

Achieving Value Through Health: Latest Evidence on Pharmacogenomics

January 25, 2023

Speakers



Michael Thompson

Moderator

National Alliance of
Healthcare Purchaser
Coalitions



K. Andrew Crighton, MD

Crighton Consulting Group;
National Alliance Medical
Director Advisory Council



Jeffrey Shaman, PhD

Coriell Life Sciences

Pharmacogenomics

Involves the role various components of the genome can affect response to a drug

- Effect on drug pharmacokinetics
 - Alters drug metabolism and therefore the amount of drug available in the plasma
- Pharmacodynamics
 - Effect of drug on its target and nontarget sites
- Idiosyncratic reactions
 - An adverse reaction such as a severe allergic reaction
- Disease pathogenesis and response to specific therapies
 - Genes and Biomarkers that can direct treatment such as CFTR gene in Cystic Fibrosis or HER2-positive breast cancer

Potential Benefits

- Improved medical decision-making
- Delivery of appropriate therapies that are tailored to a patient's sequence variants or genotype rather than the general population
- Avoidance of medications of lower efficacy
- Reduced exposure to medications that have the potential for greater toxicity, with resulting lower incidence of treatment-related side-effects and complications

Challenges to Pharmacogenetic Testing and Implementation

- Limitations in the design of published pharmacogenetic studies
- Regulatory and ethical concerns
- Lack of cost effectiveness analyses
- Need to educate patients and providers
- DTC vs Clinical Testing
- Potential delay in therapy awaiting results
- Test coverage and reimbursement

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Achieving Value Through Health: Latest Evidence on Pharmacogenomics



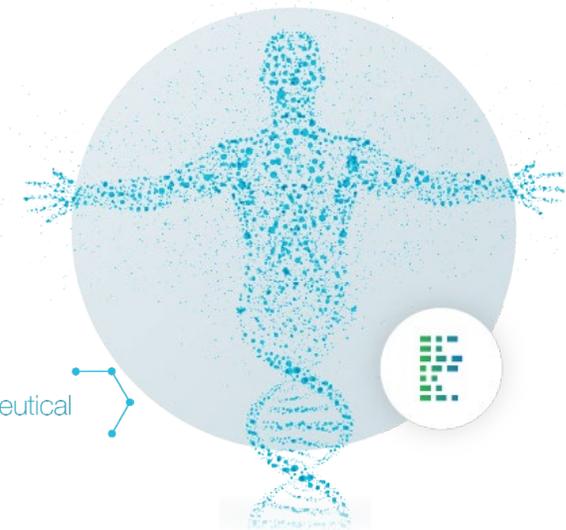
Who We Are

Coriell Life Sciences is a precision medicine company using genetic science and research to

Improve Lives

Reduce Healthcare Costs

Simplify Decision-Making



Today's Agenda

Who We Are

- Life sciences company with rich history and proven results

The Problem

- Medications don't work for everyone, and lack of treatment drives high costs/poor outcomes

A New Approach

- A member benefit enabling precision prescribing empowered by DNA testing

Proven Results

- Many large implementations and published, positive, economic and clinical outcomes

Why Now

- COVID health crisis has created unprecedented capacity and acceptance for lab testing
- COVID also created a massive demand for mental health care
- Technology, science, implementation models, and economic proof points have all achieved deployable maturity

The Current State of Prescription Drugs

1 Million

ER visits due to
adverse drug reactions³

2 Million

adverse drug
reactions annually⁴

100k

fatalities due to adverse
drug reactions⁵

- 1 in 4 Americans uses 3 or more prescription drugs.¹
- 50% of patients are on a prescription drug that fails to be effective or causes side effects.²
- Adverse drug reactions result in emergency room visits, hospitalizations, or even death.

1. CDC Fast Facts: <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm> 2. Spears BB, Health-Chiozzi M, Huff J. Trends Mol. Med. 2001;7(5):201-201. 3. 2015 IMS data 3. US Food & Drug Administration (FDA). Preventable adverse drug reactions: a focus on drug interactions. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm110632.htm>. Updated March 6, 2018. Accessed December 4, 2018. 4. Personalized Medicine Project. Section 1: basics of personalized medicine. <http://personalizedmedicineproject.weebly.com/section-1-basics-of-personalized-medicine.html>. Accessed December 4, 2018. 5. Office of Disease Prevention and Health Promotion. Adverse drug events overview. <https://health.gov/hcq/ade.asp>. Updated December 7, 2017. Accessed December 4, 2018.

Clinical Challenges to Treating Depression

Six-to-eight Weeks

Lack of response

~50% of patients with depression do not respond to their first treatment.¹

Side effects

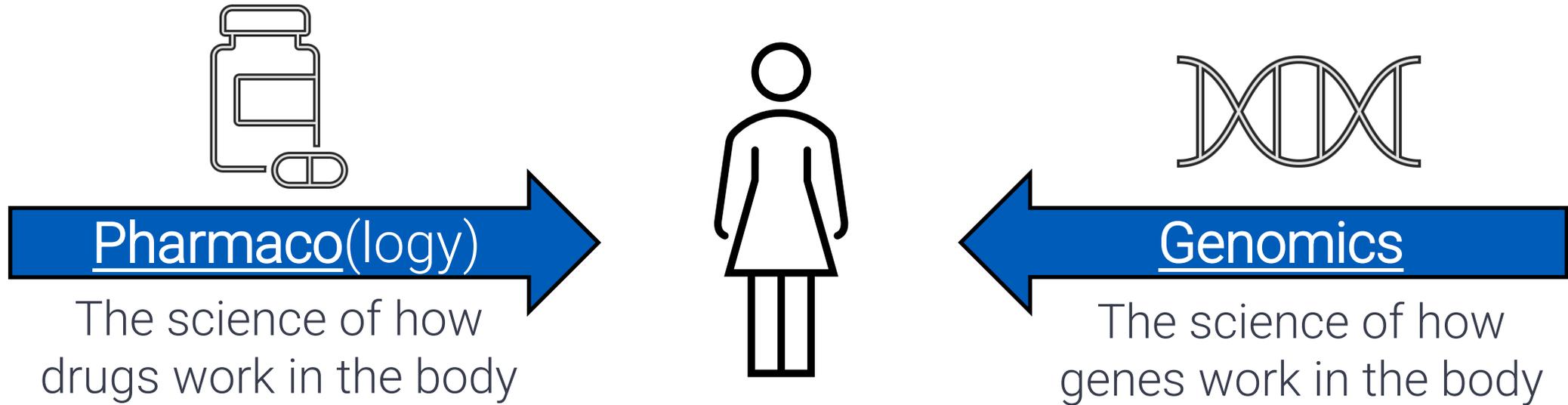
In clinical studies, up to 30% of patients discontinued treatment due to intolerable side effects.²

Nonadherence

Up to 70% of patients receiving prescriptions for antidepressant drugs are non-adherent, with side effects being the most common reason.³

