
IU School of Medicine and IU Health Research Strategic Plan

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SCHOOL OF **MEDICINE**

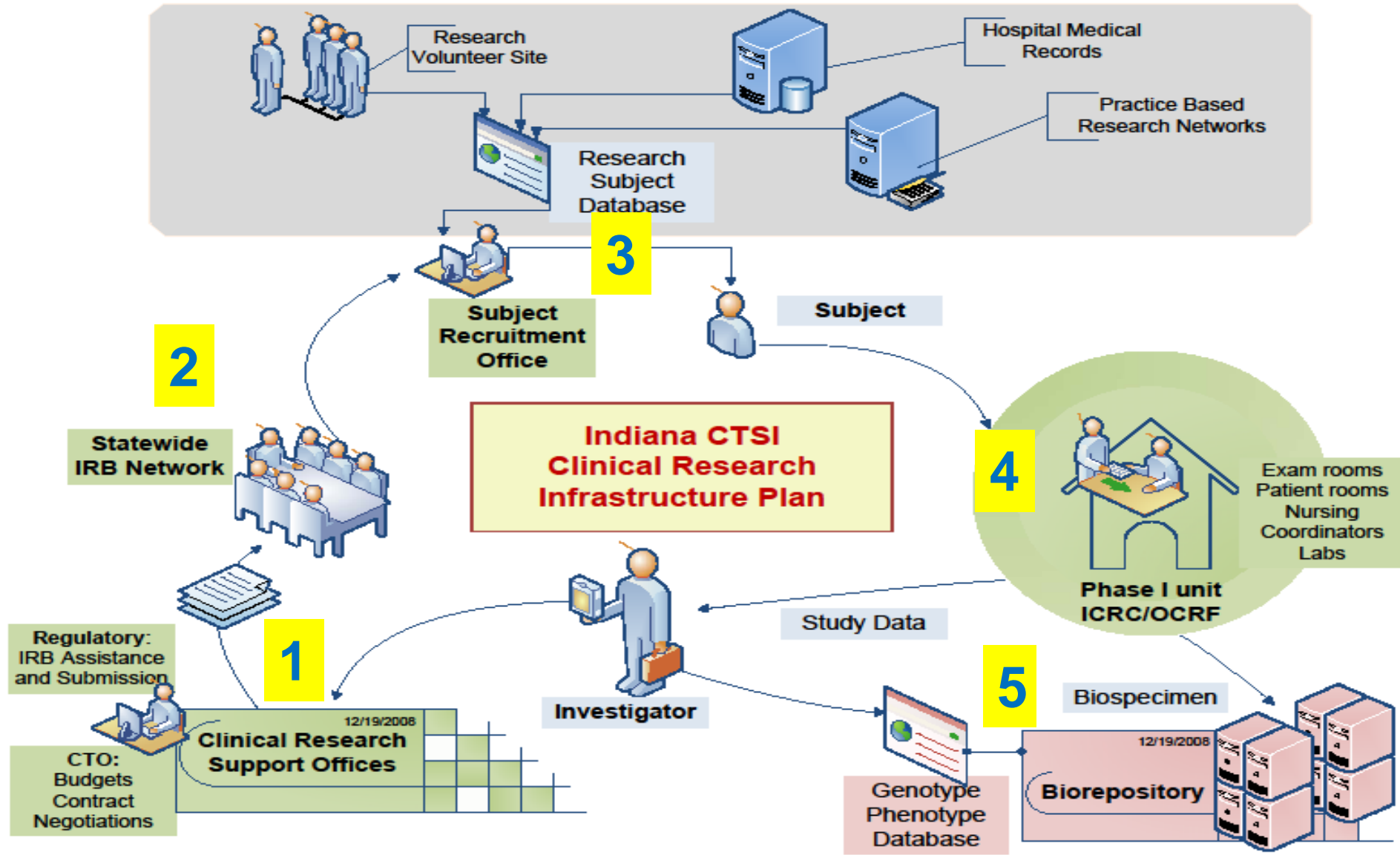


Indiana University Health

Statewide Reach of the Enterprise



IUH Clinical Research Support Infrastructure



IUH/IUSM Enterprise Research Goals

- Grow research funding (NIH is the barometer):
 - Next 12 months – grow targeted areas by 10%
- Accelerate Translation of Clinical Protocols
 - Impactful clinical trials
- Precision Health: Provide Innovative treatments and care programs to our patients
 - e.g., Genomic medicine
 - e.g., Cell and gene therapies

