

# ABSTRACT: 2017 ELAM Institutional Action Project Symposium

**Project Title:** Development of a Pharmacogenomics Research and Implementation (PGxRI) program

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**Collaborators:** David Standaert, MD, PhD (Chair); UAB School of Medicine and Health System leadership

**Background, Challenge or Opportunity:** Precision medicine, tailoring a treatment plan based on patients' unique characteristics (including genomics), is designated as a signature program at UAB. As drug therapy constitutes the cornerstone of treatment for chronic diseases, pharmacogenomics, the study of genetic variation influencing response to drugs and tailoring medications to a patients' genetics is a cornerstone of precision medicine.

Pharmacogenomics promises to improve patient outcomes optimizing drug therapy. Despite growing evidence that genotype-guided therapy (GGTx) can improve outcomes, advances in technology and decreasing costs, application of GGTx into clinical practice is limited. Integration of research and implementation efforts across a seamless framework can help address these challenges and realize the promise of pharmacogenomics for the individual patient and the population.

**Purpose/Objectives:** The Pharmacogenomics Research and Implementation (PGxRI) program will optimize drug therapy and improve patient outcomes, aligning research and clinical implementation efforts to:

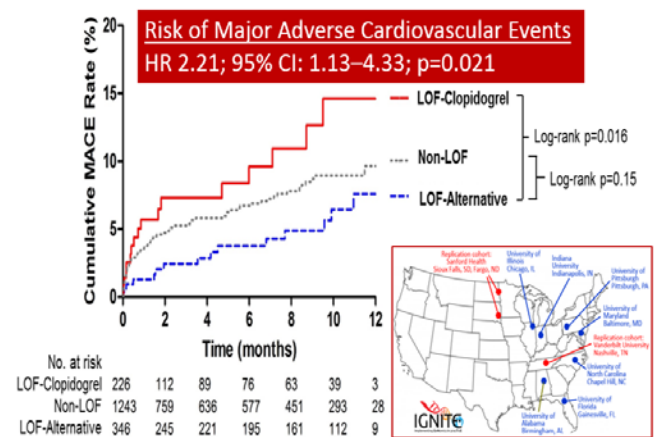
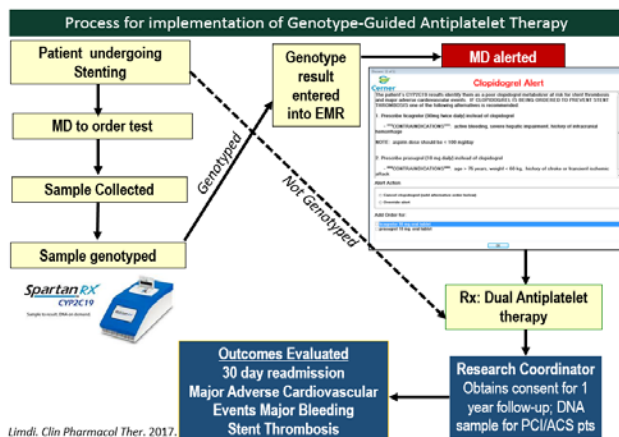
1. Build a program in PGx-IS research to drive discovery of predictors of drug response.
2. Develop the evidence-base and guidelines for genotype-guided therapy.
3. Lead the implementation of genotype-guided therapy in care and inform health policy.
4. Develop educational programming to train the next generation of practitioners in PGxRI.

**Methods/Approach:** We developed a framework to identify opportunities where GGTx can improve outcomes, develop consensus across stakeholders in the clinical enterprise and obtain institutional endorsement, build genotyping capability within our CLIA-certified molecular diagnostic laboratory, conduct testing within a timeline conducive to the provision of care, and provide clinical decision support to guide treatment selection. We also developed processes to leverage this to assess clinical and process-related outcomes, evaluate effectiveness and cost-effectiveness of GGTx, and bolster research infrastructure to fuel additional research and discovery.

