Florida Academic Cancer Center Alliance
Moffitt Cancer Center
Sylvester Comprehensive Cancer Center
UF Health Cancer Center

# The Florida Pancreas Collaborative (FPC): A Partnership Dedicated to the Early Detection and Prevention of Pancreatic Cancer

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MOFFITT CANCER CENTER    UFHealth CANCER CENTER    SYLVESTER COMPREHENSIVE CANCER CENTER UNIVERSITY OF MIAMI HEALTH SYSTEM

# utline

- ationale for studying pancreatic cancer
- oject goal, aims, design, and timeline
- chievements
- Movement towards changing state policies
- nfrastructure-building and protocol standardization
- Participant recruitment & biospecimen collection
- nterdisciplinary team building
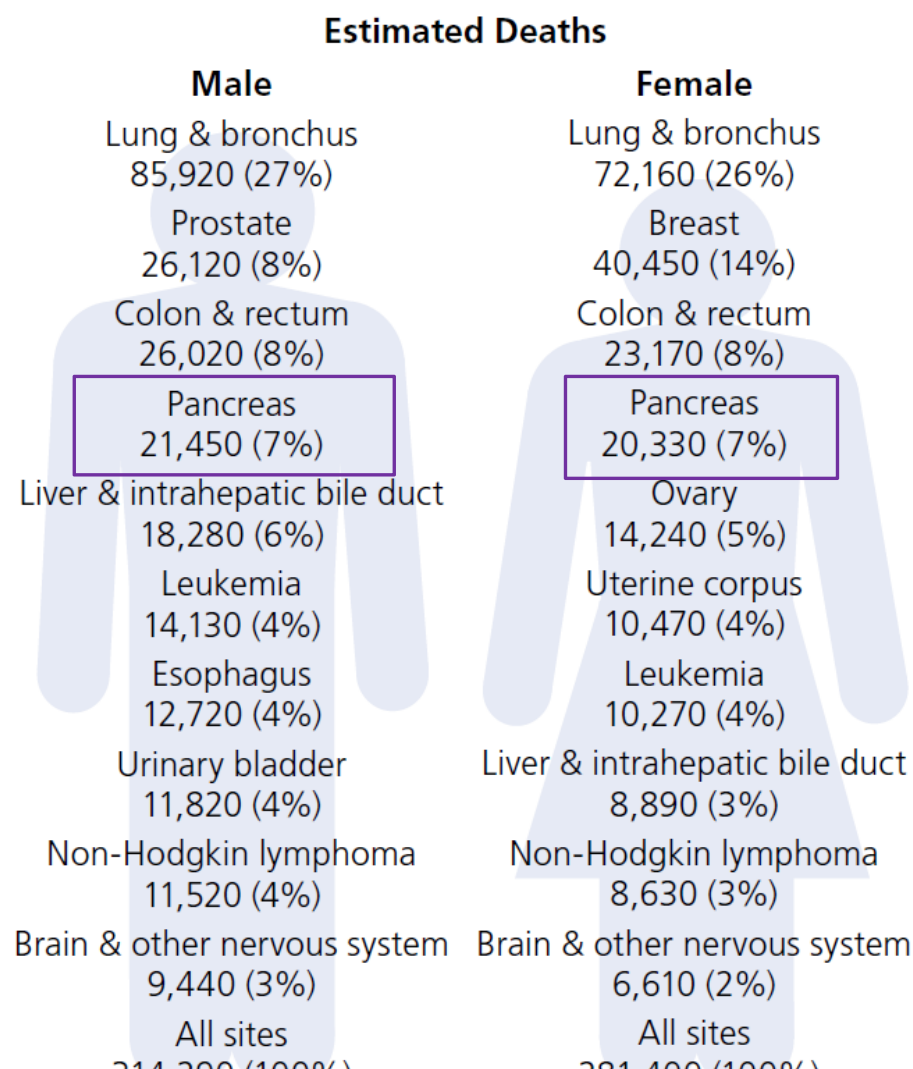- Collaborative abstracts, proposals, and publications
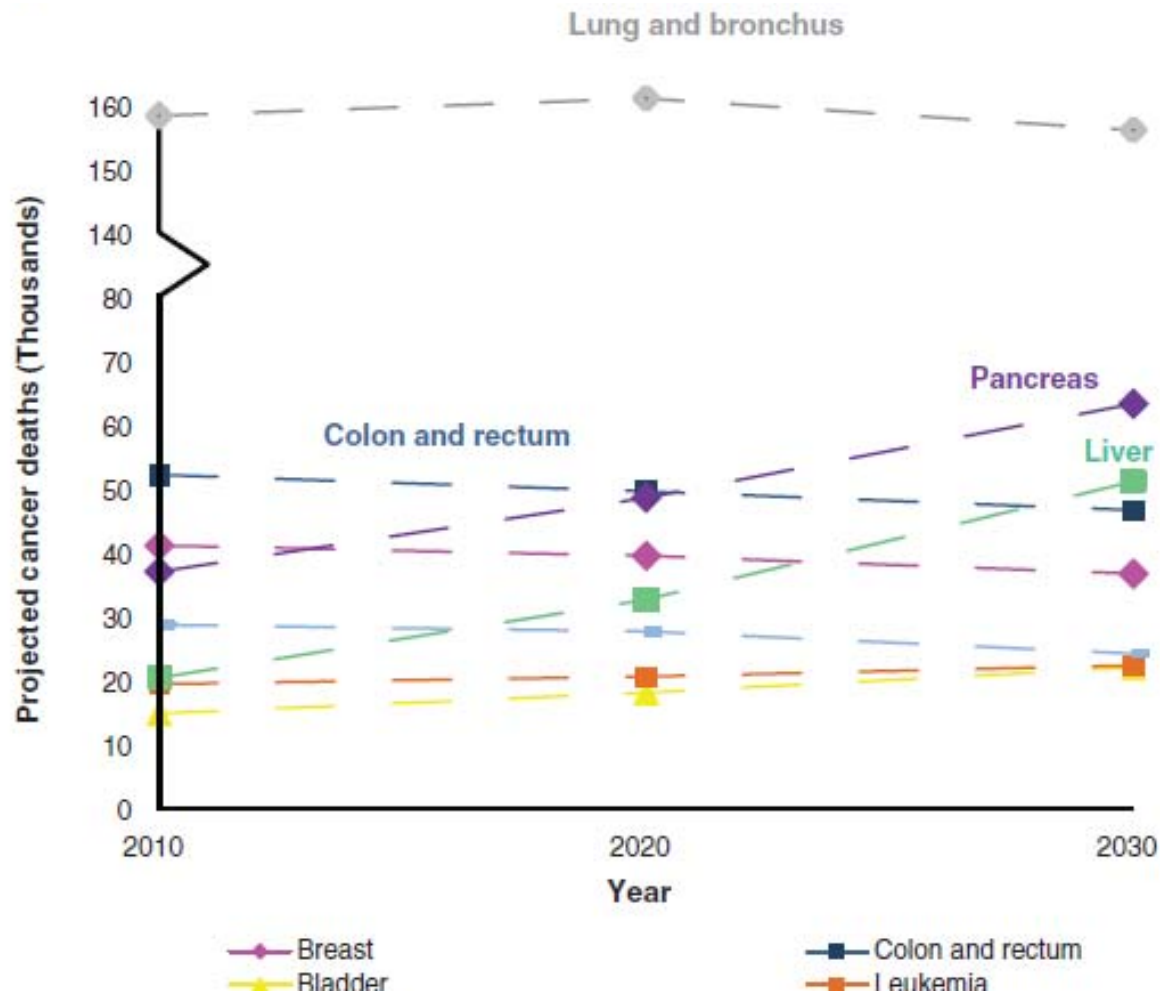- ext Steps and Future Opportunities

# STUDY RATIONALE

**Estimated Deaths**

| Male | Female |
|---|---|
| Lung & bronchus<br>85,920 (27%) | Lung & bronchus<br>72,160 (26%) |
| Prostate<br>26,120 (8%) | Breast<br>40,450 (14%) |
| Colon & rectum<br>26,020 (8%) | Colon & rectum<br>23,170 (8%) |
| Pancreas<br>21,450 (7%) | Pancreas<br>20,330 (7%) |
| Liver & intrahepatic bile duct<br>18,280 (6%) | Ovary<br>14,240 (5%) |
| Leukemia<br>14,130 (4%) | Uterine corpus<br>10,470 (4%) |
| Esophagus<br>12,720 (4%) | Leukemia<br>10,270 (4%) |
| Urinary bladder<br>11,820 (4%) | Liver & intrahepatic bile duct<br>8,890 (3%) |
| Non-Hodgkin lymphoma<br>11,520 (4%) | Non-Hodgkin lymphoma<br>8,630 (3%) |
| Brain & other nervous system<br>9,440 (3%) | Brain & other nervous system<br>6,610 (2%) |
| All sites | All sites |

# ancreatic Cancer is Projected to Become
# e **2ⁿᵈ** Leading Cancer Killer by 2020



Lung and bronchus

Projected cancer deaths (Thousands)

