Pharmacogenetics in Practice: Case Studies & Considerations for Effective Implementation

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Learning Objectives

1. Introduction and understanding of how PGx reports can be reviewed

2. Understand the limitations of PGx reports and how they can be used in a clinical context

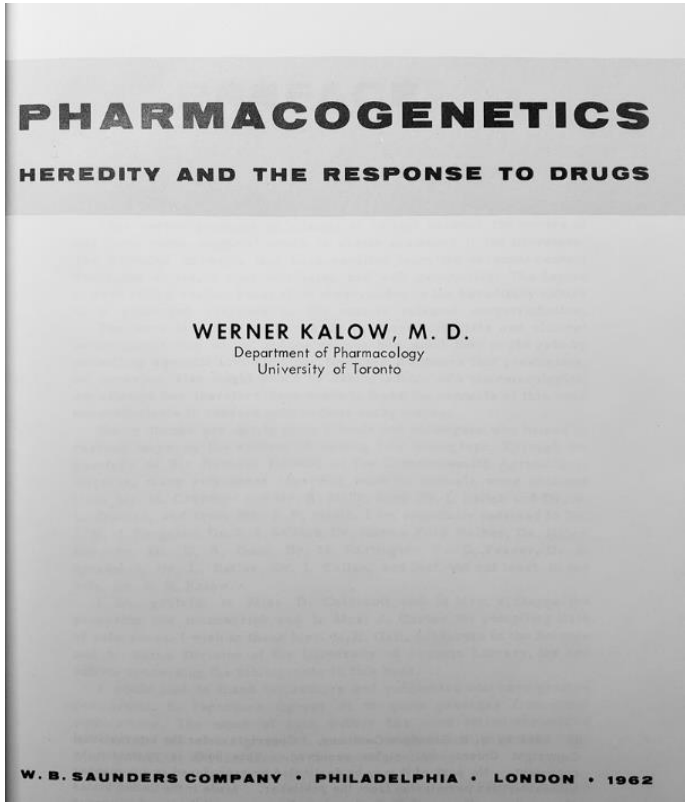
3. Identify important factors for effective implementation of PGx in a clinical setting

4. Understand the existing challenges to scale PGx as a precision medicine tool and ways to address these challenges

Agenda

- Brief introduction to PGx
- PGx Report Elements
  - Types of Reports (by indication)
  - Static Reports
  - Dynamic Reports
- Case Studies
  - Mental Health
  - Primary Care
- Important Factors for the Effective Utility of PGx in the Clinic
  - Scalability
  - Reimbursement

AN UNSUNG HISTORY



PGx Related Gene	Phenotype	Date Described	Investigator
G6PD Deficiency	Haemolytic anaemia (Fava Bean)	570 – 495 BC	Pythagoras
	Primaquine induced haemolysis	1950s	US Army
TAS2R38	Phenylthiocarbamide sensitivity	1930s	Sir Archibald Garrod
Pseudocholinesterase deficiency	Succinylcholine-induced apnea	1950s	W. Kalow
	Isoniazid-induced peripheral neuropathy	1950s	Tuberculosis Chemotherapy Centre
CYP2D6	Sparteine & Debrisoquine metabolism	1982	M. Eichelbaum
	Allele-Specific PCR Developed	1994	Johannsen et. al
CYP2D6, CYP2C19	1st FDA Approved PGx Test	2005	Roche

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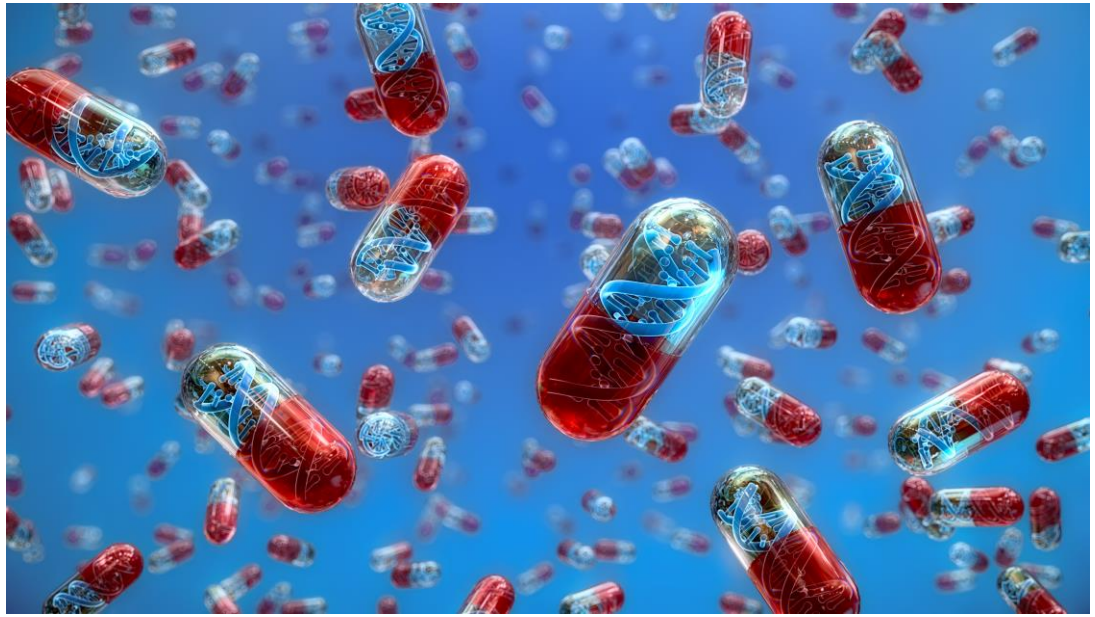
CONVERGENCE

2000 – 2015: Genomic / Molecular Advances



2012: CPT Codes Established for PGx

Table I

Examples of pharmacogenomic tests with associated CPT codes for identification and documentation.

CPT Code	Test	Description of Test
81225	CYP2C19 genotyping	Detects genetic variants of *CYP2C19* associated with variable drug metabolism
81226	CYP2D6 genotyping	Detects genetic variants of *CYP2D6* associated with variable drug metabolism
81227	CYP2C9 genotyping	Detects genetic variants of *CYP2C9* associated with variable drug metabolism
81355	VKORC1 testing	Detects genetic variants of *VKORC1* associated with warfarin therapy
81350	UGT1A1 genotyping	Detects genetic variants of *UGT1A1* associated with irinotecan toxicity
84431	11-dehydro thromboxane B2	Measures 11-dehydro thromboxane B2 in urine to determine aspirin resistance
81381	HLA B*57:01	Detects the *HLA B*57:01* allele associated with abacavir toxicity
82955	G6PD quantitative	Measures glucose-6-phosphate dehydrogenase activity
81210	BRAF mutation testing	Detects mutations in *BRAF* associated with BRAF inhibitor therapy
81275	KRAS mutation testing	Detects mutations in *KRAS* associated with KRAS inhibitor therapy
88360	HER2 expression	Detects the expression of HER2 to guide therapy with HER2 inhibitors
81235	EGFR mutation testing	Detects mutations in *EGFR* associated with EGFR inhibitor therapy
81220	CFTR profile	Detects mutations in *CFTR*, which is necessary prior to therapy with ivacaftor
87999	HIV-1 tropism testing	Determines HIV tropism for chemokine receptor 5 [CCR5], and/or chemokine receptor 4 [CXCR4] to guide therapy with receptor antagonists
81287	MGMT gene methylation	Determines *MGMT* methylation status to guide therapy with alkylating agents

Note: some tests may be components of multi-test panels offered by various companies.

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CPIC: 28 Guidelines Across 166 drugs

CPIC UPDATE

The Clinical Pharmacogenetics Implementation Consortium Guideline for *SLCO1B1*, *ABCG2*, and *CYP2C9* genotypes and Statin-Associated Musculoskeletal Symptoms

CPIC UPDATE

Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for *CYP2D6*, *CYP2C19*, *CYP2B6*, *SLC6A4*, and *HTR2A* Genotypes and Serotonin Reuptake Inhibitor Antidepressants

Citation: Clin Transl Sci (2020) 13, 116–124; doi:10.1111/cts.12692

ARTICLE

Standardizing *CYP2D6* Genotype to Phenotype Translation: Consensus Recommendations from the Clinical Pharmacogenetics Implementation Consortium and Dutch Pharmacogenetics Working Group

CPIC UPDATE

Clinical Pharmacogenetics Implementation Consortium Guideline for *CYP2D6*, *OPRM1*, and *COMT* Genotypes and Select Opioid Therapy

Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for *CYP2D6* Genotype and Use of Ondansetron and Tropisetron

CPIC GUIDELI

Check for updates

Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for *CYP2C19* and Proton Pump Inhibitor Dosing

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PGx EXPANDING CU EVIDENCE & COVERAGE

Published in final edited form as:
Genet Med. 2021 May ; 23(5): 830–832. doi:10.1038/s41436-021-01117-w.

Expanding Evidence Leads to New Pharmacogenomics Payer Coverage

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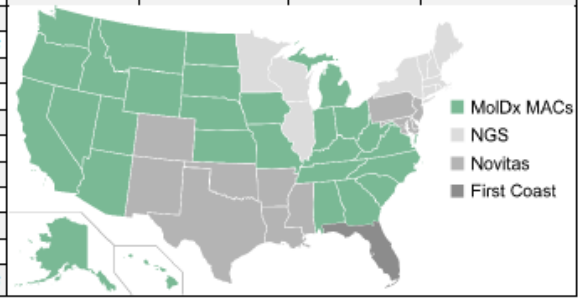
[3]Office of Quality & Patient Care, St. Jude Children's Research Hospital, Memphis, Tennessee, USA

[4]Department of Pharmaceutical Sciences, St. Jude Children's Research Hospital, Memphis, Tennessee, USA

[5]Department of Biomedical Data Science and Medicine, Stanford University, Stanford, California, USA

Supplemental Figure 1. Examples of medications and jurisdictions covered by the new LCDs.

