

Your genes. Your roadmap.™

MediMap®

Health TechNet & Pharmacogenomics (PGx)

February 16, 2018

Franziska Moeckel
AVP, Personalized Health

Your genes. Your roadmap.™

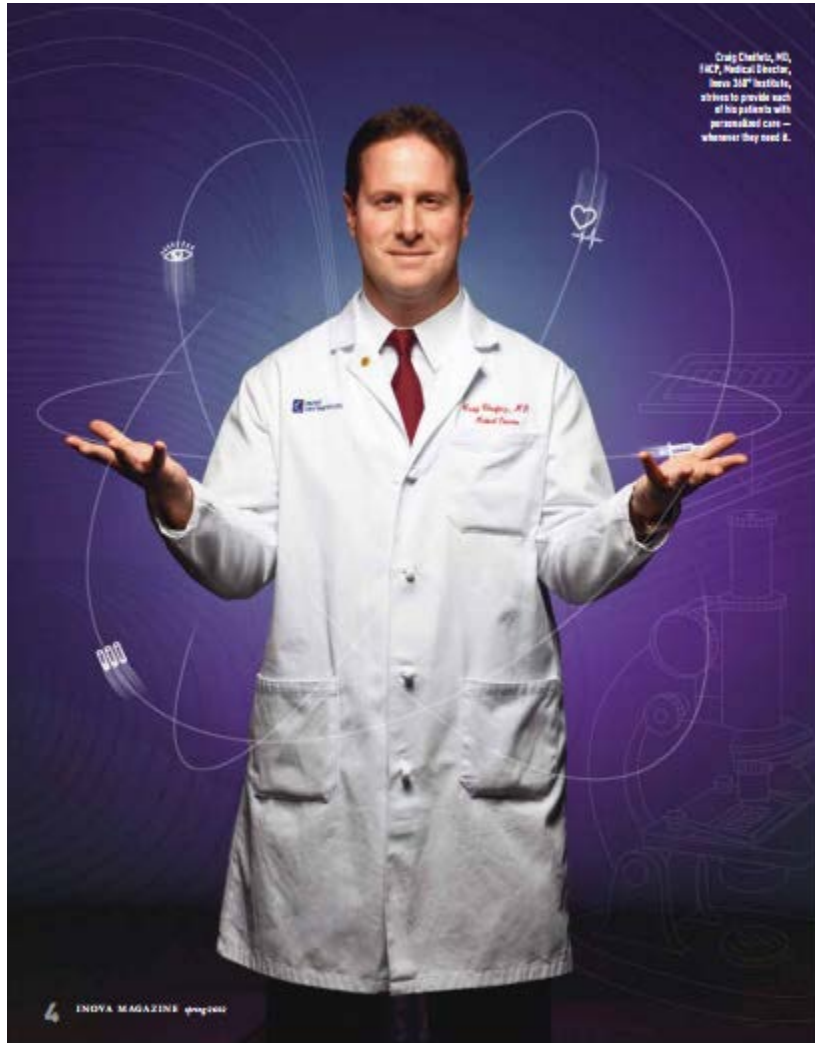
Overview

Inova's Precision Medicine Journey

MediMap® Pharmacogenomics at Inova

Implementation Considerations

What is Precision Medicine?



According to the Precision Medicine Initiative, precision medicine is...

...an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.

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Start of Inova's Precision Medicine Journey

2010

Dr. John Niederhuber
named ITMI CEO

2013

Epic (EMR) Launched
Women's Health Integrated
Research Center Operational

\$50 million gift for Inova Dwight and Martha
Schar Cancer Institute

Inova Women's Health Research Center's
first biorepository in state of Virginia

2011

ITMI Launched
First ITMI Study:
Premature Birth

2014

Inova Lab for Genomic
Medicine Launched
First Clinical Pharmacogenomics
(PGx) test

2016

Inova launches MediMap®, a
pharmacogenomics test for newborns
Formation of Inova Molecular Tumor Board
Inova Heart and Vascular Institute opens
clinical trials unit
Commonwealth of Virginia provides funding
for Global Genomics and Bioinformatics
Research Institute
NIH ECHO Grant Award (\$9.5 million)

2012

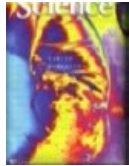
Trio Longitudinal Study
Congenital Anomalies
Study

2015

Dr. Donald Trump named
ICCRI CEO
Inova takes possession of
ICPH Campus on October 1

“Hot Areas” in “Omics”*

*As identified by Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI)



Cancer Genomics



Somatic Tumor Profile

Targeted genomic sequence of tumor tissue; used in molecular tumor board (attended by patient's family)



Pharmacogenomics



Inova Genomics Laboratory

CAP- & CLIA-certified; >7 baseline & condition-spec PGx tests; MediMap® brand; >10,000 tests run since 2016

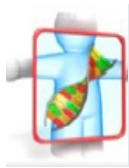


Ultra-Rare Genetic Disease Diagnostics



Congenital Disorders Study

NICU babies & adults; whole-genome-sequence (WGS); 60-70% successful diagnosis



Genomic Medicine 'Test Drive' Programs



MediMap® Baby

PGx test for newborns; 7 genes, 24 meds; at no additional charge; >97% have 1 or more actionable result



Prenatal & Newborn Genomic Analysis



First 1,000 Days of Life Study

WGS (family trios) & microbiome; genomic + survey + phenotypic data (from EHR)



