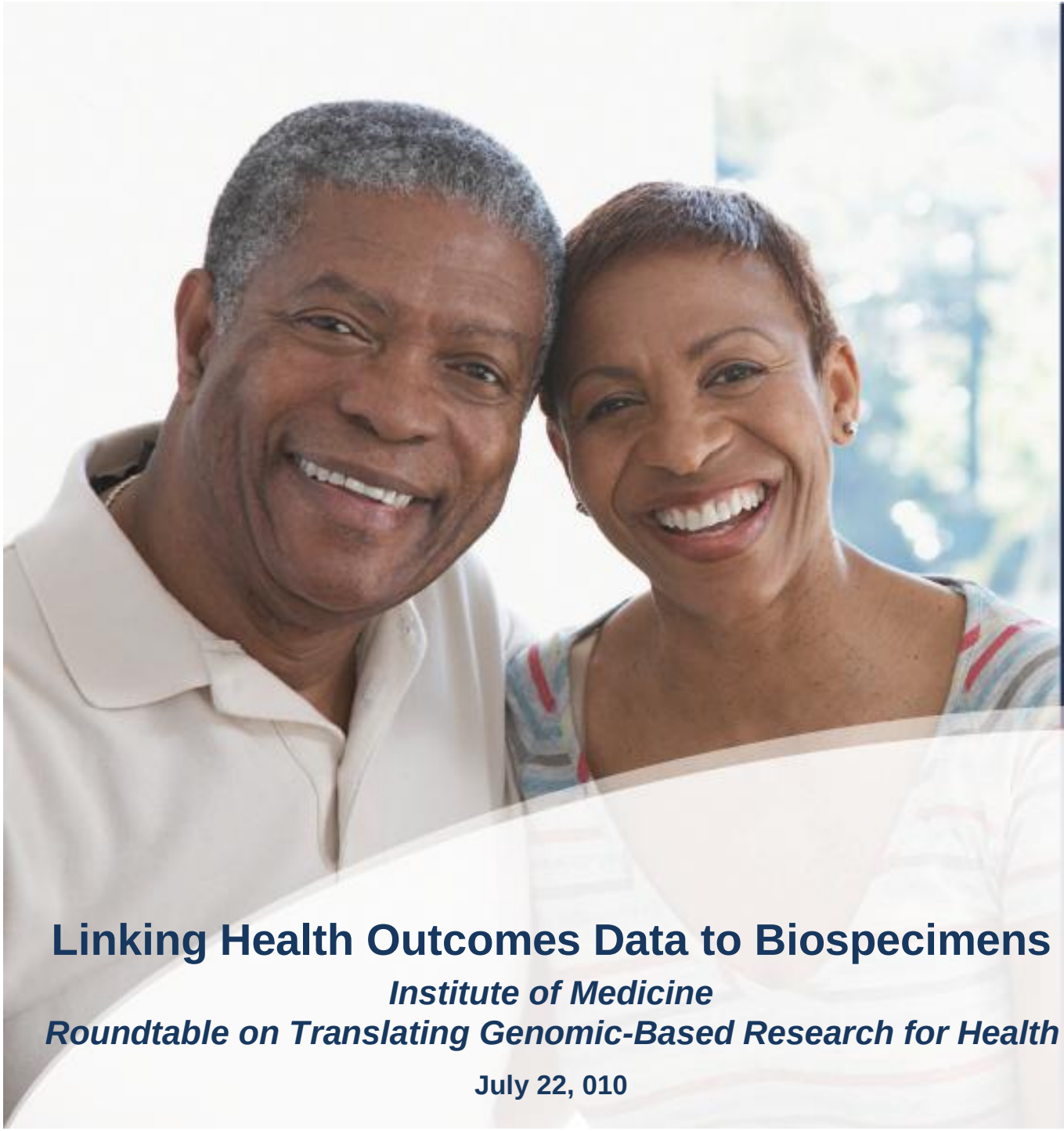


Fairbanks Institute for Healthy Communities

FAIRBANKS INSTITUTE
SCIENCE FOR HEALTHY COMMUNITIES

Linking Health Outcomes Data to Biospecimens

Institute of Medicine

Roundtable on Translating Genomic-Based Research for Health

July 22, 010

Helping Your Community Stay Healthy.

