

# **Immunovia Corporate Presentation**

May 2020 Mats Grahn, CEO



# **Forward Looking Statements**

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**Investment Highlights & Company Overview** 

**Unmet Need For Accurate Early Detection of** 02 **Pancreatic Cancer** 03 **IMMray™** Technology Platform **Agenda** The Road To Market 04 05 **IMMray™** PanCan-d Prospective Studies 06 **Pipeline Projects Summary** 

01





# **Investment Highlights**

# First Mover Advantage With IMMray™ PanCan—d

IMMray™ Platform Technology	Proprietary Blood-Based Biomarker Platform
Significant Unmet Medical Need For Early Detection Of Pancreatic Cancer	Initial Addressable Market Size (EU/US) ~ <b>\$4.4 Bn (USD)</b>
First-To-Market Opportunity IMMray™ PanCan-d	Expected Sales Starting In Q4 2020
Prospective PDAC Clinical Studies Paving The Way For Reimbursement	Interim Analysis Early 2021
Leverageable Platform: IMMray™	Pipeline Indications: Lung Cancer & Rheumatoid Arthritis



# **Immunovia At A Glance**









- Founded In 2007 At Lund University And CREATE Health In Lund, Sweden
- IP-Rights For IMMray™ Platform Tests Transferred To Immunovia AB
- HQ & Production Facility In Lund, Sweden
- Immunovia Dx Laboratories in Lund, Sweden & Marlborough, Massachusetts, USA
- ~58 Employees as of March 31, 2020
- Listed On NASDAQ Stockholm (IMMNOV)



### Leader In Antibody Microarray Technology & Early Detection Of Cancer & **Autoimmune Diseases**

- Over 18+ Years of Research And Development
- First-To-Market Highly Accurate Test For Early Detection Of Pancreatic Cancer
- Targeting Launch Of IMMray<sup>TM</sup> PanCan-d In Q4 2020 In USA followed by Europe early 2021

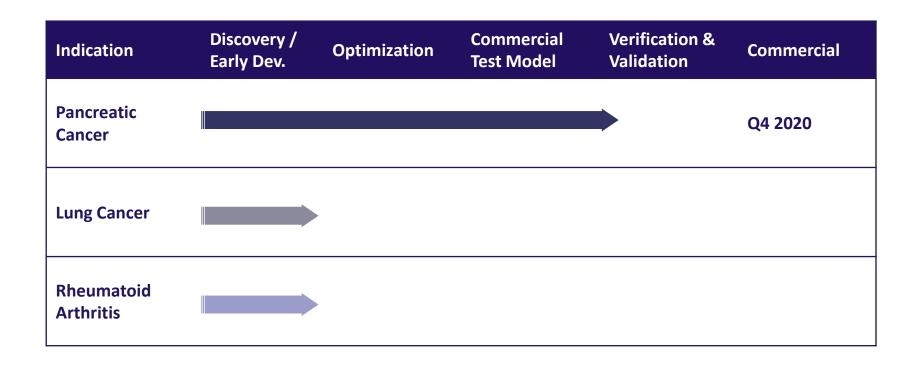


### Leverageable Platform Technology & Broad Pipeline Opportunity

- Pipeline:
  - Lung Cancer
  - **Rheumatoid Arthritis**



# Immunovia's Pipeline Projects Leveraging IMMray<sup>TM</sup>





# **Experienced Leadership** *Immunovia's Management Team*



MICHAEL PETTIGREW SVP Sales NA

- VP Sales Americas Thermo Fisher Scientific
- VP Corp Development Magellan
- VP sales GE Healthcare
- · +30 years in industry



MATS GRAHN CEO. MSc

- · CVP Marketing at Dako.
- VP Marketing at, GE Healthcare, Amersham, Pharmacia Biotech
- + 30 years in industry



ROLF EHRNSTRÖM CSO, MSc

- CSO & CVP R&D Dako.
- CSO Gyros, Amersham, Pharmacia Biotech
- +30 years in industry



HANS LILJENBORG CFO

- CFO Jolife
- CFO Vivoline
- · Owner Adays AB



LAURA CHIRICA CCO, Ph.D

- VP Sales & Mktg Euro Diagnostica AB
- Marketing Sartorious
- · Marketing Dako
- · Marketing GE Healthcare
- +20 years in industry



HANS CHRISTIAN PEDERSEN VP Business Development, Ph.D

- Director Business Development Companion diagnostics and Pharma Services, Unilabs
- Head of Companion Diagnostics and IHC reagents, Global Marketing Agilent/Dako



LOTTA BLOMGREN
Operations Director

- VP Tech. Ops Euro Diagnostica
   AR
- · Head of Supply Chain Bioglan AB
- Director Tech. Support Ferring A/S
- · Head of Process Dev. Ferring AB
- Process Dev. and Project
   Management of Astro / Pho-
- Management at Astra / Pharmacia



LINDA MELLBY VP R&D, Ph.D

- PhD Immunotechnology
- +10 years in IMMray<sup>™</sup> development and clinical studies.