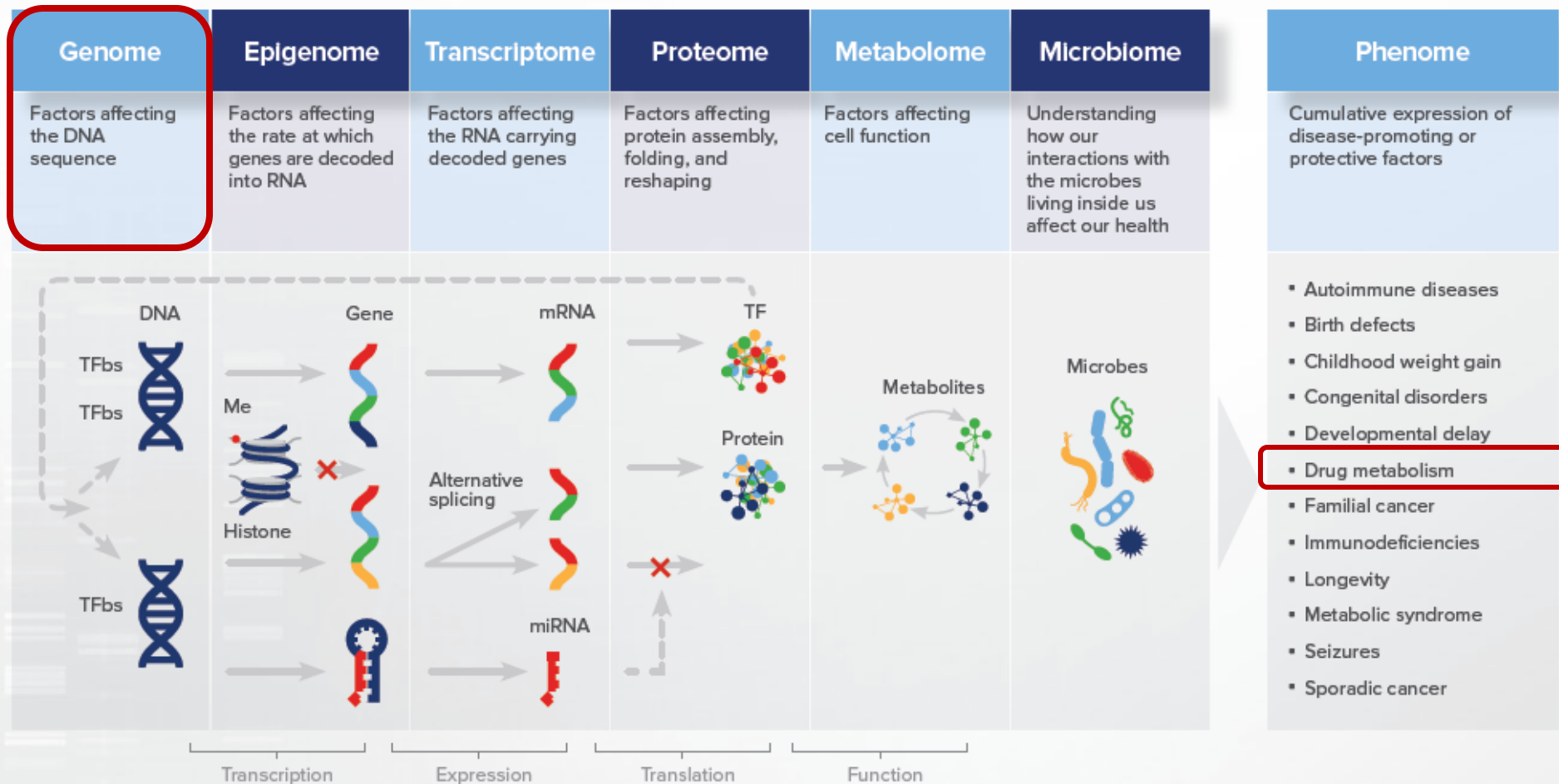
Clinical Genomics Information Systems



Unique WGS Database

Over 134 birth countries; genomic + survey + phenotypic data (from EHR)

The Study of Omics



Pharmacogenomics (PGx) defined

Pharmacology

(study of medications)



Genomics

(study of how people's
genetic information can
influence their health)

=

Pharmacogenomics

(study of how people's genes affect their response
to medications)