Drug	Gene(d	Drug	Gene(s)	Drug	Gene(s)
abacavir*	*HLA-B*	isoflurane*	*CACNA1S, RYR1*	phenytoin*	*CYP2C9, HLA-B*
allopurinol	*HLA-B*	ivacaftor*	*CFTR*	piroxicam*	*CYP2C9*
amitriptyline	*CYP2C19, CYP2D6*	lansoprazole	*CYP2C19*	rasburicase*	*G6PD*
atazanavir	*UGT1A1*	lornoxicam	*CYP2C9*	sertraline	*CYP2C19*
atomoxetine*	*CYP2D6*	meloxicam*	*CYP2C9*	sevoflurane*	*CACNA1S, RYR1*
azathioprine*	*TPMT, NUDT15*	mercaptopurine*	*TPMT, NUDT15*	simvastatin	*SLCO1B1*
capecitabine*	*DPYD*	methoxyflurane	*CACNA1S, RYR1*	succinylcholine*	*CACNA1S, RYR1*
carbamazepine*	*HLA-A, HLA-B*	nortriptyline*	*CYP2D6*	tacrolimus	*CYP3A5*
celecoxib*	*CYP2C9*	omeprazole*	*CYP2C19*	tamoxifen*	*CYP2D6*
citalopram*	*CYP2C19*	ondansetron	*CYP2D6*	tenoxicam	*CYP2C9*
clomipramine	*CYP2C19, CYP2D6*	oxcarbazepine*	*HLA-B*	thioguanine*	*TPMT, NUDT15*
clopidogrel*	*CYP2C19*	pantoprazole*	*CYP2C19*	trimipramine	*CYP2C19, CYP2D6*
codeine*	*CYP2D6*	paroxetine	*CYP2D6*	voriconazole*	*CYP2C19*
desflurane*	*CACNA1S, RYR1*	peginterferon alfa-2a or 2b	*IFNL3*	warfarin*†	*CYP2C9, CYP4F2, VKORC1*
desipramine*	*CYP2D6*				
dexlansoprazole*	*CYP2C19*				
doxepin*	*CYP2C19, CYP2D6*				
efavirenz*	*CYP2B6*				
enflurane*	*CACNA1S, RYR1*				
escitalopram*	*CYP2C19*				
fluorouracil*	*DPYD*				
flurbiprofen*	*CYP2C9*				
fluvoxamine*	*CYP2D6*				
halothane	*CACNA1S, RYR1*				
ibuprofen	*CYP2C9*				
imipramine	*CYP2C19, CYP2D6*				



The figure includes gene/drug pairs that are actionable and included in CPIC guidelines as of August 1, 2020; * indicates drugs for which FDA label considers genetic testing actionable, recommended, or required. †warfarin coverage is limited in a separate MolDx LCD (A55179). Source: https://cpicpgx.org/genes-drugs/.

States within MolDx jurisdictions (shaded green) as well as those that are outside of the MolDx [CT, IL, NH, MA, ME, MN, NY, WI, RI, and VT (administered by NGS); AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, and TX (administered by Novitas), and FL (administered by First Coast)] are shown.

Map used with permission from P.E./PharmGKB.

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SELECT PGx INDICATIONS

Indication	Class	Drug	Gene	Guideline Availability	
				DPWG	CPIC
Cardiology	Lipid lowering agents	Atorvastatin	SLCO1B1	√	-
		Simvastatin	SLCO1B1	√	√
	Anti-platelet	Clopidogrel	CYP2C19	√	√
	Anticoagulant	Warfarin	VKORC1	√	√
			CYP2C9	√	√
Mental Health	Antidepressants	Citalopram	CYP2C19	√	√
		Sertraline	CYP2C19	√	√
		Amitriptyline	CYP2C19	-	√
			CYP2D6	√	√
	Anticonvulsant	Carbamazepine	HLA-B	-	√
			HLA-A	-	√
Pain	Analgesics	Codeine	CYP2D6	√	√
		Tramadol	CYP2D6	√	-
ID	Antibiotic	Flucloxacillin	HLA-B	√	-

Source: Rollinson et. al: *Genes* (Basel). 2020 Nov; 11(11): 1337. PMID: 33198260

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PGx Report Modalities

- Static Report (.pdf)
  - Traditional report used for clinical decision support (cds) that becomes a part of the patient record.
  - Stored digitally or as a hard-copy.
  - Can be amended, but is otherwise unchanged.
- Dynamic Report (html)
  - Digital report that can be changed in real-time and re-issued based on input values (e.g. concomitant medications, co-morbidities, etc).
  - Multiple versions can be generated and be part of a digital record
  - Allows the report recommendations to change based upon evolving circumstances of the patient
- Best Practice Alerts (BPAs)
  - Embedded / popup messages within an EMR interface
  - The ‘holy grail’ of report modality, but least frequent.

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- Increased risk of adverse drug reactions.
- Contraindication
- Combination not advised
- Monitor parameters → Increase dose / Decrease dose
- Warning / Information

Antidepressants

Agomelatine	Amitriptyline (Elavil®)	Bupropion (Wellbutrin®)
Citalopram (Celexa®)	Clomipramine (Anafranil®)	Desipramine (Norpramin®)
Desvenlafaxine (Pristiq®)	Doxepin (Sinequan®)	Duloxetine (Cymbalta®)
Escitalopram (Lexapro®)	Fluoxetine (Prozac®)	Fluvoxamine (Luvox®)
Imipramine (Tofranil®)	Mianserin	Mirtazapine (Remeron®)
Nortriptyline (Pamelor®)	Paroxetine (Paxil®)	Sertraline (Zoloft®)
Trazodone (Desyrel®)	Trimipramine	Venlafaxine (Effexor®)
Vortioxetine (Trintellix®)		

Antipsychotics

Aripiprazole (Abilify®)	Brexpiprazole	Clozapine (Clozaril®)
Haloperidol (Haldol®)	Iloperidone (Fanapt®)	Lurasidone (Latuda®)
Olanzapine (Zyprexa®)	Paliperidone (Invega®)	Perphenazine (Trilafon®)
Pimozide	Quetiapine (Seroquel®)	Risperidone (Risperdal®)
Thioridazine (Mellaril®)	Zuclopenthixol	

Stabilizers and anticonvulsants

Carbamazepine (Tegretol®)	Clonazepam (Klonopin®)	Eslicarbazepine
Lamotrigine (Lamictal®)	Levetiracetam	Lithium* (Eskalith®)
Oxcarbazepine (Trileptal®)	Phenobarbital	Phenytoin
Topiramate (Topamax®)	Valproic Acid (Depakote®)	Vigabatrin
Zonisamide		

Anxiolytics / Hypnotics

Alprazolam (Xanax®)	Buspirone (BuSpar®)	Clobazam
Eszopiclone (Lunesta®)	Lorazepam (Ativan®)	Zolpidem (Ambien®)

Others

Amphetamines (Adderall®)	Atomoxetine (Strattera®)	Lisdexamfetamine
Methadone	Methylphenidate (Ritalin®)	Naloxone
Naltrexone		

PATIENT'S RESULTS REPORT | **SELECT PATIENT CHARACTERISTICS**

Patient data

Age: Adults, aged 18 to

Gender: Male / Female

Smoker:

Alcohol:

Pregnancy:

Breastfeeding:

Obesity: Present

Cardiovascular disease: Not present

Liver disease: Not present

Kidney disease: Not present

Other disorders: Select disorder...

Diet and supplements: Select diet...

OTHER DISORDERS
- Neuropsychiatric disorders

DIET AND SUPPLEMENTS
- Caffeine
- Vitamin D

Drug treatment

Psychiatric drugs: Select psychotropic drug...

Other medication: Select treatment...

Consult DailyMed

PSYCHIATRIC DRUGS
- Lorazepam
- Olanzapine
- Prochlorperazine

Apply data | Undo | Clean

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Desvenlafaxine (Pristiq®)	Doxepin (Sinequan®)	Duloxetine (Cymbalta®)
Escitalopram (Lexapro®)	Fluoxetine (Prozac®)	Fluvoxamine (Luvox®)
Imipramine (Tofranil®)	Mianserin	Mirtazapine (Remeron®)
Nortriptyline (Pamelor®)	Paroxetine (Paxil®)	Sertraline (Zoloft®)
Trazodone (Desyrel®)		
Vortioxetine (Trintellix®)		

Antipsychotics

Aripiprazole (Abilify®)		
Haloperidol (Haldol®)		
Olanzapine (Zyprexa®)		
Pimozide	Quetiapine (Seroquel®)	Risperidone (Risperdal®)
Thioridazine (Mellaril®)	Zuclopenthixol	

Stabilizers and anticonvulsants

Carbamazepine (Tegretol®)	Clonazepam (Klonopin®)	Eslicarbazepine
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Methadone	Methylphenidate (Ritalin®)	Naloxone
Naltrexone		

ACCESS TO ONLINE INTERACTIVE REPORT:

http://[redacted]/reports/NFGUS02855

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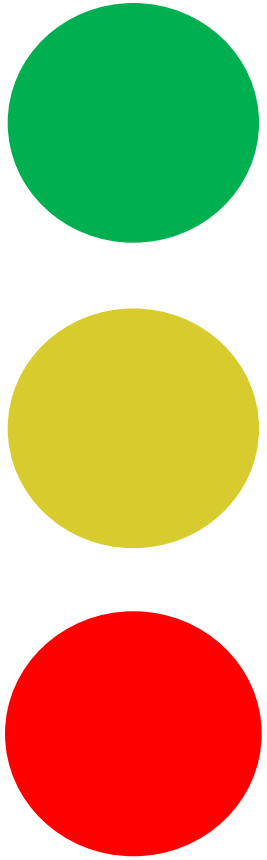
Apply data | Undo | Clean

PGx Reports: Essential Elements

- A typical PGx report includes the following sections:
  1. Current medication regimen (sometimes)
  2. Summary table of gene/drug interactions
  3. Detailed gene/drug Information and/or guidance.
  4. Genetic results summary
  5. Patient info card
  6. Methods & Limitations

- Sections may appear in different orders based on laboratory/provider input.

