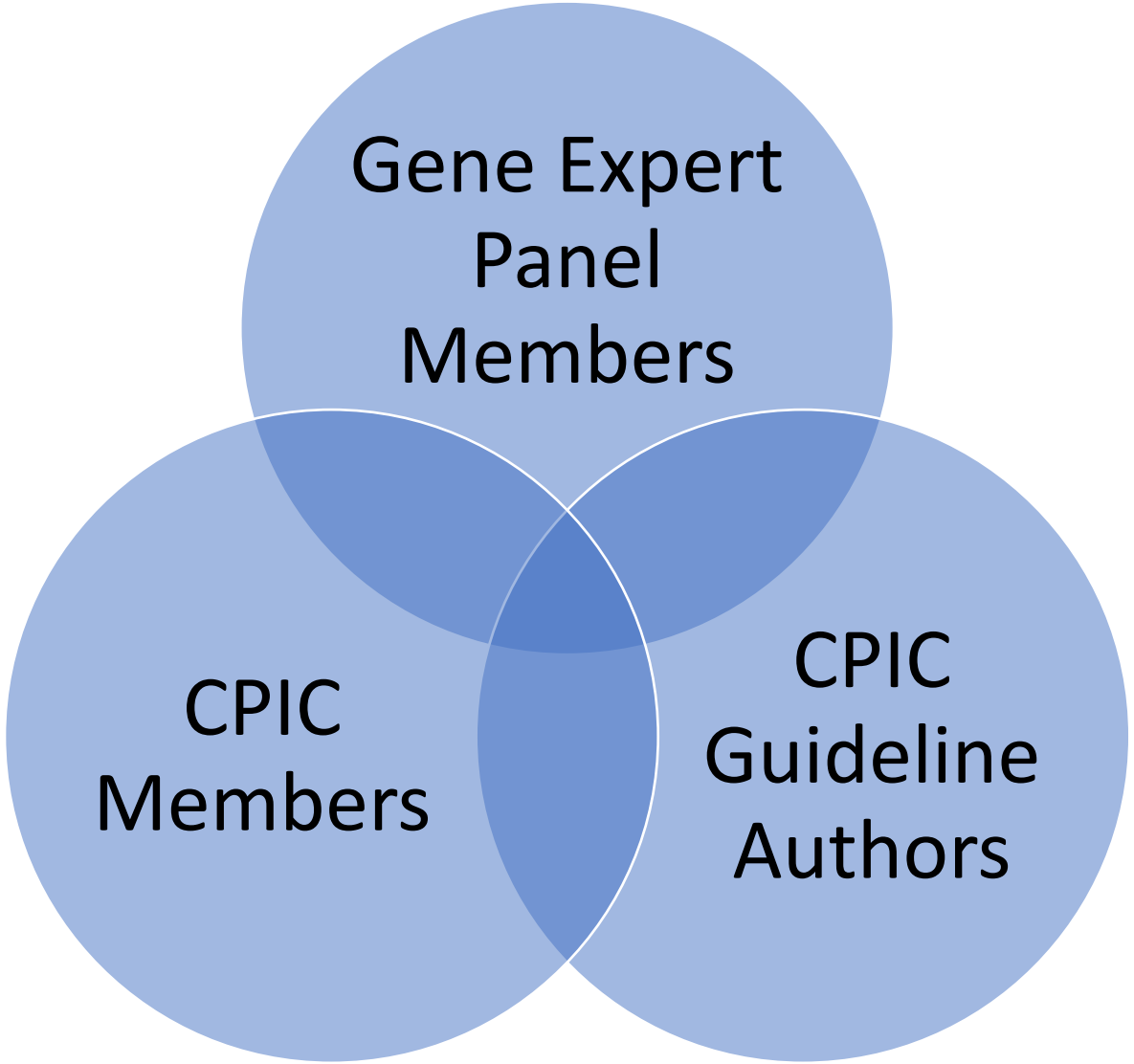
- Updated structural variants to agree with PharmVar nomenclature
- Added *140 to *163
- Added strength of evidence and updated summaries to all alleles
- Changed function assignment for *9, *32, *41, *52, *91, *109, *132