Pancreas

Colon and rectum

Liver

Year

— Breast                    — Colon and rectum
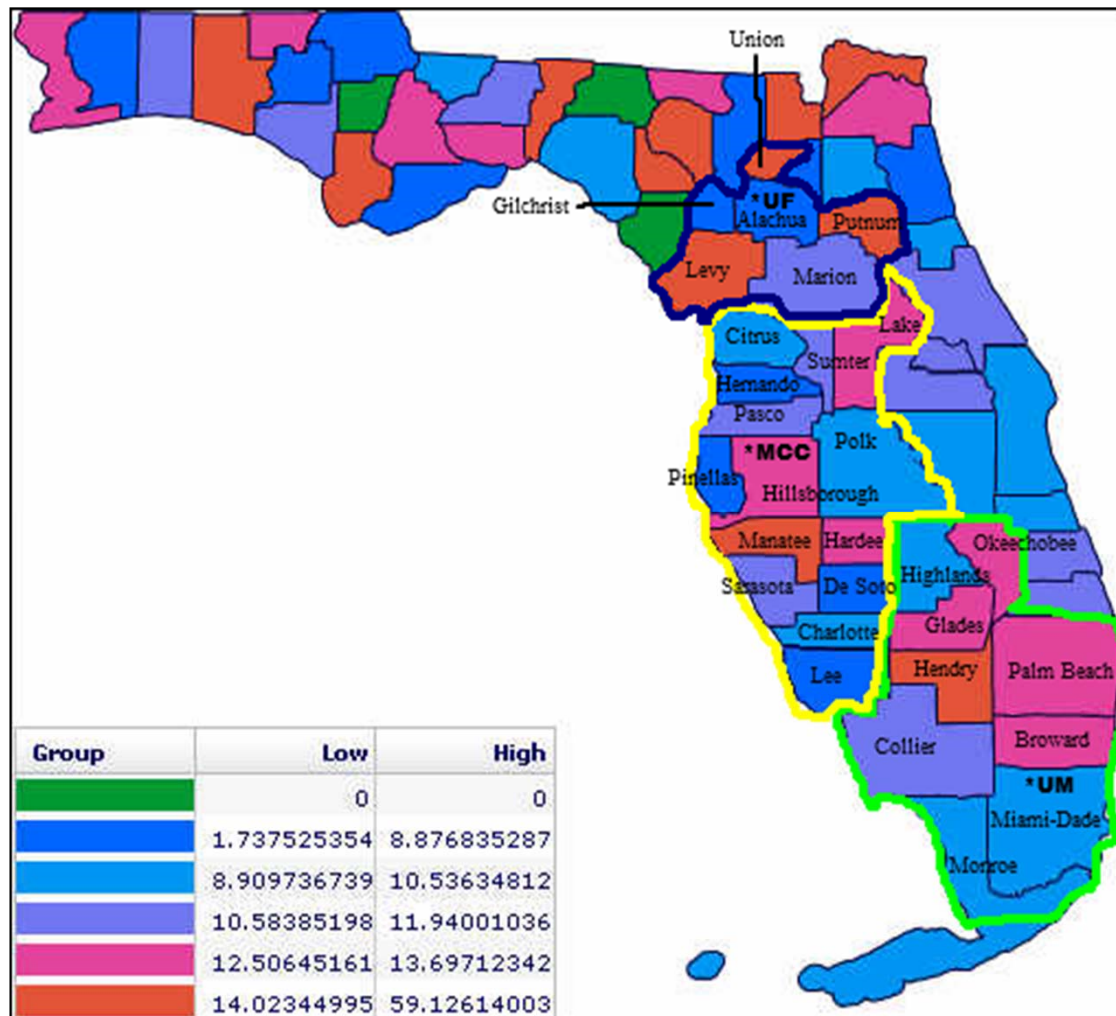— Bladder                   — Leukemia

# stimated Number of Pancreatic Cancer eaths and Death Rates, by State

| State | #<br>Deaths<br>(2016) | Death Rate*<br>Male<br>(2008-2012) | Death Rate*<br>Female<br>(2008-2012) |
|---|---|---|---|
| California | 4,390 | 11.8 | 9.3 |
| **Florida** | **3,080** | **12.1** | **9.0** |
| New York | 2,660 | 13.0 | 10.0 |
| Texas | 2,650 | 11.8 | 8.9 |
| Pennsylvania | 2,090 | 13.3 | 10.1 |
| United States | 41,780 | 12.6 | 9.6 |

*Per 100,000, age-adjusted to the 2000 US standard population

# -adjusted PC incidence rates in Florida, county (2003-2013)



| Group | | Low | High |
|---|---|---|---|
| <span style="color:green">■</span> | | 0 | 0 |
| <span style="color:blue">■</span> | | 1.737525354 | 8.876835287 |
| <span style="color:lightblue">■</span> | | 8.909736739 | 10.53634812 |
| <span style="color:slateblue">■</span> | | 10.58385198 | 11.94001036 |
| <span style="color:magenta">■</span> | | 12.50645161 | 13.69712342 |
| <span style="color:orangered">■</span> | | 14.02344995 | 59.12614003 |

# THE TIME TO INVEST IS NOW….



Academic Center Alliance → [money] → Save lives

# The urgent need for early detection and ntion strategies for pancreatic cancer (PC)

rly, operable tumors are difficult to detect.

Anatomic location of the pancreas

Symptoms occur LATE in the isease process

Jo existing biomarkers ccurately detect disease EARLY

Liver

Stomach

Bile duct

Gallbladder

Spleen

Duodenum

Small intestine

Pancreas

Colon
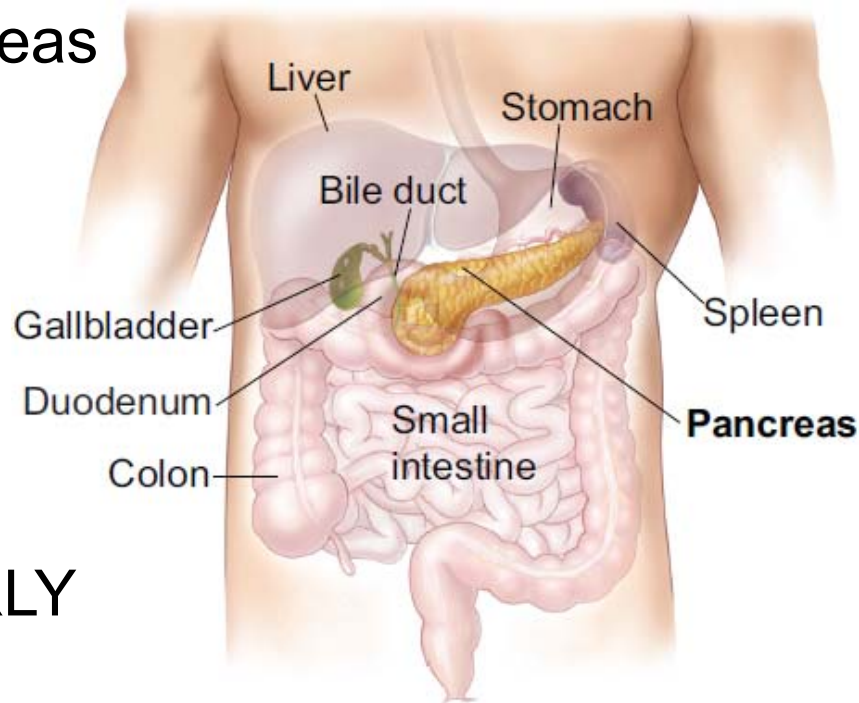
# PRIME OPPORTUNITY FOR EARLY DETECTION AND PREVENTION EFFORTS

*Precursors* to pancreatic cancer

# ee pancreatic cancer precursors exist



Normal pancreatic (duct) tissue

PanIN-1A lesion | IPMN | MCN

**Pre-cancerous pancreatic cysts**

PanIN-1B lesion | IPMN low-grade dysplasia | MCN low-grade dysplasia

IPMN=intraductal papillary mucinous neoplasms

PanIN-2 lesion | IPMN intermediate dysplasia | MCN intermediate dysplasia

MCN=mucinous cystic neoplasms

PanIN-3 lesion | IPMN high-grade dysplasia | MCN high-grade dysplasia

noninvasive

STOP   STOP

Invasive pancreatic carcinoma

# MNs

count for up to 40% of the ~150,000
ncreatic cysts detected **incidentally**
ch year in the USA.

allenging to manage due to the inability to predict:
hich lesions can be safely monitored,
hich are likely to progress to invasion, and
hich may have an associated invasive component.

verity is determined by surgery & pathologic evaluation.

nsensus guidelines exist to predict IPMN pathology
ased on standard clinical and radiologic features.
accurate for at least 30-70% of cases!

# mportant opportunities for FL

Cancer Data System (FCDS)
03-2013)

oss underestimation in # of
MN cases diagnosed and
eated in Florida each year.

w- and moderate-grade IPMNs are
n-reportable conditions.

ablish state-wide infrastructure:

ospectively identify, characterize, &
onitor incident IPMNs of *all* grades.

aluate putative risk factors for &
arkers of PC dev't & progression.



FLORIDA CANCER DATA SYSTEM Memo          4          JANUARY 2016

## Reporting Pancreatic Neoplasms

**IMPORTANT**  CLARIFICATION FOR REPORTING PANCREATIC NEOPLASMS

The classification and reporting of tumors of the pancreas can be confusing in part due to the latest terminology associated with tumors arising in the pancreas, and complicated by the mixed nature of benign, borderline, in-situ and invasive neoplasms and various histologic subtypes associated with pancreatic neo-plasms. Classification of pancreatic tumors is often rooted in the functional components of the pancreas [(neuro) endocrine or exocrine] as well as in the cellular origin and/or architecture of the tumor. And, with advancements in diagnostic imaging technology, cystic lesions of the pancreas are being detected with increased frequency, may be associated with pancreatitis, are often malignant cystic neoplasms in elderly populations, and are predic-tors of malignant potential from benign cystic neoplasms to invasive malignant tumors in general adult popula-tions. Asymptomatic tumors are usually identified incidentally on imaging for other reason.

In 2010 the World Health Organization (WHO) published the latest WHO Classification of Tumors of the Pan-creas. This latest classification includes both exocrine and (neuro)endocrine neoplasms of the pancreas with ductal adenocarcinoma still the most common and the most clinically relevant malignant tumor arising in the pancreas. Other ductal tumors [mucinous cystic neoplasms (MCN) and intraductal papillary mucinous neo-plasms (IPNM) are classified as neoplasms with various grades of dysplasia up to invasive carcinoma. High grade dysplastic tumors are now considered precursor neoplasms. A new subtype of IPNM, intraductal tubule-papillary neoplasm (ITPN), has been characterized and newly added to the IPMN group. Serous and acinar tu-mors are also classified as neoplasms with varying grades of dysplasia. Solid pseudo-papillary neoplasm (SPN) is regarded as malignant (low grade) as a matter of principle because of its inherent potential to metastasize. Se-rous cystadenomas, solid and cystic papillary (Hamoudi) tumors, lympho-epithelial cysts and simple cysts are all benign, whereas mucinous cystic neoplasms, intraductal papillary mucinous neoplasm, cystic neuroendocrine tumors, and cystadenocarcinomas are considered to be premalignant or malignant. Neuroendocrine neoplasms are characterized as Grade 1 or Grade 2 neuroendocrine tumors (NET) or high grade neuroendocrine carcinomas (NEC). Syndromatic low grade NETs are described and named according to their hormone expression pattern.