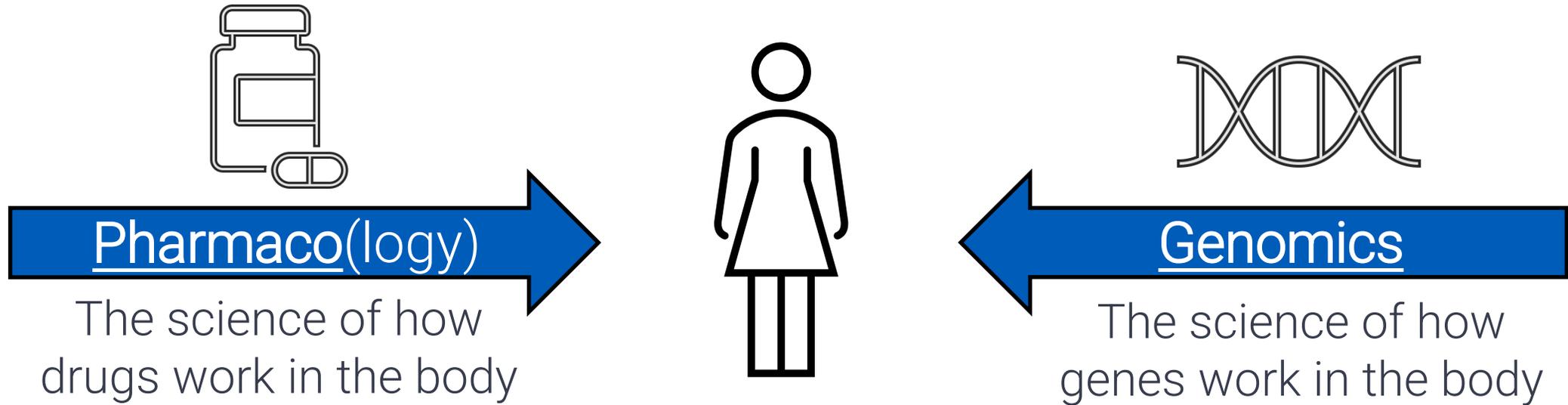
1. Al-Harbi KS. Treatment-resistant depression: therapeutic trends, challenges, and future directions. *Patient Prefer Adherence*. 2012;6:369-88.
2. Miller BJ, Bodenheimer C, Crittenden K. Second-generation antipsychotic discontinuation in first episode psychosis: an updated review. *Clin Psychopharmacol Neurosci*. 2011;9(2):45-53.
3. Ho SC, Jacob SA, Tangiisuran B. Barriers and facilitators of adherence to antidepressants among outpatients with major depressive disorder: A qualitative study. *PLoS One*. 2017;12(6):e0179290. Published 2017 Jun 14. doi:10.1371/journal.pone.0179290

Reducing Poor Outcomes Through Pharmacogenomics



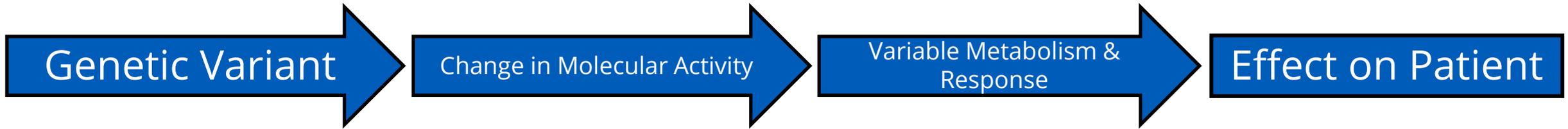
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Reducing Poor Outcomes Through Pharmacogenomics



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- Differences in how a medication works for different patients may contribute to ineffective therapy and toxicity.

Reducing Poor Outcomes Through Pharmacogenomics

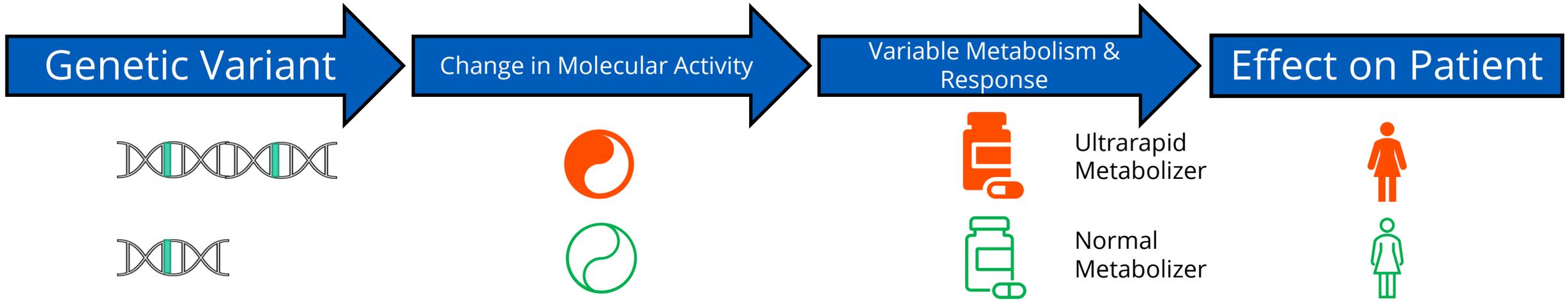


Normal
Metabolizer



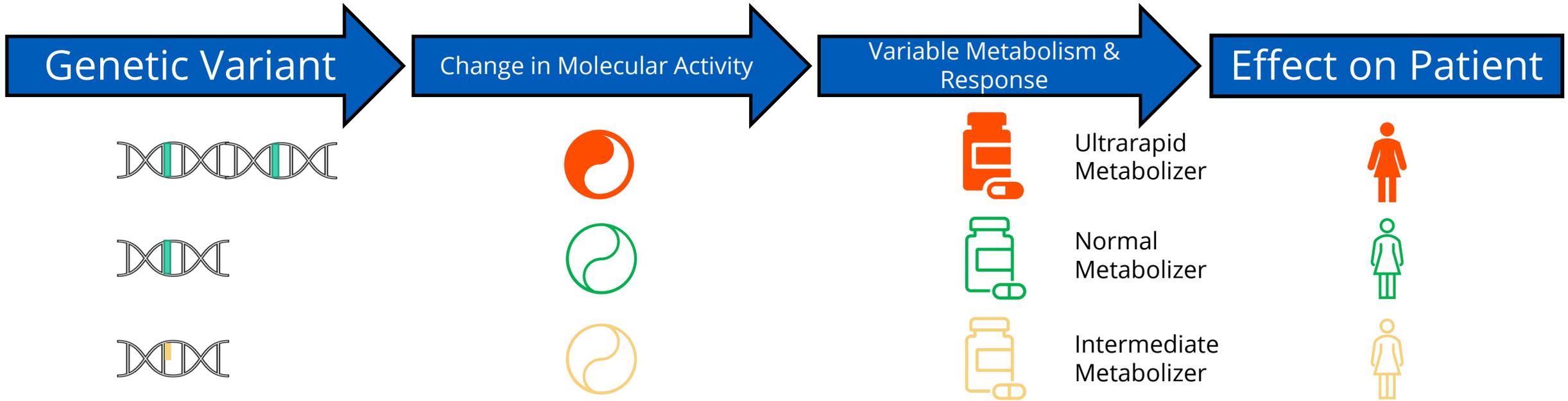
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Reducing Poor Outcomes Through Pharmacogenomics



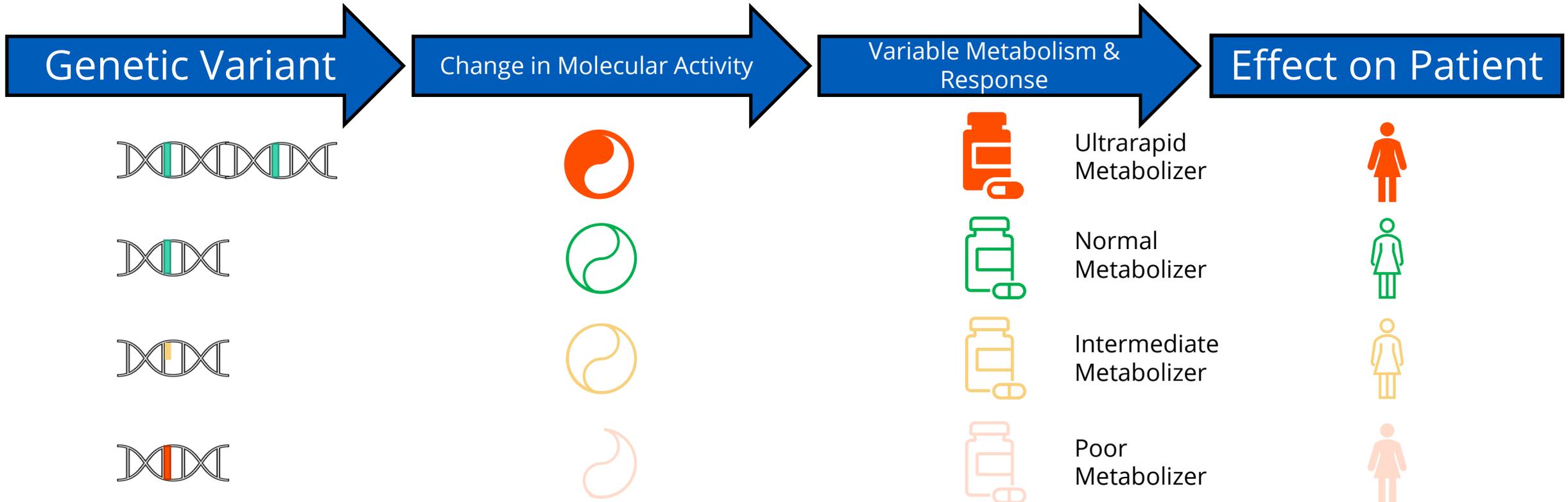
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Reducing Poor Outcomes Through Pharmacogenomics

