

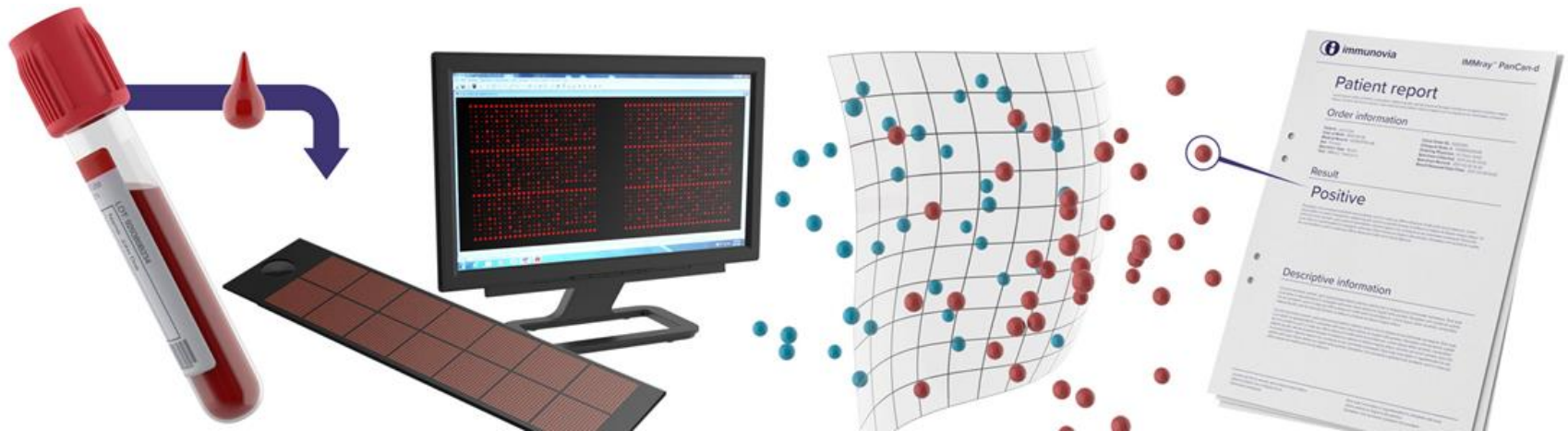
# Immunovia Overview

March 2019  
Mats Grahn, CEO

# Forward-looking Statements

*This presentation may contain forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward looking statements speak only as of the date of this presentation. Immunovia expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this presentation. You should not place undue reliance on forward-looking statements*