The Stoplight Color Motif



Use as Directed
No Genotype-Guidance Available
Increased likelihood of response

Use with Caution
Monitor dosing
Decreased likelihood of response

Use Alternative
Increased likelihood of adverse reaction
Contraindicated

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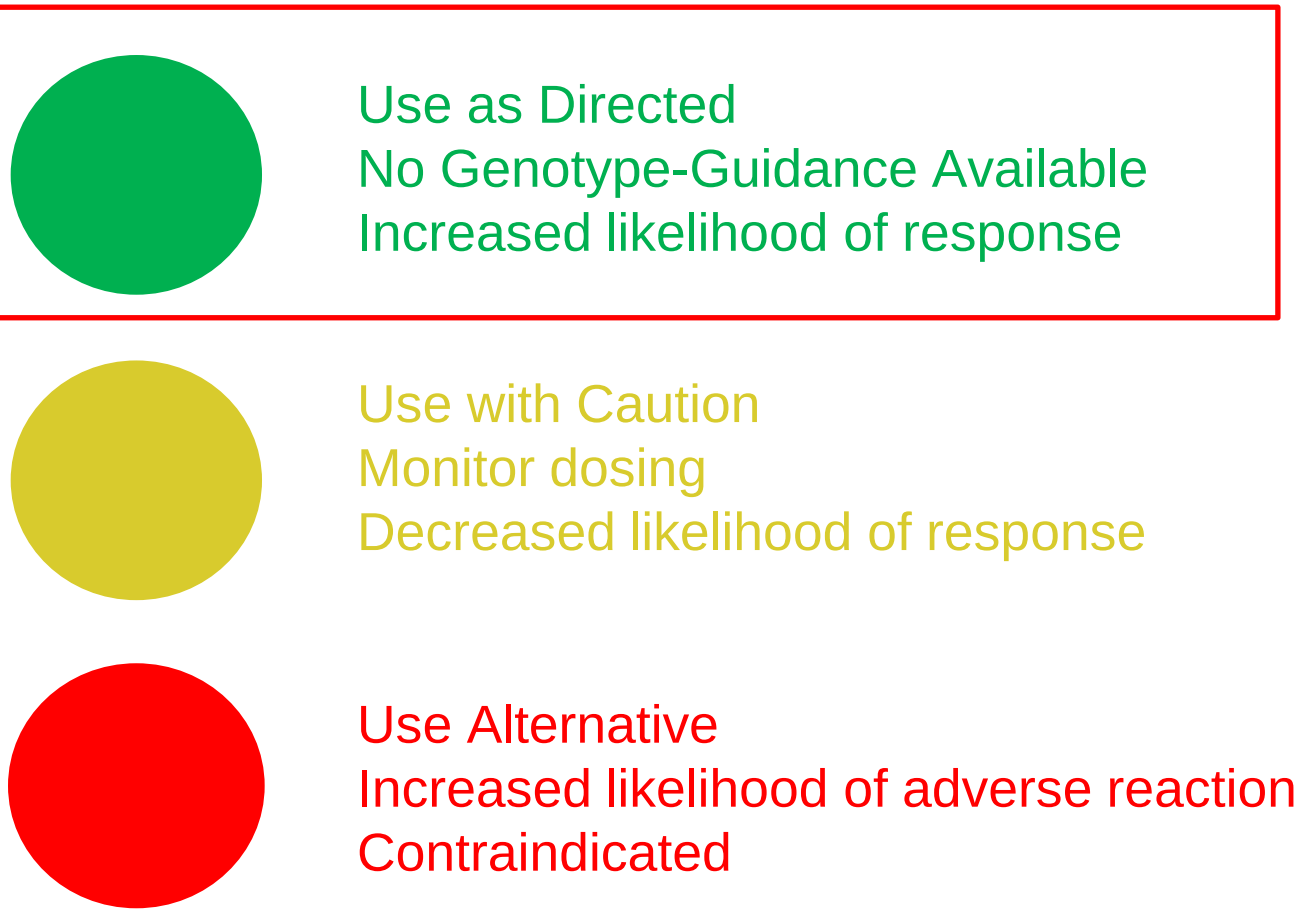
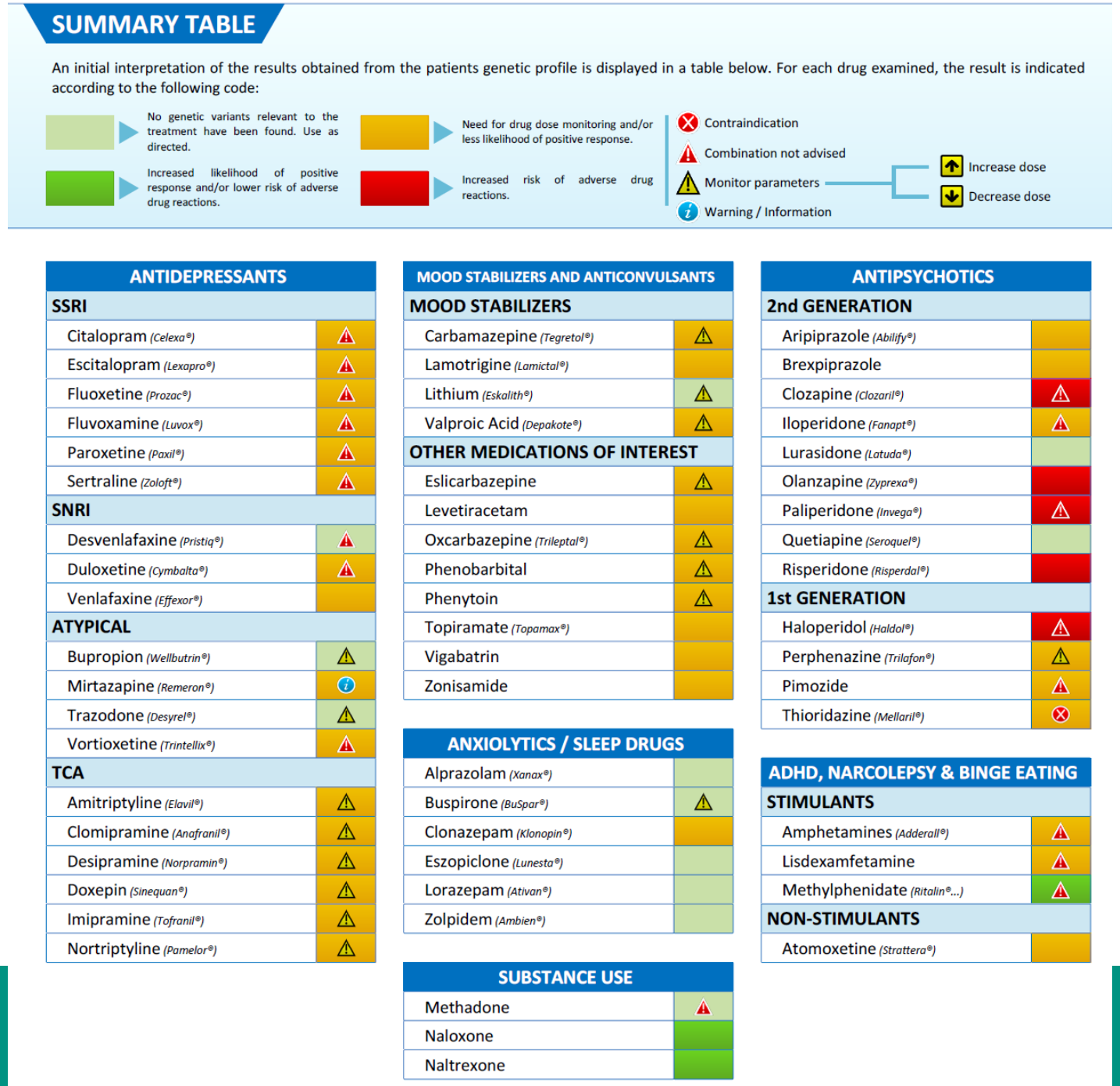
The Stoplight Color Motif





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- Combination not advised
- Monitor parameters
- Warning / Information
- Increase dose
- Decrease dose

ANTIDEPRESSANTS	
SSRI	
Citalopram *(Celexa®)*	
Escitalopram *(Lexapro®)*	
Fluoxetine *(Prozac®)*	
Fluvoxamine *(Luvox®)*	
Paroxetine *(Paxil®)*	
Sertraline *(Zoloft®)*	
SNRI	
Desvenlafaxine *(Pristiq®)*	
Duloxetine *(Cymbalta®)*	
Venlafaxine *(Effexor®)*	
ATYPICAL	
Bupropion *(Wellbutrin®)*	
Mirtazapine *(Remeron®)*	
Trazodone *(Desyrel®)*	
Vortioxetine *(Trintellix®)*	
TCA	
Amitriptyline *(Elavil®)*	
Clomipramine *(Anafranil®)*	
Desipramine *(Norpramin®)*	
Doxepin *(Sinequan®)*	
Imipramine *(Tofranil®)*	
Nortriptyline *(Pamelor®)*	

MOOD STABILIZERS AND ANTICONVULSANTS	
MOOD STABILIZERS	
Carbamazepine *(Tegretol®)*	
Lamotrigine *(Lamictal®)*	
Lithium *(Eskalith®)*	
Valproic Acid *(Depakote®)*	
OTHER MEDICATIONS OF INTEREST	
Eslicarbazepine	
Levetiracetam	
Oxcarbazepine *(Trileptal®)*	
Phenobarbital	
Phenytoin	
Topiramate *(Topamax®)*	
Vigabatrin	
Zonisamide	

ANXIOLYTICS / SLEEP DRUGS	
Alprazolam *(Xanax®)*	
Buspirone *(BuSpar®)*	
Clonazepam *(Klonopin®)*	
Eszopiclone *(Lunesta®)*	
Lorazepam *(Ativan®)*	
Zolpidem *(Ambien®)*	