Presentation Outline

- Obstacles to biospecimen access and utilization
- The Fairbanks Institute's Vision
- Making the vision operational
- The Institute's first two longitudinal studies
- How INbank™ facilitates discovery and validation research
- Future plans

Obstacles to Biospecimen Access and Utilization

"From drug development to assisted reproduction, progress in dozens of fields would be impossible without biobanks. They are the biological back end of data-driven medicine. " *Wired, May 24, 2010*

- Biospecimens may not be available
- Quality may be highly variable
- Phenotypic data may be incomplete
- Access may be restricted
- Longitudinal biospecimens may not be available
- Outcomes data for the biospecimen may not be available
- The biospecimens may not have been adequately consented
- Biospecimens from appropriate controls may not be available

The Vision

- In 2006, with seed funding of $10.5 MM from the Richard M. Fairbanks and Guidant Foundations , the Fairbanks Institute for Healthy Communities was founded by BioCrossroads (Indiana's life science initiative) in partnership with the Indiana University School of Medicine, the Regenstrief Institute, Inc. and other Central Indiana community partners
- The Founders' vision was to conduct a longitudinal study of Indiana's population in which biological specimens are linked with clinical outcomes data from the Indiana Network for Patient Care to create a novel and powerful research platform that would facilitate basic and translational research breakthroughs and lead to improved patient outcomes
- Further, by engaging the community as a partner in the creation of the Institute's research platform, resultant medical breakthroughs would have the potential to create a civic pride among Hoosiers, facilitating community participation in all Indiana research studies

Linking Outcomes Data to Biospecimens

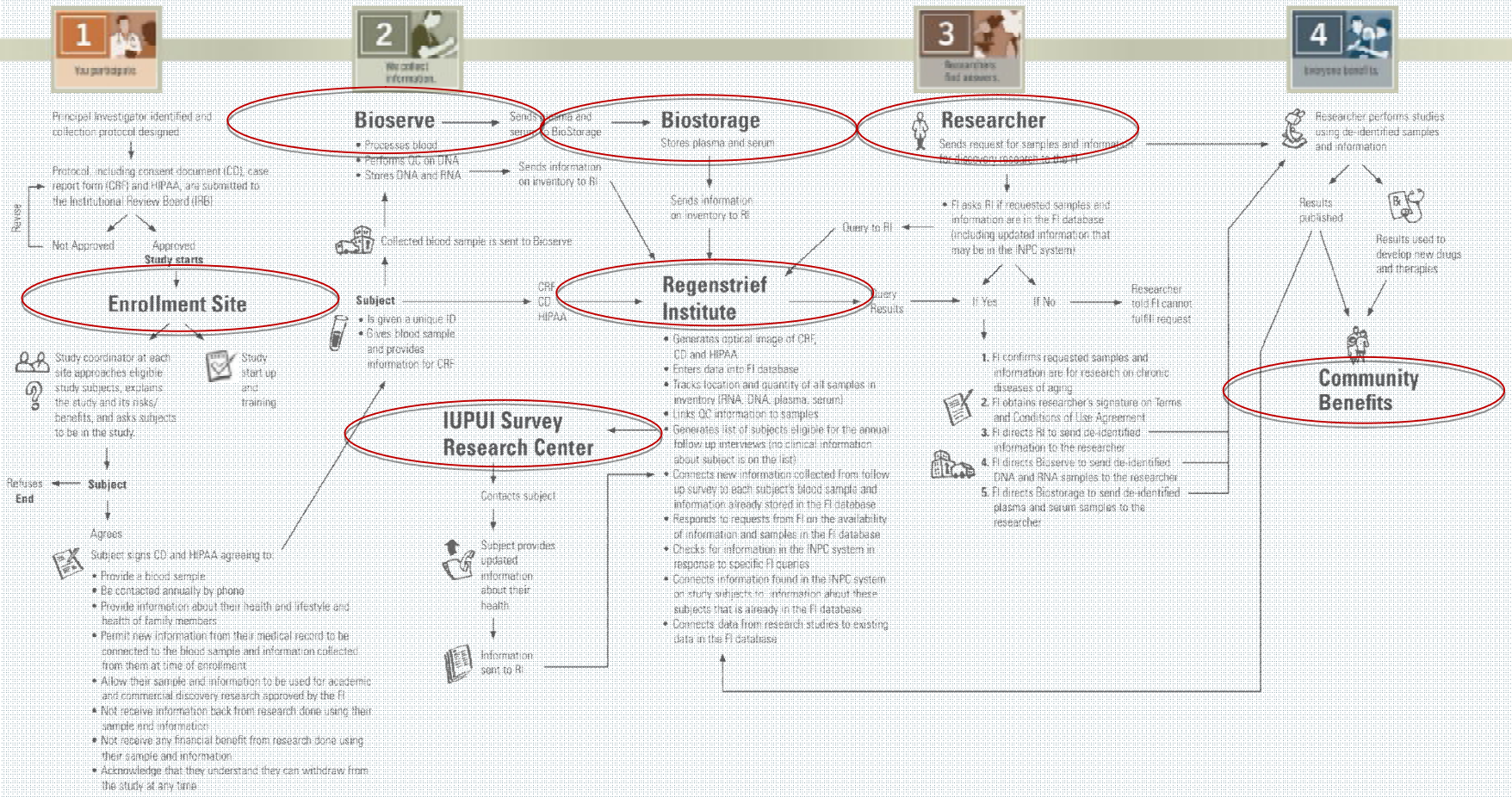
+ INPC Indiana Network For Patient Care = INbank™ Science for PERSONALIZED Medicine.