Strategy Grid for Growing Research: Priority Areas

Scientific Research Areas

Strategic Themes

Cancer
(select areas)

Neuroscience
(select areas)

Diabetes,
Cardiovascular
& Metabolism

Musculoskeletal
Disorders

Precision Health

Population Health

Innovative Therapy
(e.g., Cell based therapy)

Life Span Research

Basic , Translational and Clinical Research

IUH/IUSM Enterprise Research Goals

2. Accelerate Translation of Clinical Protocols

- ✓ PowerTrials tool is now active at all Cerner sites
- ✓ 20 Impactful clinical trials have been selected
- ✓ Patient enrolled will appear at all sites by September
- ✓ Trials will become available Enterprise-wide by Oct-Nov, 2016

Hart, Mylo - BWMC 011-226 Opened by Gray MD, Phil

Task Edit View Patient Chart Links Notifications Help

Home Patient List Quality Measures Cerner PMLaunch New Sticky Note View Sticky Notes Tear Off Attach Suspend

Hart, Mylo

Hart, Mylo Age:66 years Sex:Male Location: Allergies: shellfish, ...
Clinical Trial: On Study Adv Dir: Living w/Isolation: Standard ... Code Status: Full Res...

Menu - All

- Results
- Inpatient Summary
- Patient Summary
- ICU Summary
- Rehab Patient Care Summary
- Growth Chart

Clinical Trials

Clinical Trial/Study Enrollment History for Patient

Protocol Name	eCRF	Enrollment ID	On Study Date	Off Treatment Date	Off Study Date	Contact Info
DIAB457		ALL779_1166	8/9/2012			Griffin MD, Phyllis

Initial Protocol 8/9/2012

- Clinical Trial Management System used to record, manage and report on data associated with clinical trials
 - The system is web-based and provides users secure access from any location to record, manage and report on data associated with the operation of clinical trials.
 - Is located centrally to manage all aspects of a clinical trial
 - This is set up to work with Cerner's PowerTrials which was designed to assist identification and monitoring of patients within clinical trials.
 - is Integrated within PowerChart[®]
 - promotes Patient safety
 - allows providers to View relevant research-related information
 - Increases/improves recruitment by identifying eligible patients

Impactful Clinical Programs (2) and Clinical Trials (20) – Initial Cohort

- **Pharmacogenetics Service for Patients** - Provides opportunities for genetics based drug prescriptions for complex patients and consultation if you are treating patients using high risk combinations of multiple drugs or chemotherapy.
- Specimen Collection and Storage (2)
- Pediatric studies (5)
- Cancer (2)
- Neuroscience (5)
- Cardiology (4)
- Gastroenterology (1)
- Pulmonary/Allergy (1)

INGENIOUS Study



Collaboration:

- Indiana University School of Medicine
- Eskenazi Health System
- Indiana University Institute for Personalized Medicine
- Regenstrief Institute

Study Scope:

- Design a randomized, controlled trial that is powered to statistically support the translation of study results to real-world implementation within the targeted healthcare system

Study Aims:

Aim 1: To test the hypothesis that a CLIA certified genotyping targeted at 24 widely used drugs is associated with significant reductions in hospital and outpatient costs incurred over 1 year

Aim 2: To test whether pharmacogenetic testing is associated with significant improvements in clinical outcomes over 1 year








INGenious Patient Education Brochure*

What if your body came with its own how-to book that your doctor could read?

Well it does! Your DNA is kind of like a how-to book for your body.

