



IGNITE

Implementing
GeNomics
In pracTice

National Human Genome Research Institute Strategic Plan for the Next 10 Years

Five Pillars of Genomics Research – Nature, 2011

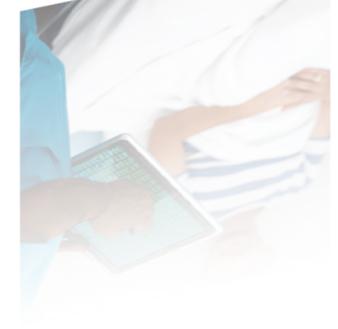
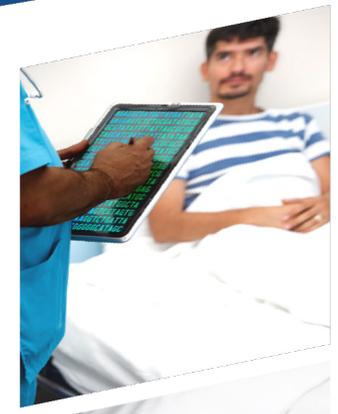
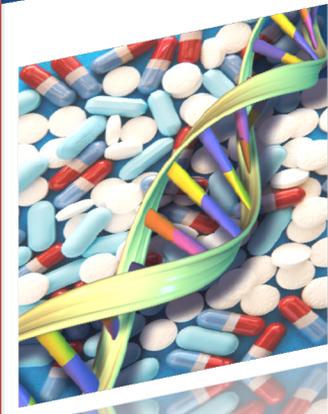
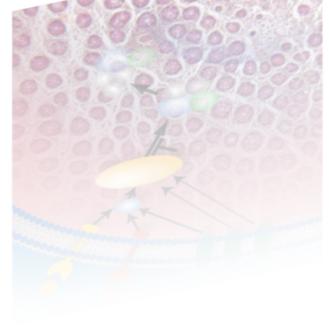
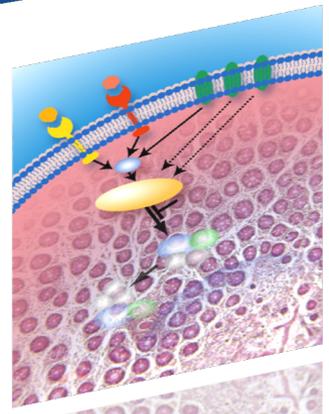
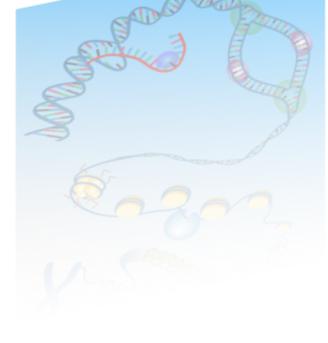
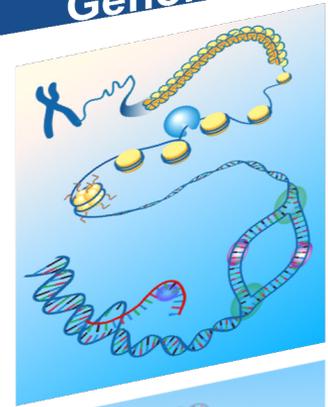
Understanding
the Structure of
Genomes

Understanding
the Biology of
Genomes

Understanding
the Biology of
Disease

Advancing
the Science of
Medicine

Improving the
Effectiveness
of Healthcare



Courtesy of Eric Green

Genomic Medicine Demonstration Projects RFA

The purpose of this funding opportunity is to support a consortium of collaborative Genomic Medicine Pilot Demonstration Projects designed **to develop methods for, and evaluate the feasibility of, incorporating an individual patient's genomic findings into his or her clinical care.**

Specific goals are.... to contribute to the evidence base regarding **outcomes** of incorporating genomic information into clinical care; and define and share the processes of genomic medicine implementation, diffusion, and sustainability in diverse settings.

IGNITE Network Goals

- **Expand and link existing genomic medicine efforts**, and develop new collaborative projects and methods, in diverse settings and populations
- **Contribute to the evidence base** regarding outcomes of incorporating genomic information into clinical care
- **Define and share the best practices** of genomic medicine implementation, diffusion, and sustainability in diverse settings

Implementation of Genomics Into practice (IGNITE consortium)

- Coordinating Center:
 - University of Pennsylvania (Stephen Kimmel)
- 3 demonstration projects:
 - University of Florida (Julie Johnson):
 - Expanding a personalized medicine genotyping program using pharmacogenetic testing and decision support in private care
 - Mount Sinai (Erwin Bottinger):
 - Using genomic risk information (*APOL1*) for care of African Americans with hypertension at risk for developing chronic kidney disease
 - Duke University (Geoff Ginsburg):
 - Using patient entered Family Health History and risk-based clinical decision support for patient care in diverse settings