Biospecimens and data collected from a population that is stable, ethnically diverse and has high rates of age related diseases

Clinical outcomes, payor, prescription and public health data from the nation's most established, data-rich health data repository

A resource that can be queried on > 8,000 clinical, laboratory and outcome variables to select biospecimens and data for genetic, pharmacogenomic, proteomic and metabolomic research studies

Creation and Use of INbank™: The Big Picture



Coronary Artery Disease Study

Coronary Artery Disease (CAD)
1,500 participants (750 cases, 750 controls)
Actively enrolling since 6/08

- Cases must have a documented history of coronary artery disease (CAD)
- Controls must not have CAD and must not have diabetes, hypertension or abnormal lipids, nor be on medications used to treat these conditions
- Clinical information on study participants can be retrospectively and prospectively updated from information available for research purposes in the Indiana Network for Patient Care (INPC)
- Health and lifestyle information is also updated inannual telephone interviews

Type 2 Diabetes Study

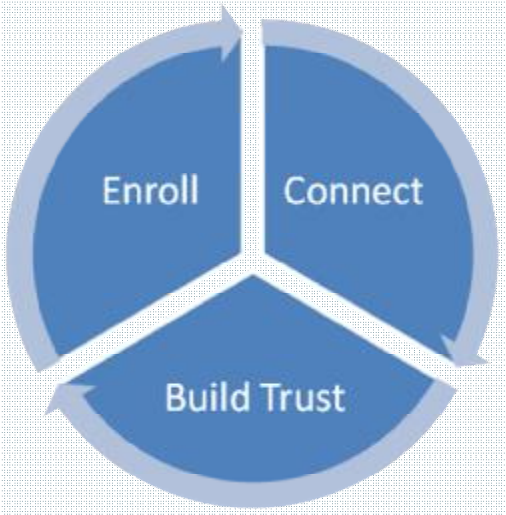
Type 2 diabetes (T2D)
1,000 participants (500 cases, 500 controls)
Actively enrolling since 10/09

- Cases must have documented type 2 diabetes as defined by the American Diabetes Association and be age 40 or older
- Controls must have a fasting blood glucose of less than 100 mg/dl and must not have hypertension, abnormal lipids, nor be on medications used to treat these conditions
- Clinical information on study participants can be retrospectively and prospectively updated from information available for research purposes in the INPC
- Additional biospecimens are collected at years 2 and 5

Engaging the Community

Ø Events and Media:
- Websites
- Flyers and brochures
- Health fairs
- Community presentations
- Community newsletters

Ø Enrollment sites:
- Hospitals
- Specialty clinics
- Primary care clinics
- Community clinics
- Dental clinics



