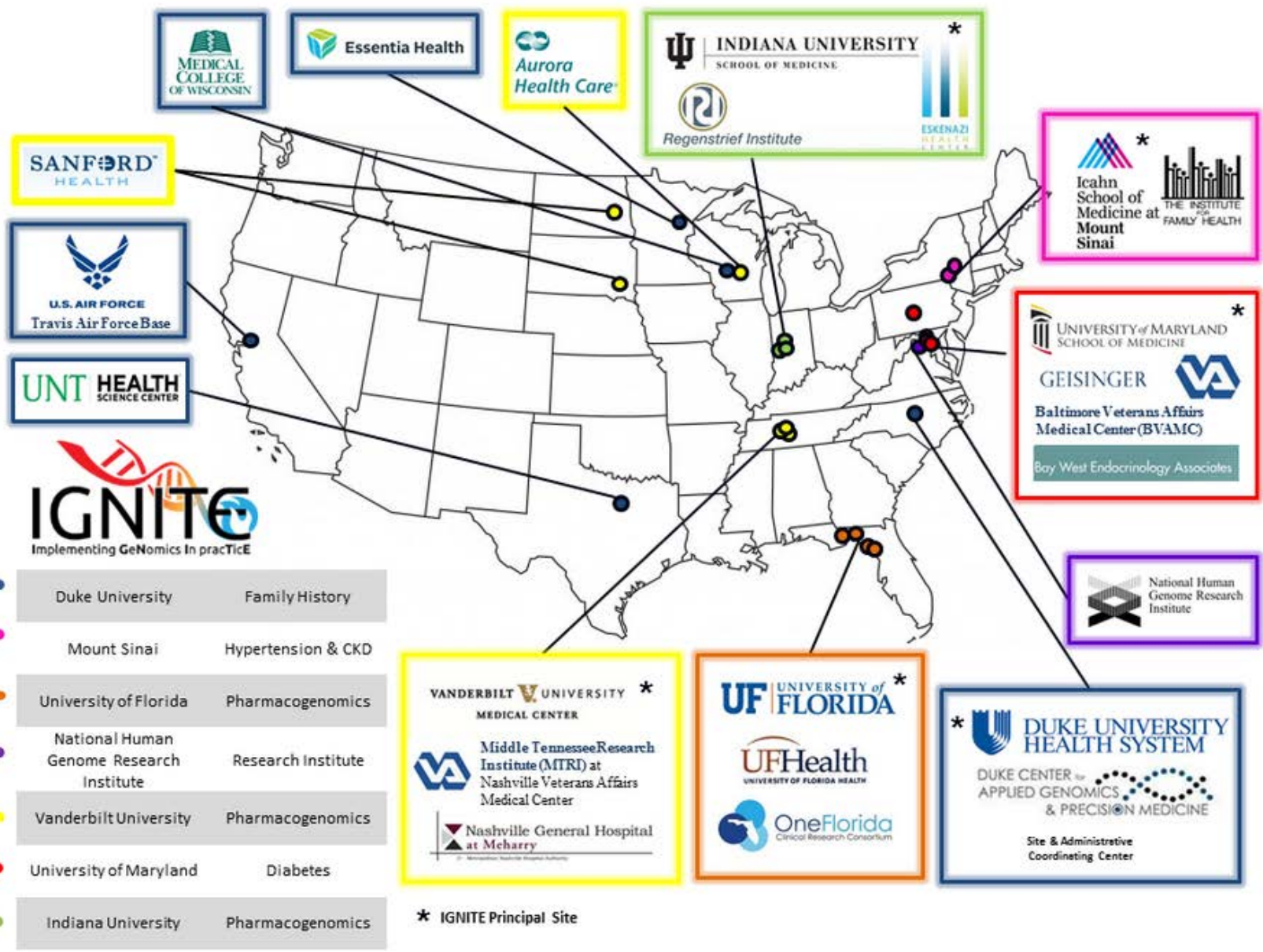




IGNITE SPARK Toolbox

Kristin Wiisanen (Weitzel), PharmD, FAPhA
Clinical Professor, University of Florida College of Pharmacy





MEDICAL COLLEGE OF WISCONSIN

Essentia Health

Aurora Health Care

INDIANA UNIVERSITY SCHOOL OF MEDICINE
Regenrief Institute
ESKENAZI HEALTH CENTER

SANFORD HEALTH

U.S. AIR FORCE Travis Air Force Base

UNT HEALTH SCIENCE CENTER

Icahn School of Medicine at Mount Sinai
THE INSTITUTE FOR FAMILY HEALTH

UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE
GEISINGER
Baltimore Veterans Affairs Medical Center (BVAMC)
Bay West Endocrinology Associates