The ICD-O-3 which is published and maintained by the WHO did publish an updated in 2011 which included new terminology and new histology codes for some of these more recently characterized neoplasms. Unfortunately, the United States has not fully imple-mented all of the new histology codes included in the 2011 ICD-O-3 Update. This does not mean that ALL in-situ and invasive neoplasms of the pancreas are not reportable... they are still reportable. The NCI SEER Program has published some clarifications on the

FCDS and DOH may change
state reporting requirements

# mportant opportunities for FL (cont'd)

**1. Target a greater breadth of pancreas cases for enrollment.**

- early-and late-stage PC cases.
- IPMNs and mucinous cystic neoplasms (MCNs).
- benign conditions (chronic pancreatitis & non-mucinous pancreatic cysts).

**2. Prospectively acquire, process, and store a variety of biospecimen types longitudinally.**

- Tumor tissue, though it may be suboptimal or limited for use.
- Collect noninvasive (blood) and invasive (cyst fluid) sources of biomarkers.

**3. Recruit healthy controls without a personal history of pancreatic disease as a comparison group.**

- Companions of cases
- High-risk cohort

**4. Further evaluate promising classes of molecular makers.**

- miRNAs

# croRNAs (miRNAs) as attractive candidate markers of *early* pancreatic malignancy

gulate cancer-related
thways.

Each miRNA regulates 1000's of genes.

markably stable in tissue d biofluids

sregulated in PC vs. rmal pancreas tissue

ferentiate between IPMN ade and/or normal ncreas tissue[1,2,3,4,5]



Regulation of metabolism of cancer cells

Regulation of cell proliferation in cancer

Regulation of apoptosis of cancer cells

Regulation of genomic instability of cancer cells

MicroRNAs

Regulation of limitless replicative potential of cancer cells

Regulation of tumor invasion and metastasis

Regulation of immune responses in cancer

Regulation of angiogenesis in cancer

e 2009; [2] Park 2011; [3] Matthaei 2012;
ky 2013; [5]Permuth-Wey 2015

# Plasma MicroRNAs as Novel Biomarkers for Patients with Intraductal Papillary Mucinous Neoplasms of the Pancreas

Jennifer Permuth-Wey[1,2], Dung-Tsa Chen[3], William J. Fulp[3], Sean J. Yoder[4], Yonghong Zhang[3], Christina Georgeades[1,5], Kazim Husain[2], Barbara Ann Centeno[6], Anthony M. Magliocco[6], Domenico Coppola[6], and Mokenge Malafa[7]

## Abstract

Pancreatic ductal adenocarcinoma (PDAC) is one of the most fatal cancers worldwide, partly because methods are lacking to detect disease at an early, operable stage. Noninvasive PDAC precursors called intraductal papillary mucinous neoplasms (IPMN) exist, and strategies are needed to aid in their proper diagnosis and management. Data support the importance of miRNAs in the progression of IPMNs to malignancy, and we hypothesized that miRNAs may be shed from IPMN tissues and detected in blood. Our primary goals were to measure the abundance of miRNAs in archived preoperative plasma from individuals with pathologically confirmed IPMNs and healthy controls and discover plasma miRNAs that distinguish between IPMN patients and controls and between "malignant" and "benign" IPMNs. Using novel nCounter technology to evaluate 800 miRNAs, we showed that a 30-miRNA signature distinguished 42 IPMN cases from 24 controls [area underneath the curve (AUC) = 74.4; 95% confidence interval (CI), 62.3–86.5, $P = 0.002$]. The signature contained novel miRNAs and miRNAs previously implicated in pancreatic carcinogenesis that had 2- to 4-fold higher expression in cases than controls. We also generated a 5-miRNA signature that discriminated between 21 malignant (high-grade dysplasia and invasive carcinoma) and 21 benign (low- and moderate-grade dysplasia) IPMNs (AUC = 73.2; 95% CI, 57.6–88.9, $P = 0.005$), and showed that paired plasma and tissue samples from patients with IPMNs can have distinct miRNA expression profiles. This study suggests feasibility of using new cost-effective technology to develop a miRNA-based blood test to aid in the preoperative identification of malignant IPMNs that warrant resection while sparing individuals with benign IPMNs the morbidity associated with overtreatment. *Cancer Prev Res; 8(9); 826–34. ©2015 AACR.*

## Introduction

Pancreatic ductal adenocarcinoma (PDAC) is the fourth leading cause of cancer deaths in the United States, with a 5-year survival rate of only 6% (1). Approximately 85% of cases present with metastases, which can be partly explained by a lack of accurate methods to detect disease at an early, operable stage (1). The detection and treatment of noninvasive precursor lesions

may offer the greatest hope in reducing morbidity and mortality. Three noninvasive PDAC precursor lesions (precancers) exist: pancreatic intraepithelial neoplasia (PanIN), mucinous cystic neoplasms (MCN), and intraductal papillary mucinous neoplasms (IPMN; refs. 2, 3). PanINs are microscopic lesions, whereas MCNs and IPMNs are macroscopic cysts accounting for over half of the approximately 150,000 asymptomatic pancreatic cysts detected incidentally in the general population each year by imaging (4). Once detected, endoscopic ultrasound (EUS)-guided fine needle aspirations are often performed to assess the degree of dysplasia, but imaging features and biomarkers obtained from such invasive procedures do not reliably predict disease severity preoperatively (3). Noninvasive approaches are needed to aid in IPMN management and prevent progression to malignancy.

miRNAs are biomarkers that regulate one-third of all protein-coding genes and promote carcinogenesis by regulating tumor suppressors and oncogenes or serving these functions themselves (5). miRNAs are excellent candidate biomarkers of early disease because of their tissue-specific expression patterns (5), their remarkable stability in tissue (6) and biofluids (7) due to their small size and protection from endogenous RNase activity, and their ability to regulate hundreds of genes and biologic pathways (5). Recent studies by our group (8) and others (9–11) have evaluated genome-wide miRNA expression in IPMN tissue, and provide data to suggest that key miRNAs may reliably differentiate low-risk/benign IPMNs (i.e., low- and moderate-grade) that can

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**Note:** Supplementary data for this article are available at Cancer Prevention Research Online (http://cancerprevres.aacrjournals.org/).

**Corresponding Author:** Jennifer Permuth-Wey, Departments of Cancer Epidemiology and Gastrointestinal Oncology, Moffitt Cancer Center and Research Institute, 12902 Magnolia Drive (MRC-CAN-CONT), Tampa, FL 33612. Phone: 813-745-5744; Fax: 813-745-6525; E-mail: jenny.wey@moffitt.org

doi: 10.1158/1940-6207.CAPR-15-0094
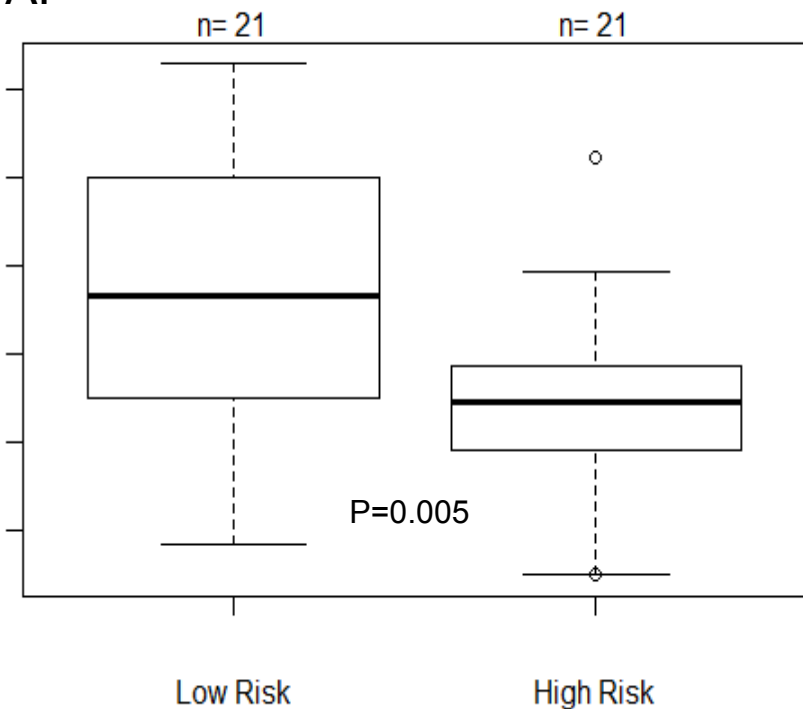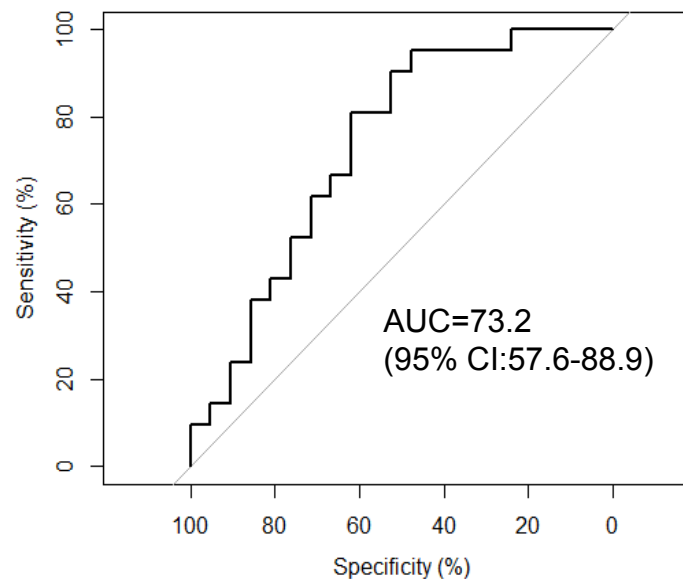
# miRNAs differentiated between low-risk and high-risk IPMN cases

miR-200a-3p, miR-1185-5p, miR-33a-5p, miR-574-3p, and miR-663b

A.



B.



AUC=73.2
(95% CI:57.6-88.9)

'Cell cycle' and Wnt signaling' were
among top-ranked pathways predicted

# PROJECT GOAL, AIMS, DESIGN, AND TIMELINE

# he Florida Pancreas Collaborative

The first state-wide multi-academic cancer center collaboration dedicated to conducting research on pancreatic cancer (PC) precursors (IPMNs), with the **ultimate goal** of promoting the early detection and prevention of PC.

