PanFam-1 Results

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Forward Looking Statements

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Revolutionizing blood-based diagnostics to **advance early detection of pancreatic cancer and increase patient survival rates**

Agenda

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1   PanFam-1 Study Results

2   Interpretation of results and lessons learnt

3   Way forward: Additional clinical data & reimbursement plan execution

4   Continuously advancing on strategic priorities

PanFAM-1 Study Overview

- Prospective, multi-center study opened January 2016, closed November 2021

- Observational study followed by interventional study (after interim analysis of IMMray PanCan-d performance)

- Target enrollment: 2,000 subjects
  Actual enrollment: 1,255 subjects

- Subjects underwent annual imaging and clinical evaluation consistent with study site's PDAC surveillance program

  - Imaging at least 1x per year (MRI, EUS, or CT)

  - Blood samples collected every 6 months

  - 3,457 blood samples collected

- Primary Endpoints: Sensitivity and specificity of IMMray® PanCan-d assay as compared to clinical diagnosis based on standard of care imaging assessment

Primary objective: Demonstrate that IMMray PanCan-d is equal to or better than the reference standard imaging procedures® as an aid in the early detection of potentially resectable pancreatic cancer in individuals with increased risk of developing pancreatic cancer

PanFAM-1 study results

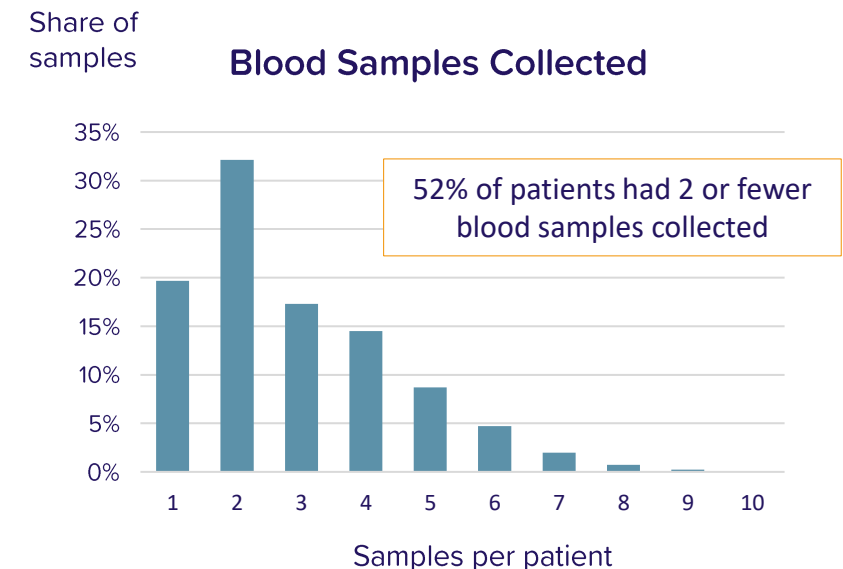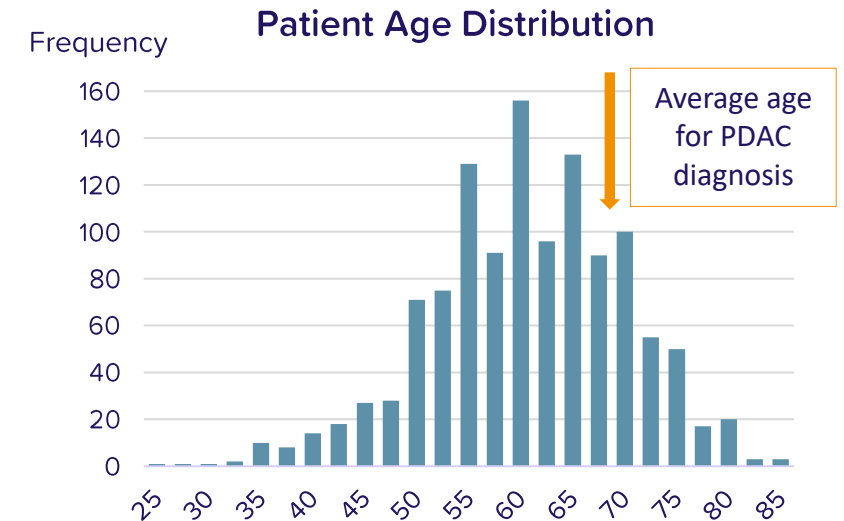|	Observed	95% Confidence Interval
Specificity	98.3%	98 – 99%
Sensitivity	66%	(broad; 2 of 3 tumors detected)

Number of tests (North American subjects): N=2,293

- Specificity of 98.3% similar to reported value in blind validation study (99%)[2]
- Insufficient PDAC diagnoses to accurately assess IMMray PanCan-d sensitivity as the confidence interval is too large
- Low PDAC incidence of 0.2% compared with estimation of 2.4% (3 of 1,255 qualified subjects developed PDAC)

1. 95% CI calculated accounting for within-subject correlations using Wilson method
2. Brand RE, Persson J, Svein Olav MD, et al. *Clin Transl Gastroenterol.* 2022;13(3):e000468.