PETER SCHULZ KNAPPE CTO, MD, Ph.D

- CSO Protagen. AG, Germany
- CSO Proteome Sciences Ltd, United Kingdom
- +30 years in industry

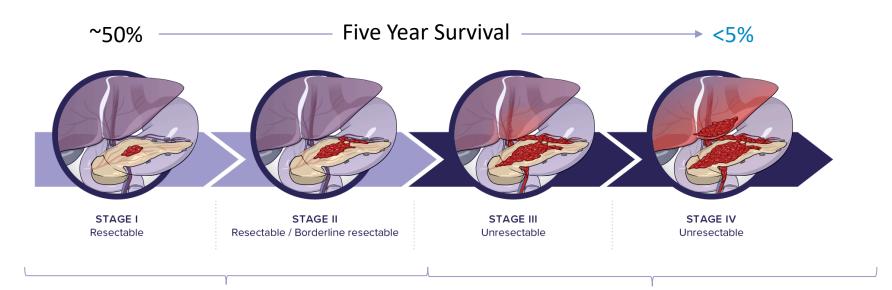
The Management Team Is Supported By An Experienced Board Of Directors And Scientific Advisory Board





# **Significant Unmet Medical Need**

# Early Detection Of Pancreatic Cancer



Early Diagnosis In Pancreatic Cancer Is The Only Hope

### **Today >80% Late Diagnosis**



4.6 Months Median Survival
Someone Diagnosed With Pancreatic
Cancer In Europe



# The Data: Pancreatic Cancer By The Numbers

Estimated Deaths By Cancer Type in the USA (2019)

### (Both Sexes Combined)



3<sup>rd</sup> Most Common Cancer By Mortality More Deaths Than From Breast Cancer (2019) Source: American Cancer Society