# pecific Aims

**m 1: To establish a prospective multi-center cohort ~100 Floridians newly-diagnosed with IPMNs and her pancreatic conditions (and healthy controls) and ild a comprehensive biorepository that complements isting single institution protocols.**

**m 2: Demonstrate that prospectively collected blood d cyst fluid can be used to evaluate the diagnostic erformance of circulating plasma and cyst fluid icroRNAs in distinguishing between 'high-sk/malignant' and 'low-risk/benign' IPMNs.**

# AIM 1

**To establish a prospective multi-center cohort of ~100 Floridians newly-diagnosed with IPMNs and other pancreatic conditions (and healthy controls) and build a comprehensive biorepository that complements existing single institution protocols.**

# RECRUITMENT EFFORTS

# ...ligibility



Kimberly Quinn
(MOF)

Amber Bouton
(UF)

Dr. Suzanne Lechner
(SCCC/UM)

...es and females 18+ who ...esent to the **GI Clinic , ...rgery, or endoscopy** at ...C, UF, or SCCC/UM with ...clinical suspicion for (or ...gnosis of) a pancreatic ...sion, mass, or cyst or ...pancreatitis based on ...ymptoms, imaging, or blood-work

...and no prior treatment)

**Approach to recruit and obtain written informed consent**

Healthy individuals 18+ without a self-reported personal history of pancreatic disease or related

# THE FLORIDA PANCREAS COLLABORATIVE
## PARTICIPATE IN PANCREATIC RESEARCH
## HELP MAKE ADVANCES POSSIBLE

Doctors and researchers at Moffitt, the University of Florida, and the University of Miami are trying to develop better ways to prevent, detect, and treat pancreatic cancer and other pancreatic conditions, and we need the help of individuals with and without pancreatic conditions.

This study seeks to discover new ways to prevent, detect, and/or treat pancreatic cancer, pancreatic cysts, and other conditions of the pancreas.

You may be able to take part in this study if:

- You are a man/woman 18 years in age or older.
- You are having an evaluation of your pancreas because of some symptoms, clinical and/or imaging findings, blood work, or because you have family history of pancreatic cancer or related conditions.
- You do not have a personal history of a pancreatic condition or symptoms, but are interested in contributing to this research.

You will not need to pay for procedures performed as part of this study (blood draws).

We are collecting contact information for people who may be interested in participating in this study. Please contact Kimberly Quinn at 813-745-1060 or FPC@Moffitt.org if you are interested in participating or want more information.

'Researchers, doctors, patients, friends, and families united in the prevention and early detection of pancreatic cancer and other conditions of the pancreas.'

MOFFITT | UFHealth | SYLVESTER

## RESPONSE CARD

...reas Collaborative: A Partnership Dedicated
...ction and Prevention of Pancreatic Cancer.

...archers at Moffitt, the University of Florida,
...y of Miami are trying to develop better ways
..., and treat pancreatic cancer, and we need
...duals affected by pancreatic conditions
...iduals without pancreatic conditions.

...es below that apply to your current situation:

...rocess of undergoing an evaluation regarding
...gs that involve my pancreas.

...diagnosed with pancreatic cancer or another
...the pancreas.

...anion/friend/family member of an individual who
...eatic condition.

...or pancreatic cancer due to my family history of

...of the boxes below to let us know if you are
...cipating in this important study.

...terested in participating in this study and would
...ormation.

...__)_____ - _____

...ould like to speak with my doctor about this
... deciding.

...interested in participating in this study and do
...e contacted about it.

...):

...y to participate/do not have time.

.../ill to participate.

...his study is relevant to me.

...e specify):_____
_____

...s form and mail/fax it to:

... Dr. Permuth
...nter

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## WHERE CAN I GET
## ADDITIONAL INFORMATION
## ON PANCREATIC CANCER?

**Pancreatic CancerAction Network**
www.pancan.org

**PANCREATIC CANCER ACTION NETWORK**
ADVANCE RESEARCH. SUPPORT PATIENTS. CREATE HOPE.

**National Cancer Institute**
www.cancer.gov/cancertopics/types/pancreatic

NATIONAL Cancer INSTITUTE

**American Cancer Society**
www.cancer.org/cancer/pancreaticcancer/index

American Cancer Society®

MOFFITT CANCER CENTER    UF Health CANCER CENTER    U SYLVESTER COMPREHENSIVE CANCER CENTER UNIVERSITY OF MIAMI HEALTH SYSTEM

For inquiries about *FPC*, lease contact us at:
FPC@moffitt.org

or

813-745-XXXX
(or toll-free at 1-800-XXX-XXXX xXXXX)

Funded by:

**The Florida Academic Cancer Center Alliance**
http://www.floridacanceralliance.com/

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# THE FLORIDA
# PANCREAS
# COLLABORATIVE

PARTICIPATE IN PANCREATIC RESEARCH
HELP MAKE ADVANCES POSSIBLE

*The Florida Pancreas Collaborative (FPC)*

*A partnership dedicated to the early detection
and prevention of pancreatic cancer*

*"Researchers, doctors, patients, and families united in
efforts to prevent, detect, and treat pancreatic cancer"*

## ...DUCTION

...laboratory technologies are available to
...important advances in the early detection,
...ention, and treatment of pancreatic cancer
...other conditions affecting the pancreas,
...ding pancreatic cysts and pancreatitis.

...eed up these research advances, it is important
...llect and study biological specimens such as
...y fluids (i.e. blood) donated by individuals with
...*without* pancreatic conditions.

...combined with information regarding age,
...r, presenting symptoms, history of medical
...itions, and other factors, knowledge gained
...such biospecimens can change the ways
...ors diagnose and treat a person's disease
...re 1).
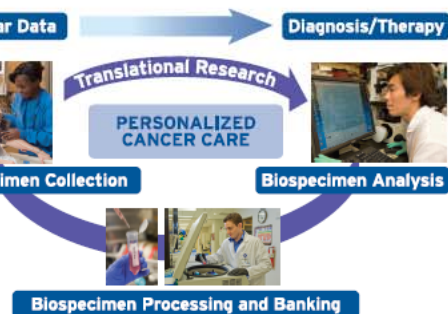


*...he critical role of biospecimens in personalized medicine.*

## ...IS THE *FLORIDA PANCREAS* ...ABORATIVE (FPC) AND WHAT ...PURPOSE?

*...FPC* is a partnership between researchers
...patients at Moffitt Cancer Center, University
...orida and University of Miami who are
...itted to:

...covering factors that may aid in the
...evention, early detection, and/or treatment
...pancreatic cancer and other conditions of
...e pancreas.

...celerating the translation of research
...vances to those affected by or at-risk for
...ncreatic conditions.

## WHY PARTICIPATE?

- Studies based on these efforts may help us:
  - understand why some people develop cancer (or pre-cancerous conditions) and some do not.
  - understand the roles of lifestyle, genetic, and environmental factors in cancer.
  - improve the medical care of those with or at risk for pancreatic conditions.
- We will contact you about other studies for which you may be eligible to participate.
- We will update you on the newest advances in pancreatic research through periodic newsletters.

## WHO CAN PARTICIPATE?

- You may be able to take part in this study if:
  - you are a male or female 18 years of age or older.
  - you are having an evaluation of your pancreas because of some symptoms, clinical and/or radiologic imaging findings, blood-work, or because you have a family history of pancreatic cancer or related conditions.
  - you do not have a personal history of a pancreatic condition or symptoms, but are interested in contributing to this research.

## WHAT IS INVOLVED IF I PARTICIPATE?

- Completion of a consent form.
- Filling out a questionnaire at an initial visit and during periodic follow-up.
- Donation of biospecimens such as blood at a time that is convenient for you. Efforts will be made to collect samples during routine procedures.
- Providing permission for the research team to contact you regarding future studies for which you may be eligible to participate.

## WHAT ARE THE BENEFITS OF PARTICIPATION?

- There may be no direct benefit to you from participation. However, the information and biospecimens you provide will be useful in learning more about the biology of pancreatic conditions.
- This new knowledge may lead to clinical testing for new ways to help people at increased risk for pancreatic cancer, as well as the discovery of new drugs for treating and preventing pancreatic conditions.

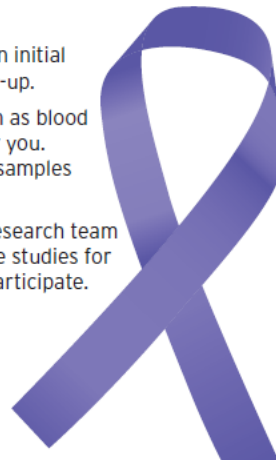## WHAT ARE THE COSTS OF PARTICIPATION?

- You will not need to pay for any procedures performed specifically for this study.
- Tests or procedures obtained as part of routine care will be your responsibility.
- Your participation is entirely voluntary. If you decide not to participate, you will not jeopardize present or future medical care or treatment.
- You may stop participation at any time.

## WHAT ABOUT MY PRIVACY?

- Data collected from this study will only be used for research purposes. Results of any tests will not become part of your medical record. Results may be published in a scientific journal, but your identity will not be released.

## WILL I KNOW THE RESULTS OF THIS IMPORTANT RESEARCH?

- If clinically useful information arises as a result of this study, we may contact you or a person whom you designate to discuss optional clinical tests or studies.
- We also plan to update you on new developments through a study newsletter.