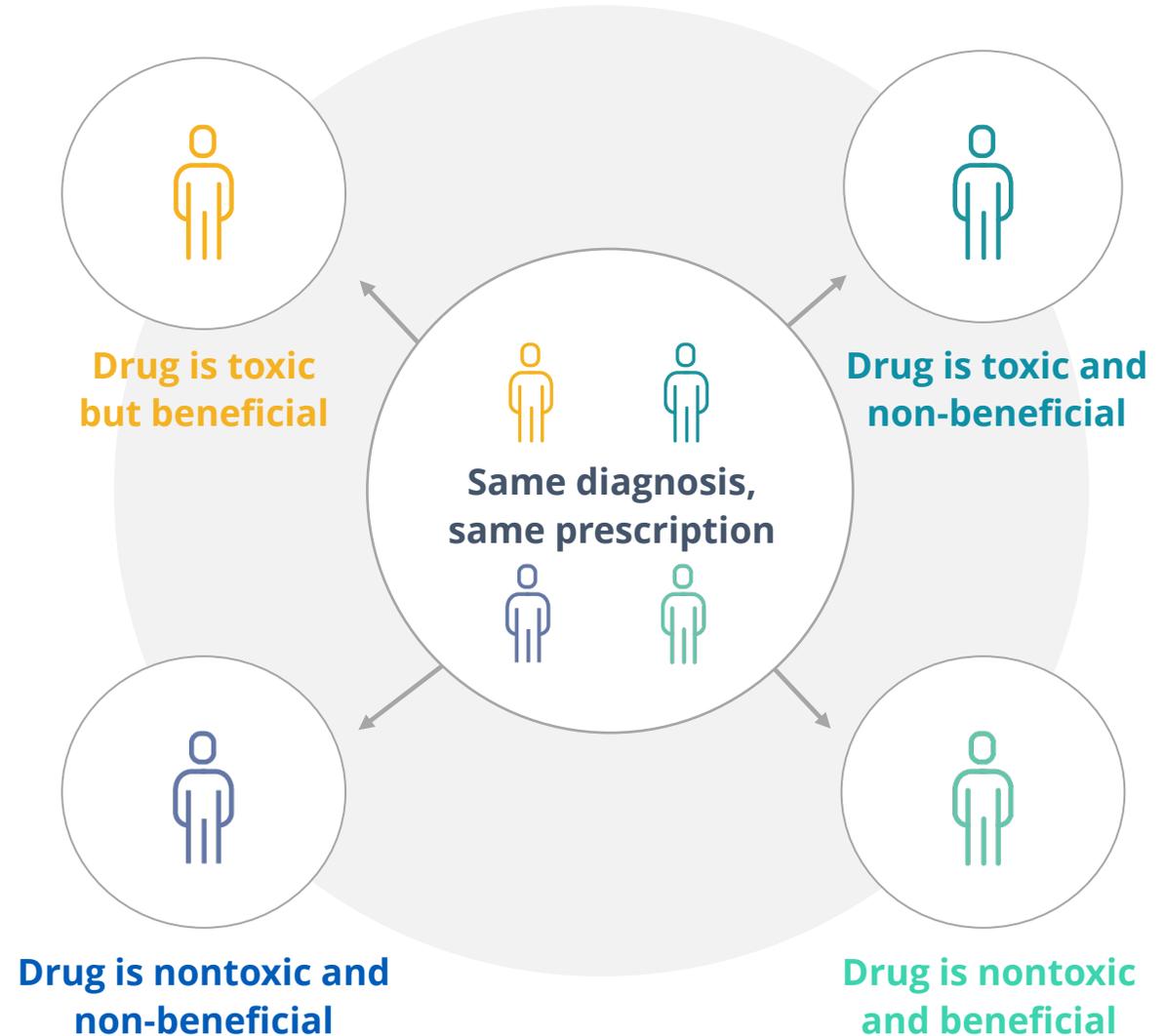


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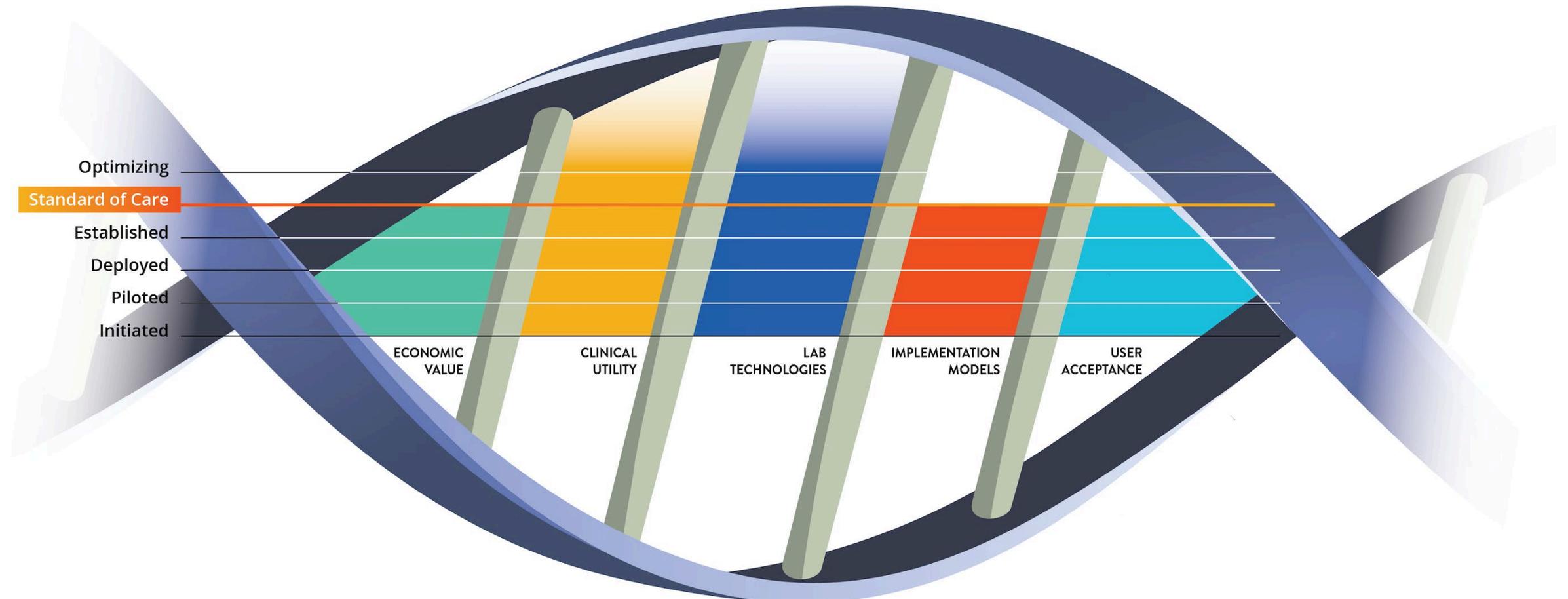
Pharmacogenomics: Your DNA Matters

Pharmacogenomics (PGx)