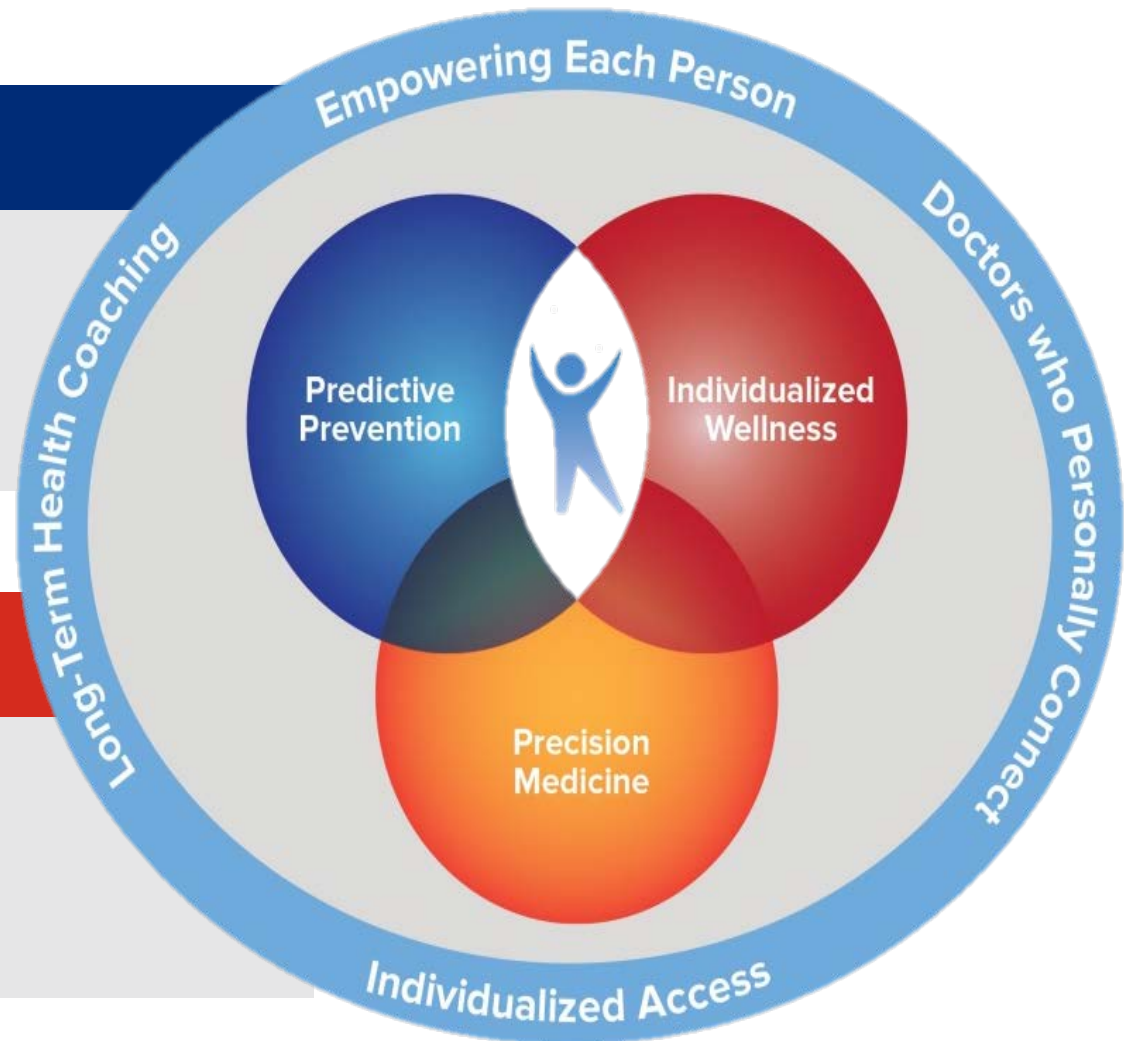


INOVA'S MISSION

To optimize the health and well-being of each individual we serve

INOVA'S VISION 2020

To be the global leader in developing and applying personalized health



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2014

Inova Lab for Genomic Medicine Launched

First Clinical Pharmacogenomics (PGx) test

2015

Expansion of single-gene-single-drug tests

Total of 11 tests live

Pilot deployment with physician champion

Inova funded; no reimbursement

Development of first panel test for newborns; 44 beta-tests

2016



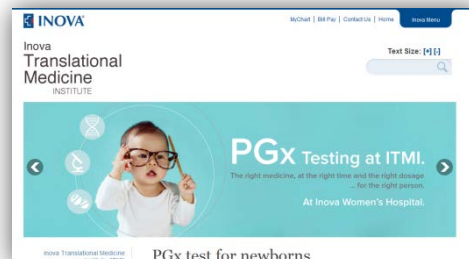
First pharmacogenomic panel test for newborns launched with opening of new Women's & Children's hospital; 7 genes/25+ meds; >3,600 babies tested

Covered in worldwide "DNA Evolution" issue of NatGeo



Development of MediMap® brand umbrella for PGx testing at Inova

Launch of second MediMap panel for VIP360° Concierge Medicine / Corporate Health; >350 adults tested

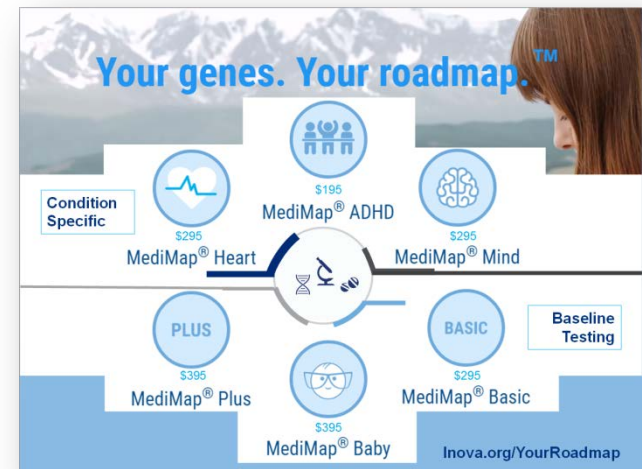


2017

Creation of brand umbrella *Your genes. Your roadmap.™* for all genetic testing at Inova; >14,000 individuals tested

Launch of WGS offering – MyMap™

Inova Genomics Laboratory (IGL) receives CAP accreditation



Your genes. Your roadmap.™

**Condition
Specific**



\$295

MediMap® Heart



\$195

MediMap® ADHD



\$295

MediMap® Mind



\$395

MediMap® Plus



\$395

MediMap® Baby



\$295

MediMap® Basic

**Baseline
Testing**



Inova.org/YourRoadmap

How it work?