**Outcomes and Evaluation Strategy:** We used this framework to implement genotype-guided antiplatelet therapy in acute coronary syndromes patients undergoing percutaneous coronary intervention. The initiation spanned several months with parallel efforts focused on building consensus with the cardiologists, obtaining approval from the pharmacy and therapeutics committee, validating genotyping platform in the hospital molecular diagnostic laboratory, and implementation of workflow into electronic medical record with genotype guided decision support.

**Impact:** The implementation effort engaged a team of clinicians, pharmacists, pathologists, informaticians and researchers across UABs clinical, administrative and research enterprise. We published this framework and process outcomes including a 70-minute test turn-around-time and 66% acceptance of treatment recommendation. GGTx reduced the major adverse cardiovascular events by 50% in a collaborative analysis presented at AHA (Nov 2016).

As we expand our efforts beyond "one-gene-at-a-time" to combinatorial pharmacogenomics, this framework will provide a foundation to engage larger teams across our organization to implementation of genotype-guided therapy in personalizing therapy for patients with disorders such as depression, cancer, and pain.





# Program in Pharmacogenomics Research and Implementation Science (PGxRIS)

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**Collaborators:** David Standaert, MD, PhD (Chair); UAB School of Medicine and Health System Leadership.

## Background/ Opportunity

- Precision medicine, (PM) is a signature program at UAB.
- Pharmacogenomics is a cornerstone of precision medicine.
- A robust program which supports our institutions research, clinical care, and educational missions is vital to both; effective and cost-effective care for individual patients and the population.

## Purpose/ Objectives

**Vision:** To improve patient outcomes through optimization of drug therapy.

**Mission:** Build and lead a Program in Pharmacogenomics Research and Implementation Science (PGxRIS) to

1. Drive discovery of predictors of drug response.
2. Develop evidence-base and guidelines for genotype-guided therapy.
3. Lead the implementation of genotype-guided therapy and inform policy.
4. Develop educational programming in PGxRIS.

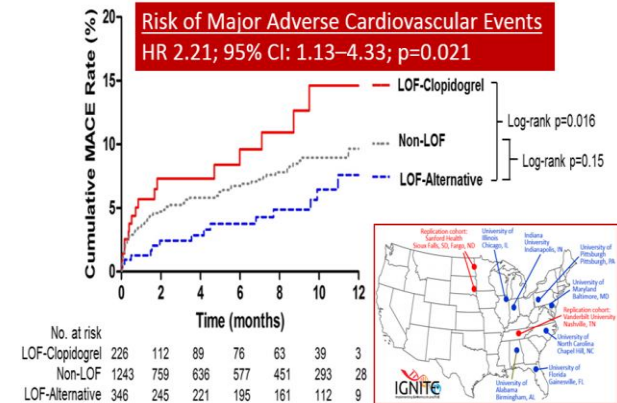
## Methods/ Approach

Developed a UAB specific framework to:

1. Identify opportunities where genotype-guided therapy (GGTx) can improve outcomes.
2. Establish process of consensus development and obtain institutional endorsement.
3. Leverage / build genotyping capability.
4. Develop and deploy clinical decision support to guide treatment selection.
5. Establish processes to assess outcomes, evaluate effectiveness of GGTx.
6. Understand emerging research priorities and bolster research infrastructure.
7. Develop a plan for sustaining, and possibly expanding GGTx.

## Outcomes/ Evaluation

- Published implementation process paper.
- Evaluated effectiveness of GGATx.
- Cost-effectiveness analysis is ongoing.



## Discussion/ Next steps

- The process for implementation and evaluation of reactive GGTx is established.
- Pre-emptive GGTx using a gene-panel approach is under planning.

## Summary/ Conclusion

As drug therapy is the mainstay of chronic disease management, pharmacogenomics is the cornerstone of precision medicine.

Prescribing the right medication, at the right dose, for the right patient can improve both patient outcomes and population health.

Program in Pharmacogenomics Research and Implementation Science: Clinical Implementation Strategy