Using DNA to see what drugs will be safe and effective

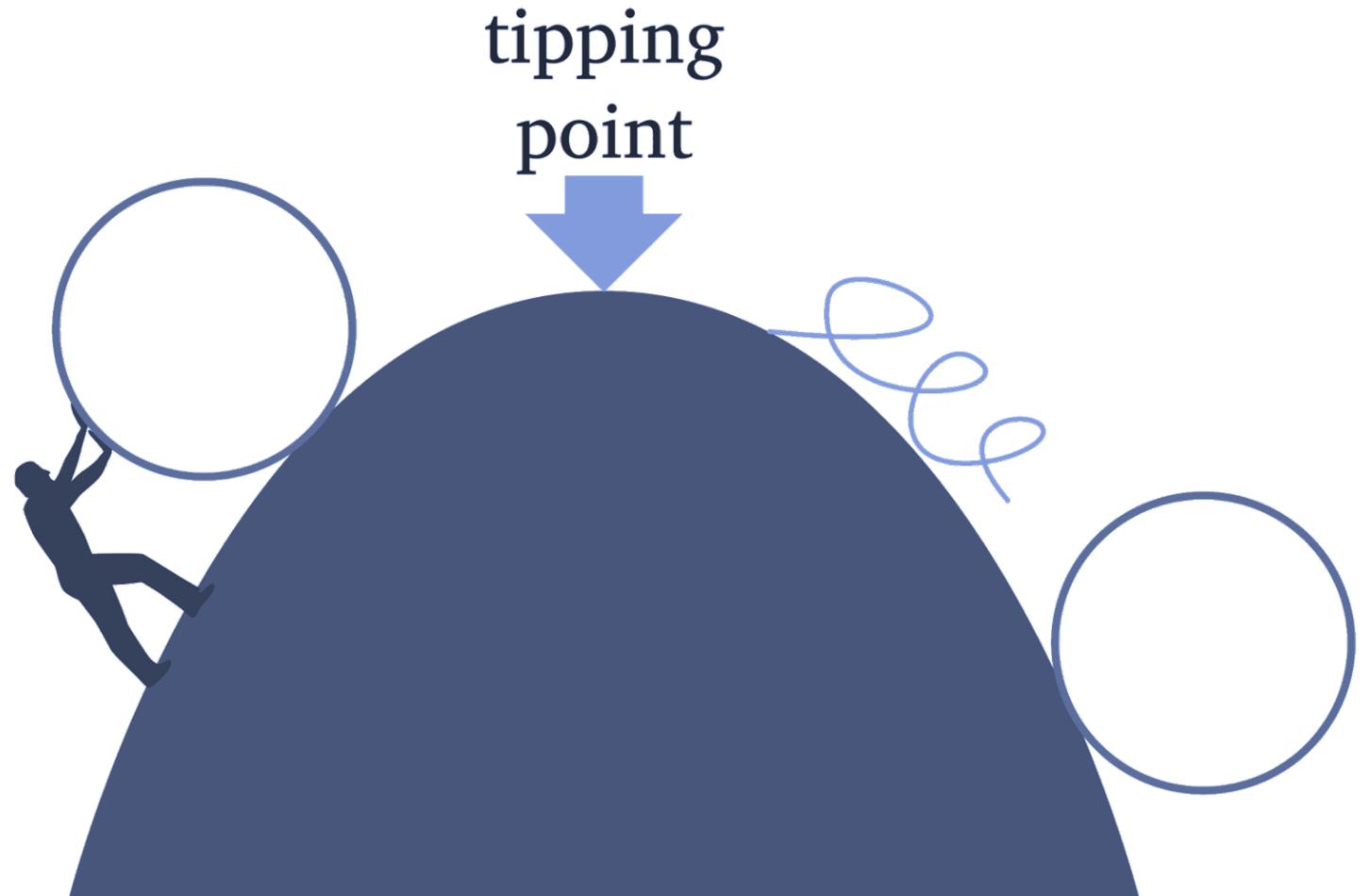


Precision Medicine Isn't the Future It's Already Here

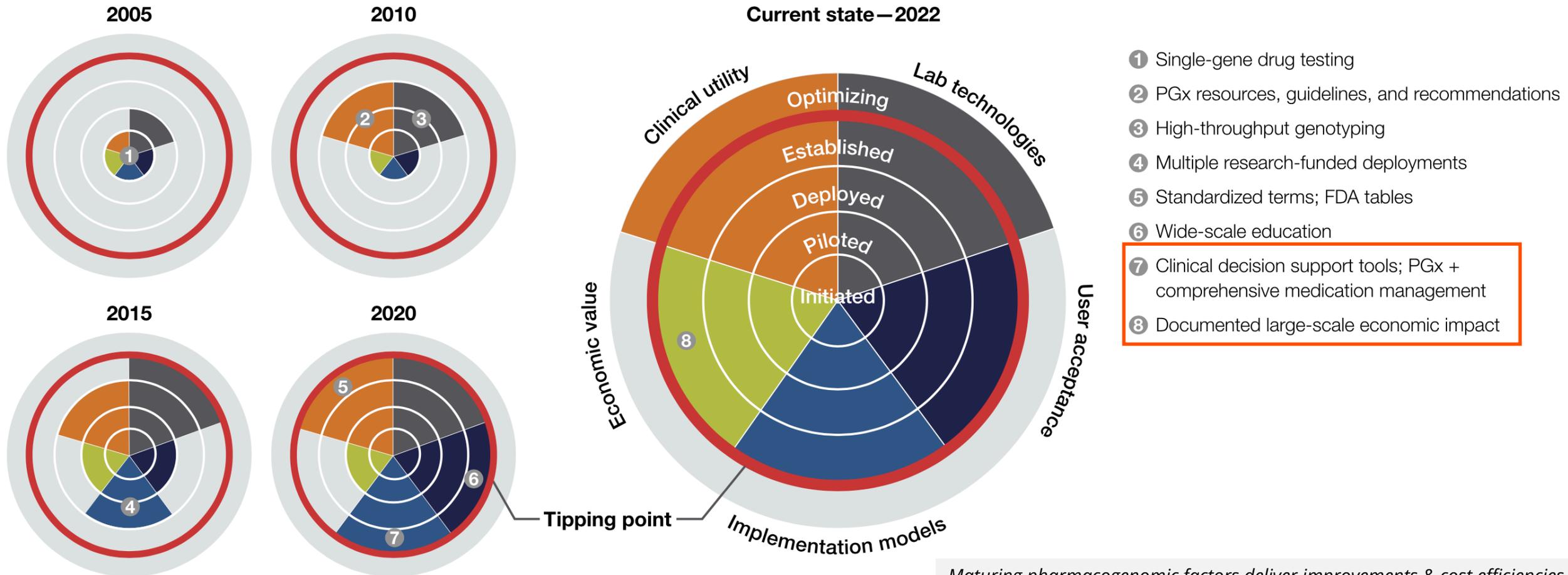


Readiness for Large Scale Pharmacogenomics

- Lab Technologies
- Clinical Utility
- Implementation Models
- Economic Value
- User Acceptance



Readiness for Large Scale Pharmacogenomics



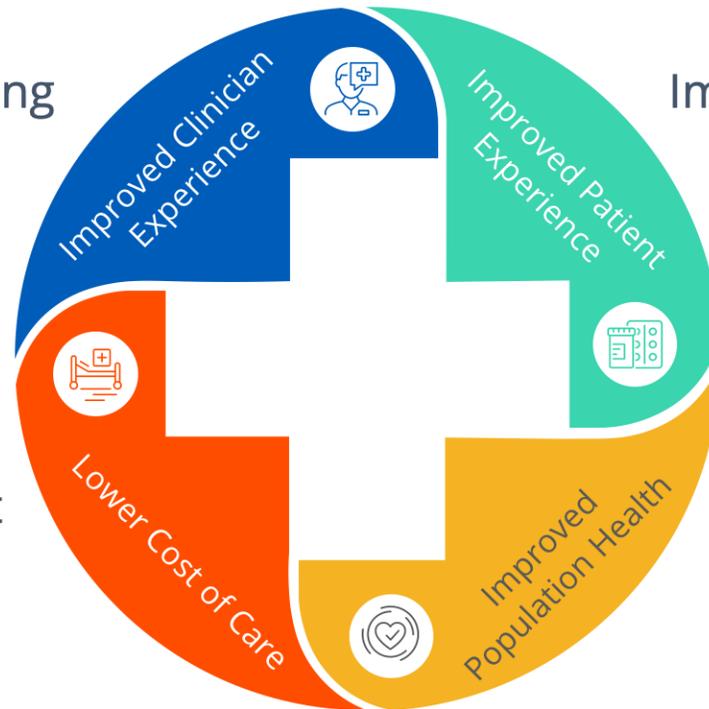
Maturing pharmacogenomic factors deliver improvements & cost efficiencies
 Cambridge University Press: 06 October 2022
 Joseph P. Jarvis, Scott E. Megill, Peter Silvester and Jeffrey A. Shaman

Reducing Poor Outcomes Through Pharmacogenomics

PGx can identify the potential for ineffective therapy and toxicity and help reduce unplanned hospital admissions and improve healthcare's quadruple aim.