Physicians

**Patients &
Individuals**

Payers

**Lab &
Hospital Ops**

How it work?



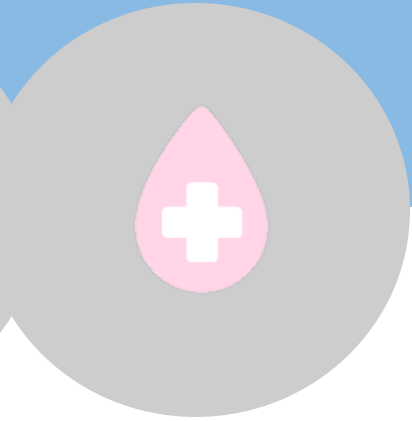
Physicians



**Individuals
& Patients**



Payers



**Lab &
Hospital Ops**

Physicians & Ordering Options for MediMap®

1

Inova Genomics
Laboratory physicians
place order in Epic



Patient appointment at IGL

IGL physician will receive
Epic notification to view PDF
results.

MediMap® results are
mailed to patient.

2

Inova physician places
order in Epic



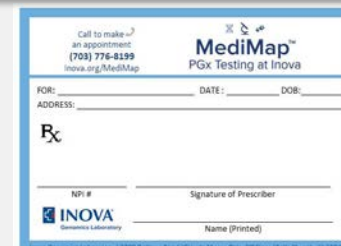
Patient appointment at IGL

Ordering physician will
receive Epic notification to
view PDF results.

MediMap® results are
mailed to patient.

3

Physician writes
MediMap® prescription



Call to make an appointment:
(703) 776-8199
inova.org/MediMap

MediMap[™]
PGx Testing at Inova

FOR: _____ DATE: _____ DOB: _____
ADDRESS: _____

Rx _____


NPI # _____ Signature of Prescriber _____
INOVA _____
Name (Printed) _____

Patient appointment at IGL

Physician NPI is used to place
order in Epic. Prescription is
scanned into Epic.

MediMap® results are mailed to
patient and ordering physician

Epic & BPAs



INOVA MEDIMAP[®] PLUS PHARMACOGENOMICS REPORT

PATIENT INFORMATION	SPECIMEN DETAILS	ORDERED BY
NAME: NEWTEST ASAP	ACCESSION #: 17-322	BIZHAN AARABI
MRN: 16100731	TYPE: BIOCAL	
DOB: 8/28/1946	COLLECTED: 7/31/2017	
SEX: Male	RECEIVED: 7/31/2017 REPORTED: 8/10/2017	

POTENTIALLY IMPACTED MEDICATIONS

Category	Drug Class	Standard Precautions	Use With Caution	Consider Alternatives
Anesthesia	Injectable Anesthetics	Propofol (Diprivan)		
Anticancer Agents	Antifolates	Methotrexate (Trexall)		
	Protein Kinase Inhibitors	Gefitinib (Iressa)		
	Thiopurines	Azathioprine (Azasan, Imuran) Mercaptopurine (Purinethol, Purinan) Thioguanine (Tabloid)		
Cardiovascular	Angiotensin II Receptor Antagonists	Azilsartan (Edarbi, Edarbyclor) Candesartan (Atacand) Eprosartan (Teveten) Irbesartan (Avapro) Losartan (Cosar, Hyzaar) Olmesartan (Benicar) Telmisartan (Micardis) Valsartan (Diovan, Entresto)		
	Antianginal Agents	Ranolazine (Ranexa)		
	Antiarrhythmics	Flecainide (Tambocor) Mexiletine (Mexitil) Propafenone (Rythmol)		
	Anticoagulants	Apixaban (Eliquis) Dabigatran Etesilate (Pradaxa) Edoxaban (Savaysa) Fondaparinux (Arista) Rivaroxaban (Xarelto) Warfarin (Coumadin)		
	Antiplatelets	Clopidogrel (Plavix) Prasugrel (Effient) Ticagrelor (Brilinta) Vorapaxar (Zontivity)		

- Results populate EHR
- Reports to patients and physicians
- Expert “back-up”

Private

Patient Location: None
Unit: None
Bed: None

Weight: 3.37 kg
Birth Weight: 3645 g
Code/Adv Dir: No Current Order

Allergies: No Known Allergies
ADA Special Needs: None
Pref Language: **Unavailable**
Need Interp: **No**

PC: None
Research: None
PCP w/phone: None

Attend Prov: None
Birth GA: 40w1d
CGA: None

Place orders (Enc Date: 4/9/2016) - Wt: (Not entered for this visit) Ht: (Not entered for this visit)

Snapshot
Chart Review
Review Flowsh...
Results Review
Synopsis
Growth Chart
Medications
Immunizations
Order Entry
Education
Communications
ADA Special Ne...
Patient Station
Orders Only Enc...

Medications (1 Order)

codeine 15 MG tablet

Take 1 tablet (15 mg total)
Print, R-0

This patient has undergone Comprehensive Pharmacogenomic Panel - MediMap. This panel includes the drugs you are prescribing/dispensing and may contain relevant dosing guidance. Please review result prior to proceeding: .