National Human Genome Research Institute

VANDERBILT UNIVERSITY MEDICAL CENTER
Middle Tennessee Research Institute (MTRI) at Nashville Veterans Affairs Medical Center
Nashville General Hospital at Meharry

UNIVERSITY OF FLORIDA
UFHealth
UNIVERSITY OF FLORIDA HEALTH
OneFlorida Clinical Research Consortium

DUKE UNIVERSITY HEALTH SYSTEM
DUKE CENTER for APPLIED GENOMICS & PRECISION MEDICINE
Site & Administrative Coordinating Center

Create a Customized Implementation Guide
CYP2C19-Clopidogrel Testing

Click here to get started!

Or Search our implementation tools by topic:

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Genomics in Practice?**

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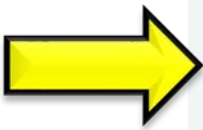


**Researching
Genomics in Practice?**

Search **Research** Tools

Search...





Clinicians

[ALL](#) / [CLINICIANS](#) / [RESEARCHERS](#) /

Browse resources intended to help clinicians implement genomics in patient care, or [SEARCH BY KEYWORD](#).

How to Get Started: Implementing Genomic Medicine

Just getting started? The tools below provide background information, benefits of adoption of genomic medicine in patient care, and summarize key challenges and stakeholders to consider for your implementation.

Ready to begin implementing? See specific resources below for common pharmacogenomic and genomic medicine implementations.

+ Clinical Implementation of Genomic Medicine and Pharmacogenomics

+ CYP2C19 - Clopidogrel

+ CYP2D6 - Opioids

+ CYP2D6 and CYP2C19-SSRIs

+ TPMT - Thiopurines

+ Family History

+ APOL1

+ MODY

– CYP2D6 and CYP2C19-SSRIs

+ Evidence Overview: CYP2D6 and CYP2C19-SSRIs

+ Clinical Pharmacogenetics Implementation Consortium Guideline Resources: CYP2D6 and CYP2C19 – SSRIs

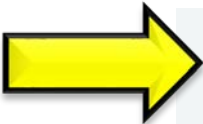
– PharmGKB Resources: CYP2D6 and CYP2C19-SSRIs

- [CYP2C19 Clinical Pharmacogenetics Information Page](#)
- [CYP2D6 Clinical Pharmacogenetics Information Page](#)
- [FDA Label for Citalopram and CYP2C19](#) *NEW*
- [FDA Label for Escitalopram and CYP2C19](#) *NEW*
- [FDA Label for Fluvoxamine and CYP2D6](#)
- [FDA Label for Paroxetine and CYP2D6](#) *NEW*
- [FDA Label for Sertraline and CYP2C19](#) *NEW*
- [Citalopram Pathway Diagram, Pharmacokinetics](#) *NEW*
- [Paroxetine Pathway Diagram, Pharmacokinetics](#) *NEW*

+ Genotyping Resources: CYP2D6 and CYP2C19

+ Clinical Decision Support: CYP2D6 and CYP2C19-SSRIs

+ Resources for Patients and Providers: CYP2D6 and CYP2C19-SSRIs



Researchers

[ALL](#) / [CLINICIANS](#) / [RESEARCHERS](#) /

Browse resources from the IGNITE Network and other researchers or [SEARCH BY KEYWORD](#).

Implementation Research in Genomic Medicine

The research and data collection tools below provide sample consent forms, surveys, data dictionaries, and other resources for conducting implementation science research in genomic medicine from the IGNITE Network researchers and affiliates.

— Research Tools

+ Study Recruitment and Education Materials

+ Consent Forms

+ Online Resources

— Data Collection

+ Data Dictionaries

+ Provider Surveys

+ Patient Surveys

+ Student/Learner Surveys

+ Collaborative Agreements

– Data Collection

+ Data Dictionaries

– Provider Surveys

- [Provider Knowledge of Genetic Testing after Implementation](#)
Developed to assess primary care providers' beliefs, attitudes and practices toward APOL1 genetic testing one year after GUARDD study implementation. More at [Science Direct](#).
- [Provider Practices in Genetic Testing for Kidney Disease Survey](#)
Developed to assess primary care providers' beliefs, attitudes, and practices towards APOL1 genetic testing prior to GUARDD study implementation. More at [Science Direct](#).
- [Provider Demographics and Practice Characteristics Survey](#)
Developed by IGNITE Common Measures Working Group to standardize collection of self-reported provider demographics and practice characteristics.
- [Provider Baseline Knowledge of Genetic Testing Survey](#)
Developed by IGNITE Common Measures Working Group to standardize collection of pre-implementation information from providers.
- [MODY Provider Survey](#)
Source: University of Maryland
- [TPMT-Thiopurine Provider Pre-Implementation Survey \(Gastroenterology\)](#) ^{NEW}
Source: University of Florida
- [TPMT-Thiopurine Provider Pre-Implementation Survey \(Pediatric Hematology/Oncology\)](#) ^{NEW}
Source: University of Florida