5-yr Survival is 5-9% Due to Late Detection Source: US NCI

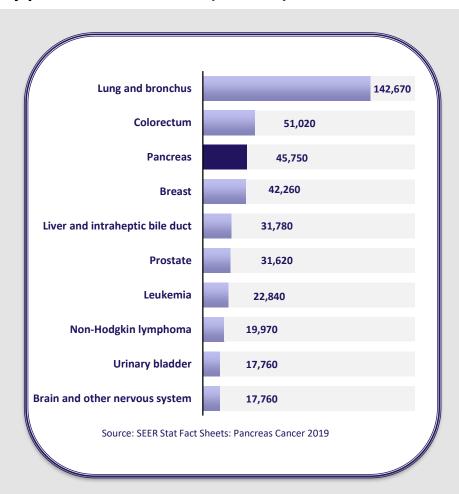


5-yr Survival Can Be ~50%

If Detected Early

Source: Pancreatic Cancer Registry In Japan - 20

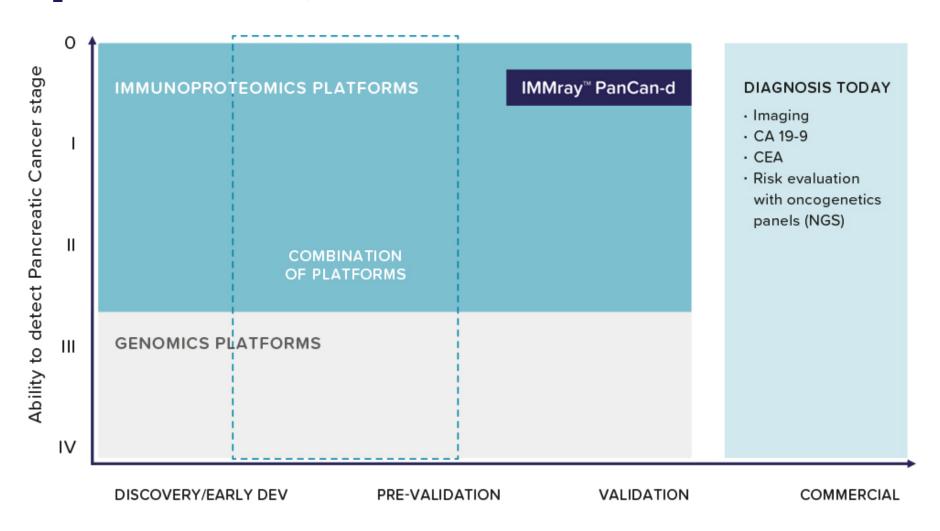
Years Of Experience, 2004





# **Current Technologies For Pancreatic Cancer**

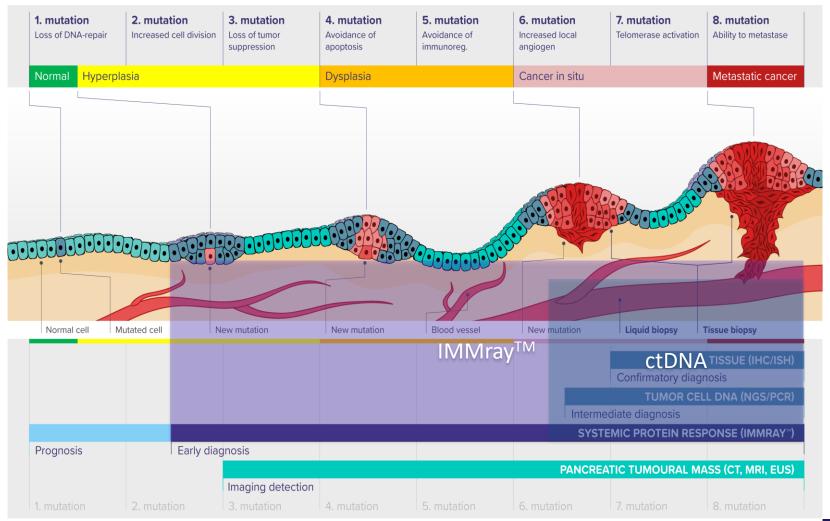
# **Detection and Diagnosis**





# The Advantage Of Early Diagnosis Of Cancer

IMMray™ vs. ctDNA





## **Pancreatic Cancer:**

# 3 High Risk Groups

### Hereditary Familial



- Familiar autosomal ≥ 2 close fam members
- Familiar non-autosomal ≥3 close fam members
- BRCA1/2 Hereditary
- FAMMM p16, CDKN2A
- Peutz Jeghers
- Lynch Syndrome
- Hereditary pancreatitis
- 2-132 risk of developing pancreatic cancer

# Early symptoms



- Depression
- Indigestion/Nausea
- Jaundice
- Mid back pain
- Upper abdominal pain
- Pain on eating
- Fatigue
- Unexplained weight loss
- Diabetes

### NOD



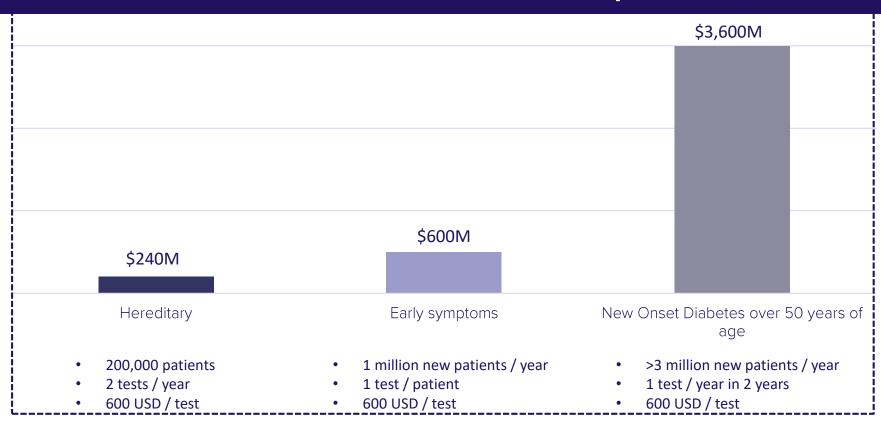
- New onset diabetes type
   Il after 50 years of age
- 8-10 times increased risk of developing pancreatic cancer 1-3 year after diagnosis



# **IMMray<sup>™</sup> Targets A Large Growing Market**

Initial Addressable Market in EU/US: ~\$4.4bn (USD)

## **Pancreatic Cancer Risk Groups**

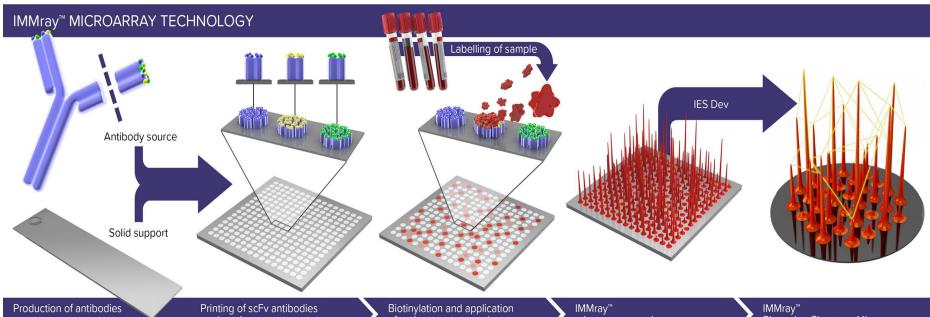






# The IMMray<sup>TM</sup> Platform

Measuring The Immune System's Response To Disease In A Single Drop Of Blood



- 10<sup>10</sup> scFv antibodies in library
- In-house production of antibodies
- Optimized microarray surface for binding scFv

### on the microarray

- Fully automated high throughput robot printer
- One antibody per spot
- Discovery format >400 antibodies

### of patient serum samples

- Patient serum < 100ul</li>
- Biotinylation pretreatment of serum
- Apply serum to IMMray™ microarray

### microarray scanning

- IMMray™ microarray scanned with standard fluorescence scanner
- Signal intensity from each spot corresponds to analyte concentration

### Biomarker Signature Microarray

- IMMray™ Evaluation Software Dev (IES Dev) translate scanned image to a biomarker signature
- · Industry Standard Format
- · Commercial 10-35 Abs in the signature
- 14 samples per microarray