# Recruitment database


Maria Gomez

# STANDARDIZING OPERATING PROCEDURES:

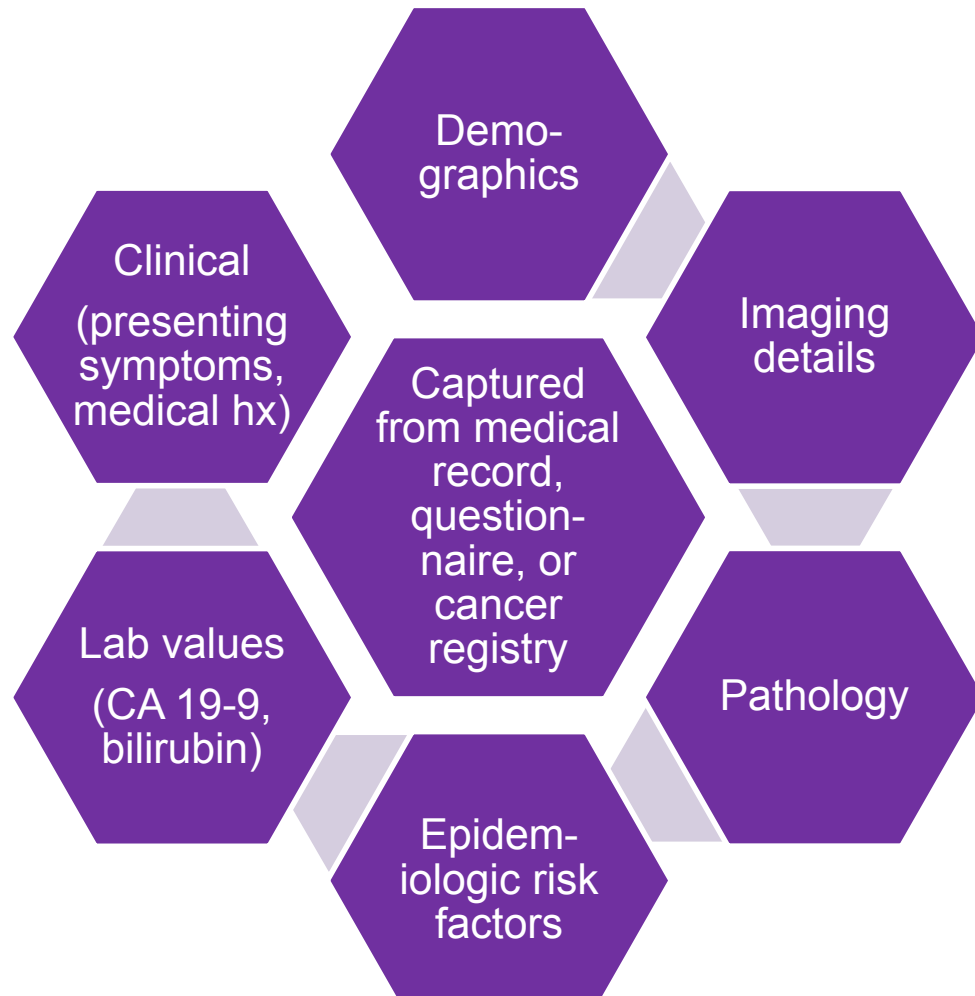Biospecimen collection/processing/ storage

Data collection/harmonization

# Florida Pancreas Collaborative Biospecimen Collection Details

| men Type volume quested) | Collect From Cases/ Controls | Timepoint (s) and Procedure(s) for Collection | Processing / Storage Information |
|---|---|---|---|
| e | Yes/No | • Residual surgical specimen (tumor & normal) | Residual tissue processed and stored according to **SOPs**. |
| 0 mL tubes; A, 1 red) | Yes/Yes | • Baseline/initial visit (via venipuncture)<br>• 4-6 wks post-surgery, if applicable<br>• If no surgery or treatment, 1 year after baseline | Process for plasma, genomic DNA, and serum using **SOPs**; aliquot into 4- 0.5 mL cryovials; store at -80° C. |
| luid ) | Yes/No | • At time of EUS-guided diagnostic biopsy and via aspiration from surgically resected | Use **SOPs**;  aliquot (8- 0.5 mL cryovials), store at -80° C. |

# Working towards a centralized data repository

Demo-graphics

Clinical (presenting symptoms, medical hx)

Imaging details

Captured from medical record, question-naire, or cancer registry

Lab values (CA 19-9, bilirubin)

Pathology

Epidem-iologic risk factors

# REDCap™

**FPC**

Save Record
Save and Continue

- My Projects
- Project Home
- Project Setup

Project status: **Development**

**Data Collection** / Edit instruments

- **Record Status Dashboard**
  - View data collection status of all records
- **Add / Edit Records**
  - Create new records or edit/view existing ones

Record ID **1**   Select other record

Data Collection Instruments:
- 🔴 **Demographics**

🔒 Lock all forms

**Applications**

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Record Locking Customization
- E-signature and Locking Mgmt
- Data Quality
- API and API Playground
- REDCap Mobile App

**Help & Information**

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your REDCap administrator.

---

Actions: | Modify instrument | Download PDF of instrument(s) ▽

⭐ VIDEO: Basic data entry

## 📄 Demographics

🖊 Editing existing Record ID **1**

| Record ID | **1** |
| --- | --- |
| | (To rename this record, modify the value immediately below.) |
| Record ID | 1 |
| Medical Record Number of Patient | 123 |
| Name of the patient | John Doe |
| Name of the institution | ⦿ Moffitt  ◯ UM  ◯ UF   reset |
| Gender | ⦿ Male  ◯ Female   reset |
| Patient's date of birth | 03-06-1963  📅  Today  M-D-Y |
| Date of diagnosis | 01-11-2016  📅  Today  M-D-Y |
| Age at diagnosis | 53   View equation |
| Hispanic or not hispanic | Hispanic ▽ |
| Race | African American ▽ |

Caucasian
African American
Hispanic
Asian
Other/Unknown

**Form Status**

| Complete? | |
| --- | --- |

**Lock this record for this form?**

If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

☐ 🔒 Lock

Save Record
Save and Continue

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# AIM 2

**Demonstrate that prospectively collected blood and cyst fluid can be used to evaluate the diagnostic performance of circulating plasma and cyst fluid microRNAs in distinguishing between 'high-risk/malignant' and 'low-risk/benign' IPMNs.**
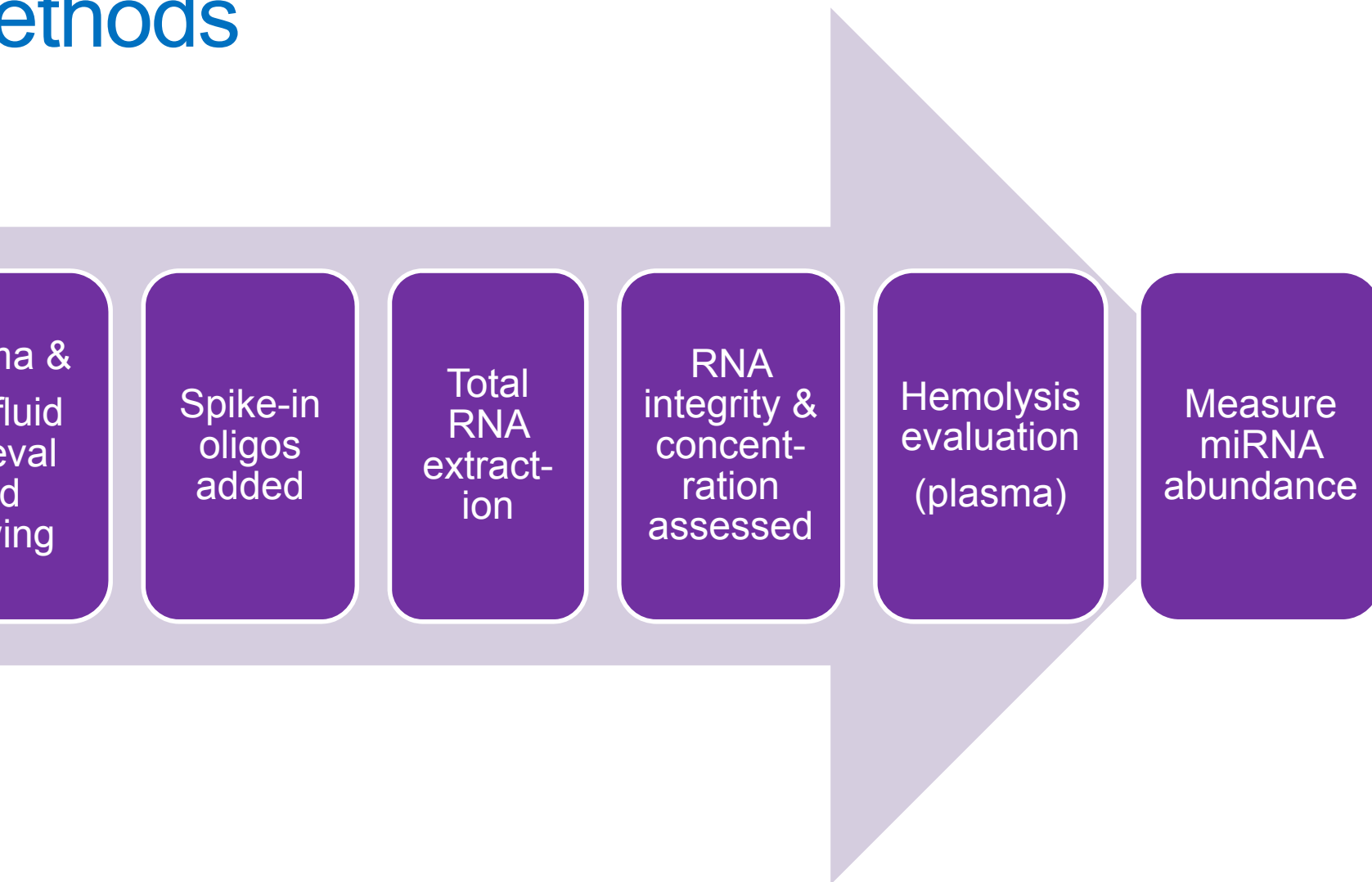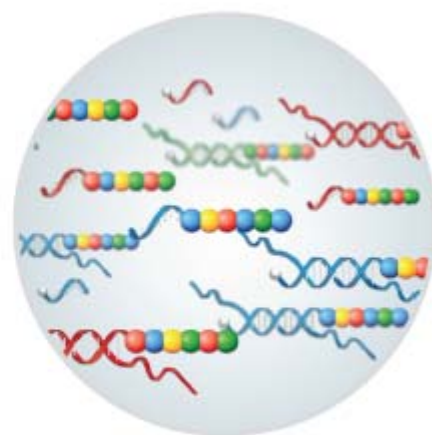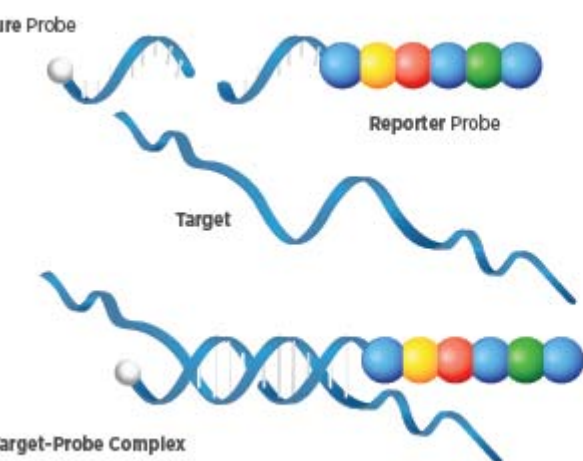
# tudy population