Role of the Coordinating Center

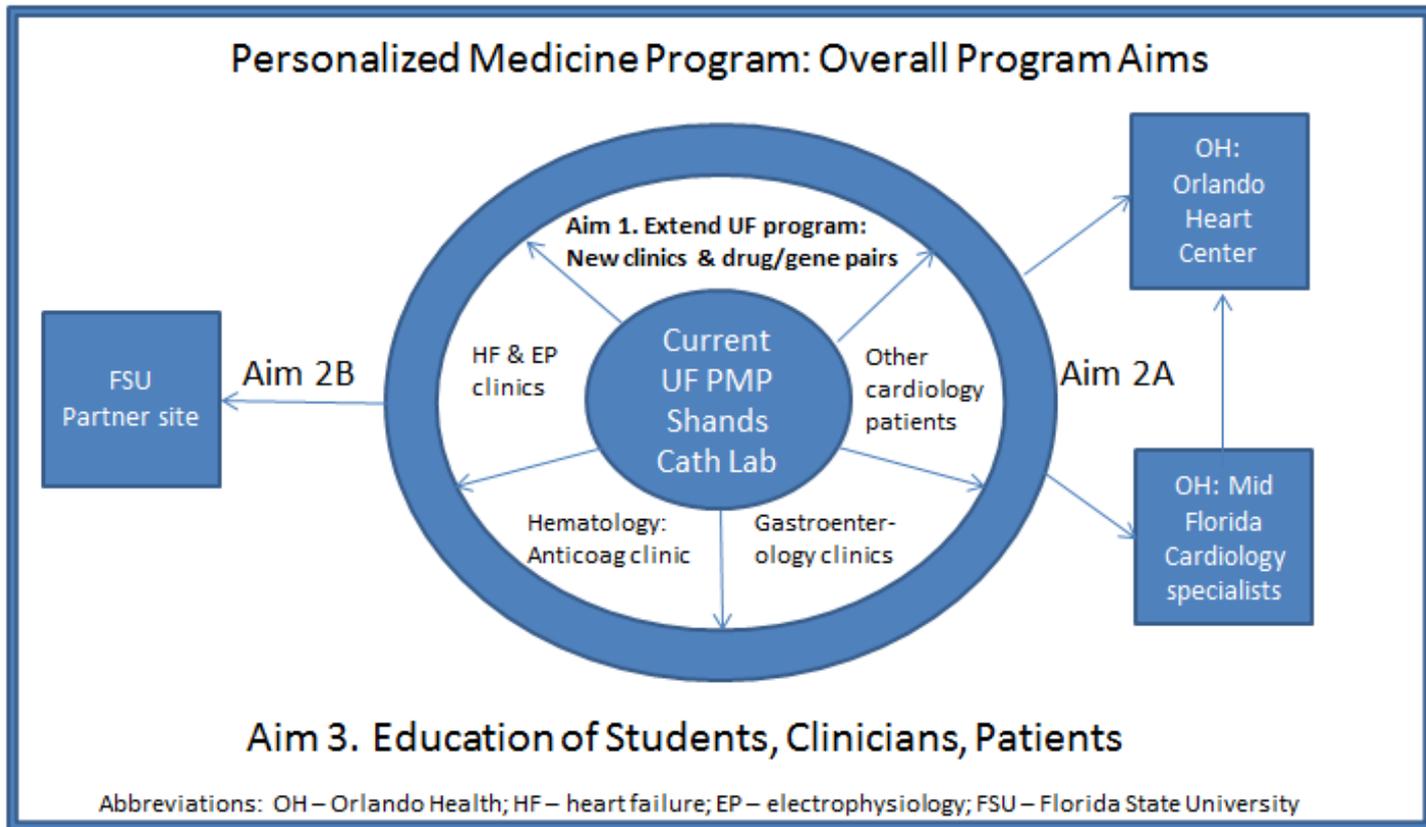
- Network hub
- Facilitate application of framework to guide implementation research
- Facilitate synergies among projects
- Establish repository of study data and measures
- Enable communications internally and externally
- Develop strategies for outreach to other groups
- Engage an expert scientific panel