Revised AS and phenotype

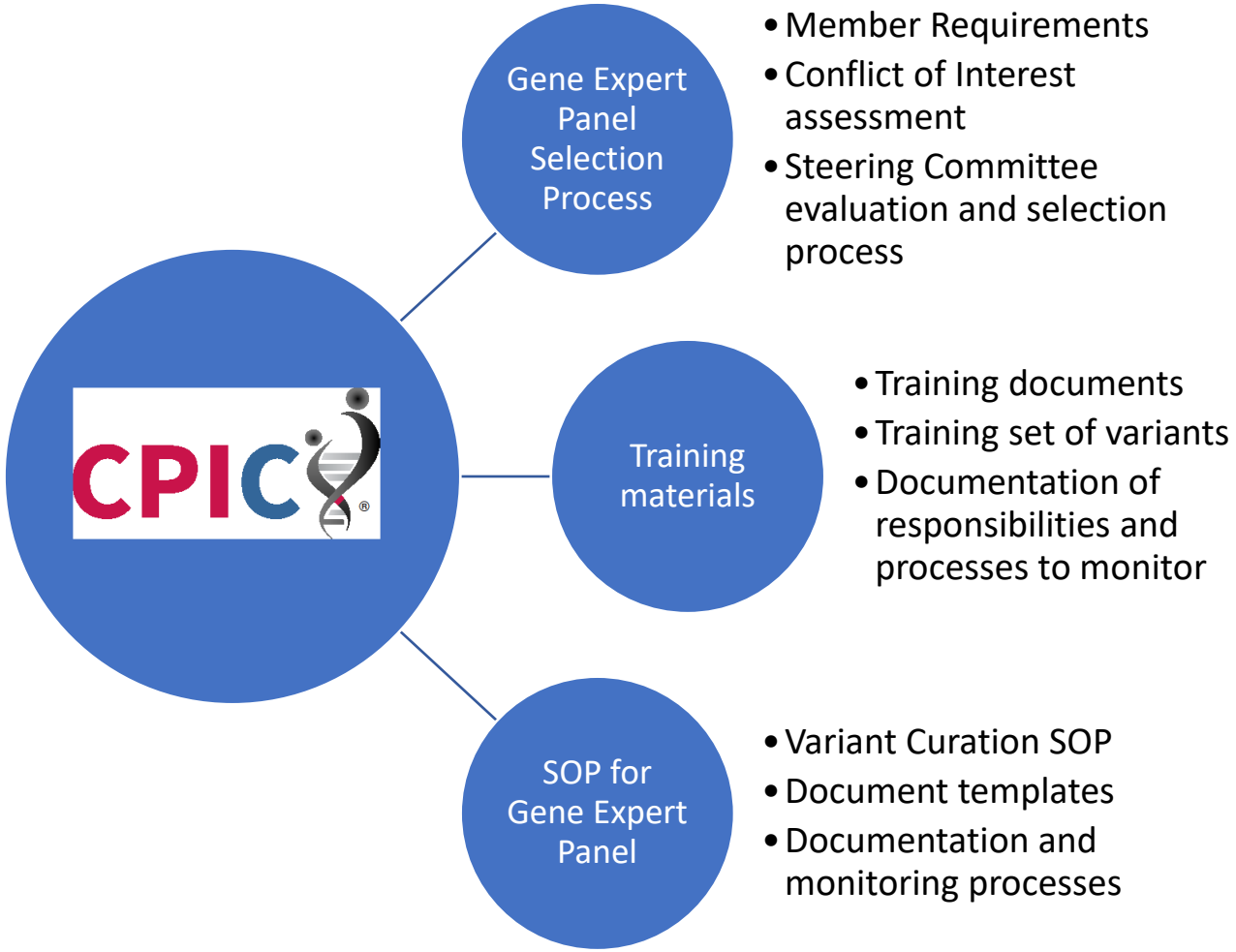
Diplotype	OLD AS/phenotype	Revised AS/phenotype (*41 AS 0.25)
*1/*41	1.5/NM	1.25/NM
*41/*41	1/IM	0.5/IM
*41/no function	0.5/IM	0.25/IM

CPIC to a establish Gene Expert Panel for each DME/transporter gene

- As the number of guidelines and authors continues to grow, it is not logistically feasible to maintain author guideline work, engagement with variant function evaluation and reevaluation
- A smaller dedicated group of individuals with gene expertise will be created and tasked with this responsibility: those requesting approval as comprehensive expert status



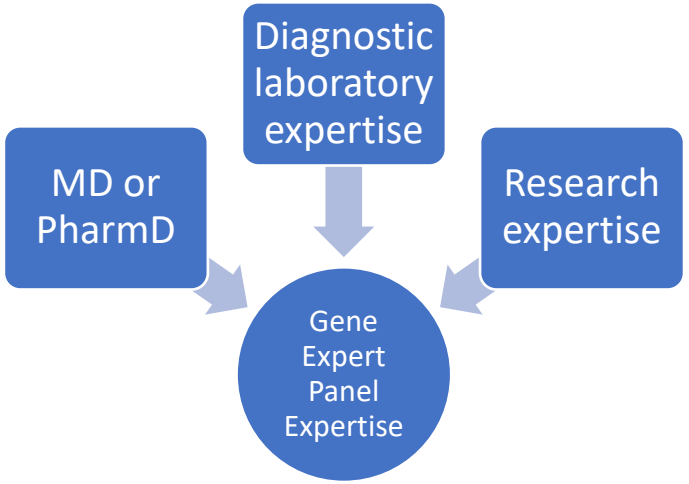
CPIC to create documents/procedures to establish and support Gene Expert Panels