# **IMMray™** Platform

Apply serum to IMMray<sup>™</sup> microarray

# Patient Sample Testing In The Lab

Signal intensity from each spot

corresponds to analyte concentration

### IMMray™ Dx LABORATORY ANALYSIS Day 1-2 Day 3 1 immunovia IMMray PanCan-d Patient report Positive Patient serum labelled and Scanning **Bioinformatics** Actionable result for clinician IMMray™ Dichotomization Power applied to IMMray™ microarray IMMray<sup>™</sup> microarray about the patient status • Standard serum sample, <100 μl Immunovia advanced bioinformatics IMMray™ microarray scanned with Yes/no answer about the Biotinylation pretreatment of serum standard fluorescent scanner algorithm, IMMray™ Evaluation patient status

Software Dx (IES Dx), translate

the patients immune response

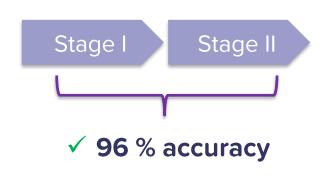
scanned image to a snapshot of

· Actionable result for clinician



# **Discovery and Development Studies**

# IMMray™ PanCan-d



JOURNAL OF CLINICAL ONCOLOGY

BIOLOGY OF NEOPLASIA

### Serum Biomarker Signature-Based Liquid Biopsy for Diagnosis of Early-Stage Pancreatic Cancer

Linda D. Mellby, Andreas P. Nyberg, Julia S. Johansen, Christer Wingren, Børge G. Nordestgaard, Stig E. Bojesen, Breeana L. Mitchell, Brett C. Sheppard, Rosalie C. Sears, and Carl A.K. Borrebaeck

Author affiliations and support information (if applicable) appear at the end of this article.

Published at jco.org on August 14, 2018. Clinical trial information: NCT03311776.

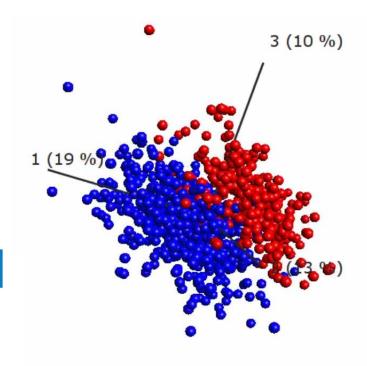
Corresponding author: Carl A.K.
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borrebaeck@immun.lth.se.

#### 7 0 0 1 11 7 0

#### nose

Pancreatic ductal adenocarcinoma (PDAC) has a poor prognosis, with a 5-year survival of < 10% because of diffuse symptoms leading to late-stage diagnosis. That survival could increase significantly if localized tumors could be detected early. Therefore, we used multiparametric analysis of blood samples to obtain a novel biomarker signature of early-stage PDAC. The signature was derived from a large patient cohort, including patients with well-defined early-stage (I and II) PDAC. This biomarker signature was validated subsequently in an independent patient cohort.

#### **Patients and Methods**







# The Optimization Study *IMMray™ PanCan-d*

### **Pancreatic Cancer**

### All controls

PDAC Stage I-IV

Symptomatic Diabetes Healthy

PDAC			Controls				
Sta	age I	Stage II	Stage III	Stage IV	Healthy controls	Symptomatic controls (without diabetes)	Diabetes controls
No.	20	34	21	61	217	480	90

**VS** 



# **Patients With Concerning Symptoms**

### The Criteria

### **Concerning Symptoms**

- Abdominal pain
- Change in bowel habits
- Jaundice
- Weight loss
- Reflux
- Bloating
- Dyspepsia
- Gastritis
- New onset diabetes
- Other...

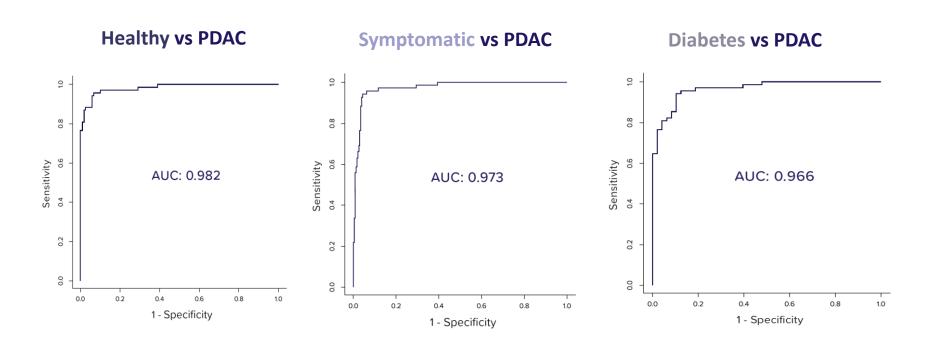
### **Correct Diagnosis Examples**

- Pancreatitis, acute or chronic
- Liver disease
- Biliary duct diseases
- Gallstone disease
- Reflux/gastritis disease
- Abdominal pain, NOS "not otherwise specified"
- Inflammatory bowel disease
- Many other diagnoses...