Objectives for the UF Health Genomic Medicine Program

- Pharmacogenetics focus:
 - actionable examples with substantial evidence and relatively large effect sizes
 - Regulatory backing through FDA labeling
 - Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines
- Program objectives:
 - Genotype patients on broad panel of genetic polymorphisms to model pre-emptive genomic data approach
 - Develop informatics systems to handle large scale genomic data linked to electronic health record
 - Define when and how to use genetic data in patient care through systematic evidence evaluation and institutional program approval process
 - Support clinical use through electronic clinical decision support
- Evaluate impact on patient safety, process outcomes and costs of care
- Clopidogrel – CYP2C19 implementation launched June 2012

PI: Julie Johnson (Johnson@cop.ufl.edu)

UF IGNITE Project Aims



Aim 1 – extend pharmacogenetics implementation to other drug-gene pairs at UF Health

Aim 2 – extend beyond UF, to large private health system (Orlando Health) and community setting (FSU network)

Aim 3 – educational programming for clinicians, health science students and patients

Genomic Medicine Pilot For Hypertension And Kidney Disease In Primary Care: Bottinger, PI

- Clinical Context
 - Excess kidney failure burden in Blacks is a Major Health Disparity
 - 5 times higher risk for progression to end stage renal failure (ESRD)
 - 10 years younger at initiation of dialysis or kidney transplantation
 - 28% of ESRD is associated with hypertension
- Genetic Context
 - APOL1 variants have significant effect on kidney failure risk in Blacks
 - Two risk copies are associated with ~ 5-fold increased risk for kidney failure
 - ~ 3Mn African Americans (14%) have two APOL1 risk allele copies
- Study Objectives
 - To establish an effective EHR-enabled implementation of APOL1 risk-informed management of hypertension for a large primary care network in New York City
 - To examine how point-of-care APOL1 risk information affects patient and provider behavior and whether it reduces blood pressure-associated kidney failure risk

Genomic Medicine Pilot For Hypertension And Kidney Disease In Primary Care

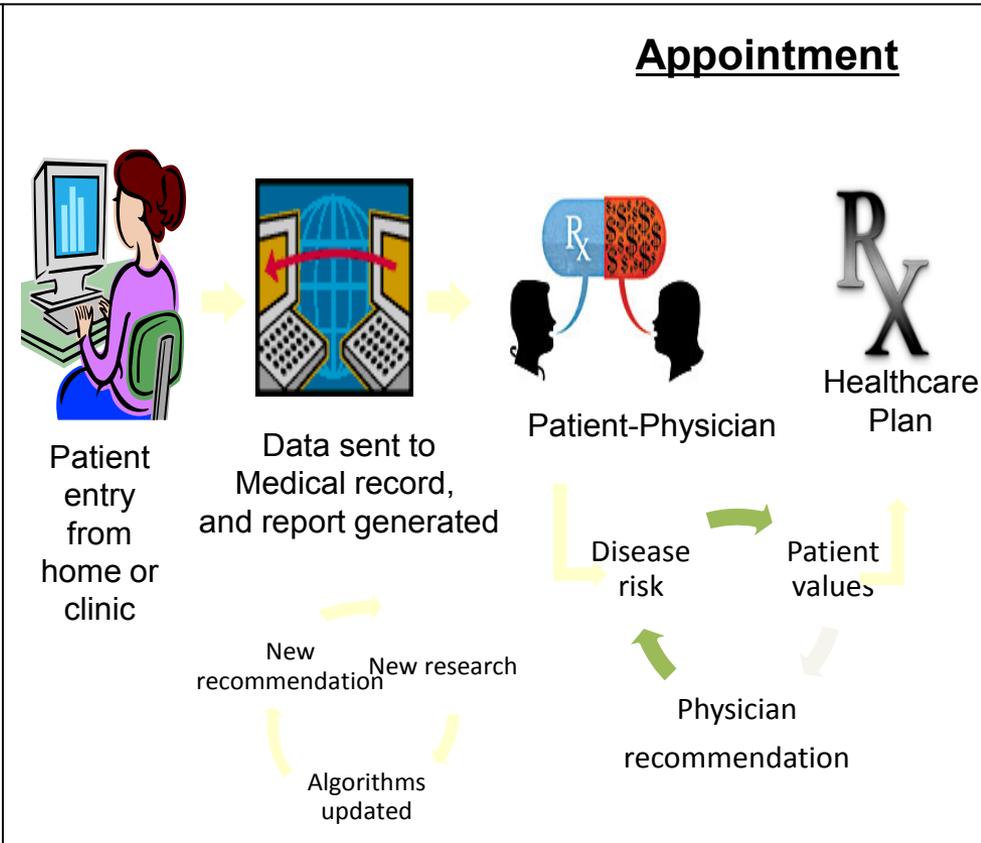
- Research Setting
 - 4 Academic Primary Care Practices at Mount Sinai Health System (MSHS)
 - 8 Community Primary Care Practices at The Institute for Family Health (IFH)
- Study Design
 - Cluster randomized trial assigning practices (providers) to CDS intervention with or without APOL1 genetic risk to guide blood pressure treatment and kidney tests
 - Enroll 900 hypertensive Blacks each at APOL1-informed practices to test and return APOL1 results or at conventional CDS practice without APOL1 testing
 - Follow provider and patient behavior and collect clinical care data for 1 year
- Study Endpoints
 - % patients achieving recommended blood pressure control to reduce complication risk
 - Blood pressure
 - % patients who receive appropriate kidney function tests
 - Secondary: process measures; provider and patient beliefs, attitudes, behavior