+ Patient Surveys

+ Student/Learner Surveys

+ Collaborative Agreements

Genomic Medicine Implementation Guides

- Develop a reproducible, user-friendly mechanism by which users can navigate Toolbox resources to build a customized guide based on implementation needs
- Use *CYP2C19*-Clopidogrel as a model for first guide in collaboration with the IGNITE Pharmacogenetics Working Group (Lead: Larisa Cavallari, PharmD)



Create a Customized Implementation Guide

CYP2C19-Clopidogrel Testing

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Implementation Framework

- National Implementation Research Network Stages of Implementation
 1. *Exploration*
 - Decide to adopt; create team
 2. *Installation*
 - Changes to practice setting; training first implementers
 3. *Initial Implementation*
 - Begin implementation; Gain support from leadership
 4. *Full Implementation*
 - Monitor, communicate; use feedback to strengthen implementation

Implementation Stage	No. of Pubs
Exploration <ol style="list-style-type: none"> 1. Scientific evidence, experience, unmet need 2. Review successful implementations 3. Identify local champions/adopters 	 21 9 17
Installation <ol style="list-style-type: none"> 1. Identify/engage stakeholders/leadership 2. Develop clinical workflow 3. Genotyping procedures 4. Informatics/CDS 5. Provider/Patient Education 6. Evidence Review Body/Process 7. Financial Plan 8. Identify Metrics 	 19 19 23 24 17 13 12 15
Initial Implementation <ol style="list-style-type: none"> 1. Launch service 2. Monitor workflow adherence 3. Continuously engage stakeholders 4. Monitor and collect metrics 	 8 5 8 10
Full Implementation <ol style="list-style-type: none"> 1. Identify and address challenges 2. Continue evidence evaluation 3. Expand project 4. Pilot new implementation 	 13 7 12 10

IMPLEMENTATION GUIDE FOR CYP2C19-CLOPIDOGREL TESTING

Answer the questions below to generate your own customized implementation guide for implementing CYP2C19-clopidogrel testing in your practice. These questions assess the current status of your implementation process to determine how best to configure your guide.

Your customized implementation guide will contain stepwise instructions, recommendations, and information resources to help you complete and maintain a successful implementation of CYP2C19-clopidogrel testing. This guide was created by experts in genomic medicine with real experience in implementing this genetic test in a clinical setting.

You'll be able to access your guide in two ways: through a unique, permanent URL and by downloading a PDF document.

Please note that this guide's functionality may vary based on the web browser that is used. This guide is best viewed in Chrome.



Have you completed the following implementation steps?	Not Yet Started	In Progress	Completed
Gather institutional support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop genetic test ordering and interpretation process	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Establish reimbursement sources/processes for genetic test	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Integrate genetic data into the EHR	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop provider education materials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Develop patient education materials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Establish workflow for clinical pharmacogenetics implementation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Implementation Guide for CYP2C19-Clopidogrel Testing

Available tools:

Step 1: Gather Institutional Support

With respect to clinical implementation of pharmacogenetics, gathering institutional support can be defined as follows:

1. Collecting and disseminating institution-specific data to justify implementation (e.g. formulary considerations, medication-use frequency, specialty therapeutic areas, clinician expertise, patient demographics)
2. Gathering evidence to support clinical utility of your implementation (e.g. primary literature, clinical practice guidelines, likelihood of a clinically actionable result, relevant patient outcomes associated with genotype-guided therapy)

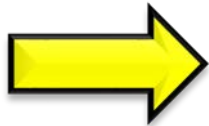
Provided resources include an overview of the supporting evidence, clinical guidelines, relationship between the gene-drug pair, and sample data collection metrics that can be disseminated to raise stakeholder (e.g. physicians, pharmacists, laboratory specialists, informaticians, educators) and administrative support for the implementation.