60 incident cases of surgically-resected, pathologically confirmed IPMNs

- 40 high-risk; 20 low-risk
- Recruited in Aim 1 (~20 from each institution).
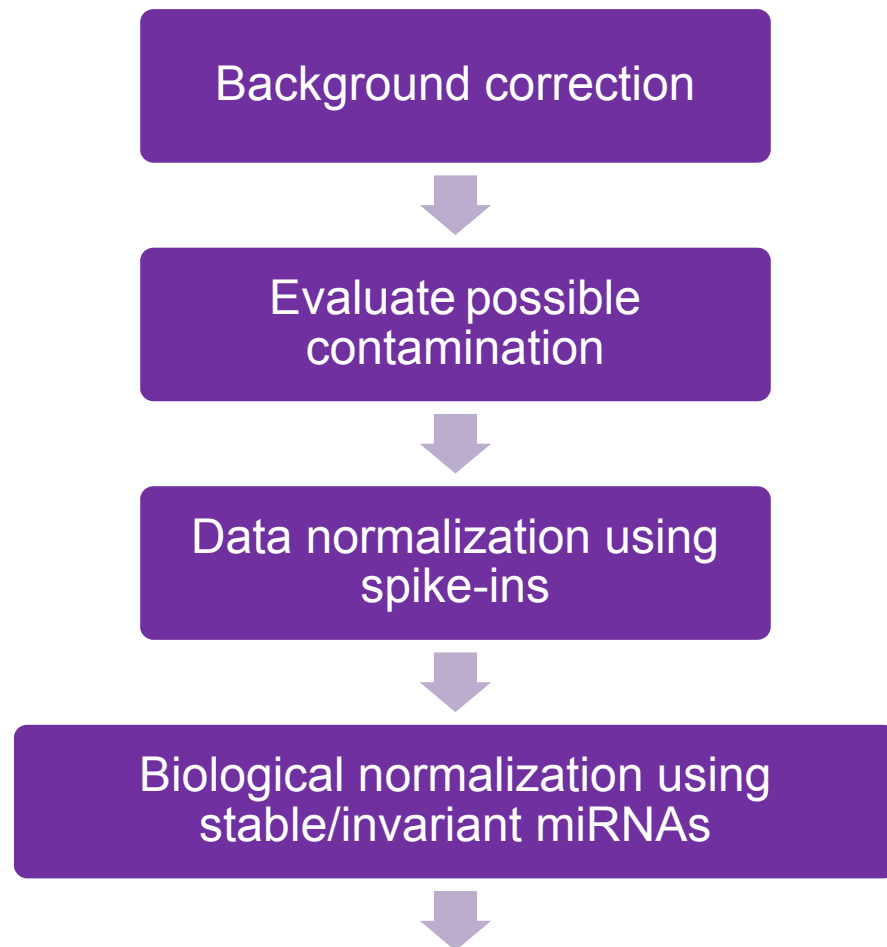- Banked pre-operative plasma and cyst fluid.

# anostring's nCounter Human v3 miRNA xpression Assay Codeset



solution phase hybridization

| Barcode | Counts | Identity |
|---------|--------|----------|
| | 3 | XLSA |
| | 2 | FOX5 |
| | 1 | INSULIN |

eset contains: 800 human miRNAs (including the 5 candidate miRNAs);
          6 positive controls; 8 negative controls;
          5 human mRNA housekeeping genes

roducibility and cross-site validation
Subset of 10 samples (plasma & cyst fluid) will be evaluated at all
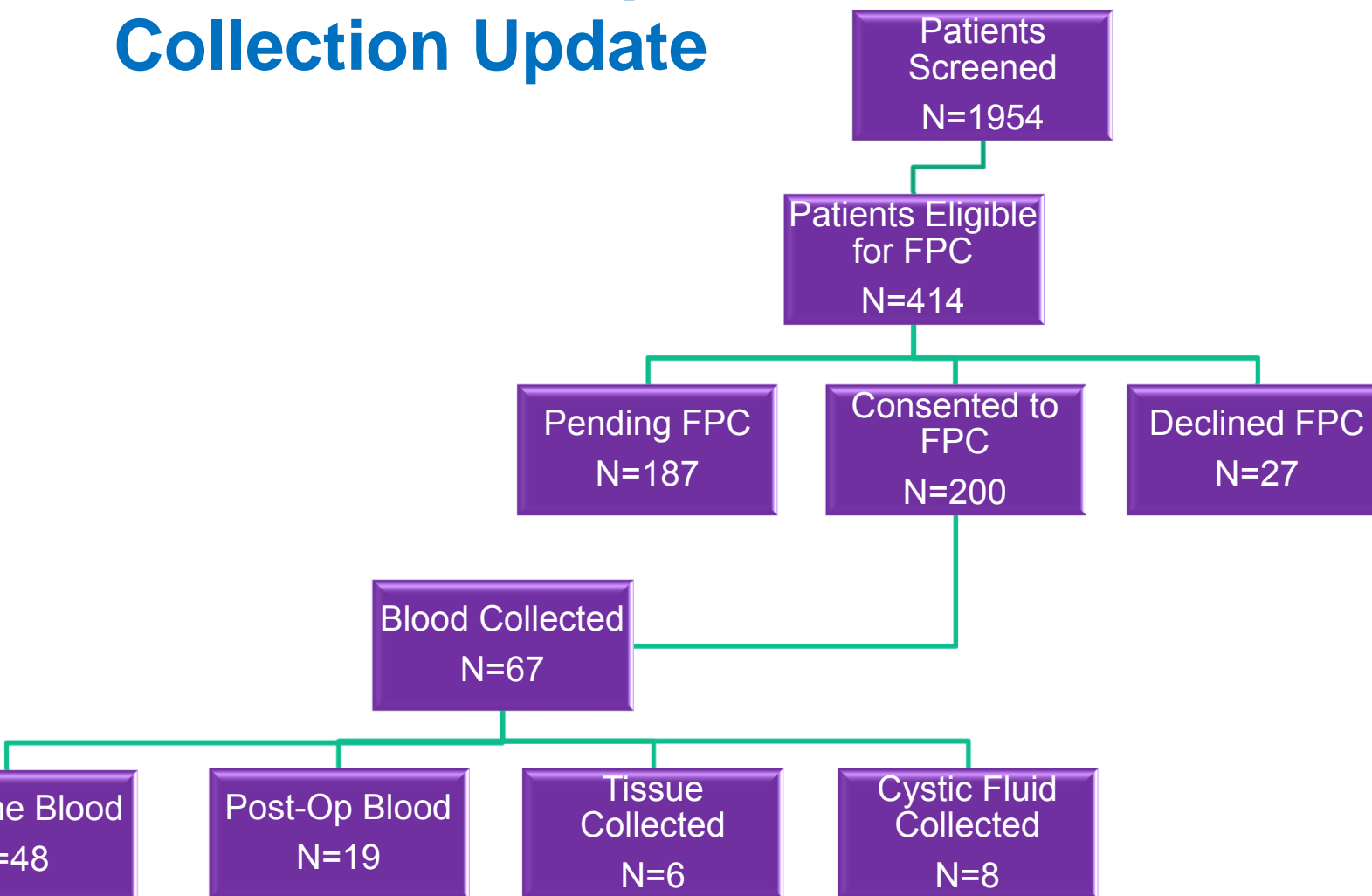hree sites.

# ata Processing, QC, and Analysis

Background correction

↓

Evaluate possible contamination

↓

Data normalization using spike-ins

↓

Biological normalization using stable/invariant miRNAs

↓

Linear models for microarray data (LIMMA) and principal component
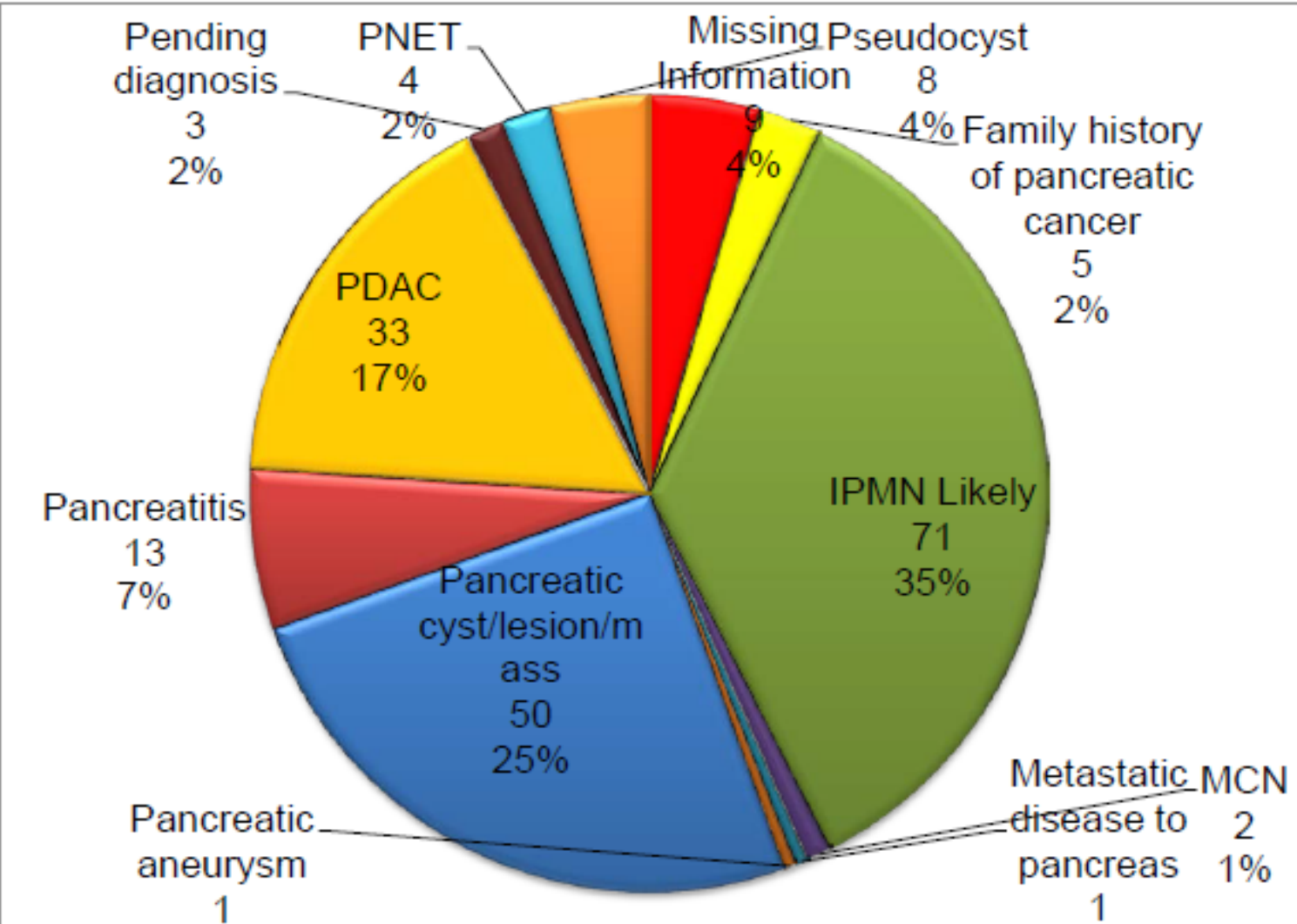
# roposed Timeline