[Link to chart review](#)

Accept Cancel

PGx (Evidence Level) Review Bodies

Evidence Level 1	Actionable	ESTABLISHED EVIDENCE-BASED CLINICAL GUIDELINES	Recommendations extracted from evidence based guidelines issued by international pharmacogenetic consortia, professional societies or regulatory bodies (CPIC, DPWG, FDA, EMA, CPNDS, ACMG)*. Recommendations suitable for implementation in a clinical setting. Guidelines may be updated as new knowledge arises.
Evidence Level 2	Informative	DRUG-GENE ASSOCIATIONS REQUIRING FURTHER INVESTIGATION	There are no established evidence based guidelines issued by experts. The evidence documenting the genetic associations may be limited or insufficient. In some cases the evidence is still disputed. Recommendations are informative and implementation in a clinical setting is optional.



DPWG: Dutch Pharmacogenetics Working Group



How it work?



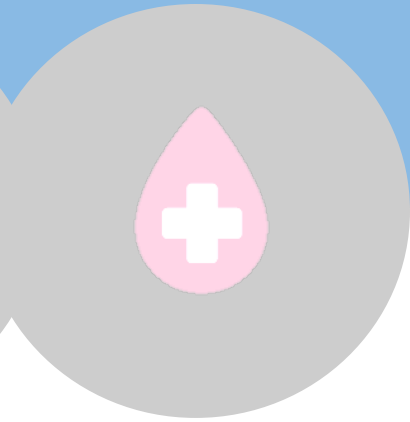
Physicians



**Individuals
& Patients**



Payers



**Lab &
Hospital Ops**

What we provide



Your genes. Your roadmap.[™]

[HOME](#)[MYMAP[™]](#)[MEDIMAP[®]](#)[ABOUT US](#)[PHYSICIANS](#)[PLAN YOUR VISIT](#)[FAQ](#)[CONTACT US](#)

DISCOVER MORE ABOUT INOVA'S GENETIC TEST OFFERINGS



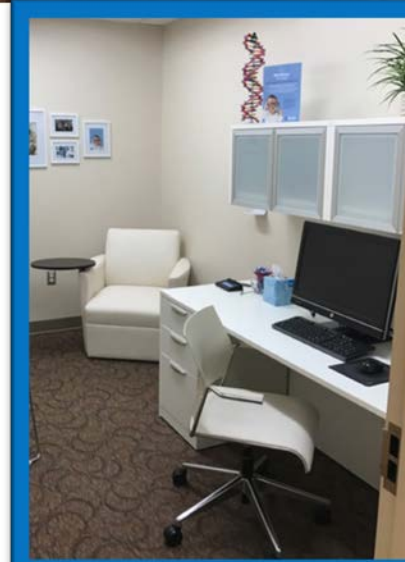
MyMap[™]

Unlock your genetic code to guide you through medical and lifestyle needs – risk for disease, proper medication use, diet and lifestyle. Discover what makes you...you.

[LEARN MORE](#)

MediMap[®]

Gain new insights on how your genes influence your response to commonly prescribed medications. The right drug, at the right dose, for the right person.

[LEARN MORE](#)

Patients & Individuals interested in MediMap®

1 | Make an Appointment



2 | Access to a genetic counselor



3 | Complete Authorization & other forms



6 | Receive MediMap® test results



5 | Inova Genomics Laboratory processes sample



4 | Get swabbed



7 | Share results with physician.



8 | Ask our genetic counselors



Reporting



MEDIMAP® PLUS PHARMACOGENOMICS REPORT

PATIENT INFORMATION

NAME: NEWTEST ASAP
MRN: 15100731
DOB: 8/28/1945
SEX: Male




SPECIMEN DETAILS

ACCESSION #: 17-322
TYPE: BUCCAL
COLLECTED: 7/31/2017
RECEIVED: 7/31/2017
REPORTED: 8/10/2017

ORDERED BY

BIZHAN AARABI

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	Protein Kinase Inhibitors	Gefitinib (Iressa)		
	Thiopurines	Azathioprine (Azasan, Imuran)		
		Mercaptopurine (Purinethol, Purixan)		
		Thioguanine (Tabloid)		
Cardiovascular	Angiotensin II Receptor Antagonists	Azilsartan (Edarbi, Edarbyclor)	<div> RED CATEGORY (STOP)</div> <ul style="list-style-type: none">• Medications in this category may not work well or may cause harm.• If a person is prescribed one of these medications, then a change in medication may be recommended.• In some cases, a change in medication may be strongly recommended.	
		Candesartan (Atacand)		
		Eprosartan (Teveten)		
		Irbesartan (Avapro)		
		Losartan (Cozaar, Hyzaar)		
	Antianginal Agents	Olmесartan (Benicar)		
		Telmisartan (Micardis)		
	Antiarrhythmics	Valsartan (Diovan, Entresto)		
		Ranolazine (Ranexa)		
	Anticoagulants	Flecainide (Tambocor)		<div> YELLOW CATEGORY (USE CAUTION)</div> <ul style="list-style-type: none">• These medications also may not work as well or cause unwanted side effects.• If a person is prescribed one of these medications, then a change in medication may be recommended.• A change in medication may not be needed.
Mexiletine (Mexitil)				
Propafenone (Rythmol)				
Apixaban (Eliquis)				
Dabigatran Etexilate (Pradaxa)				
Antiplatelets	Edoxaban (Savaysa)	<div> GREEN CATEGORY (GO)</div> <ul style="list-style-type: none">• Based on the test results, these medications should work as well as usual.• They may be prescribed as usual.		
	Fondaparinux (Arixtra)			
	Rivaroxaban (Xarelto)			
	Warfarin (Coumadin)			
	Clopidogrel (Plavix)			

RED CATEGORY (STOP)

- Medications in this category may not work well or may cause unwanted side effects.
- If a person is prescribed one of these medications, then a change in dose with close monitoring may be recommended.
- In some cases, a change in medication may be strongly recommended.