SUBSTANCE USE	
Methadone	
Naloxone	
Naltrexone	

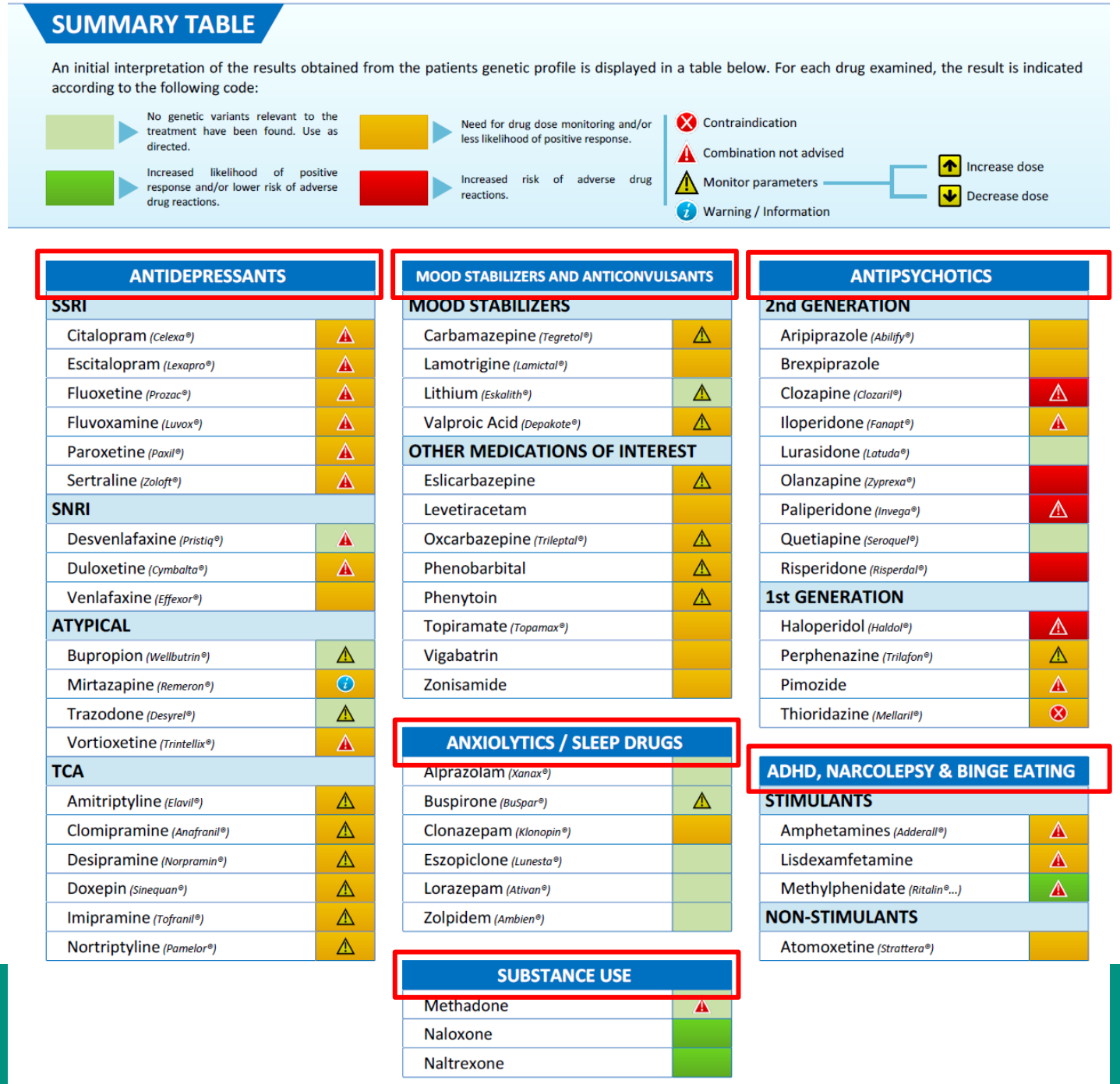
ANTIPSYCHOTICS	
2nd GENERATION	
Aripiprazole *(Abilify®)*	
Brexpiprazole	
Clozapine *(Clozaril®)*	
Iloperidone *(Fanapt®)*	
Lurasidone *(Latuda®)*	
Olanzapine *(Zyprexa®)*	
Paliperidone *(Invega®)*	
Quetiapine *(Seroquel®)*	
Risperidone *(Risperdal®)*	
1st GENERATION	
Haloperidol *(Haldol®)*	
Perphenazine *(Trilafon®)*	
Pimozide	
Thioridazine *(Mellaril®)*	

ADHD, NARCOLEPSY & BINGE EATING	
STIMULANTS	
Amphetamines *(Adderall®)*	
Lisdexamfetamine	
Methylphenidate *(Ritalin®...)*	
NON-STIMULANTS	
Atomoxetine *(Strattera®)*	

Well Organized Reports

Not just alphabetic!

PRECISION GENETICS



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- Increased likelihood of positive response and/or lower risk of adverse drug reactions.
- Need for drug dose monitoring and/or less likelihood of positive response.
- Increased risk of adverse drug reactions.
- Contraindication
- Combination not advised
- Monitor parameters
- Warning / Information
- Increase dose
- Decrease dose

ANTIDEPRESSANTS

SSRI	
Citalopram *(Celexa®)*	Combination not advised
Escitalopram *(Lexapro®)*	Combination not advised
Fluoxetine *(Prozac®)*	Combination not advised
Fluvoxamine *(Luvox®)*	Combination not advised
Paroxetine *(Paxil®)*	Combination not advised
Sertraline *(Zoloft®)*	Combination not advised
SNRI	
Desvenlafaxine *(Pristiq®)*	Combination not advised
Duloxetine *(Cymbalta®)*	Combination not advised
Venlafaxine *(Effexor®)*	Need for drug dose monitoring and/or less likelihood of positive response.
ATYPICAL	
Bupropion *(Wellbutrin®)*	Monitor parameters
Mirtazapine *(Remeron®)*	Warning / Information
Trazodone *(Desyrel®)*	Monitor parameters
Vortioxetine *(Trintellix®)*	Combination not advised
TCA	
Amitriptyline *(Elavil®)*	Monitor parameters
Clomipramine *(Anafranil®)*	Monitor parameters
Desipramine *(Norpramin®)*	Monitor parameters
Doxepin *(Sinequan®)*	Monitor parameters
Imipramine *(Tofranil®)*	Monitor parameters
Nortriptyline *(Pamelor®)*	Monitor parameters

MOOD STABILIZERS AND ANTICONVULSANTS

MOOD STABILIZERS	
Carbamazepine *(Tegretol®)*	Monitor parameters
Lamotrigine *(Lamictal®)*	Need for drug dose monitoring and/or less likelihood of positive response.
Lithium *(Eskalith®)*	Monitor parameters
Valproic Acid *(Depakote®)*	Monitor parameters
OTHER MEDICATIONS OF INTEREST	
Eslicarbazepine	Monitor parameters
Levetiracetam	Need for drug dose monitoring and/or less likelihood of positive response.
Oxcarbazepine *(Trileptal®)*	Monitor parameters
Phenobarbital	Monitor parameters
Phenytoin	Monitor parameters
Topiramate *(Topamax®)*	Need for drug dose monitoring and/or less likelihood of positive response.
Vigabatrin	Need for drug dose monitoring and/or less likelihood of positive response.
Zonisamide	Need for drug dose monitoring and/or less likelihood of positive response.

ANXIOLYTICS / SLEEP DRUGS

Alprazolam *(Xanax®)*	Increased risk of adverse drug reactions.
Buspirone *(BuSpar®)*	Monitor parameters
Clonazepam *(Klonopin®)*	Need for drug dose monitoring and/or less likelihood of positive response.
Eszopiclone *(Lunesta®)*	Increased risk of adverse drug reactions.
Lorazepam *(Ativan®)*	Increased risk of adverse drug reactions.
Zolpidem *(Ambien®)*	Increased risk of adverse drug reactions.

SUBSTANCE USE

Methadone	Combination not advised
Naloxone	Increased likelihood of positive response and/or lower risk of adverse drug reactions.
Naltrexone	Increased likelihood of positive response and/or lower risk of adverse drug reactions.

ANTIPSYCHOTICS

2nd GENERATION	
Aripiprazole *(Abilify®)*	Need for drug dose monitoring and/or less likelihood of positive response.
Brexpiprazole	Need for drug dose monitoring and/or less likelihood of positive response.
Clozapine *(Clozaril®)*	Combination not advised
Iloperidone *(Fanapt®)*	Combination not advised
Lurasidone *(Latuda®)*	Increased risk of adverse drug reactions.
Olanzapine *(Zyprexa®)*	Increased risk of adverse drug reactions.
Paliperidone *(Invega®)*	Combination not advised
Quetiapine *(Seroquel®)*	Increased risk of adverse drug reactions.
Risperidone *(Risperdal®)*	Increased risk of adverse drug reactions.
1st GENERATION	
Haloperidol *(Haldol®)*	Combination not advised
Perphenazine *(Trilafon®)*	Monitor parameters
Pimozide	Combination not advised
Thioridazine *(Mellaril®)*	Contraindication