| th(s) | 1-2 (Sept/ Oct 15) | 3-4 (Nov/ Dec 15) | 5-6 (Jan/ Feb 16) | 7-8 (Mar/ Apr 16) | 9-10 (May/ Jun16) | 11-12 (Jul/ Aug16) |
|---|---|---|---|---|---|---|
| k | | | | | | |
| alize Ps* | X | X | | | | |
| ruitment* | X | X | X | X | X | X |
| A raction ** 2) | | | | | X | X |
| NA filing 2) | | | | | X | X |
| istical lysis | | | | | | X |

# cruitment and Biospecimen Collection Update

**Patients Screened**
N=1954

**Patients Eligible for FPC**
N=414

**Pending FPC**
N=187

**Consented to FPC**
N=200

**Declined FPC**
N=27

**Blood Collected**
N=67

**...e Blood**
...=48

**Post-Op Blood**
N=19

**Tissue Collected**
N=6

**Cystic Fluid Collected**
N=8

# Preliminary Diagnosis of Participants (N=200)

# Preliminary Diagnosis of Participants with Baseline Blood Collected (N= 48)



Pie chart showing:
- IPMN Likely 17, 36%
- PDAC 10, 21%
- PNET 3, 6%
- Pseudocyst 4, 8%
- Pancreatitis 3, 6%
- Pancreatic cyst/lesion/mass/nodule 8
- Pancreatic aneurysm 1
- MCN 1, 2%
- Metastatic disease to pancreas 1, 2%
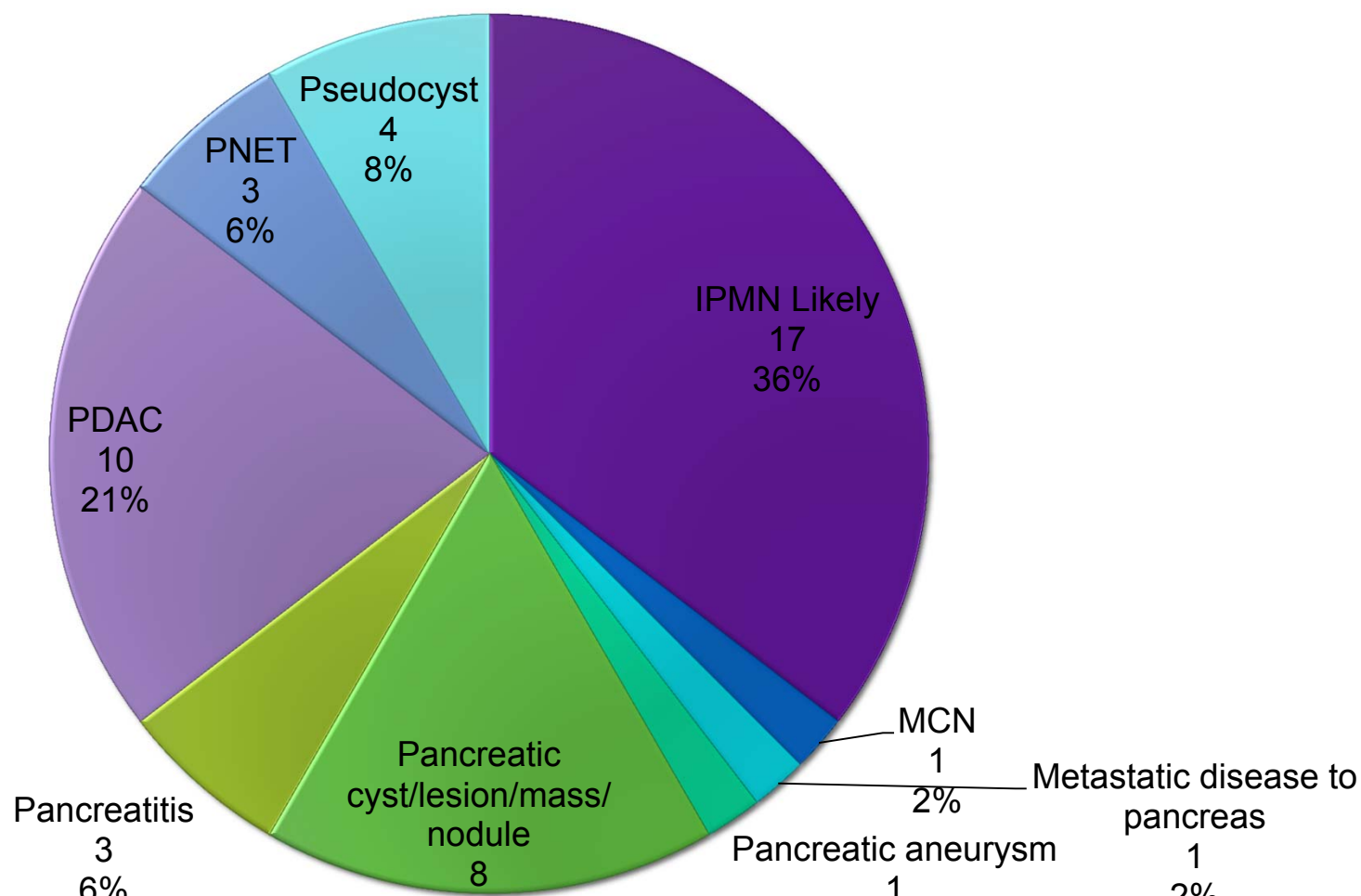
# Pathology of participants who have undergone surgery (N=27)



- Autoimmune Pancreatitis — 2 — 7%
- IPMN — 6 — 22%
- MCN — 1 — 4%
- PDAC — 8 — 30%
- Report pending — 4 — 15%
- PNET — 2 — 7%
- Pseudocyst — 4 — 15%
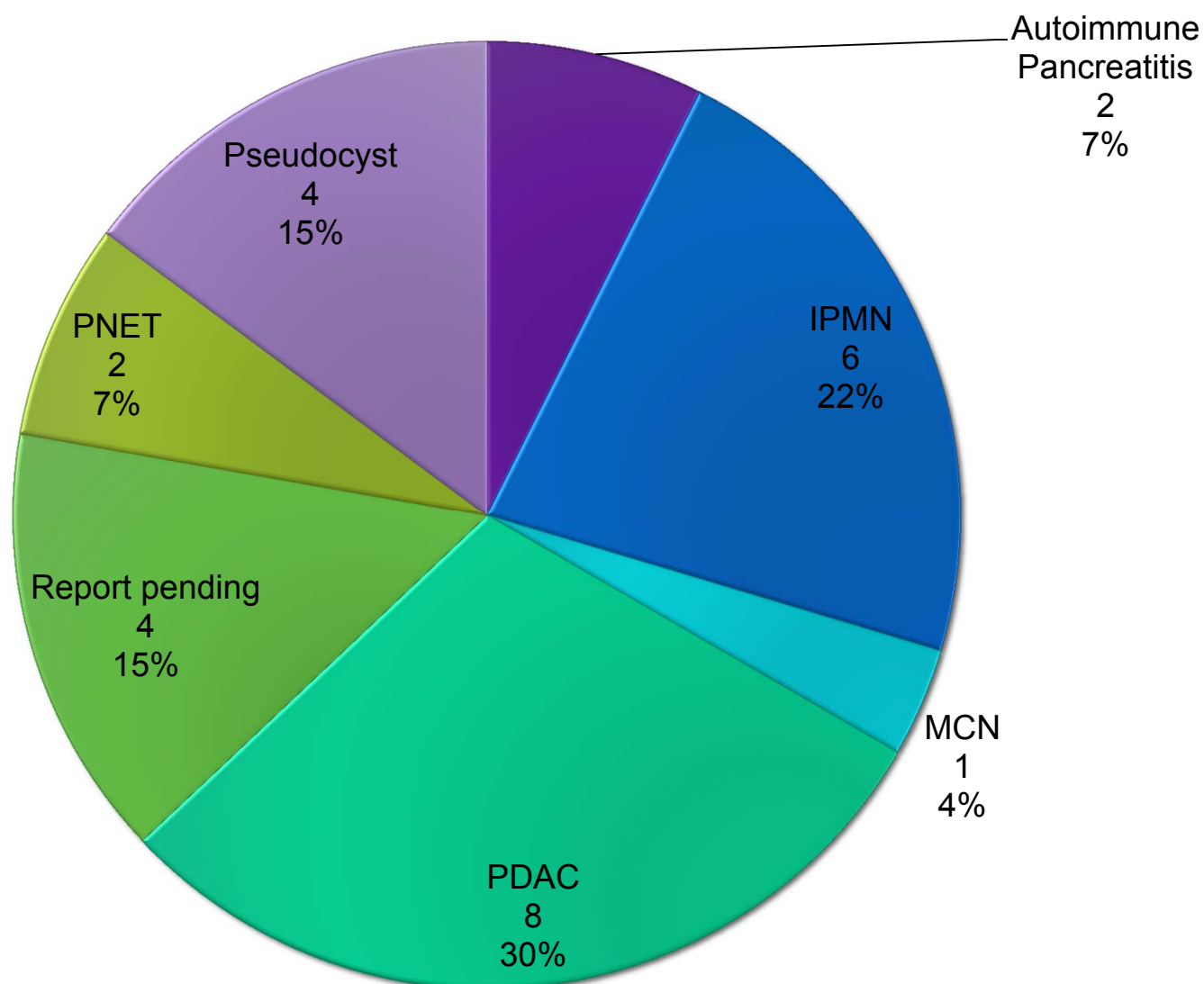
# TEAM SCIENCE