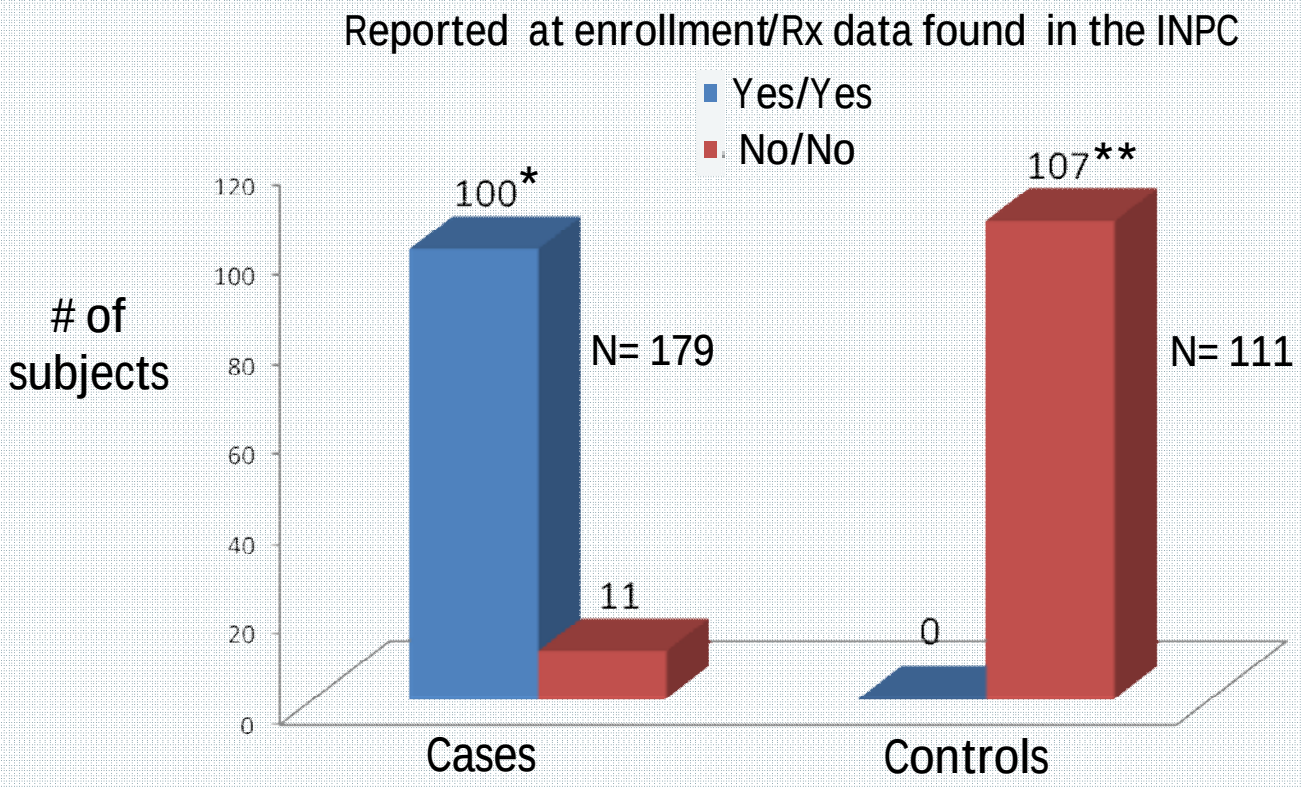
Ø Community Roundtables:
- Forum for the community and researchers to dialog
- Spotlights the community's role in research
- 20+organizations represented at first event

Ø Board:
- Founders
- Community representatives

Ø Community Partners:
- Universities
- CTSI/CHEP
- Medical groups
- Community groups

Ø Community Outreach and Engagement Committee:
- 14 community leaders representing academia, government, and community

Longitudinal Statin Use in CAD Study Subjects



* These subjects could be selected if compliance with prescribed statin therapy is important

** These subjects would make ideal controls in studies of patients on statin therapy

Overcoming Obstacles with INbank™

INbank™ was designed to facilitate discovery and validation research by linking high quality biospecimens with outcomes data

- Biospecimens and data in INbank™ are consented to allow:
  - broad based research use by academic, government and commercial researchers,
  - access to study participants' medical records to obtain additional health information
  - re-contact of study participants should additional blood samples be needed
- Data collected at enrollment can be augmented with longitudinal health data obtained via queries of a metropolitan-based EMR (Indiana Network for Patient Care) which includes:
  - clinical data from more than 40 hospitals, public health departments, laboratories, imaging centers and large group practices across Indiana
  - data gathered from commercial payors
  - medication usage data obtained from Surescrips-RxHub, LLC, the nation's largest prescribing network
- Access does not encumber intellectual property

Future Plans

- Complete enrollment in the CAD and Diabetes studies
- Continue to monitor data accrual on study participants
- Build awareness of INbank™ in the research community to drive use of INbank™ and publications that lead to advancements in patient care
- Seek partners interested in generating data that enhances the scientific value of INbank™
- Evaluate options for a third platform in cancer or neuroscience and seek a partner to help in the launch of this platform

"The breadth and depth of the phenotypic information linked to the biospecimens in INbank™ sets a new standard in biobanking."

Kevin Krenitsky, MD, President Enzo Clinical Labs

INbank™ Science for PERSONALIZED Medicine.

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