PI Contact: Erwin Bottinger erwin.bottinger@mssm.edu

Genomic Medicine: Family Health History Evaluation in Diverse Care Settings

Ginsburg, PI

1. To optimize the collection of patient entered FHH in diverse clinical environments for coronary heart disease, thrombosis, and selected cancers
2. To export FHH data to an open clinical decision support platform and return CDS results to providers and patients. To explore the integration of genetic risk and FHH data at selected sites
3. To assess the clinical and personal utility of FHH using a pragmatic observational study design to assess reach, adoption, integrity, exposure, and sustainability, and to capture, analyze, and report effectiveness outcomes at each stakeholder level: patient, provider, and clinic/system
4. To take a leadership role in the dissemination of guidelines for a FHH intervention across diverse practice settings



Genomic Medicine: Family Health History Evaluation in Diverse Care Settings Ginsburg, PI

- Evaluate across broadly diverse settings and populations

Geographic diversity

5 national sites

35 clinics in 7 states

Population diversity

Rural/underserved

EMR and non-EMR

Minority groups

Provider diversity

Specialty

Age/Race



Evaluation: Implementation Sciences methodology

- Qualitative and Quantitative assessments
- Ease of use
- Benefits of education/Talking with Family
- Location/Type of device used to access
- Need for assistance
- Language

FHH: Effectiveness Outcomes

| | Patient | Provider | System |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Emotional | <ul style="list-style-type: none"> SF-12 (quality of life) Patient Activation Measure Prochaska Stage of Change Satisfaction and anxiety Quality of clinical encounter Barriers to Model use | <ul style="list-style-type: none"> Satisfaction Knowledge Barriers to Model use Concur with CDS Quality clinical encounter Quality CDS for care | <ul style="list-style-type: none"> Staff satisfaction Organizational readiness to change (ORCA) Implementation climate |
| Behavioral | <ul style="list-style-type: none"> Medication adherence (Morisky) % exercising (Stanford Brief Activity) % eating 3 servings fruits/veggies per day (Rapid Food Screener) % smoking % ideal BMI Implemented provider rec (uptake) | <ul style="list-style-type: none"> Discussion of prevention Discussion of risk % time CDS output used (uptake) % adherence to CDS | <ul style="list-style-type: none"> Work flow/processes Implementation policies and practices Implementation climate Intervention values and task fit |
| Biological | <ul style="list-style-type: none"> Demographics FHH | <ul style="list-style-type: none"> FHH documentation & counseling | <ul style="list-style-type: none"> % completion MeTree™ time to complete FHH |
| Clinical | <ul style="list-style-type: none"> Laboratory Data (i.e. LDL) Screening tests performed Screening complications Vital Signs, Weight and BMI Number of medications | <ul style="list-style-type: none"> Disease control goals met Referrals made | <ul style="list-style-type: none"> % high risk patients % w/ risk based screening % w/ screening compl. % w/ disease at goal Visit length/Wait times |
| Financial | <ul style="list-style-type: none"> Socio-economic status Medication costs | | <ul style="list-style-type: none"> Office/ ER visits, hospitalizations Model resource needs Impact on family members |

IGNITE: Three Working Groups

- **Implementation Working Group**
 - To share, evaluate, and disseminate what implementation strategies work and don't work – when, where, and why – across diverse genomic medicine implementation projects
- **Dissemination, Outreach, Education, Economics, and Sustainability**
 - To plan, facilitate, and track IGNITE activities in each of five areas: dissemination, outreach, education, economics, and sustainability
- **Process and Effectiveness Measures Working Group**
 - To identify a core set of process and effectiveness measures that can be used across projects, to develop new measures as needed, and to assist the other two working groups with measurement issues

Future Plans

- Expansion of the IGNITE Network to other sites (pending)
- Implement data sharing plan and share data
- Develop best practices in genomic medicine implementation and disseminate
- Develop standard process and clinical outcome metrics that can be used across genomic medicine implementation projects
- Engage payers on defining outcomes for reimbursement – read: “sustainability”