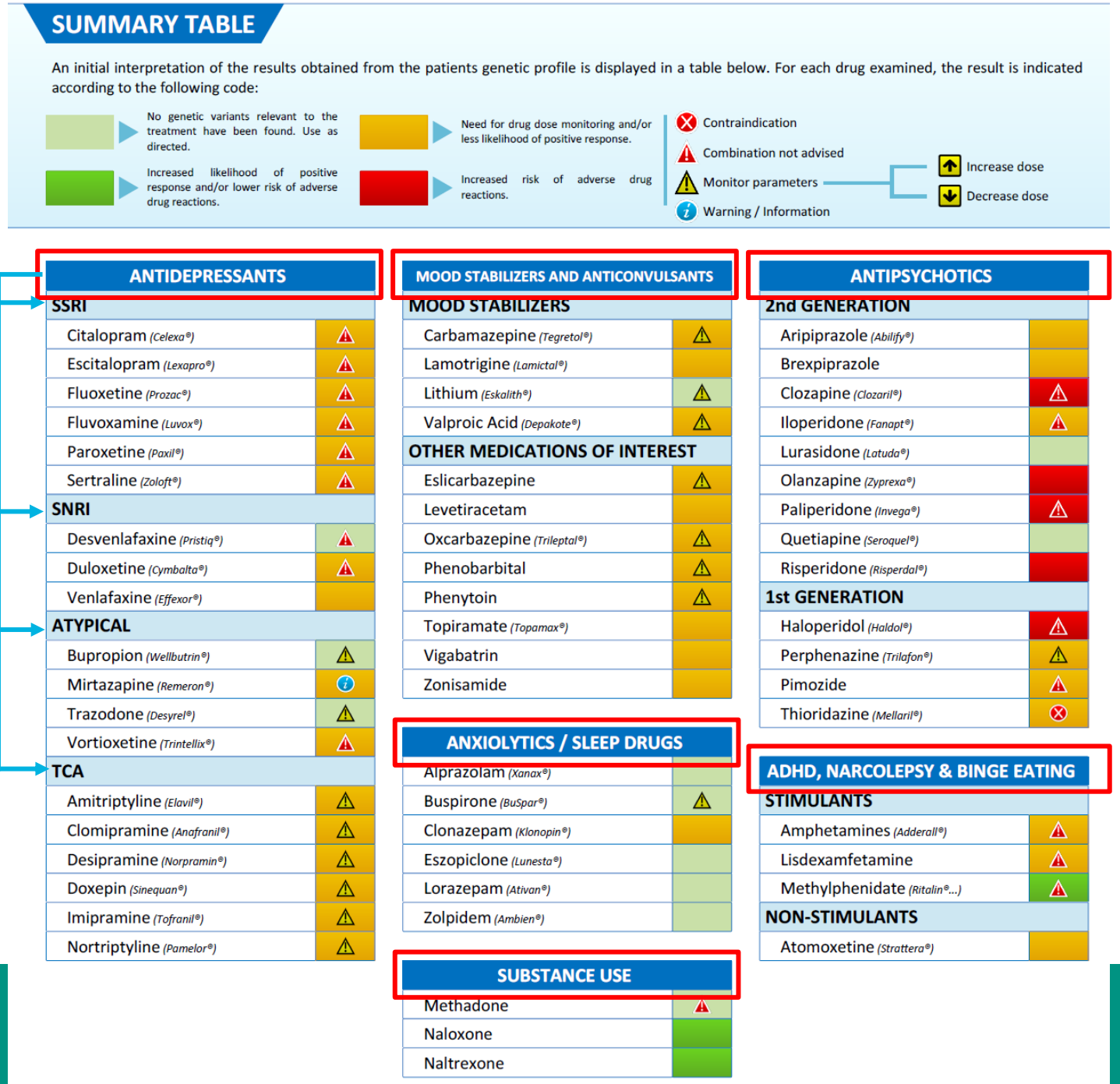
ADHD, NARCOLEPSY & BINGE EATING

STIMULANTS	
Amphetamines *(Adderall®)*	Combination not advised
Lisdexamfetamine	Combination not advised
Methylphenidate *(Ritalin®...)*	Combination not advised
NON-STIMULANTS	
Atomoxetine *(Strattera®)*	Need for drug dose monitoring and/or less likelihood of positive response.

Well Organized Reports

Not just alphabetic!

PRECISION GENETICS



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Escitalopram *(Lexapro®)*	⚠
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Fluvoxamine *(Luvox®)*	⚠
Paroxetine *(Paxil®)*	⚠
Sertraline *(Zoloft®)*	⚠
SNRI	
Desvenlafaxine *(Pristiq®)*	⚠
Duloxetine *(Cymbalta®)*	⚠
Venlafaxine *(Effexor®)*	
ATYPICAL	
Bupropion *(Wellbutrin®)*	⚠
Mirtazapine *(Remeron®)*	ⓘ
Trazodone *(Desyrel®)*	⚠
Vortioxetine *(Trintellix®)*	⚠
TCA	
Amitriptyline *(Elavil®)*	⚠
Clomipramine *(Anafranil®)*	⚠
Desipramine *(Norpramin®)*	⚠
Doxepin *(Sinequan®)*	⚠
Imipramine *(Tofranil®)*	⚠
Nortriptyline *(Pamelor®)*	⚠

MOOD STABILIZERS AND ANTICONVULSANTS	
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Levetiracetam	
Oxcarbazepine *(Trileptal®)*	⚠
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Phenytoin	⚠
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Vigabatrin	
Zonisamide	

ANXIOLYTICS / SLEEP DRUGS	
Alprazolam *(Xanax®)*	
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Clonazepam *(Klonopin®)*	
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SUBSTANCE USE	
Methadone	⚠
Naloxone	
Naltrexone	

ANTIPSYCHOTICS	
2nd GENERATION	
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Brexpiprazole	
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Iloperidone *(Fanapt®)*	⚠
Lurasidone *(Latuda®)*	
Olanzapine *(Zyprexa®)*	
Paliperidone *(Invega®)*	⚠
Quetiapine *(Seroquel®)*	
Risperidone *(Risperdal®)*	
1st GENERATION	
Haloperidol *(Haldol®)*	⚠
Perphenazine *(Trilafon®)*	⚠
Pimozide	⚠
Thioridazine *(Mellaril®)*	⊗

ADHD, NARCOLEPSY & BINGE EATING	
STIMULANTS	
Amphetamines *(Adderall®)*	⚠
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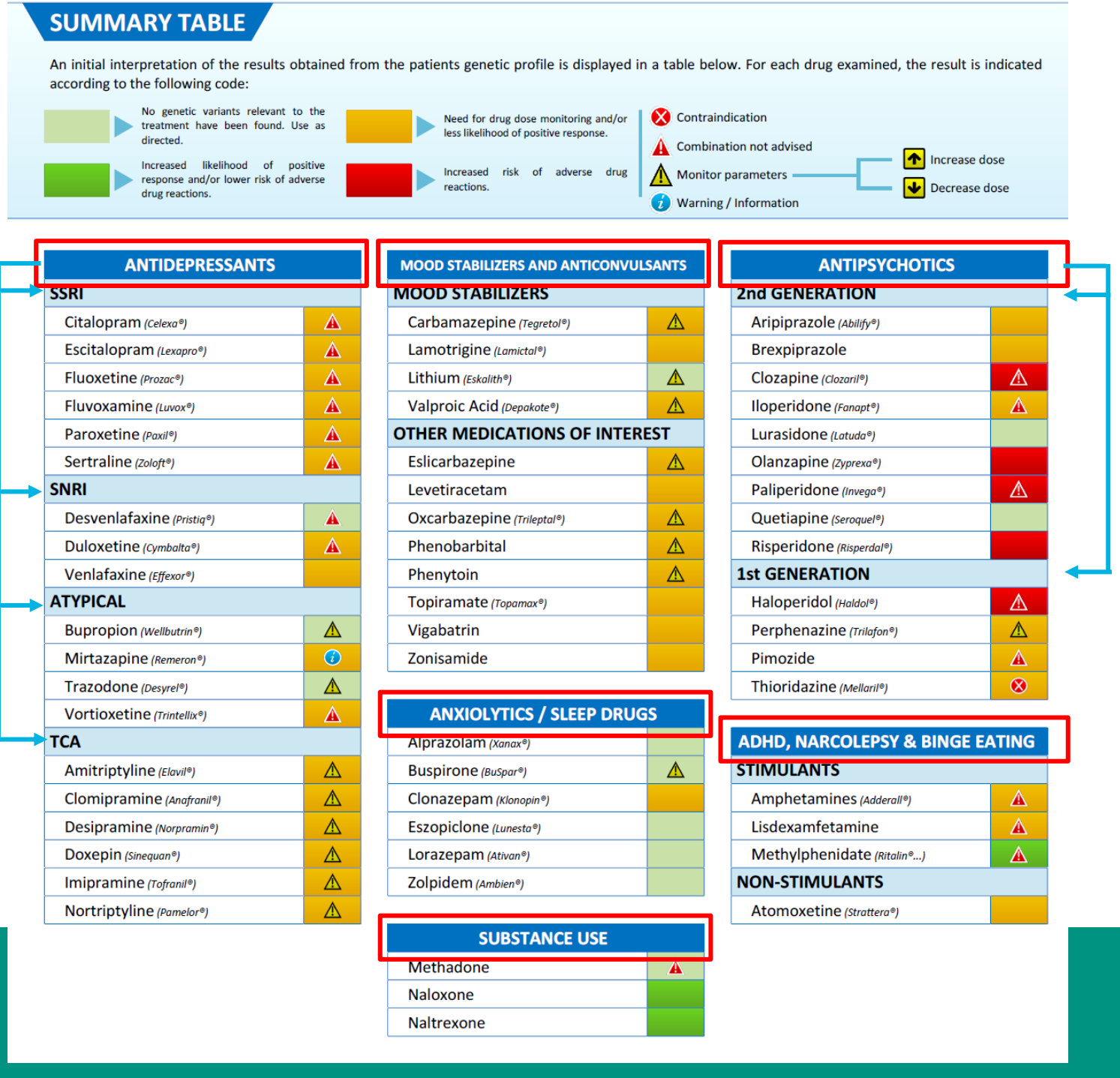
PRECISION GENETICS



Well Organized Reports

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PRECISION GENETICS

Report Demo:

1. Primary Care (Static)
2. Mental Health (Dynamic)

PRECISION GENETICS

Case Study

DEMOGRAPHIC DATA AND DIAGNOSIS

16-year-old adolescent, adopted at the age of 2 months**.** Severe Attention-Deficit Hyperactivity Disorder (ADHD) and conduct disorder, childhood onset at 5 years old.

Other features:

- Before the age of 3, was very disruptive (difficult-to-raise child")
- From 3 to 10-yo, several behavioral problems at school and home
- At the age of 10, frequent and severe antisocial behavior, including delinquent behavior and drug abuse
- Foster care at 11-year-old, at the residential care:
  - Restless behavior, emotional coldness, fighting with other adolescent mates, and severe insomnia
  - He tried trafficking different types of illegal drugs
  - He frequently ran away
  - Poor school achievement, IQ78

PRECISION GENETICS

Case Study Continued

CLINICAL HISTORY

Effects of pharmacotherapy (before using PGx-guided treatment):

- Refractory to most of the medications used at foster care and reported several side-effects.
- Conduct disorder was impossible to control even using up to 10 different drugs at the same time.