YELLOW CATEGORY (USE CAUTION)

- These medications also may not work as well or cause unwanted side effects.
- If a person is prescribed one of these medications, then a change in dose with some extra monitoring may be recommended.
- A change in medication may not be needed.

GREEN CATEGORY (GO)

- Based on the test results, these medications should work as expected.
- They may be prescribed as usual.

Patient Information Card: A wallet-sized patient information card is located on the last page of the MediMap™ VIP 360° report. This card is a summary genetic report for you to share with your healthcare providers (at Inova or elsewhere) including pharmacists. The purpose of this card is also to allow your PGx results to be reinterpreted in the future. We recommend sharing the full report with other healthcare providers.

Your genes. Your roadmap.™

Based on that genetic profile, it listed medications that might cause unwanted side effects like the ones he was experiencing.

“Lo and behold, the statins are bloody dangerous for me,”

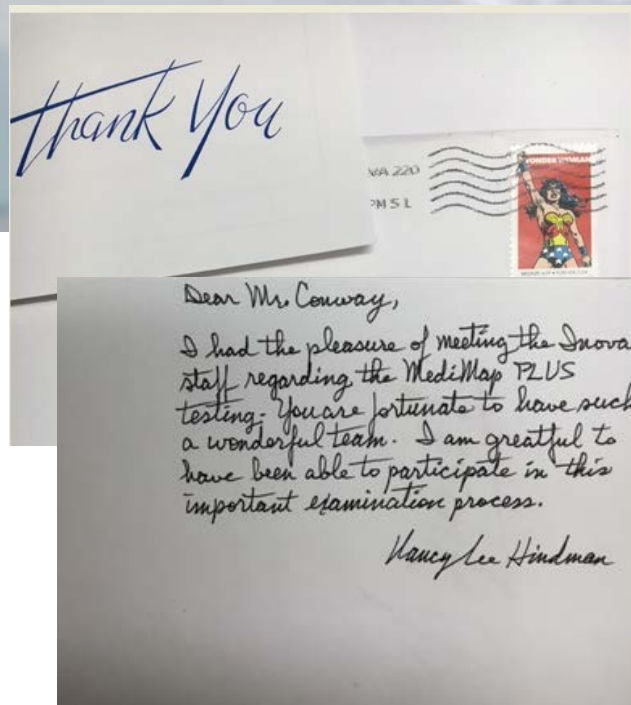
“They just do a mouth swab and 4 to 6 weeks later you get this pretty little report back.”


-Hodson said.

“As soon as we heard about MediMap, we knew right away we wanted to do this. The testing is innovative and cutting-edge, exactly what Inova aims to be.”

“What appealed to me was that we would know what medications would be compatible with her system later, and if they’re not, we don’t even have to try them — we can go to the ones we know work for her,”

-Calla’s mom, Sarah Johnson, an obstetrics nurse at Inova and Clinical Director of Family Centered Care.



 **Tasha Minor Hall** My baby is a medimap baby
Like · Reply · Message · 1 · August 23 at 5:25pm

 **Carol Williams Lewis**



Like · Reply · Message · August 12 at 1:46pm



Dizzy Poe We got to have the testing done on our baby after she was born in January. We just got the results back last month. I am hoping that soon we can have our other children tested. The information is so helpful to know.

Like · Reply · Message · Yesterday at 12:22am

Plavix 75 mg
Clopidogrel

Oral use
28 Film-coated tablets
Plavix® is a registered trademark.