Doctors from INGenious are doing a study to see if reading parts of your DNA will help your doctor pick medicines that fit you better. Someone may talk to you about this study today.

How does the study work?

-  You get a little bit of blood drawn.
-  Some of this blood goes to the Indiana Biobank.
-  The rest goes to a lab and your DNA is read.
-  Just like how your DNA controls the color of your eyes, it also controls how your body works with medicines.
-  The lab looks for clues in your DNA that show how your body works with medicines.
-  The clues from your DNA are added to your electronic medical record.
-  Your doctor can look at the clues in your electronic medical record to help pick what medicine is best to give you.



Okay, so what might I get out of this?

Your doctor will be able to see some parts of your DNA and **hopefully** choose better medicines or doses for you.

The first time.

Without nasty side affects.

Why just hopefully?

Researchers believe that if your doctor could see parts of your DNA, it would be easier to choose the medicine or dose that will work best for you. Doctor Dexter and Doctor Skaar are doing a study to test this idea. If you choose to be part of the study, you will be helping them prove that this idea is correct.

More questions about the study? Call (317) 274-2810.

What's the Biobank?

The Indiana Biobank is like a big lock box full of folders where each folder holds a different person's DNA and health story. Researchers can ask the Biobank to send information from these folders to help with learning about how to help people stay healthy. There are never any names shared. If you agree to give your information to the Biobank, they will keep it until you call and tell them you don't want them to anymore.

More questions about the Biobank? Call (317) 274-5688.

Some medicines work differently for each of us. Picking one without knowing how your body will use it is kind of like:

Buying a shirt without trying it on first: it might not always fit right.



Your DNA could help your doctor pick because it tells your unique story of how different medicines fit you. Scientists call this Pharmacogenetics.

but

We won't know if having doctors use Pharmacogenetics will really mean less problems with medicine until we try it out. That's why we're doing this study!

Fishing without knowing what bait to use: you have to try bait after bait until one works.



*Created through a collaboration of Clinical Pharmacology, the IU CTSI and The Heron School of Art

Indiana University INGenious Leadership Team

Paul Dexter MD
Todd Skaar PhD



Ann Holmes PhD
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Victoria Pratt PhD