# **Excellent Optimization Study Results**

IMMray™ PanCan-d



**Results Combining IMMray™ PanCan-d And CA19-9** 

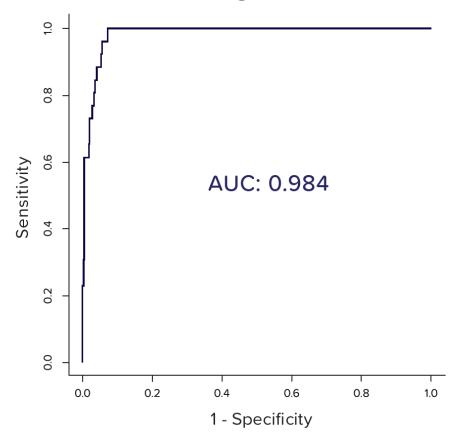


# **Excellent Optimization Study Results**

Early Diagnosis vs All Controls Results

### Results Combining IMMray<sup>™</sup> PanCan-d And CA19-9

### **Controls vs PDAC Stage I and II**





# **Commercial Test Model Study**

IMMray™ PanCan-d



- Completed according to plan
- Confirmed results from optimization study with accuracies ~95% For diagnosing pancreatic cancer vs all controls
- 1,113 samples from 8 hospitals in US and EU, show IMMray™ PanCan-d robustness
- Patenting registration ongoing





## **Road to Sales Start Q4 2020**

# IMMray™ PanCan-d



IMMray<sup>™</sup> PanCan-d discovery and development studies



Discovery and development studies published in Journal of Clinical Oncology





IMMray<sup>™</sup> PanCan-d

- signature and
- Full IMMray<sup>™</sup>



Succesfully completed: AUC~95% for PDAC vs symptomatic, diabetic and healthy controls





IMMray PanCan-d commercial test model study

- Test the
- Fine tune algorithm



Succesfully completed: AUC~95% for PDAC vs symptomatic, diabetic and healthy controls







- Locked signature and algorithms

Results

Q3 2020



- and algorithms
- Blinded samples



Launch

Results

Sales start Q4 2020

Sales Start O4 2020

Prospective studies

Reimbursed sales

Self pay-sales

Q4 2020

Confirmatory market expansion studies

2016 - 2018 2019-2021 2022-2024



# Sales Start Target Q4 2020 COVID-19 Related Delay & Updated Timeline

Due to the lock down and the Emergency Order in Massachusetts from March, 23, 2020, to May, 25, 2020, Immunovia has revised the company's timeline and sales start date for IMMray™ PanCan-d.

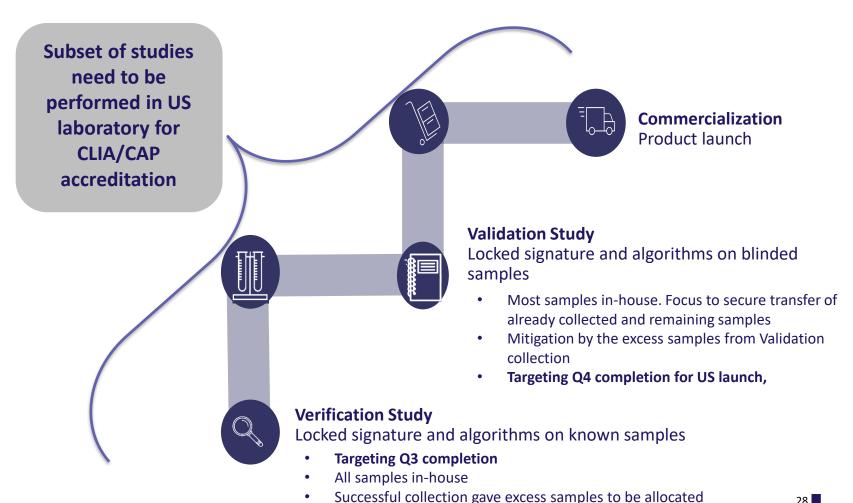
	Revised Target
Verification Study	Q3 2020
Validation Study	Q4 2020
Commercial Launch of IMMray™ PanCan–d	Q4 2020

Immunovia's IMMray™ PanCan-d remains the first-to-market highly accurate test for early detection of pancreatic cancer



# **Remaining Steps to Launch**

IMMray<sup>™</sup> PanCan-d Remains First-to-Market Diagnostic for Early detection of Pancreatic Cancer

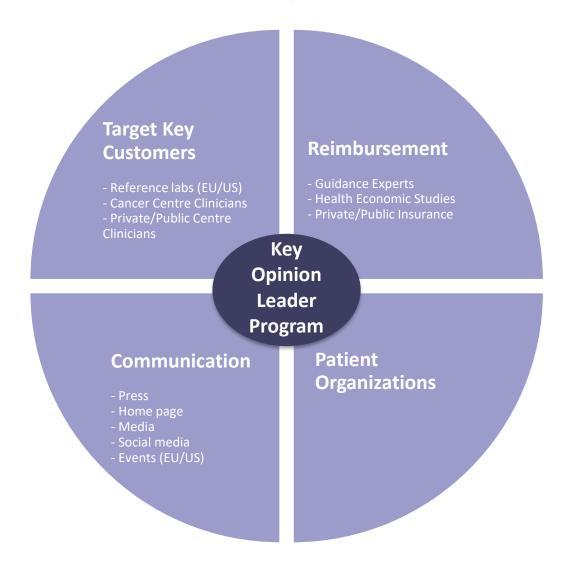


to Validation study



# **Leveraging The Largest KOL Network**

IMMray™ PanCan-d Main Programs





# Positioning IMMray™ PanCan-d

# Focused Targeting of Sales and Marketing

Asymptomatic

**Hospital Pancreatic Cancer Clinics** 

Early symptoms

Primary care evaluation

Symptoms and positive imaging HPB / Gastro clinic

recurrence

HPB / Gastro

Pancreatic cancer

Familiar / hereditary individuals NOT in screening

Familiar / hereditary individuals in screening programs

Frontline diagnostics / Adjunct diagnostics

Disease recurrence monitoring tests

High risk screening test to work in conjunction with existing imaging tests to improve sensitivity and specificity