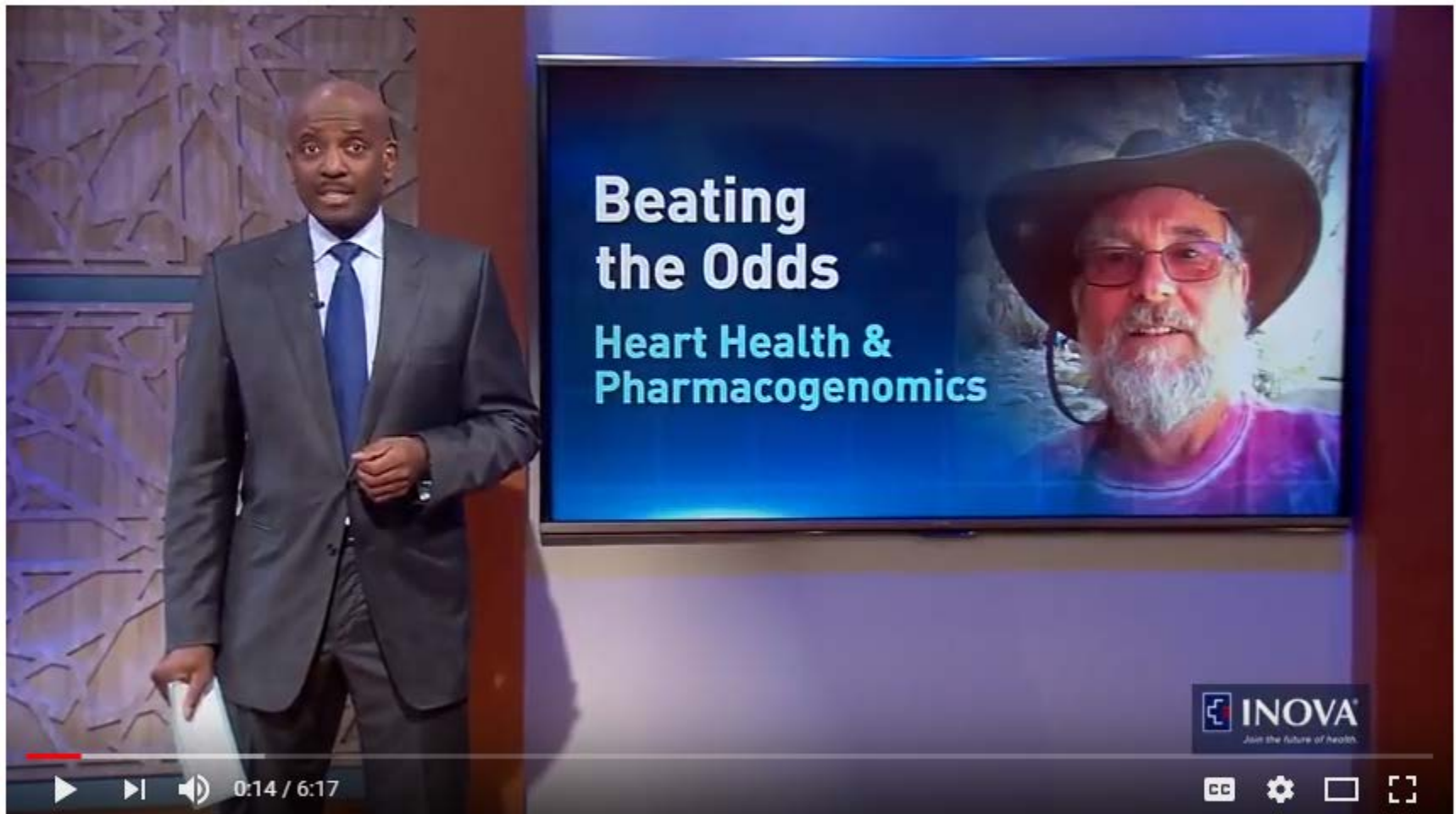
Description

Catalyst for many reactions involved in drug metabolism & controls the metabolism of over 70% of prescribed drugs. CYP2C19 helps metabolize xenobiotics (Mephenytoin, Diazepam, & Barbiturates) & several groups of drugs (Proton Pump Inhibitors & Antiepileptic's) in the body. **Patients' with reduced CYP2C19 are poor metabolizers for Plavix, hence they may remain at risk for heart cardiovascular death. 2% - 14% of the U.S. population has reduced CYP2C19 enzymes. If variant present, patient should receive alternative medication.**

WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS

See full prescribing information for complete boxed warning.

- Effectiveness of Plavix depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19.
- Poor metabolizers treated with Plavix at recommended doses exhibit higher cardiovascular event rates following acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function.
- Tests are available to identify a patient's CYP2C19 genotype and can be used as an aid in determining therapeutic strategy.
- Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers.



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How it work?



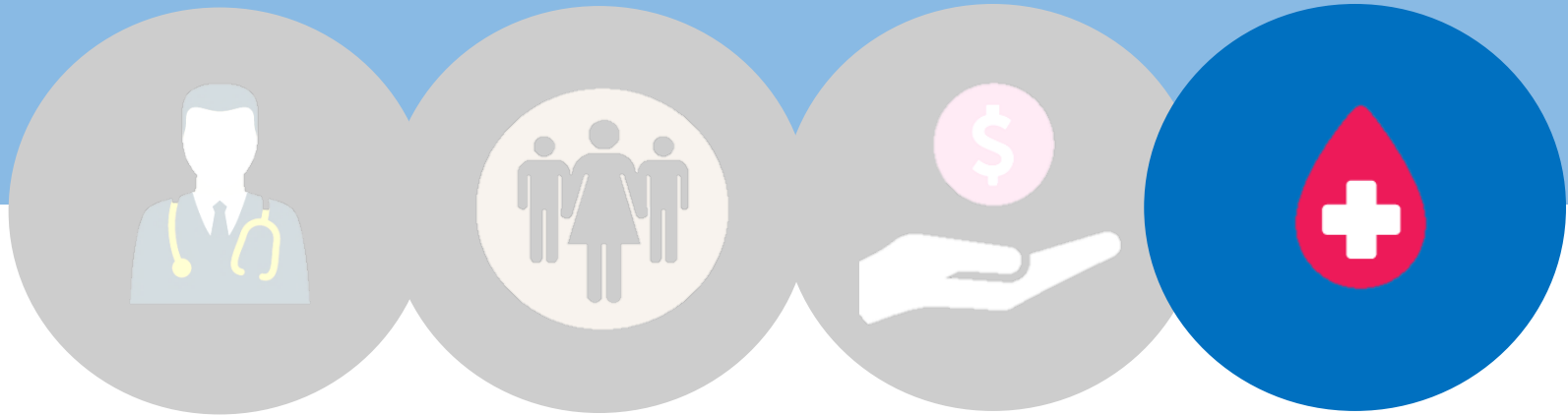
Physicians

**Individuals
& Patients**

Payers

**Lab &
Hospital Ops**

How it work?