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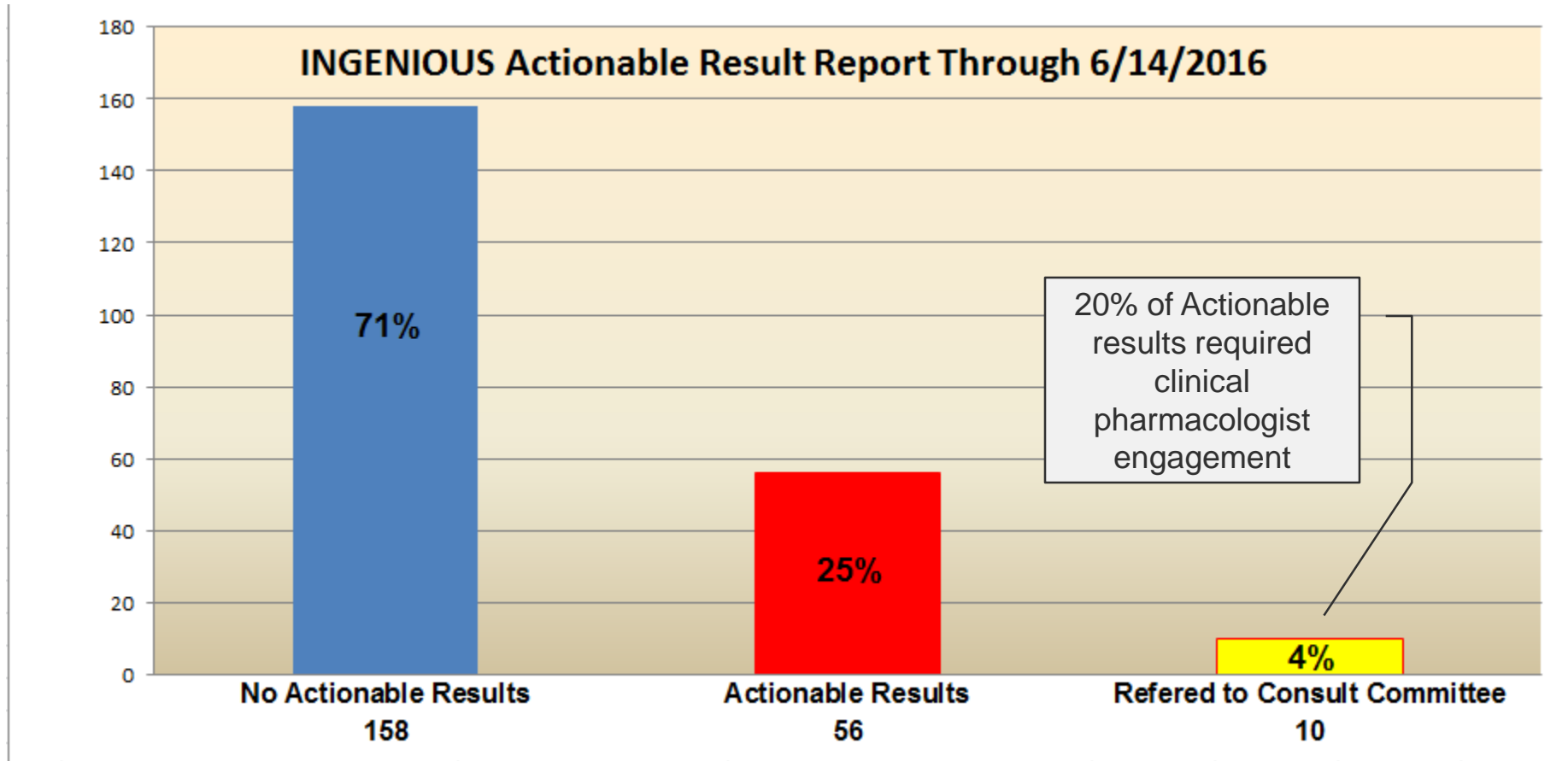
These are the researchers leading this study.



Indiana University Health

INGENIOUS Actionable Results

A significant number of actionable results (recommended change in selection or dose of drug) are being reported to Eskenazi providers



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* Data from INGENIOUS Redcap Database of 214 Complete Results

