

IMAGING WORKING GROUP RECOMMENDATIONS

July 9, 2018 Early Detection Initiative meeting

Overall goal: show a stage-shift in diagnosis of pancreatic ductal adenocarcinoma (PDAC)

- Detect Stage 1 tumor (<2cm) at 75% sensitivity

Working Group charge: Guidance for Early Detection Initiative (EDI) protocol on:

- Imaging modality (CT vs MRI)
 - Specific instrument parameters
- Criteria for repeat imaging (baseline/serial)
- Clinical workup (EUS, etc)
- Follow-up on ambiguous findings in the pancreas
- Follow-up on ambiguous findings outside the pancreas

Imaging modality: Various modalities were discussed with pro's and con's relevant to the EDI study design. Research CT was identified as the most favorable initial imaging approach, followed by clinical standard-of-care, which in most cases will be by endoscopic ultrasound (EUS). MRI can be performed if CT contrast is contraindicated.

Imaging approach	Pro	Con	Relative Rank
Research CT, if positive clinical EUS	Easiest to obtain Least expensive	Negative CT may miss lesions	High
Research MRI, if positive, clinical EUS	No radiation Superior resolution More heterogeneity More pancreatic incidental findings	Cost (with equivalent sensitivity) Lesser availability More heterogeneity More pancreatic incidental findings	Low
Research CT & Research EUS	Most exhaustive sensitivity More diagnostic yield Enables comparison	Greater risk Greater cost Potential accrual problem	High
Research CT & Research MRI	Potentially higher sensitivity Non-invasive Enables comparison	May still need clinical EUS More incidental findings	Low
Research CT & Research MRI & Research EUS	Highest sensitivity Highest diagnostic performance	Highest cost Potential accrual problem	Medium

Instrument parameters: Multidetector CT

Slice: 8 slice scanner as minimum

Imaging phases:

- Pre-contrast phase (optional)
- Pancreatic protocol phase
- PV phase (required)

Delayed phase (optional)
IV contrast: 3-5 cc (with 5 cc preferred)
Slice thickness: 2.5 mm (minimum), 1 mm (preferred)
Coronal and sagittal reformations

Repeat imaging: at 6 months if first is negative

Ambiguous findings in pancreas:

Cysts
Calcifications
Other masses
Main duct dilation
Fatt pancreas
Pancreatitis
atrophy

Ambiguous findings outside pancreas:

ERADS E0-E4 grading
Standard of care follow-up



NCI/PanCAN Early Detection Initiative for Pancreatic Cancer

Kick-Off Meeting Agenda

July 9, 2018

NCI Shady Grove Campus | 2E 908

8:30am – 8:45am	Welcome from Steering Committee	<i>Lowy, Matrisian and Chari</i>
8:45am – 9:45am	Overview of New Onset Diabetes cohort study and vision for EDI	<i>Suresh Chari</i>
9:45am – 10:00am	Charge to the Committees	<i>Lynn Matrisian</i>
10:00am – 10:30am	Break Discussion	
10:30am – 12:30pm	Breakout Sessions around specific topics	<i>All participants</i>
12:30pm - 1:00pm	Lunch (on your own)	
1:00pm – 2:00pm	Additional break-out time around topics not covered	
2:00pm – 2:30pm	Committee Chairs Meet Networking for Members	
2:30pm – 4:30pm	Report-out of Committees – 20 mins each (10 min presentation, 10 min discussion)	
	Design Committee	<i>Ziding Feng</i>
	Imaging WG	<i>Walter Park</i>
	Biomarkers	<i>Anirban Maitra</i>
	Modeling WG	<i>Bechien Wu</i>
	Recruitment and Retention Committee	<i>Barbara Kenner</i>
4:30pm – 5:00pm	Wrap-up and Closing Remarks	<i>Steering Committee</i>

Committees and Break-Out Topics:

Members	Meeting Objectives/Topics
Steering Committee	
Douglas Lowy, Deputy Director, NCI Suresh Chari, Project PI, Mayo Clinic Lynn Matrisian, CSO, PanCAN	
Design Committee Room 2E 034	
Ziding Feng, MDA, Chair Steven Piantadosi, Harvard U Philip Prorok, NCI Yingqu Zhao, Fred Hutchinson William Hoos, PanCAN support	<ul style="list-style-type: none"> Overall biostatistical design <ul style="list-style-type: none"> For model validation/use For biomarker validation For stage shift
Sieves Committee/Imaging WG Room 2E 904	
Walter Park, Stanford, Chair Eric Tamm, MDA Avinash Kambadakone, MGH Eugene Koay, MDA Elliot Fishman, Johns Hopkins David Weinberg, Fox Chase, ACRIN Guillermo Marquez, NCI Cassadie Moravek, PanCAN support	<ul style="list-style-type: none"> Elements of EDI protocol <ul style="list-style-type: none"> CT vs MRI, protocol Triggers for clinical work-up and repeat imaging Ambiguous finding in pancreas Incidental findings in and outside of the pancreas How to detect a <2cm tumor for stage shift
Sieves Committee/Biomarkers WG Room 2E 032	
Anirban Maitra, MDA, Chair of WG and Sieves Committee Rosalie Sears, OHSU Brian Wolpin, Harvard U Eithne Costello-Goldring, Liverpool Mike Goggins, Johns Hopkins Sudhir Srivastava, NCI Maya Bader, PanCAN support	<ul style="list-style-type: none"> Criteria for use of retrospective samples Parameters of success for a validated biomarker Criteria for eventual incorporation into a prospective study Criteria for incorporation of additional sample collection

Members	Meeting Objectives/Topics
Sieves Committee/Modeling WG Room 2W 904	
Bechien Wu, KPSC, Chair Yu-Xiao Yang, U Penn Stephen van den Eeden, KPNC Ayush Sharma, Mayo Clinic Kevin Dodd, NCI Amy Westermann, PanCAN support	<ul style="list-style-type: none"> Criteria to determine if a model is ready to be incorporated up-front into study Elements of EDI protocol <ul style="list-style-type: none"> Follow up of H, M, L risk groups Modeling beyond baseline – reapplying at different time points Specimen collection for low risk group
Recruiting and Retention Committee Room 2E 908	
Barbara Kenner, KFRF, Chair Eva Lustigova, KPSC Allison McElvaine, ADA Richard Frank, Western Conn Gwendolyn Parker, VCU (NCORP) Worta McCaskill-Stevens, NCI Kieran Mather, IU Ashok Saluja, U Miami Donna Manross, PanCAN Support	<ul style="list-style-type: none"> Develop a strategic plan that will clarify and manage barriers of recruitment for each site and facilitate timely recruitment <ul style="list-style-type: none"> Process for contacting individuals identified by eligibility algorithm Process for contacting individuals identified by clinical model Barriers and potential solutions to recruiting – physician & staff barriers Recruitment enhancements
Core Team	
Lola Rahib, PanCAN Jo Ann Rinaudo, DCP, NCI Jackie Dahlgren, Fred Hutchinson Valerie Holzherr, PanCAN Support Emily Lyons, PanCAN operations Support	Suresh Chari (see above) Anirban Maitra (see above) Lynn Matrisian (see above) Barbara Kenner (see above) Sudhir Srivastava (see above) William Hoos (see above)
Special Guests	
Stephen James, NIDDK Steve Pandol, Cedars-Sinai Bernard Parker, NCI, NCORP Robert Martin, U Louisville	

GREY – unable to attend July 9th meeting