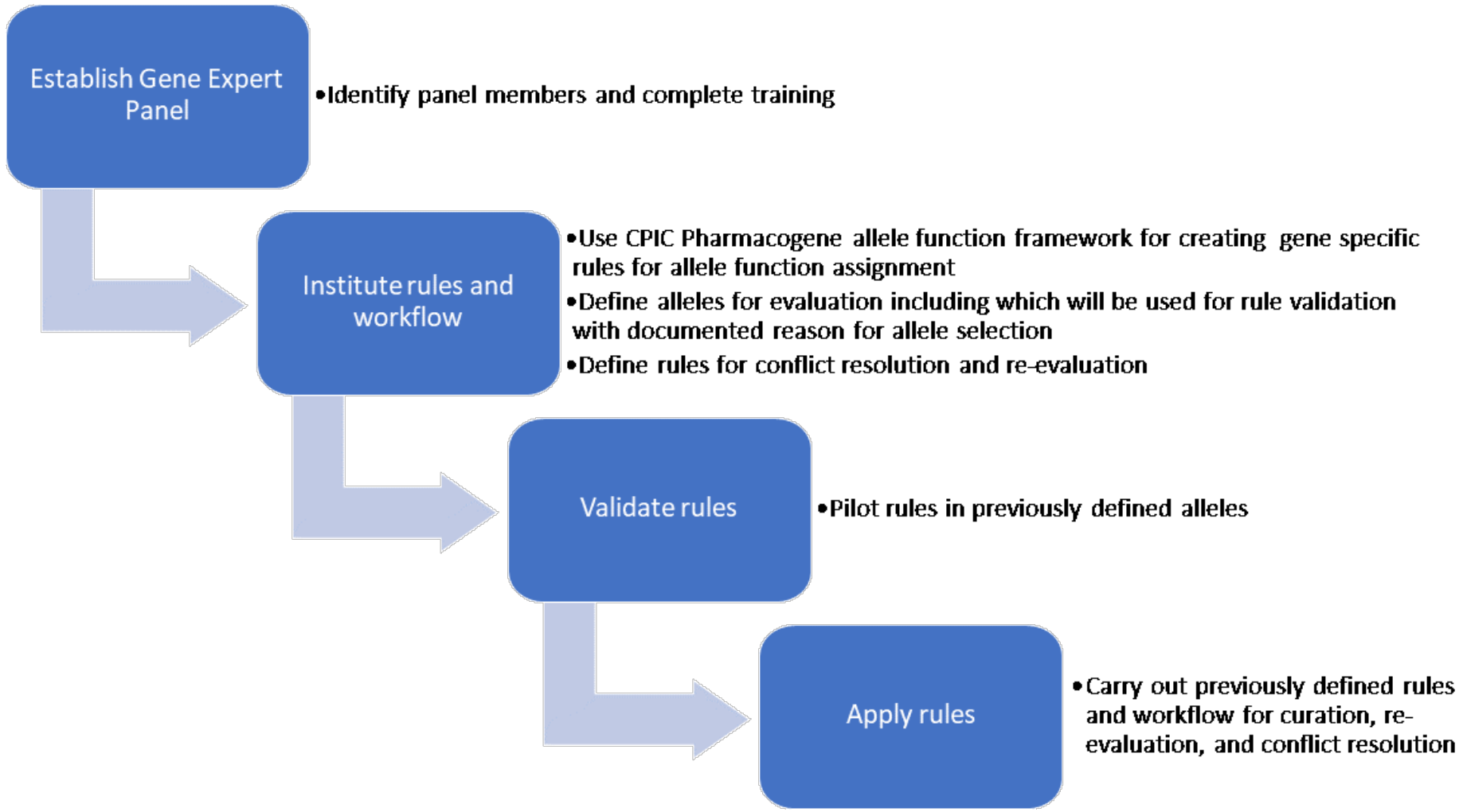
Gene Expert Panel Members

- Each Gene Expert Panel will be a multidisciplinary and multi-institutional group consisting of three or more members who have expertise in at least one of the following areas with all areas of expertise represented in the panel
  - Scientific expertise on gene function
    - Diagnostic laboratory expertise
    - Research expertise
  - Medical/Clinical professionals with **relevant** expertise
  - Representatives from PharmVar, ClinGen, PharmGKB, specialty gene databases
  - CPIC staff will be part of the Gene Expert Panel to support variant curation activities
- Each panel will have at least 3 or more academic or commercial institution and global participation

*Expertise is defined as relevant experience to the disease, gene, functional assays, and statistical analyses



Overview of Gene Expert Panel Process



Reminders

- PGx testing survey research participation (deadline **March 7th**)-sent to CPIC members 2/27
- Please fill out attendance poll for every call you attend
- Send us any guidelines that are citing CPIC guidelines
- Email Kelly.caudle@stjude.org if you would like to be considered for the CYP3A5 gene expert panel

CPIC™
Clinical Pharmacogenetics Implementation Consortium

Thank you!!!

Team

CPIC Co-Principal Investigators
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Stanford University

Co-Investigator
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Stanford University

James M. Hoffman, Pharm.D.
St. Jude Children's Research Hospital

Stanford CPIC Coordinator
Michelle Whirl-Carrillo, Ph.D.
Stanford University

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University of Florida

Stuart Scott, Ph.D.
Icahn School of Medicine at Mount Sinai

Sara Van Driest, M.D., Ph.D.
Vanderbilt University

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Partners Healthcare

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Partners Personalized Medicine

Justin B. Starren, M.D., Ph.D.
Northwestern University

- And:
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