# The immune system response in a single drop of blood



# Immunovia sites: Lund Sweden, Boston US

HQ, Reference lab & production, Lund, SE

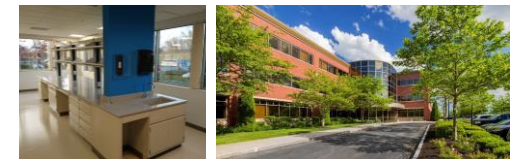


immray® Dx Laboratories

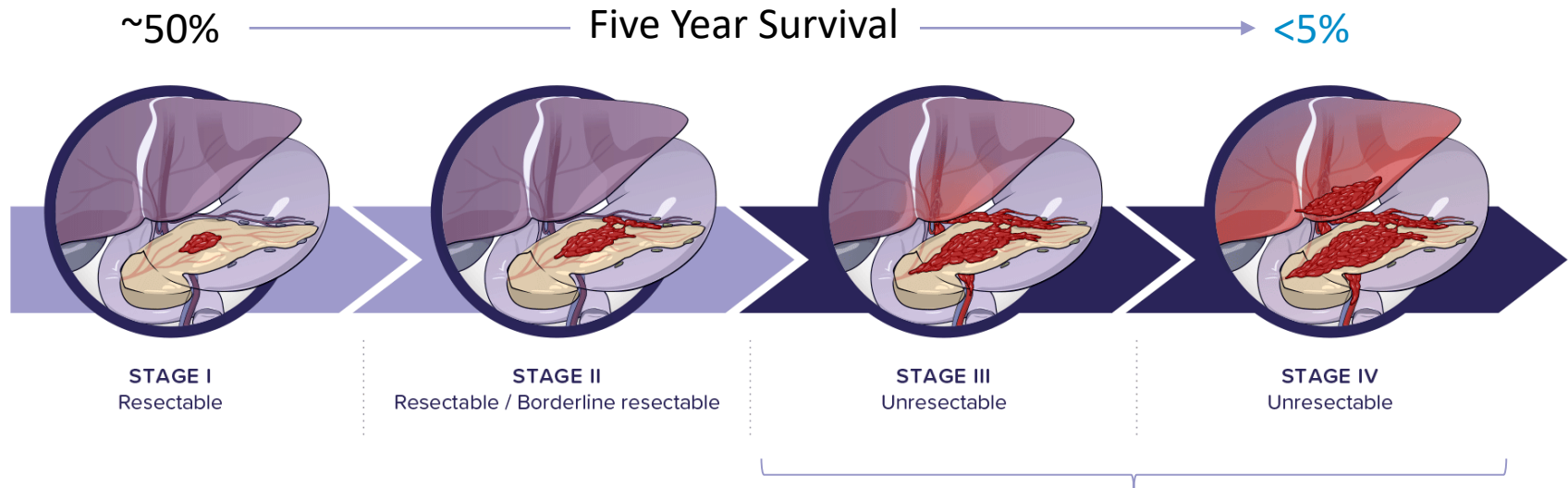


Immunovia Inc, Boston, USA

Headquarters staff



# First Product: IMMray™ PanCan –d



Early diagnosis in pancreatic cancer is the only hope

TODAY >80% LATE DIAGNOSIS



4.6 MONTHS MEDIAN SURVIVAL  
FOR SOMEONE DIAGNOSED WITH  
PANCREATIC CANCER IN EUROPE



# Pancreatic Cancer by the numbers

ESTIMATED DEATHS USA , 2016  
By cancer type, both sexes combined

3<sup>rd</sup>

3<sup>rd</sup> most common cancer by mortality

More deaths than from breast cancer (2015)

Source: American Cancer Society

5%

5-yr survival is 5-8%

Due to late detection

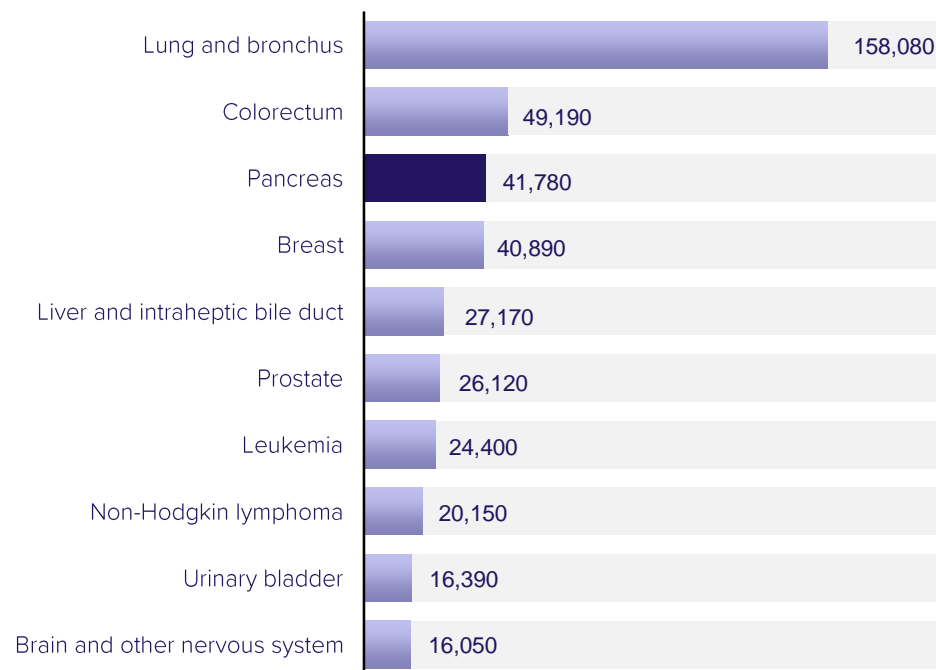
Source: US NCI

~50%

5-yr survival can be ~50%

If detected early

Source: Pancreatic Cancer  
Registry in Japan - 20 Years of Experience, 2004



Source: SEER Stat Fact Sheets: Pancreas Cancer 2016

# 3 high risk groups for pancreatic cancer

4.2 Million people yearly

## Hereditary Familial



- Familiar autosomal  $\geq 2$  close fam members
- Familiar non-autosomal  $\geq 3$  close fam members
- BRCA1/2 Hereditary
- FAMMM p16, CDKN2A
- Peutz Jeghers
- Lynch Syndrome
- Hereditary pancreatitis