To aid /confirm the diagnosis of symptomatic patients and for high risk patients i.e. Type II diabetes over 50 years old

To help identify / monitor the recurrence of the pancreatic cancer

PanFAM-1

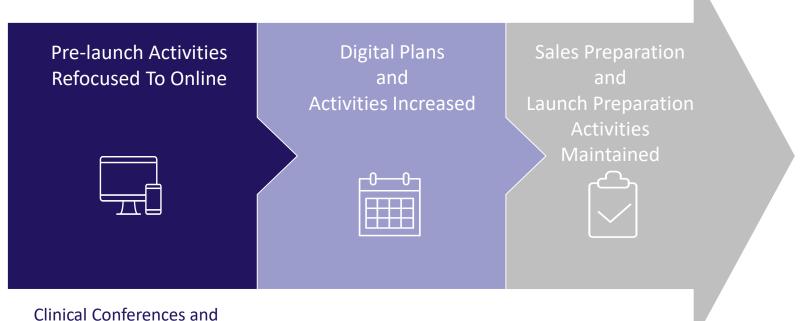
PanSYM-1

Not addressed

PanDIA-1



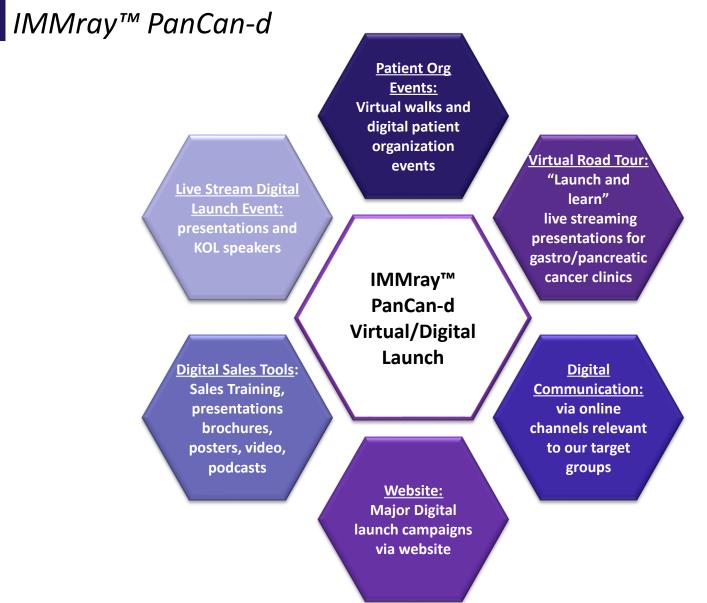
# **Commercial Launch Preparations**



Patient Organization
meetings cancelled or
postponed due to COVID-19



Virtual/Digital Launch Plan – 6 Key Activities





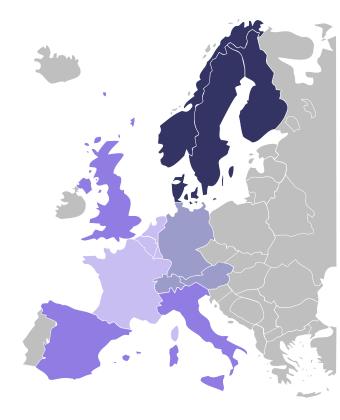
# **Launch Priorities for IMMray™ PanCan-d**

Countries with prospective site centers, PanFAM, PanSYM, PanDIA, FPC screening programs, diagnostic/GI centers and private health systems

## **Priority Order:**

- 1. USA
- 1. Sweden/Nordic
- 2. UK
- 2. Spain / Italy
- 2. Canada
- 3. DACH
- 3. Benelux
- 4. France







# **Commercialization Strategy in Place**

Sales Force Focused On Gastro Centers In Prio Countries



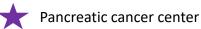
### **Targets And Patient Flow Mapped**

Marketing /Communication Planned

- Online/Digital Marketing and Selling Tools and Channels
- All Relevant Pancreatic Cancer **Events And Conferences**
- Patient Organization Support

All Logistics Steps In Place From Test **Requistion To Providing A Test Report To The** 

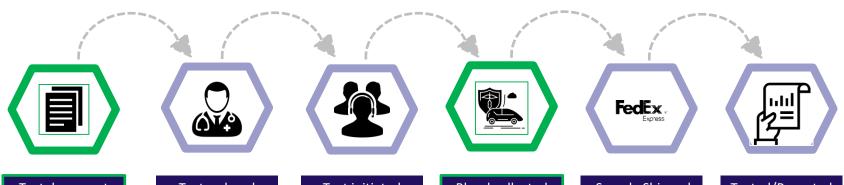
National Pancreas Foundation Accredited Center





# IMMray™ PanCan-d Logistics In Place

# Clinician And Patient Convenience Enable Market Penetration



### Test document

Test requisition and supporting materials tailored for easy ordering.