Care Team Well-Being

Increased efficiency and accuracy without requiring the prescribing physician to learn genetics and pharmacology



Improved Quality of Care

Personalized Medicine at its core—address each patient's goals to improve safety and efficacy.

Where can it be used?

- Neurology
- Behavioral health
- Oncology^{1, 2}
- Cardiology
- Immunology
- Infectious disease
- Gastroenterology
- Endocrinology
- Anesthesiology
- and more...

Lower Cost

Decreased pharmacy, total healthcare, and out-of-pocket spend

Better Outcomes

Decreased adverse reactions and events associated with medication misadventures. Improved medication safety and efficacy

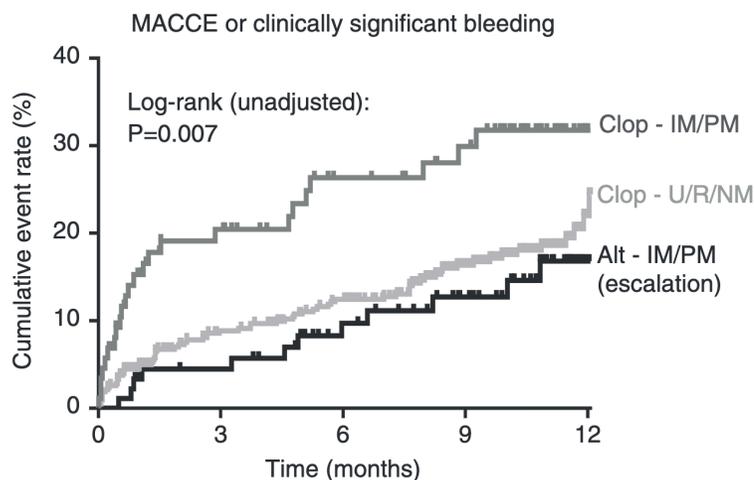
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Improving Outcomes for Patients Using PGx

Improved cardiovascular outcomes

- After a percutaneous coronary intervention (PCI), patients who continued clopidogrel despite being intermediate or poor metabolizers of clopidogrel showed an **increased risk of a major adverse cardiovascular or cerebrovascular event** (MACCE) or bleeding compared to patients who were given alternate therapy¹
 - Adjusted hazard ratio (HR) = 2.89 (95% CI 1.44-6.13, $P = 0.003$)
- Patients who continued clopidogrel and were normal, rapid, or ultra-rapid metabolizers of clopidogrel showed no difference in MACCE or bleeding
 - Adjusted HR = 1.37 (95% CI 0.76–2.70, $P = 0.304$)

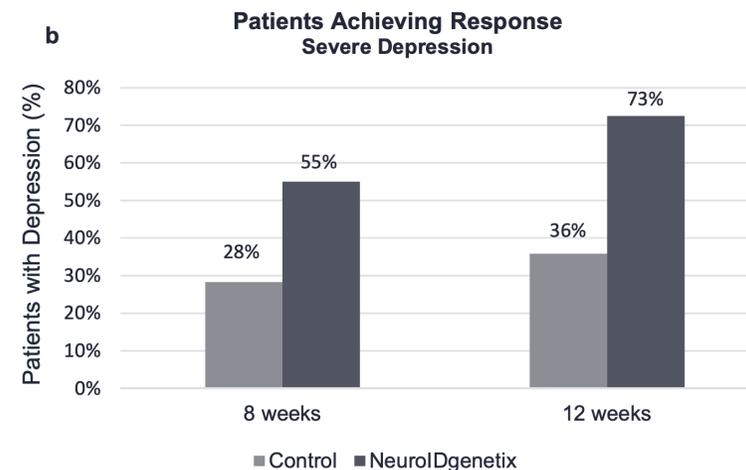


¹ Martin J, et al. Frequency and clinical outcomes of CYP2C19 genotype-guided escalation and de-escalation of antiplatelet therapy in a real-world clinical setting. *Genet Med*. 2019

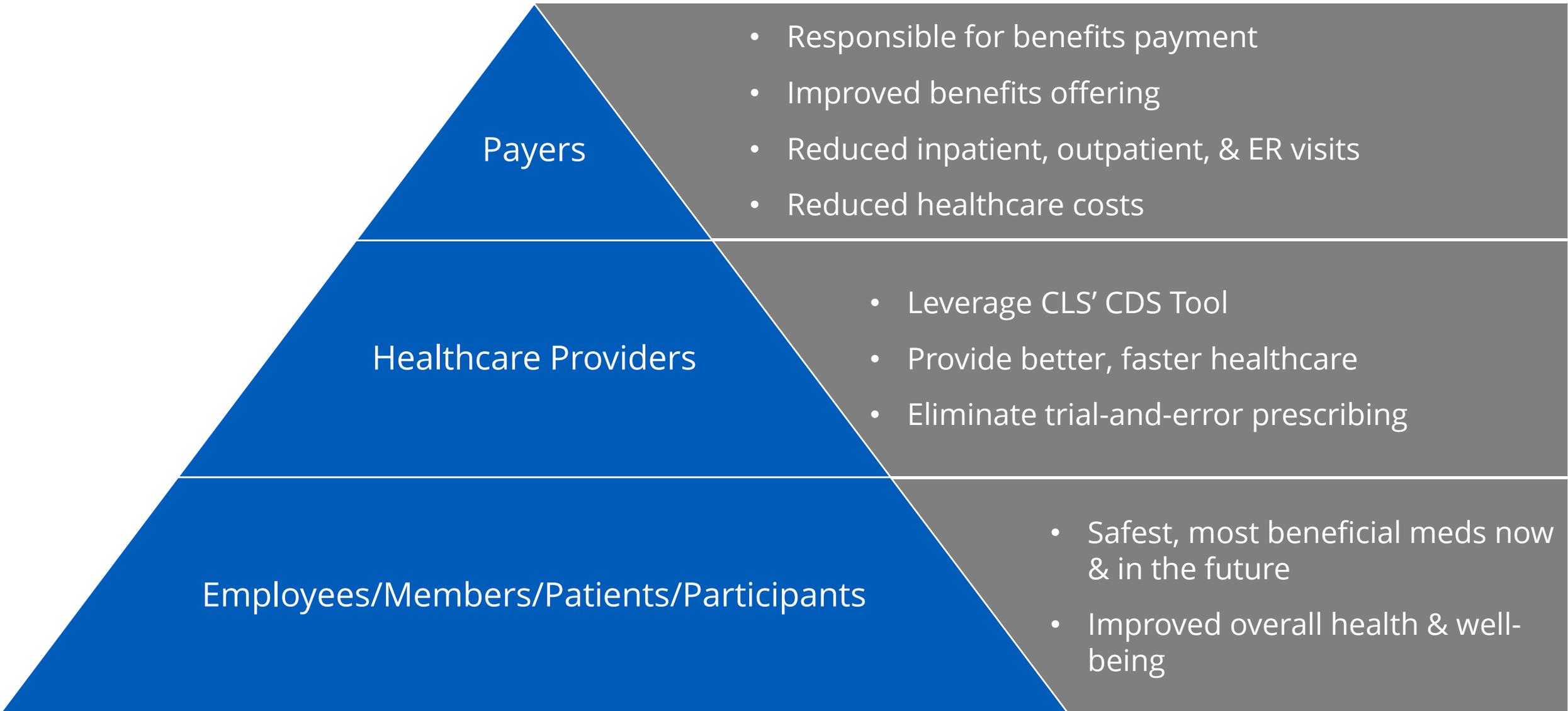
² Bradley P, et al. Improved efficacy with targeted pharmacogenetic-guided treatment of patients with depression and anxiety: A randomized clinical trial demonstrating clinical utility. *J Psychiatr Res*. 2017.