Independent analysis performed by Biostatisticians at the Biostatistics and Epidemiology Data Analytics Center (BEDAC) at Boston University in Boston, Massachusetts

The IMMray™ PanCan-d test met its primary endpoint of specificity comparable to imaging in the study. Sensitivity however could not be evaluated due to the low number of PDACs among study participants.

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PanFAM-1 study shortfalls

- Prevalence of PDAC in familial surveillance was 0.2%, which was lower than the ~1% in other studies

- Not enough blood samples/imaging results for each patient due to site onboarding time and COVID-19

  - Study needed longer observation period to get more PDAC diagnoses in the study population

  - 52% of patients had 2 or fewer blood samples collected (full study participation over 4 years would have yielded 9 samples per patient)

  - Most participants had only 1 or 2 imaging studies to compare with IMMray PanCan-d results

- Failure to provide a quality/accuracy assessment of imaging results

Patient Age Distribution

Frequency

Average age for PDAC diagnosis

Blood Samples Collected

Share of samples

52% of patients had 2 or fewer blood samples collected

Samples per patient

Additional Findings

- The high negative predictive value (NPV >99%) of IMMray PanCan-d in a high-risk screening population is confirmed
- IMMray PanCan-d yields negative results in individuals with uncomplicated IPMNs, suggesting its utility in surveillance of individuals with cystic pancreatic lesions who are at risk for PDAC

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IMMray® PanCan-d: Blinded validation study

IMMray™ PanCan-d

Publication: **Clinical and Translational Gastroenterology 2022**

PDAC stage I-II versus familial/hereditary

586 patient samples

56 PDAC Stages I & II

111 PDAC Stages III & IV

11 EU/US sites

Specificity **99**%

Sensitivity **89**%

Validation
Blinded clinical samples

Lewis Null excluded
CA19-9 values <2.5 U/ml are Lewis Antigen Null genotype (le/le), patients don't express CA19-9

Robust clinical validation study process

Path forward to generate additional clinical data

Pioneers Physician Experience Program	Investigator-Initiated Studies	Real-world Evidence Studies	Payer Demonstration Pilots	Large Scale Clinical Trials
• 6-month program at 16 U.S. high-risk surveillance programs • No charge IMMray PanCan-d tests for patients who consent to sending imaging report to Immunovia • Generate real-world evidence comparing IMMray PanCan-d results to imaging • Opportunity to collect provider feedback on clinical utility of IMMray in medical management decision making	• Support targeted investigator-initiated studies with key opinion leaders • Example: Evaluate IMMray PanCan-d performance in patients undergoing surgery for pancreatic cysts	• Real world evidence to demonstrate clinical utility • Could be executed as retrospective database studies or a prospective registry study • Could assess a variety of endpoints (e.g., impact on clinician decisions, patient compliance with surveillance)	• Pilot to demonstrate clinical utility in a specific payer's population • Will consider a variety of endpoints (e.g., impact on clinician decisions, patient compliance with surveillance) • Discussions with payers ongoing to secure alignment on study design	• PanDIA – 6,000 prospectively-collected samples from individuals with new onset diabetes • Assessing best approach for large-scale clinical utility trials • Could initiate sponsored trials or participate in an industry consortium (e.g., Precede)

Executing reimbursement plan for US insurance coverage

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- Extensive payer insights obtained; value proposition refined (2021)

- Laboratory CAP accreditation received (Mar 2021)

- Final publication of **peer-reviewed blinded validation study** in Clinical and Translational Gastroenterology journal[1] (Feb 2021)

- Pioneers in Pancreatic Cancer physician experience program initiated (Apr 2022)

- PLA code submitted (Apr 2022)

- Head of Market Access hired (May 2022)

- Pricing recommendation for the Clinical Lab Fee Schedule (CLFS) submitted to Centers for Medicare & Medicaid Services (Jun 2022)

- PanFAM-1 study results announced. Specificity further validated. Sensitivity not assessed due to low number of PDACs (Jun 2022)

- Discussions with regional & national payers, specifically payer validation studies of IMMray to generate evidence for policy decisions (2H 2022)

- KOL and clinicians who will advocate with payers engaged (Q3 & Q4 2022)

- Contracting for payer internal validation partnerships (Q4 2022-Q2 2023)

- First commercial payer demonstration project signed (Q1 2022)

- Initial commercial reimbursement expected (Q4 2022 or 2023)

- PLA code and CLFS pricing active (Jan 2023)

2022 – Executing on strategic priorities

Clinical validation for IMMray™ PanCan-d	Commercial traction	US reimbursement plan	Expanding market access	Roadmap for discovery programs
✓Publication of peer-reviewed validation study	✓In-market execution ✓New mgmt. team to scale operations and drive growth ✓Clinician experience program ongoing	✓Experienced Head of Market Access hired ✓Executing on plan for pancreatic cancer ✓CAP Accreditation of Lab ✓PLA code application filed	✓Additional validation for more pancreatic cancer risk groups ongoing ▪ E.g., New Onset Diabetes	✓Full focus on pancreatic cancer ✓Other indications in AI and lung cancer deprioritized

Q&A

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