- [Evidence Overview of CYP2C19-Clopidogrel Presentation](#)
IGNITE Network
- [Publication List: CYP2C19-Clopidogrel Evidence Overview](#)
IGNITE Network
- [CPIC Guideline for CYP2C19-Clopidogrel](#)
Clinical Pharmacogenetics Implementation Consortium
- [CPIC Tutorial Series Video: Clopidogrel and CYP2C19 Summary](#)
PharmGKB, Clinical Pharmacogenetics Implementation Consortium

[See all tools](#) +

Here's your customized Implementation Guide for CYP2C19-Clopidogrel Testing

[Start Over »](#)



Online Guide

[BOOKMARK THIS PAGE](#)

Downloadable Guide

[DOWNLOAD PDF VERSION](#)

This guide contains the following implementation steps:

- Step 1: [Gather Institutional Support](#)
- Step 2: [Develop Genetic Test Ordering and Interpretation Process](#)
- Step 3: [Establish Reimbursement Source/Process for Genetic Test](#)
- Step 4: [Integrate Genetic Data Into the EHR](#)
- Step 5: [Develop Provider Education Materials](#)
- Step 6: [Develop Patient Education Materials](#)
- Step 7: [Establish Workflow for Clinical Pharmacogenetics Implementation](#)

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-  [Evidence Overview of CYP2C19-Clopidogrel Presentation](#)
IGNITE Network
-  [Publication List: CYP2C19-Clopidogrel Evidence Overview](#)
IGNITE Network
-  [CPIC Guideline for CYP2C19-Clopidogrel](#)
Clinical Pharmacogenetics Implementation Consortium
-  [CPIC Tutorial Series Video: Clopidogrel and CYP2C19 Summary](#)
PharmGKB, Clinical Pharmacogenetics Implementation Consortium

Step 2: Develop Genetic Test Ordering and Interpretation Process

Pharmacogenetic tests must be processed in a Clinical Laboratory Improvement Amendments (CLIA)-licensed laboratory in order for the results to be used clinically, which means that it is crucial to establish a genetic test ordering and interpretation process in conjunction with an in-house or outside laboratory.

Provided resources include a summary/listing of pharmacogenetic testing platforms, relevant genetic variants, laboratories, and guidance on the translation from genotype to phenotype.

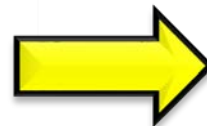
-  [Summary of CYP2C19 Platforms and Variants by Site](#)
IGNITE Pharmacogenetics Working Group
-  [CYP2C19 Genotype Translation Table](#)
University of Florida Health Personalized Medicine Program
-  [CYP2C19 Genotype Translation Table](#)
Icahn School of Medicine at Mount Sinai
-  [Standard Operating Procedure: CYP2C19 Genotyping Utilizing the Spartan Rx System](#)
University of Pennsylvania

Here's your customized Implementation Guide for CYP2C19-Clopidogrel Testing

[Start Over »](#)

Online Guide

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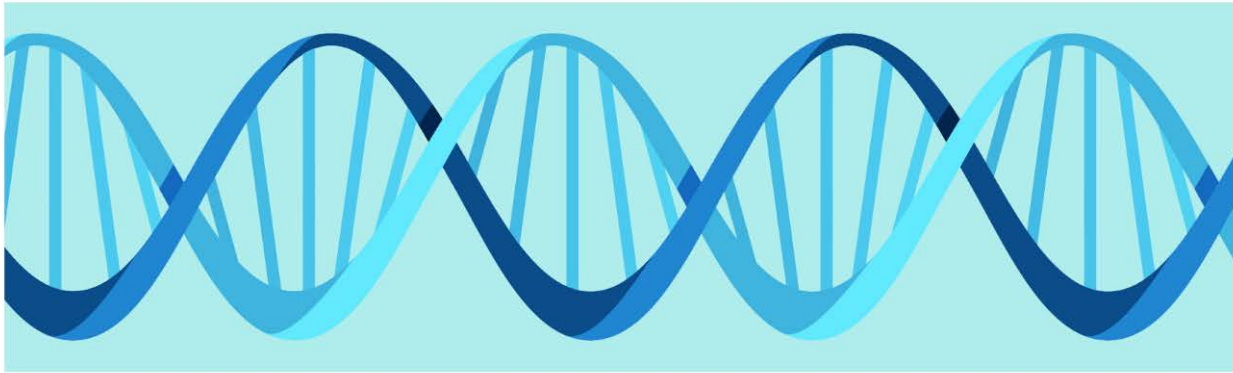


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Implementation Guide for CYP2C19-Clopidogrel Testing

[Start Over »](#)

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Funding to support this website provided by the National Human Genome Research Institute (U01 HG 007269).

This guide contains the following implementation steps:

Step 1: Gather Institutional Support

Step 2: Develop Genetic Test Ordering and Interpretation Process

Step 3: Establish Reimbursement Source/Process for Genetic Test

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 - J. Kevin Hicks, PharmD, PhD
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