Improved behavioral health outcomes

- Pharmacogenomic testing has been shown to increase the number of patients with major depression who responded with antidepressant therapy²
- Remission rates were also improved after 12 weeks
 - 35% PGx vs 13% control
- NNT for additional patient with severe depression to respond after 12 weeks = 3



Who It Benefits



Implementation and Outcomes of a Genetics-Empowered Medication Management Program

Medication Safety Program

CLS' Medication Safety Program process is designed to provide the information to **make informed decisions**.

Completely **turnkey implementation** and management:
From an initial ROI assessment, to member communications, all the way through to test results delivery and detailed reporting.



Population Analysis & Targeting



POPULATION ANALYTICS



ENGAGEMENT & ENROLLMENT



SAMPLE PROCESSING



PHARMACIST REVIEW & REPORT



IMPROVED HEALTH & SAVINGS

- Predictive population analysis provides insight into the **appropriateness** of a comprehensive medication safety program for your organization.
- Identifies which **members of the population** would benefit; Available for employees, spouses, and dependents.
- Details potential **ROI**.



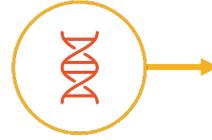
Outreach & Engagement



POPULATION ANALYTICS



ENGAGEMENT & ENROLLMENT



SAMPLE PROCESSING



PHARMACIST REVIEW & REPORT



IMPROVED HEALTH & SAVINGS

Knowledge is power
Your DNA can help determine how safe and effective some medications will be for you. The test will empower you and your doctors with genetic information that may improve which medications you are prescribed. These results may reduce adverse drug reactions and side effects and improve how you feel every day.

Interested?
To enroll, we will need the following information from you:
• Date of birth
• Current mailing address
• You will also be asked about certain lifestyle factors, foods, and drinks that can impact the safety and effectiveness of your medications.
Your answers will only be used by your healthcare providers and never shared with your employer.

Medication Management Program Leveraging Pharmacogenomics Testing

A partnership of:
EXPRESS SCRIPTS®
CORIELL LIFE SCIENCES
Power in Knowing™

To enroll, or for more information, please visit:
coriell.com/enroll-thermofisher

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1. Send your sample in the box and step it in your mailbox. Labels, postage and postage meter have been provided.

2. The results of your DNA test will be analyzed by Coriell Life Sciences and sent to you via email in a secure format.

3. A pharmacist from Coriell Life Sciences will review your results and discuss any next steps.

Focusing on you
Your employer is committed to healthcare coverage with the very best options available. Coriell Life Sciences is committed to helping your treatment be more effective and safer for you.

Can I participate?
During the initial phase, only those members who directly contacted this division will be able to enroll.

Testing designed to ensure your medications are effective, safe, and beneficial for you.

No cost
For a limited time, the medication management program leveraging genetic information is being made available to you by your employer at no cost.

Medications do not work in the same way for everyone. Your DNA determines how well and effectively many medications will be for you. Have your genetic tests can help your pharmacist and doctor make better choices for you.

CORIELL LIFE SCIENCES | HYATT®

A New Wellness Benefit for Hyatt Employees

Are you, your spouse, or adult dependent taking medications for **diabetes, high blood pressure, depression, high cholesterol, or asthma?**

Find out if these medications are the safest and most effective option with a new wellness benefit from Hyatt.

- You'll learn why you may or may not respond to current and future medications or if you're likely to exhibit side effects.
- Your results will be explained during a 1:1 consultation with a trained pharmacist and provided for you to discuss with your doctor.
- Your results are always 100% confidential, just like all of your other health records. They won't impact your benefits.

For a limited time, this wellness benefit is provided at no cost. Take the first step to personalized knowledge for better health today.
(888) 456-9184 • Monday – Friday 9 a.m. to 5 p.m. EST

Want to check eligibility or have a question? Scan here.

coriell.com/hyatt

Hundreds of your colleagues and their families have already participated in Corigen®, a free, at-home DNA testing program for medication safety.

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CORIELL LIFE SCIENCES | EXPRESS SCRIPTS®

Limited Time Wellness Benefit for Thermo Fisher Scientific Employees

are safe and effective.

- Results won't impact your benefits and will be 100% confidential, just like all of your other health records.
- You could learn which medications may cause you to have adverse drug reactions or may not be the most effective option.
- You'll receive a Medication Action Plan (MAP): a complete, personalized report you can review with your doctor on medications you are taking now and those you may take in the future.

For a limited time, this wellness benefit is provided at no cost from your employer. Take the first step to personalized knowledge for better health.

Scan here to enroll:
www.coriell.com/postcard1

CLASSICAL PERIODIC POSTAGE AND PERMIT NO. 1058

Wendy Fogerty
1306 ROEBUCK DR
COATESVILLE, PA 19320-4852

To enroll: www.coriell.com/postcard1
Questions? enrollment@coriell.com

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Available through **HealthTrust** | CORIELL LIFE SCIENCES

Dear << Test First Name >>,

You and your medically covered spouse and dependent(s) are eligible for a health benefit, the Corigen® Medication Safety Program, which includes **at-home DNA testing for medication safety**, provided by Coriell Life Sciences, available through HealthTrust at no additional cost to you. This simple test identifies medications that are ineffective or unsafe for you based on your DNA and lifestyle factors.

Like knowing your allergies, knowing which medications you may not respond to well is important information for you and your provider to have regarding your prescriptions now and in the future.

Order your free DNA test kit

Your health information, including program and DNA test results, are only shared with you and your physician, will never be shared with HealthTrust or your employer, and will not impact your health coverage or health benefits.

Clinical Decision Support



POPULATION ANALYTICS



ENGAGEMENT & ENROLLMENT



SAMPLE PROCESSING

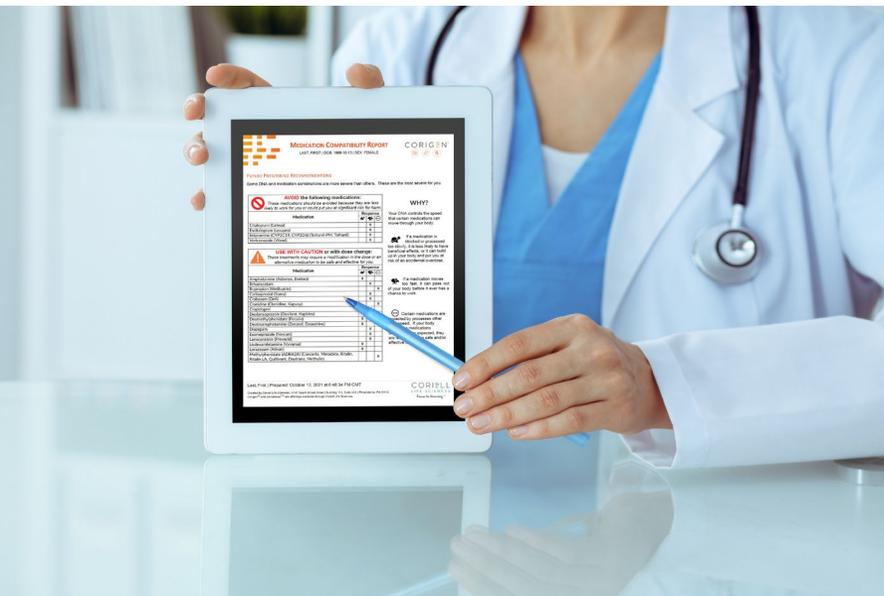


PHARMACIST REVIEW & REPORT



IMPROVED HEALTH & SAVINGS

CLS proprietary software, GeneDose LIVE™ allows teams of pharmacists and physicians to review the genetic and non-genetic concerns for individual patients and **quickly shows which alternatives would be best suited.**



The **Medication Compatibility Report** provides a clear and concise way for the pharmacist to communicate the updated plan to the prescriber.

Results: Improved Member Health & Savings



POPULATION ANALYTICS



MEMBER ENGAGEMENT & ENROLLMENT



SAMPLE PROCESSING



PHARMACIST REVIEW & REPORT



IMPROVED MEMBER HEALTH & SAVINGS

Actionable Results & Benefits

- Improved overall **health outcomes**.
- Improved **quality of life**.
- Reduced **pharmacy spend**.
- Reduced medication **side effects & adverse reactions**.
- Decrease in number & cost of **outpatient visits**.
- Reduction in number of **emergency department visits & hospitalizations**.