PHARMACOLOGICAL TREATMENT

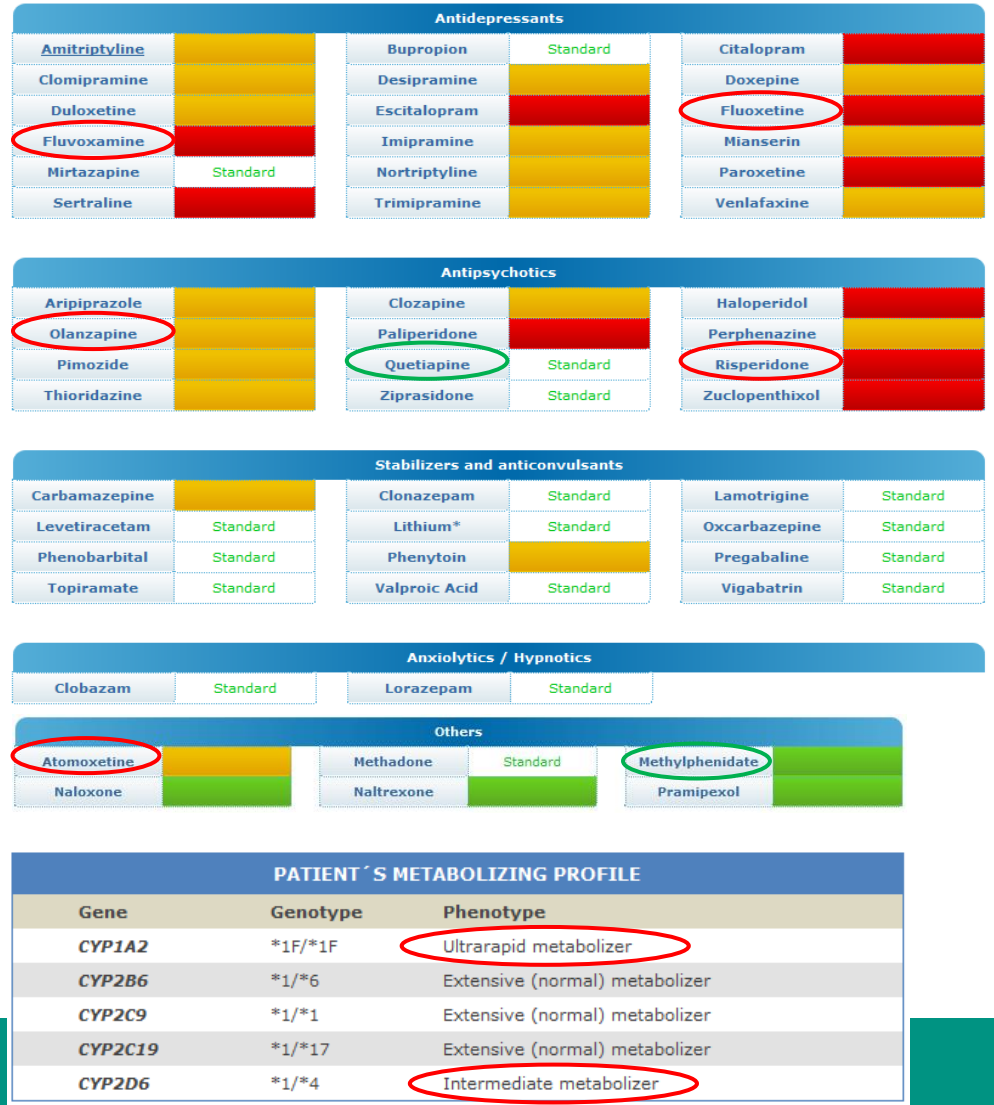
Psychiatric medication:

- Atomoxetine 80 mg/d
- Methylphenidate 20 mg/d
- Risperidone 4 mg/d
- Olanzapine 20 mg/d + Melatonin 2 mg/night – because of insomnia
- Propranolol 5 mg/d – because of palpitations and anxiety
- Biperiden 4 mg/d – neck dystonia and akathisia during the last 4 years
- Lorazepam 3 mg/d – for anxiety

Previously, had been treated with fluoxetine, fluvoxamine, carbamazepine, aripiprazole, paliperidone, and thioridazine, at usual dosages, without any positive results.

August 2014 – PGx testing initiated (14-year-old, prescribed after last runaway).

Case Study Continued



PATIENT´S METABOLIZING PROFILE

Gene	Genotype	Phenotype
CYP1A2	*1F/*1F	Ultrarapid metabolizer
CYP2B6	*1/*6	Extensive (normal) metabolizer
CYP2C9	*1/*1	Extensive (normal) metabolizer
CYP2C19	*1/*17	Extensive (normal) metabolizer
CYP2D6	*1/*4	Intermediate metabolizer

PHARMACOGENETIC EVALUATION

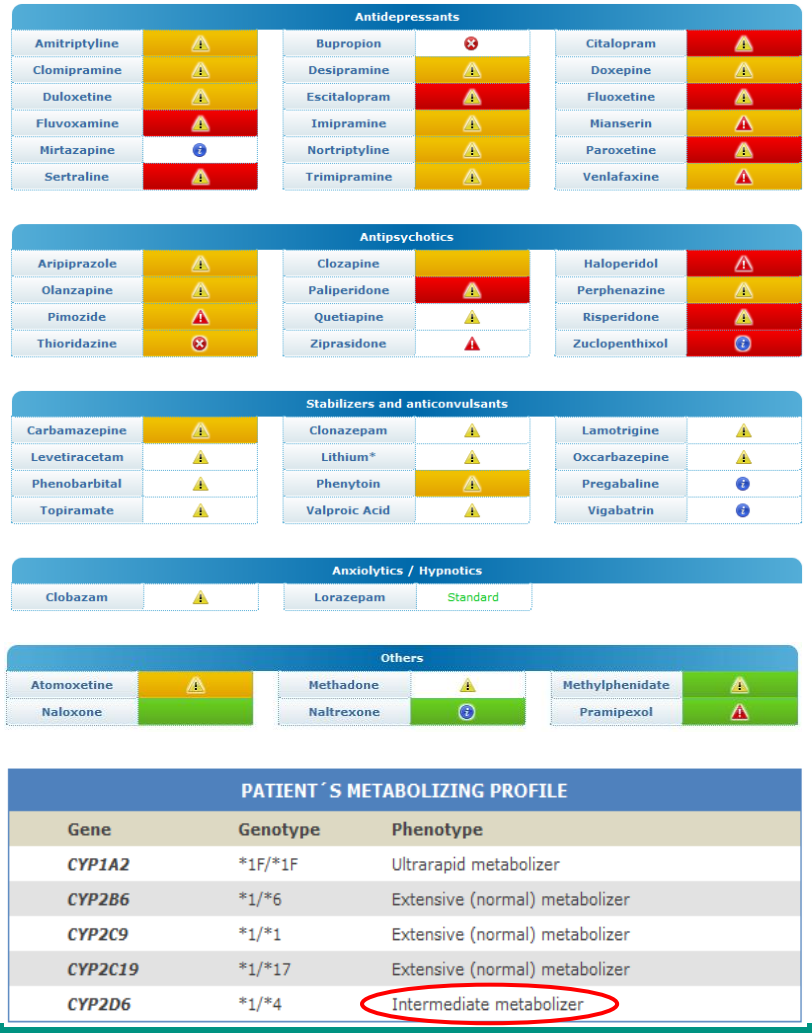
Interpretation:

- *CYP1A2* UM phenotype may explain why insomnia was still present, even at high olanzapine doses (plus melatonin).
- Decreased therapeutic response to both fluoxetine and fluvoxamine could be explained by the *5HTTLPR* S/S genotype.
- *AKT1-DDIT4-FCHSD1-RPTOR* genes allele variation increase the risk of extrapyramidal symptoms when using either risperidone or paliperidone, as observed.
- *CYP2D6* IM phenotype combined with polypharmacy often results in PM phenotype, explaining adverse effects with atomoxetine and risperidone. 2D6 PM phenotype could also interfere with clozapine plasma levels (FDA labelling cautions dose reductions may be necessary)

PRECISION GENETICS

Blasco-Fontecilla, H. Clinical utility of pharmacogenetic testing in children and adolescents with severe mental disorders. *Journal of Neural Transmission* (2018). April 6 [Epub adead of print].

Case Study Continued

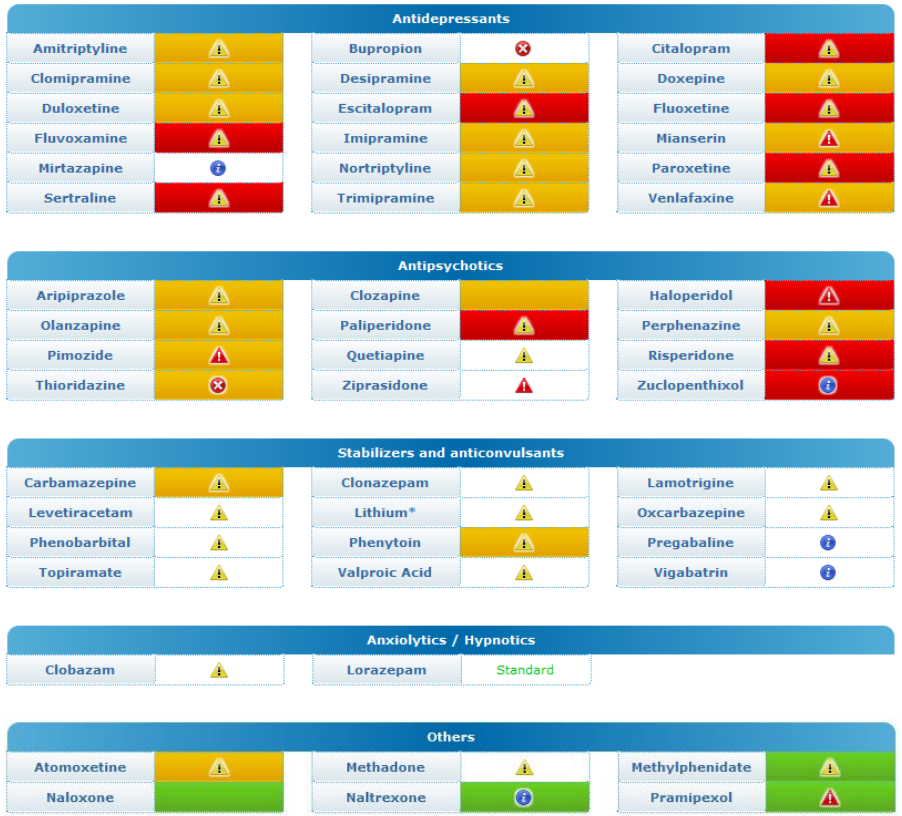


CHANGES INTRODUCED POST TESTING

Pre-testing last treatment	Post-testing changes	Reasons
Methylphenidate 20 mg/d	Dose optimization up to 70 mg/d	Patient carrier of variants of higher likelihood of good response Drug not substrate for CYP2D6
Atomoxetine 80 mg/d	Progressive withdrawal	Adverse effects (palpitations, anxiety) possibly explained by the IM phenotype of CYP2D6
	Quetiapine addition up to 300 mg/d	One of the 2 APs Indicated as “standard” in the test Aim: Olanzapine/Risperidone substitution
Olanzapine 20 mg/d	Progressive withdrawal	Inefficacy because of poor drug exposure due to the UM phenotype for CYP1A2
Risperidone 4 mg/d	Progressive withdrawal	Extrapyramidalism (indicated by the test and present in the patient)
Biperiden 5 mg/d	Discontinuation	EPS disappears after antipsychotic drug substitution
Propranolol 4 mg/d	Discontinuation	Previous side effects disappeared thus to the reported medication changes

PRECISION GENETICS

Case Study Conclusion



FOLLOW-UP

- Progressive improvement of ADHD-core symptoms, antisocial behavior, and insomnia.
- Overt aggressive and delinquent behavior eventually disappeared.
- For the first time in his life, was able to behave properly and do homework around two hours a day.
- Later on, he began a supervised, paid-job as a gardener. He has been working for more than one year without any problem.
- He was also able to engage in cognitive-behavior therapy
- Was given more autonomy, and began to spend more time with his parents.