Physicians

**Individuals
& Patients**

Payers

**Lab &
Hospital Ops**

The Genetic Information Nondiscrimination Act of 2008 (Approved May 21, 2008)

To prohibit discrimination on the basis of genetic information with respect to health insurance and employment.

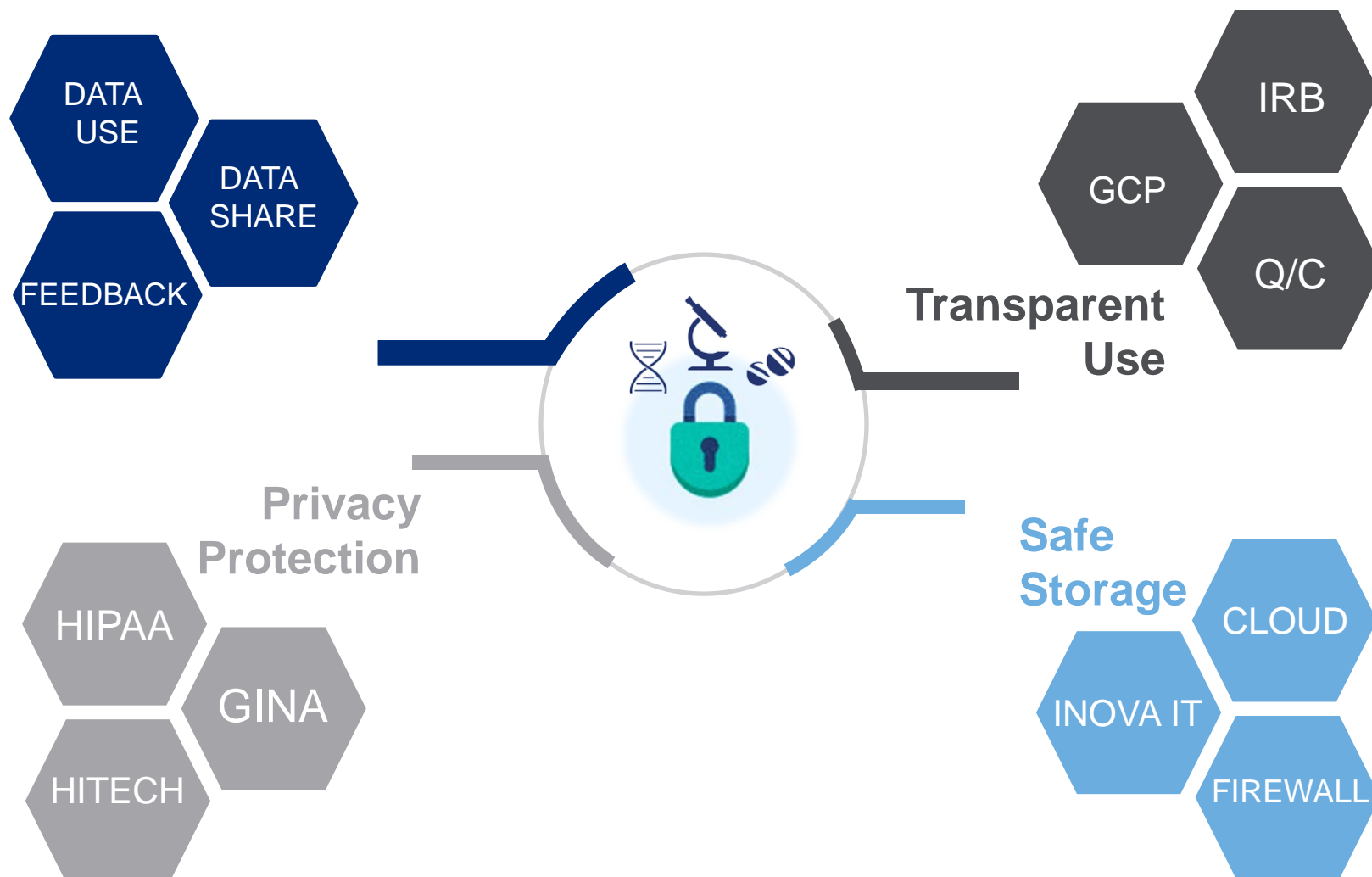
*Note: Currently excludes life insurance, disability insurance, and long-term care insurance.



Factors to consider for Inova:

- **Inova is a health system / provider...**
...rendering services to patients who are also employed by Inova.
- **Inova is a self-insured employer...**
...offering health plan choices to its employees and their dependents (incl. access to a wellness program).
- **Inova has an in-house CAP-accredited and CLIA-certified genomics laboratory (IGL)...**
...providing genetic testing services to patients (who could also be Inova employees).

Genomic Data Safety



PGx → MediMap® → Your genes. Your roadmap.™



MediMap® Newborn was conceived in late 2015, born in January 2016, and received siblings in 2017.

First registered
commercial product
at Inova!



Your genes. Your roadmap.™


MediMap®
PGx Testing

MyMap™
Whole Genome Sequencing


HealthyHeartMap™
Coming soon!

Your genes. Your roadmap.™

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MediMap[®]

Interested to learn more about MediMap[®] testing?

Would like to schedule an appointment?
(doctor's referral not required)

We want to hear from you!



MediMap@inova.org

703.776.8200

inova.org/MediMap

Franziska.Moeckel@inova.org