Case Study: Program Success

Teachers' Retirement System of the State of Kentucky

10,000+
retired teachers have already enrolled



66%

Participants were on medications that react poorly with DNA



3 out of 5

Retirees had a change to their medications recommended



87%

Retirees were at high-risk of drug-drug interactions

Case Study: Program Success

Teachers' Retirement System of the State of Kentucky

Table 1. Population characteristics for the intervention and control groups in the 12 month pre-program period.

Population Characteristics for Pre-Program Period			
Variables	Intervention (n = 5288)	Control (n = 22,357)	p-Value
Age in Years, avg (SD)	73.7 (5.7)	74.0 (6.2)	0.0007
65–74, n (%)	3249 (61%)	13,382 (60%)	<0.0001
75–84	1696 (32%)	6849 (31%)	
≥85	343 (6%)	2126 (10%)	
Sex, n (%)			1
Female	3523 (67%)	14,893 (67%)	
Male	1765 (33%)	7464 (33%)	
Charlson Comorbidity Index, avg (SD)	3.6 (1.4)	3.6 (1.5)	1
0–2, n (%)	1113 (21%)	4789 (21%)	0.3509
3–4	3144 (59%)	13,056 (58%)	
5+	1031 (19%)	4512 (20%)	
Number of Medications, avg (SD)	13.0 (8.4)	11.9 (8.3)	<0.0001
0, n (%)	79 (1%)	584 (3%)	<0.0001
1–2	223 (4%)	1281 (6%)	
3–4	429 (8%)	1997 (9%)	
5–7	786 (15%)	3788 (17%)	
8–10	904 (17%)	3703 (17%)	
11+	2867 (54%)	11,004 (49%)	

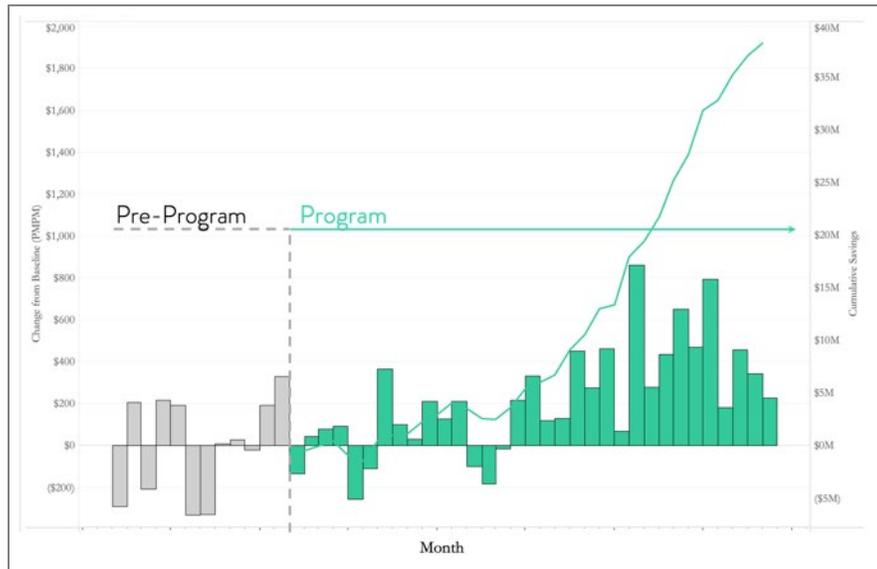
Abbreviations: avg, average; SD, standard deviation.



Jarvis, J.P.; Peter, A.P.; Keogh, M.; Baldasare, V.; Beanland, G.M.; Wilkerson, Z.T.; Kradel, S.; Shaman, J.A. Real-World Impact of a Pharmacogenomics-Enriched Comprehensive Medication Management Program. *J. Pers. Med.* 2022, 12, 421. <https://doi.org/10.3390/jpm12030421>

Case Study: Cost Savings Achieved at 32 months

Teachers' Retirement System of the State of Kentucky



Resulting PMPM cost avoidance of **\$218.82**

Per member cost savings at 32 months: **\$7,002.24**

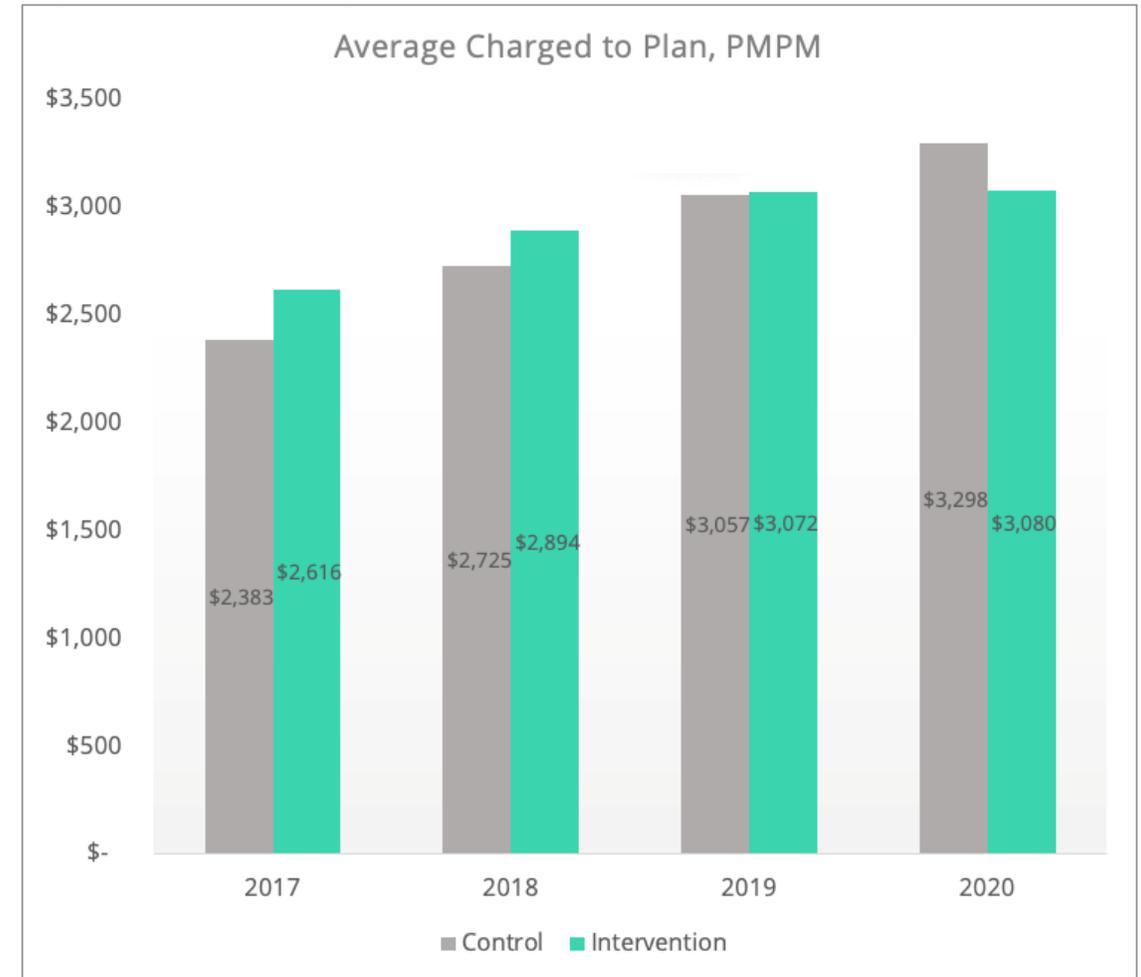
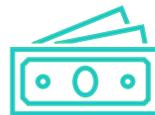
Cumulative cost savings at 32 months: **\$37M**

Jarvis, J.P.; Peter, A.P.; Keogh, M.; Baldasare, V.; Beanland, G.M.; Wilkerson, Z.T.; Kradel, S.; Shaman, J.A. Real-World Impact of a Pharmacogenomics-Enriched Comprehensive Medication Management Program. *J. Pers. Med.* 2022, 12, 421. <https://doi.org/10.3390/jpm12030421>