✓ **The poor clinical response to the medications and the reported side effects made impossible to adhere to drug therapy.**

✓ **PGx testing at an initial stage might have avoided polypharmacy, reduced side effects and increasing adherence.**

PRECISION GENETICS

Critical Factors for PGx Implementation

- Scalability
- Reimbursement
- Physician Adoption

SCALABILITY: ORDERING / INTAKE

- Key elements:
  - Panel selection
    - Comprehensive panel, sub-panel (mental health, cardiovascular, etc), single-gene
  - Demographics
    - Age
    - Ethnicity
  - Indications for ordering
    - ICD-10s
    - Previous failed therapy
    - Existing medications
    - Gene/drug pairs
    - Lifestyle factors
      - Co-morbidities
      - Supplements
  - Informed Consent
    - Patient consent for genetic testing
    - Physician signature for medical necessity & order

PRECISION GENETICS with MUSC Health

Physical and Billing Address:
645 Meeting Street Charleston, SC 29403
877.843.0544 (phone) • 866.645.9526 (fax)
CLIA# 42D2115298

CANCER GENOMICS (CGx) SCREENING TEST REQUISITION

TEST REQUESTED (CHOOSE ONLY ONE TEST PANEL)

☐ **Comprehensive Test Panel**

ATM, APC, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, DICER1, EPCAM, GALNT12, GREM, HOXB13, MEN1, MET, MITF, MLH1, MLH3, MRE11A, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NTHL1, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, RET, RNF43, RPS20, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, VHL

☐ **Breast Cancer Genetic Test Panel**

ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, STK11, TP53

☐ **Ovarian Cancer Genetic Test Panel**

ATM, BRIP1, EPCAM, MLH1, MSH2, MSH6, PMS2, RAD51C, RAD51D, STK11

☐ **Single-Gene Assay**

Gene to be assayed: _____

☐ **Single Variant Assay**

Variant to be assayed: _____

SAMPLE COLLECTION DATE (mm/dd/yyyy): ____/____/____

PATIENT INFORMATION

Patient Name (Last, First): | Street Address | City | State | Zip

Phone: | Date of Birth: | Biological Sex: ☐Male ☐Female

Patient Ethnicity: ☐Caucasian ☐African American ☐Hispanic ☐Asian ☐American Indian/Native Alaskan
"REQUIRED" ☐Hawaiian/Pacific Islander ☐Ashkenazi Jewish ☐Sephardic Jewish ☐Other/Unknown (please specify) _____

PATIENT PAYMENT/INSURANCE INFORMATION

☐INSURANCE BILLING (Include copy of both sides of insurance card) ☐PATIENT SELF-PAY (If billing address is different from above, please list)

Street | City, State | Zip

Patient Relation to Policy Holder: ☐ Self ☐ Spouse ☐ Child | Name and DOB of Policy Holder

Primary Insurance Company | Subscriber Number | **Policy Number** | **Group Number**

Insurance Type: ☐ Commercial ☐ Medicare ☐ Medicaid

Secondary Insurance Company | Subscriber Number | Policy Number | Group Number

Insurance Type: ☐ Commercial ☐ Medicare ☐ Medicaid

I request and authorize Precision Genetics to perform the designated test(s) on the sample provided by me as well as provide clinical reporting for the attached sample. I, the undersigned, understand that I am responsible for all copays and deductibles, and for amounts not covered by insurance. By signing this authorization, I acknowledge that payments be made on my behalf to Precision Genetics for any services provided to me by Precision Genetics. I also allow the release of any medical information necessary to process this claim. I understand that no tests other than those requested above will be performed. I understand that DNA from the attached sample may be kept by the laboratory for up to 25 years, used for internal laboratory quality assurance purposes, and, in some cases, DNA may be used by the laboratory for new test development and research purposes after all identifying information has been removed.

Patient Name (Print): _____ **Patient Signature:** _____

Date: _____

PHYSICIAN DIAGNOSIS INFORMATION/ICD-10 CODES (Report codes that best describe the reasons for performing the test)
PLEASE IDENTIFY A MINIMUM OF THREE CODES (page 2)

Diagnostic Code 1_____ Diagnostic Code 2_____ Diagnostic Code 3_____

Diagnostic Code 4_____ Diagnostic Code 5_____ Diagnostic Code 6_____

ICD-10 codes:
unspecified female breast_____

☐ Z80.3 Family history of malignant neoplasm of breast cancer
☐ Z80.41 Family history of malignant neoplasm of ovary
☐ Z80.0 Family history of malignant neoplasm of digestive organs
☐ Z85.42 Family history of neoplasm of prostate
☐ C50.919 Malignant neoplasm of unspecified site of
☐ C56.9 Malignant neoplasm of unspecified ovary
☐ Other ICD-10:_____

ORDERING PHYSICIAN INFORMATION

Physician NPI # | **Physician Name** | **Facility Name/Office Contact**

Street Address | City | **State** | Zip

Contact Phone | Physician Email | **Contact Email (Required for access to patient test results)**

CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY FOR GENETIC TESTING

By signing this form, the medical professional acknowledges that the individual/family member authorized to make decisions for the individual (collectively, the "Patient") has been supplied information regarding and consented to undergo selected testing, substantially as set forth in Precision Genetics informed consent for selected testing and has been informed that Precision Genetics may notify them of clinical updates related to test results (in consultation with the ordering medical professional as indicated). I agree to allow Precision Genetics to facilitate the provision of pre-test, counseling, if required by insurer, services by a third-party service, unless otherwise indicated by checking this box. ☐

Physician Signature: _____ **Date:** _____

RELATIVE RISK SCORES FOR BRCA1 and/or BRACA2 genes

☐ My patient meets the following eligibility criteria to perform this analysis.
* Female, 18-84 years old
* No personal history of breast cancer
* No personal history of a germline mutation in the following genes: *ATM, BARD1, CDH1, CHEK2, NF1, PALB2, PTEN, STK11, TP53*
* Genetic test order must include the *BRCA1* and/or *BRCA2* genes

PATIENT PERSONAL HEALTH HISTORY

Weight: ____lbs | Parity Status: ☐ Parous ☐ Nulliparous | Menopause status: ☐ Pre-menopausal ☐ Peri-menopausal ☐ Post-menopausal

Height: ____ in | Age at first live birth:_____ | Age at menarche:_____ | Age at Menopause: _____

Has the patient had germline genetic testing for the *BRCA1/BRCA2* gene?
☐ Yes ☐ No ☐ Unknown testing result
"If yes, what was the patient's germline BRCA1 genetic test result?
☐ Positive ☐ Negative ☐ VUS ☐ Positive ☐ Negative ☐ VUS
"If yes, what was the patient's germline BRAC2 genetic test result?
☐ Positive ☐ Negative ☐ VUS

Has the patient ever used hormone replacement therapy (HRT)?
☐ Yes ☐ No ☐ Unknown
If yes, indicate HRT type (select one): ☐ Estrogen only ☐ Combined ☐ VUS
If yes, indicate the years of usage:
☐ Current User: Used for _____ total years Intended to use for _____ years
☐ Used less than 5 years ago: Used for _____ total years Used last ____years ago
☐ Used 5 or more years ago
☐ Unknown

BREAST HEALTH HISTORY

Has the patient had a prior abnormal breast biopsy of the following type? (check all that apply):

☐ Hyperplasia (not typical)
☐ Atypical hyperplasia
☐ Lobular carcinoma in-situ (LCIS)
☐ Prior biopsy, result unknown

Has the patient had a breast density assessment?
☐ Yes ☐ No ☐ Unknown

If yes, indicate method and measure below (check all that apply)
☐ Hologic Volumetric Density _____%
☐ VAS Percentage Density _____ %
☐ BIRADS ATLAS Density (select one):
☐ Almost entirely fatty ☐ Scattered fibroglandular density
☐ Heterogeneously dense ☐ Extremely dense

FAMILY HISTORY

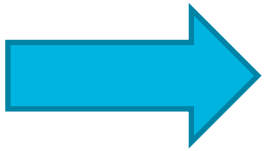
Have any of the patient's blood relatives had breast and/or ovarian cancer or BRCA genetic testing? ☐ Yes ☐ No ☐ Unknown

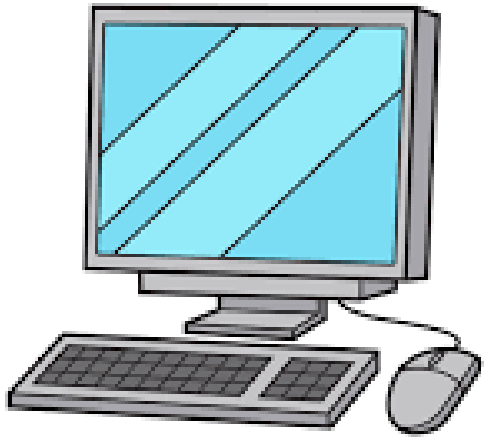
How many of the below relatives does the patient have?
*number of sister(s): _____
*number of daughter(s): _____
*number of maternal aunt(s): _____
*number of paternal aunt(s): _____

Relative's Relationship to Patient	Maternal/Paternal	Breast/Ovarian Diagnosis	BRCA1/BRCA2 test Results
_____	☐ Maternal ☐ Paternal	☐ Breast ☐ Ovarian	Variant: _____ Pathogenicity _____
_____	☐ Maternal ☐ Paternal	☐ Breast ☐ Ovarian	Variant: _____ Pathogenicity _____
_____	☐ Maternal ☐ Paternal	☐ Breast ☐ Ovarian	Variant: _____ Pathogenicity _____
_____	☐ Maternal ☐ Paternal	☐ Breast ☐ Ovarian	Variant: _____ Pathogenicity _____