### Test ordered

Signed Test Requistion sent to Immunovia or ordered online

### Test initiated

Customer Support receives order and initiates test

### **Blood collected**

Phlebotomy is performed at a location convenient for the patient.

### Sample Shipped

Serum is shipped using special shipper keeping blood sample cool. Delivered next day to Immunovia Dx Laboratories at 10.30 am.

### Tested/Reported

Testing performed and result report sent to clinician.



# **Strong Patient Organization Collaboration**

Example: Pancreatic Cancer Awareness Walks











24,000 Participants In 2018 37,500 Participants In 2019 Digital Meetings In 2020







# Prospective Studies Impacted By COVID-19

- All sites involved in the three ongoing prospective
   pancreatic cancer studies are following their respective
   national recommendations and regulations for health and
   safety and, thus, many have therefore in general stopped
   clinical trial activities, including blood sample collection
- The interim analysis of PanFAM-1 may be postponed to Q1/Q2 2021, depending on the development of the COVID-19 pandemic situation
- PanDIA-1 interim analysis will not be affected as sample collection is well advanced already at this stage
- We are confident that we also will be able to enter the interventional phase of PanSYM as planned in early 2021, to show clinical utility of differential diagnosis of pancreatic cancer versus symptomatic non-PDAC patients



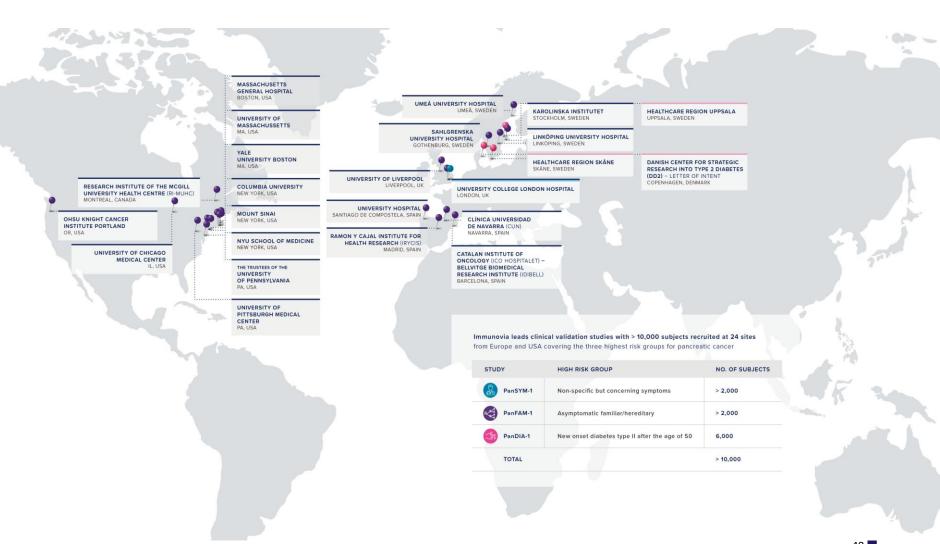
# immunovia IMMray™ PanCan-d Prospective Clinical Studies +10,000 subjects in three major risk groups for PDAC

PanSYM-1	PanFAM-1	PanDIA-1
Non-specific But     Concerning Symptoms	Asymptomatic     Familiar/Hereditary	<ul> <li>New Onset Diabetes         Type II After The Age Of         50     </li> </ul>
<ul> <li>University College of London In Collaboration With Diagnostic Centers In The Whole UK</li> </ul>	<ul> <li>25 Pancreatic Diseases         Reference Centers From             USA, Canada, Sweden, UK,             Spain     </li> </ul>	3 Hospitals In Sweden
> 2 000 Samples	> 2 000 Samples	> 6 000 Samples
Interim Analysis H1 2021	Interim Analysis H1 2021	Interim Analysis H1 2021
Final Read Out 2022	Final Read Out 2022	Final Read Out 2023