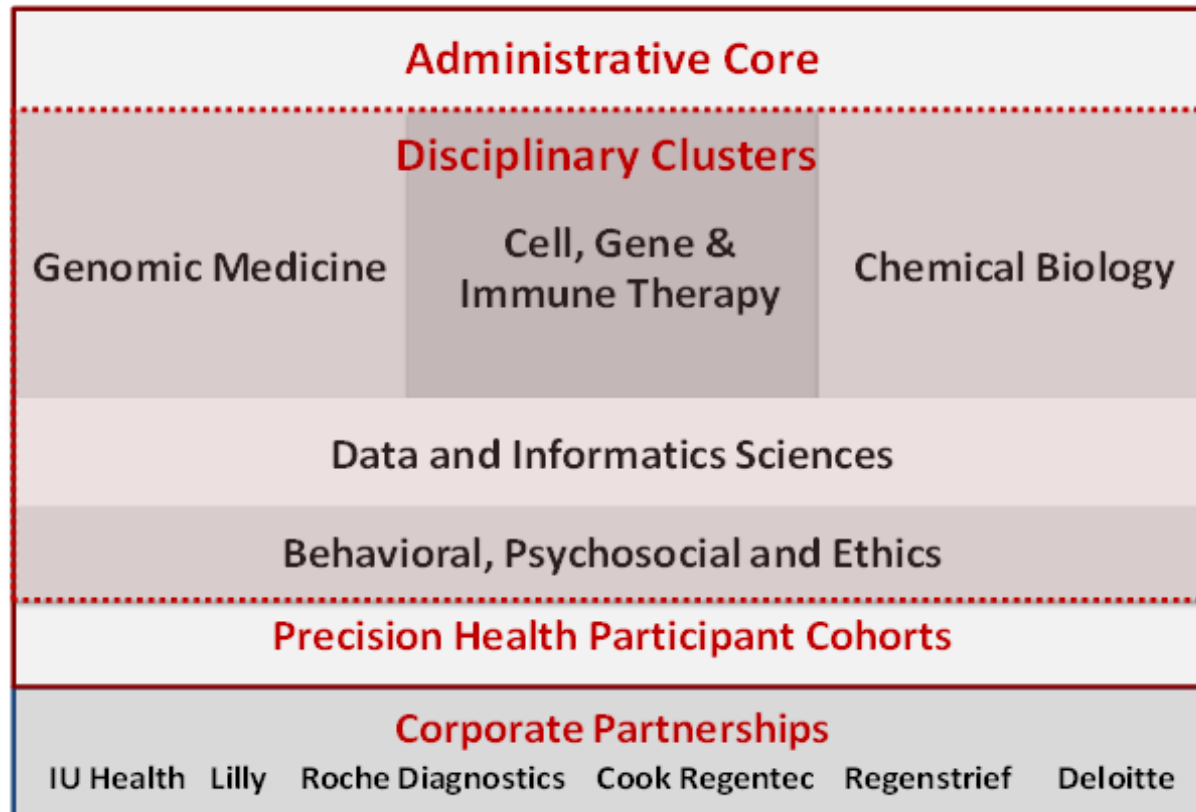
Precision Health

Understanding and optimizing the prevention, treatment and outcomes of human diseases through a more precise definition of the genetic, developmental, behavioral, and environmental factors that contribute to an individual's health.

Precision Health Initiative – Grand Challenge



Precision Health Initiative



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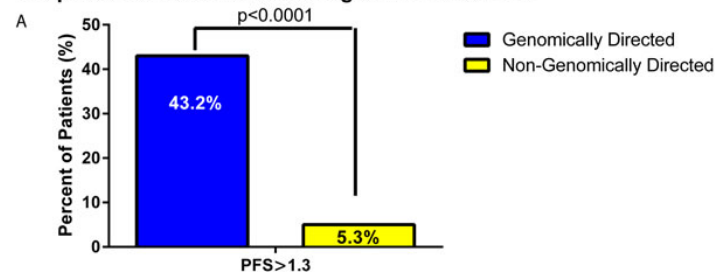
Impactful Clinical Programs in Cancer

- **Precision Genomics Clinic for Cancer** –

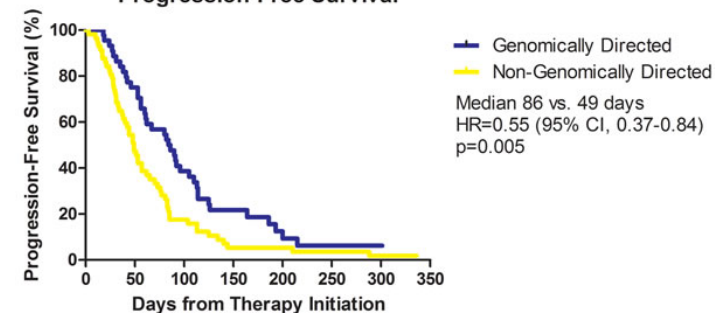
Provides referral opportunities for patient care and consultation to providers who are treating cancer patient who would like to have genetic sequencing of their tumor done to tailor their chemotherapy.

(Radovich, Schneider , et al. 2016)

Proportion of Patients Achieving a PFS Ratio > 1.3



Progression-Free Survival



- **Pharmacogenetics for chemotherapy patients** - Significant benefit in avoiding excessive adverse effects such as neuropathies with vincristine and paclitaxel etc.
- **Car-T cell therapies** - Provides opportunities for cell therapies for cancers