Case Study: Program Success

Teachers' Retirement System of the State of Kentucky

Claim Type	Reduction
Inpatient	14.9%
Emergency Department	6.8%
Outpatient	1.9%



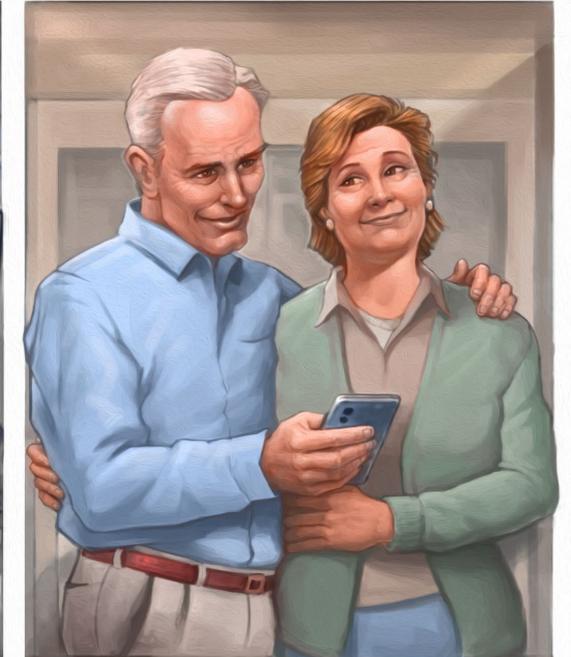
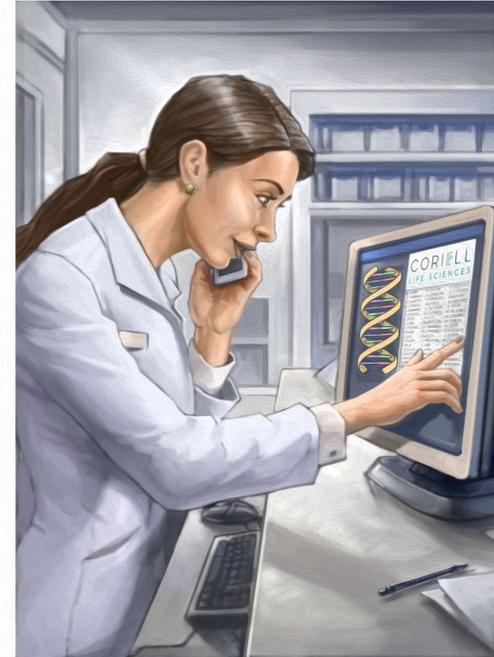
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Some Economic Studies

	Study Scope	Results
International hotel chain	<ul style="list-style-type: none">• 500 employees	<ul style="list-style-type: none">• 6.1x ROI after 12 months
Large manufacturing company	<ul style="list-style-type: none">• 1000 employees• PGx cohort & High-Risk cohort	<ul style="list-style-type: none">• 10.1x ROI after 18 months• Enabled by concerted member targeting
Quest Diagnostics	<ul style="list-style-type: none">• 1000 employees	<ul style="list-style-type: none">• 2 papers published, 3rd in process• 6.4x ROI after 12 months
State of New Hampshire	<ul style="list-style-type: none">• State employees, retirees and their dependents• 55,000 eligible members	<ul style="list-style-type: none">• Data analysis pending

Active Aging or Medication Side Effect?

Patient's Medications								Side Effects
Metoprolol	Simvastatin	Eliquis®	Omeprazole	Ergocalciferol	Calcium + Vitamin D	Multivitamin	B-Complex	
•	•		•		•			Abdominal Pain
		•						Bleeding
•								Bradycardia†
•	•		•	•	•	•	•	Constipation†
•								Depression†
•			•					Diarrhea†
•			•					Dizziness†
•				•				Fatigue†
							•	Flushing
	•		•	•		•		Headache
•								Heart Failure†
•		•						Hypotension†
	•		•					Infection†
	•							Insomnia
	•							Myalgia†
•	•		•	•				Nausea
•		•	•					Rash



Prather A, Aifaoui A, Shaman JA. Idiopathic Symptoms Resolved by Pharmacogenomics-Enriched Comprehensive Medication Management: A Case Report. *Cureus*. 2022 Feb 2;14(2):e21834. doi: 10.7759/cureus.21834. PMID: 35145831; PMCID: PMC8809208.

Participant Testimonials



"Mystery solved! I'm n
doctor to discuss the
recommendation to c
less of my current me

—Participating Member



"I found this extremely useful and
beneficial! The results confirmed
susp
imp

—Participating Member



"It provides a level of comfort know
medications I might be prescribed
be productive since I now have the
results to make informative decisions."

—Participating Member



"I learned that **Ibuprofen at
recommended dosage levels is not
ideal for my genetics** and that I
can handle all the opioids! Go me!"

—Participating Member



"When I was younger, I was put on
Lexapro. I was maxed out on the dose
and it wasn't helping me. **Thanks to
this test, I now know it's because I
metabolize that drug differently and
there are better options for me.**"

"I shared this information with my
doctor and he **switched to a different
family of medications that will have a
better profile for me.** This study
empowered my doctor and myself to
make an informed change."

—Participating Member



"I learned a lot about myself and found
medications that work better for me.
I've been recommending DNA testing
to people who are having trouble with
their medications and am even **getting
one done for my son.**"

—Participating Member



"Everything was super easy from
sign up to talking with a pharmacist
about my results. I was so excited
when I found out my employer was
offering this for free!"

—Participating Member



"As a result of my DNA testing, my
doctor **changed my antidepressant,
and the result is amazing!** My family
doctor is **very impressed with this
program** and would like more of her
patients to take the test."

—Participating Member



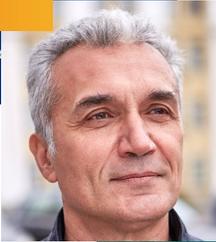
It's already changed what I am paying
and the frustration of not knowing if
I'm taking a med for no reason."

—Participating Member



my medications! They were good in
telling me **how my medications were
working.** Excellent program."

—Participating Member



"Having
treme
peace
what
on facs."

—Participating Member



personal experience as to the benefits of
this technology during future trainings."

"**Very valuable program!**
Our country should do
this test at birth for
every child."

—Participating Member



"This is a fabulous program. I am very
grateful that I could participate!"

—Participating Member

My family and friends agree this **type of
testing would be very useful.** Now they
all want to get it done."

—Participating Member



"The **focus on potent
medications and po**
was very useful. I even
help my siblings."

—Participating Member



"I am grateful for the program
experience an ongoing strugg
my blood pressure and, throu
Program, **discovered that the
medication prescribed is not
effective due to my DNA.**"

—Participating Member



to alert our doctor to
issue AND (most
importantly) have data to support our
request. **This will become relevant as
our medicines change over time.**"

—Participating Member



Key Learnings

- Pharmacists empowered with clinical decision support tools amplify the impact of pharmacogenetic testing
- Participant eligibility assessment can significantly improve cost savings
- Patients have a high degree of skepticism. Program sponsor endorsement and encouragement is key to enrollment
- Pharmacovigilance > one-time testing with review



Takeaways

- Clinical test that should have targeted implementation
 - Personalized/Relevant
 - Predictable/Repeatable
 - Actionable
- Utilize your second opinion or health navigation partner to quickly identify members that could benefit
- Have candid conversations with medical carrier on process to evaluate and reimburse for appropriate testing
- Ensure your formulary is flexible and not a barrier to pharmacogenetic directed treatment
- Have a trusted resource to assist you in evaluating, on-boarding and monitoring personalized medicine offerings for you population

Discussion



Michael Thompson

Moderator

National Alliance of
Healthcare Purchaser
Coalitions



K. Andrew Crighton, MD

Crighton Consulting Group;
National Alliance Medical
Director Advisory Council



Jeffrey Shaman, PhD

Coriell Life Sciences

Upcoming Webinars and Events

Recognizing Implicit Bias and Using Data to Overcome It

February 21, 2023, 12:30 p.m.-2 p.m.

Townhall: The Interplay Between Mental Health & The Spectrum of Addiction

March 22, 2023, 3 p.m.-4 p.m.

2023 Leadership Summits

June 28 -29



National Alliance
of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

2023 LEADERSHIP SUMMITS

Surviving to Thriving | Architecting for Value | Innovation & Integration

JUNE 28-29 | Nashville, Tennessee

All times are ET