# Three Prospective Studies

10,000 Subjects via KOL Network

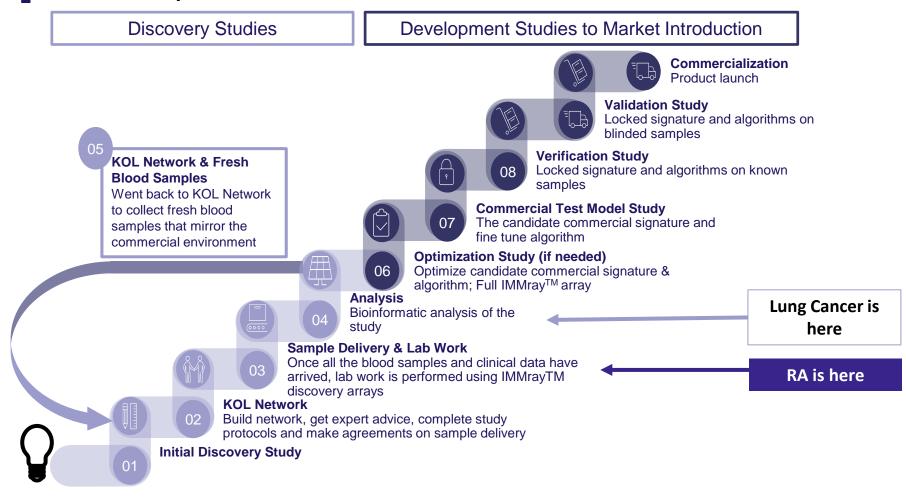






# **Process Overview for Pipeline Projects**

# Initial Study Results to Market





# **Lung Cancer**

- ✓ Pharma Study 1: Completed. Lung cancer stage I-IV vs healthy
- ✓ Study 2: Ongoing. Lung cancer stage I-IV healthy and symptomatic controls
- Building KOL network

### 1. Early Diagnosis

### **Current healthcare status**

- Symptoms of lung cancer often occur at an advanced, non-curable stage
- Screening ongoing in US by LDCT\* in high risk people,
   8M ELIGIBLE IN US. +2M to 4M if COPD\* is added
- Europe potentially to adopt LDCT screening
- LDCT has a low specificity, 25% false positive

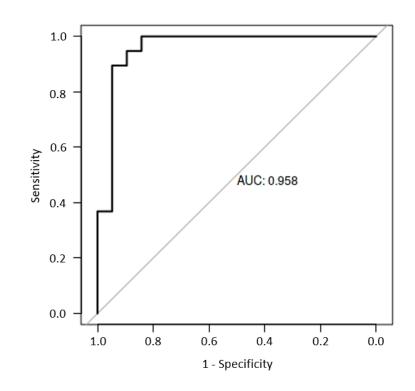
### **Clinical needs:**

- Differentiate false and true positives after LDCT
- Screening of risk groups for early detection before imaging

Next steps: Retrospective studies by Immunovia

\*LDCT = Low Dose CT

\*COPD = Chronic obstructive pulmonary disease





## **Rheumatoid Arthritis**

### **IMMray™** RA-d Target Clinical Use:

Early RA - PRIMARY CARE	Developing RA	Established RA - REUMATOLOGITS
Patients with pain and unclear early symptoms		Patients with pain and clear clinical symptoms
EULAR recommendation for early RA	Referral to specialist	ACR criteria and scoring CCP test: specificity 96%; sensitivity 72%
~80% CCP negative	~50% CCP negative	~25-30% CCP negative

### **Next steps - RA**



# RA discovery studies

- Double negative vs healthy
- All RA vs healthy



# RA discovery studies

- RA vs controls with other diseases having RA like symptoms
- Define candidate commercial signature and algorithm



# RA signature test study

- Test the candidate signature
- Fine tune algorithm



### **Verification study**

- Locked signature and algorithms
- Known samples



### **Validation study**

- Locked signature and algorithms
- Blinded samples





# **Summary**

Focused on IMMray<sup>TM</sup> PanCan-d Sales Start in Q4 2020

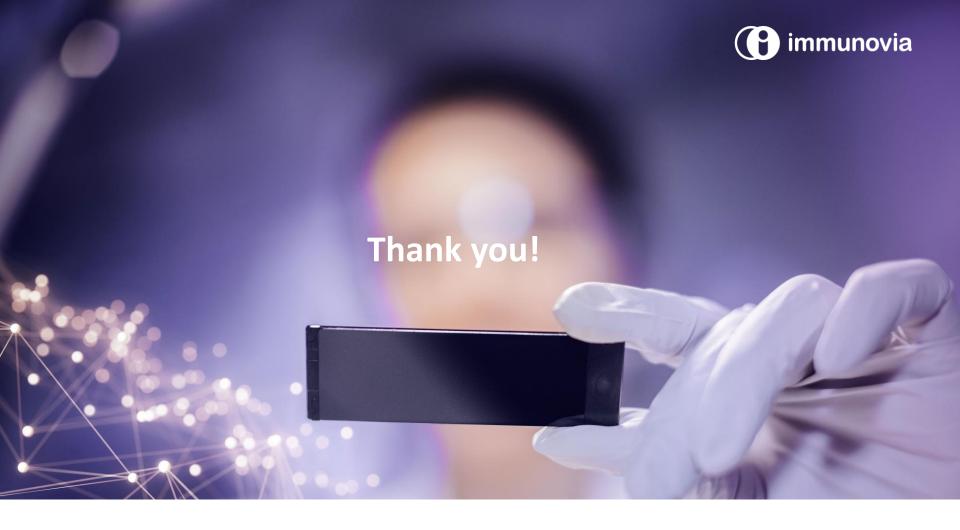
Excellent Results for Optimized IMMray<sup>TM</sup> PanCan-d Across All Target Groups

First To Market Solution For Early Detection Of Pancreatic Cancer – Addressable Market Opportunity of ~\$4.4 Billion (USD)

PanFAM-1, PanSYM-1, PanDIA-1: Largest, >10.000 Subjects Prospective Studies

Largest KOL Network – Pancreatic Cancer

Robust Pipeline Targeting Lung Cancer and Rheumatoid Arthritis



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