# Building an Interdisciplinary Team

*...emiology &Genetics*    *Surgery*    *Oncology*    *Biostatistics*
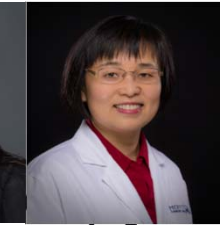
Wang    Malafa    Hodul    Merchant    Trevino    Springett    Chen    Kim

*...scopy*    *Immunology*        *IT/ Bioinformatics*
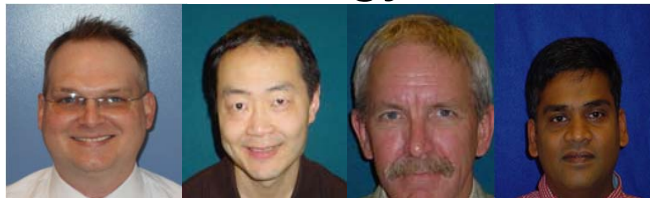
Harris    Abate-Daga        Rivera    Carvajal   G-Calderon
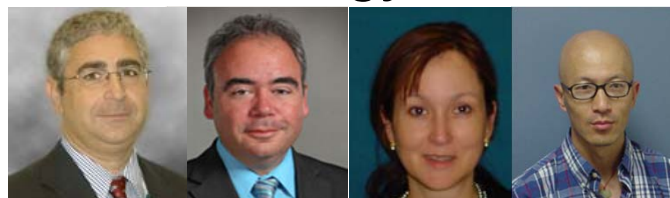
*Radiology*        *Pathology*

# Partnering with Patient Advocates

Pushing clinically-relevant, impactful science forward…

# ong-term goal

Develop a clinical decision-making tool that has dded diagnostic value in predicting IPMN athology beyond that provided by standard adiologic and clinical characteristics.

non-invasive
cost-effective
eliable
objective
can easily be
ntegrated clinically

Radiomic features

miRNA expression

Clinical data/radiologic features
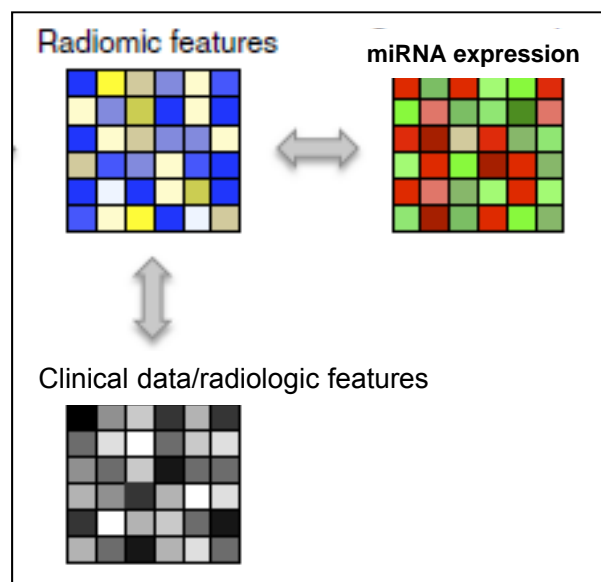
**Low-risk IPMN**
(low- or moderate grade)
**Surveillance**

**High-risk IPMN**
(high-grade or invasive)
**Surgery**

# Abstracts, Proposals, Publications

| hat | Where |
|---|---|
| bstract (ral presentation) | American Association for Cancer Research (AACR)-Japan Joint Conference (Feb 2016) |
| bstract (oster presentation) | AACR Annual Meeting (April 2016) |
| roposal | NCI (R21) (Submitted Oct 2015) |
| roposal | American Cancer Society Research Scholars Grant (Submitted Nov 2015) |
| roposal | NCI (R01 resubmission) (To be submitted March 2016) |
| ublication | under review, *Radiology* |
| ublication | published on-line, *Future Oncology* |

# Partnering to advance early detection and prevention efforts for pancreatic cancer: the Florida Pancreas Collaborative
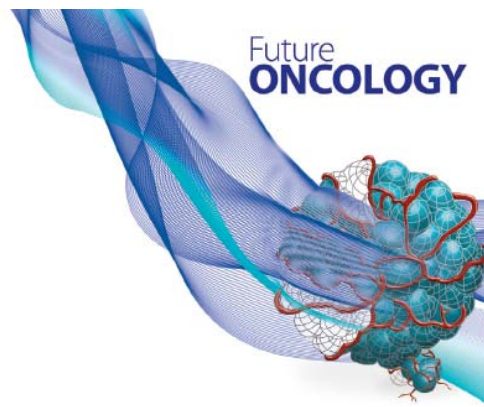
Jennifer B Permuth*[1,2], Jose Trevino[3], Nipun Merchant[4] & Mokenge Malafa[2];
on behalf of the Florida Pancreas Collaborative

## Team science as a necessity for making advancements in pancreatic cancer research

"Alone we can do so little; together we can do so much." This quote by Helen Keller embodies the overarching goal of transdisciplinary team science, which is to bring together investigators, community partners and translational collaborators from various disciplines and fields to integrate concepts, theories, methods and approaches from a breadth of expertise to solve real-

and incidence and death rates, pancreatic cancer is projected to surpass breast, prostate and colorectal cancer and become the second leading cause of cancer deaths by 2020 [3]. Thus, it is critical that researchers and funding agencies invest in transdisciplinary pancreatic cancer research efforts now.

## Focusing on early detection & prevention by studying commonly detected pancreatic cancer

"...the overarching goal of transdisciplinary team science ... is to bring together investigators, community partners and translational collaborators from various disciplines and fields to integrate concepts, theories

# ext steps/ Future Opportunities

ontinued recruitment/ specimen collection (Aim 1)

art tackling Aim 2

ojects underway

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# Florida Academic
# Cancer Center Alliance

Moffitt Cancer Center
Sylvester Comprehensive Cancer Center
UF Health Cancer Center

| About | Directors | Partner Institutions | News & Events ▾ | Research ▾ |

Home  ›  Research  ›  **Florida Pancreas Collaborative**

**Florida Pancreas Collaborative**

- **Florida Pancreas Collaborative Research Team**

**Awarded Grants**

**Funding Opportunities**

## Florida Pancreas Collaborative

Among the top causes of cancer death in the United States and Florida, pancreatic cancer is the deadliest, with a 5-year relative survival rate of 7%. This dismal prognosis is primarily attributed to the lack of early detection strategies. Based on changing demographics and incidence and death rates, pancreatic cancer is projected to surpass breast, prostate, and colorectal cancer and become the *second* leading cause of cancer deaths by 2020. Coinciding with the rise in pancreatic cancer incidence and mortality has been an increase in the radiologic detection of cystic lesions of the pancreas including intraductal papillary mucinous neoplasms (IPMNs). IPMNs are the most common pancreatic cancer precursors and account for 40% of the 150,000 asymptomatic pancreatic cysts detected *incidentally* through computed tomography (CT) or magnetic resonance imaging (MRI) each year. The only way to treat these cysts and examine severity is through surgical resection and pathological evaluation.  However, pancreatic resection is associated with significant risks of morbidity (including long-term diabetes) and even mortality.

# ext steps/ Future Opportunities (cont'd)

- Renewal of FACCA award
  - Need to continue to build a strong infrastructure

- Secure extramural funding
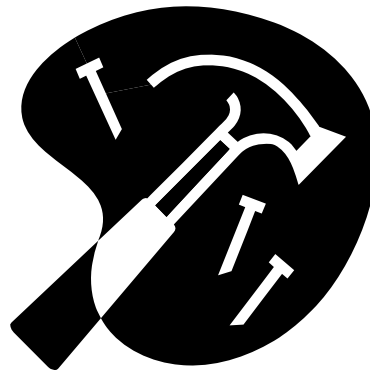
# nt opportunities

## 15-289 Pancreatic Cancer Detection Consortium (U01)

**elopment and testing of new molecular and imaging narkers** to identify patients at high risk for PC **ue to genetic factors or presence of precursor lesions**

be conducted by **multi-disciplinary** teams.

areas:

**entification and testing of biomarkers in bodily fluids for rly detection of PDAC or its precursor lesions**;

termine **which pancreatic cysts are likely to progress to ncer**; develop **molecular- and/or imaging-based approaches** screening populations at high risk of PDAC;

**nduct biomarker validation studies;**

**llect specimens longitudinally & establish a biorepository.**

**deadlines: 4/26/16; 8/21/16; 4/26/17**

# knowledgements

MOFFITT CANCER CENTER    UFHealth CANCER CENTER    SYLVESTER COMPREHENSIVE CANCER CENTER UNIVERSITY OF MIAMI HEALTH SYSTEM

**tt Cancer Center**

| | | |
|---|---|---|
| el Abate-Daga | Pamela Hodul | |
| nand Balagurunathan | Sarah Hoffe | Geoffrey Zhang |
| cca Bohinc | Kun Jiang | Sean Yoder |
| go Carvajal | Jongphil Kim | Jason Klapman |
| ara Centeno | Dung-Tsa Chen | |
| hen | Robb Lamont | **University of Miami/SCCC** |
| Choi | Kujtim Latifi | **Suzanne Lechner** |
| enico Coppola | Qian Li | **Nipun Merchant** |
| ew Doepker | Anthony Magliocco | Danny Yakoub |
| elle Fournier | **Mokenge Malafa** | |
| eth Gage | Sonia Orcutt | **University of Florida** |
| to Garcia | Steve Permuth | Amber Bouton |
| tina Georgeades | Kimberly Quinn | **Jose Trevino** |
| rt Gillies | Cynthia Harris | |
| ermo Gonzalez-Calderon | Silvana Papa | |
| Gomez | Xia Wang | |

**Florida Academic Cancer Center Alliance**