PRECISION GENETICS

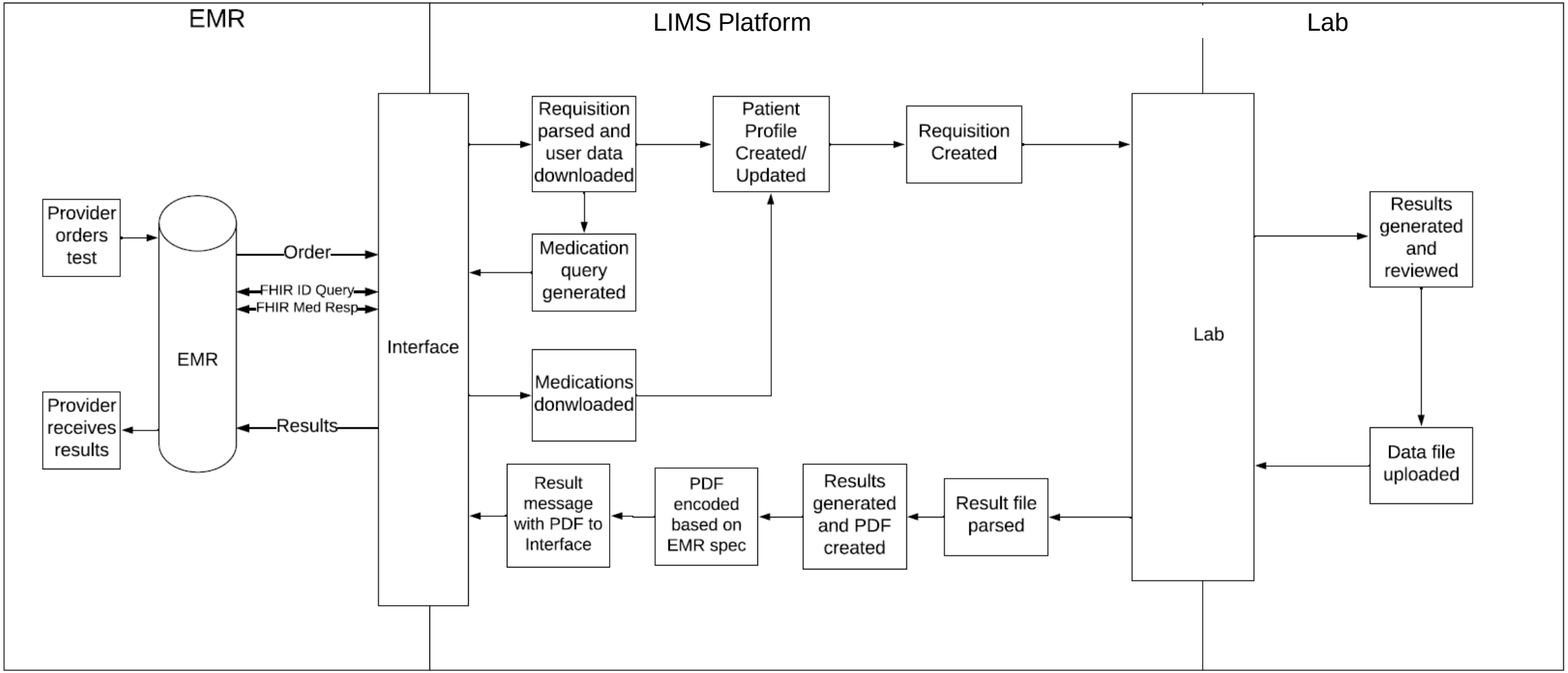
SCALABILITY





PRECISION GENETICS

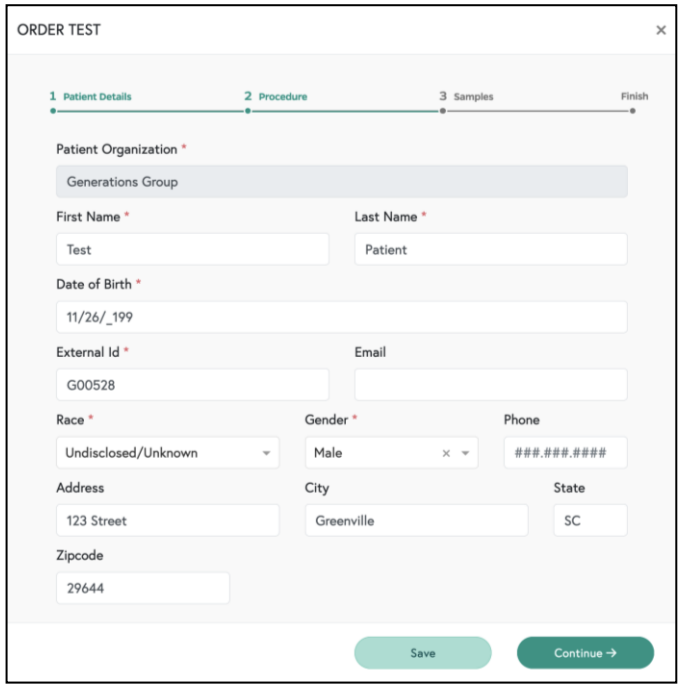
IT Scalability



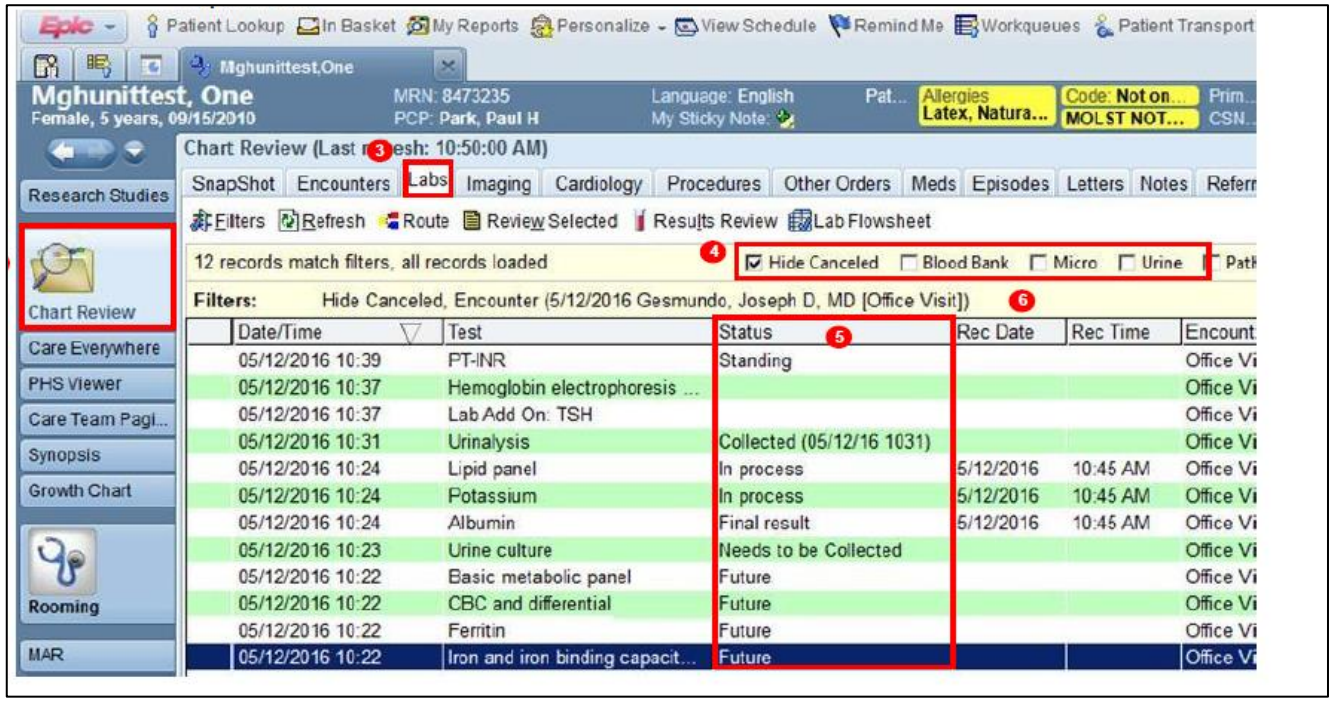
Electronic Ordering / Resulting

Physician Order / Result Portal

EMR Orderable / Resulted



API



PRECISION GENETICS

Reimbursement

- Reimbursement touches on every aspect of testing
- Easy to get lost in the details for each policy
- Policies from the same payer may seem contradictory
- Be aware of differences in policies between payers
  - Medicare vs. commercial
  - Commercial vs. commercial

Reimbursement - Medicare

- LCD L38294 (MolDx) requires the following documentation:
  - The clinical record must clearly show the use of or intent to prescribe a drug that has known drug-gene interactions that require a PGx test to be ordered to define the safe use of that drug in that patient.
  - Documented, specific gene/drug interaction that has CPIC level A/B recommendations
  - Indication that is related to the drug of interest
  - The results of the genetic test will impact the medical management of the individual.

Reimbursement - Commercial

- BCBS (CAM 218) requires the following:
  - Prior-authorization (PA)
    - prior means prior!
  - Drug considered is listed on the policy (listed by gene)
    - “Testing for the *XXX* genotype once per lifetime (please see policy guideline)* is considered **MEDICALLY NECESSARY** for individuals being considered for therapy with any of the medications listed below, or who are in their course of therapy with a medication listed below, to aid in therapy selection and/or dosing”
  - Once per lifetime testing regardless of indication
  - See list of excluded genes in the policy.

LCD - MolDX: Pharmacogenomics Testing (L38294)

Article - Billing and Coding: MolDX: Pharmacogenomics Testing (A58318)

Pharmacogenetic Testing - CAM 218

Category:

Laboratory

Department:

Medical Affairs

Physician Adoption

- Providers are busy!
- Provide continuing education
  - Grand Rounds
  - Video Tutorials
  - Invited Speakers
  - Internal communication / education programs
  - Physician champions

Key Points

- ✓ PGx has matured and will continue to expand into the clinical space.
- ✓ PGx guidance can be delivered via multiple modalities, but share common features.
- ✓ Focus on current therapy and how the patient's genotype may affect their metabolism and/or response.
- ✓ Use clinical judgement and experience combined with genotype-guided information when considering alternatives, discontinuation, or dose-adjustment.
- ✓ IT solutions are a necessary part of PGx implementation.
- ✓ Reimbursement touches all aspects of PGx, from intake, to panel design, to resulting.
- ✓ Continuous efforts are necessary for provider adoption.

THANK YOU!

PRECISION GENETICS