2-132 risk of developing pancreatic cancer

## NOD



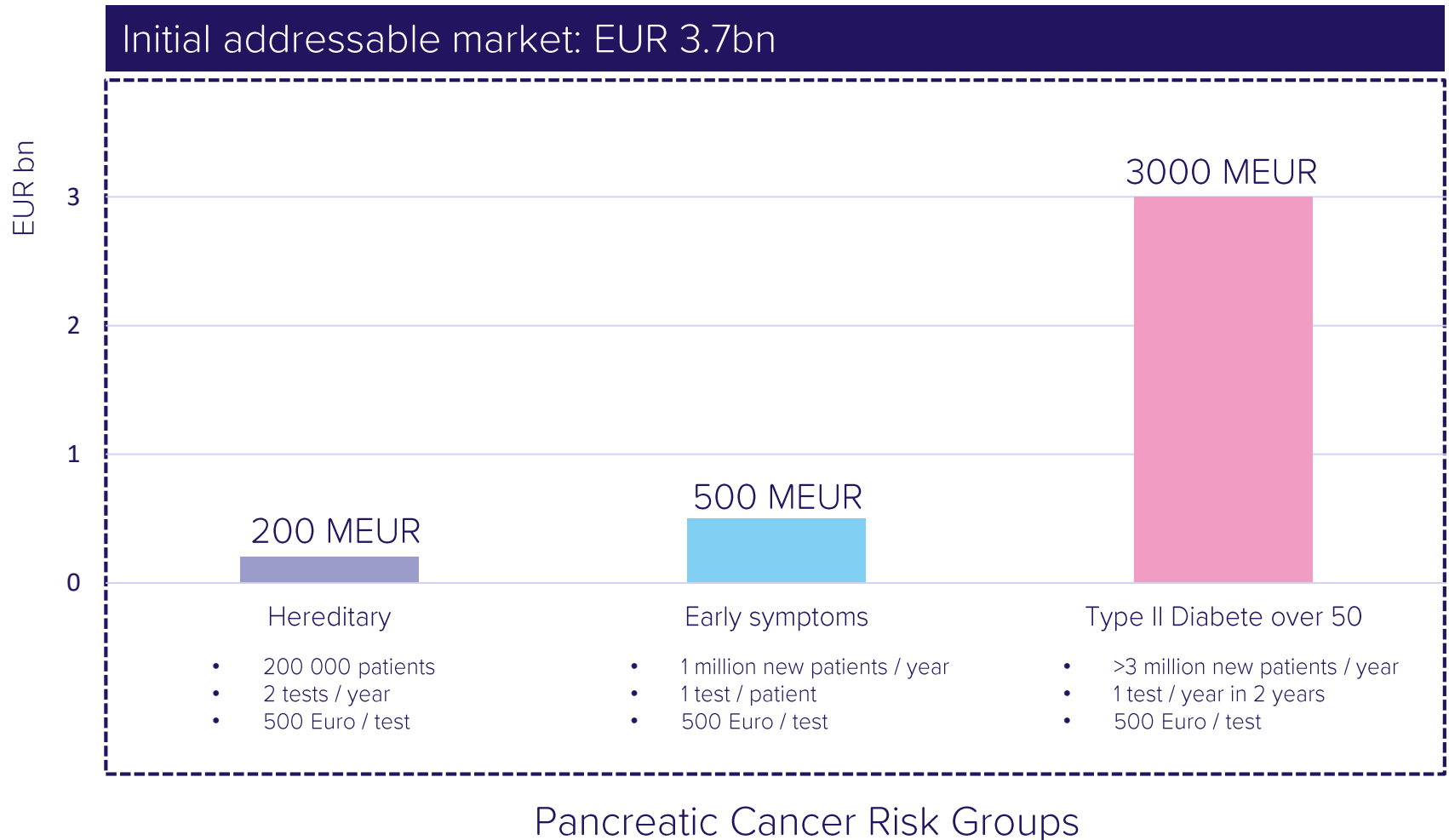
- NEW ONSET DIABETES TYPE II AFTER 50 YRS OF AGE
- 8-10 Risk of developing pancreas cancer 1-3 year after diagnosis

## Early Symptoms



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

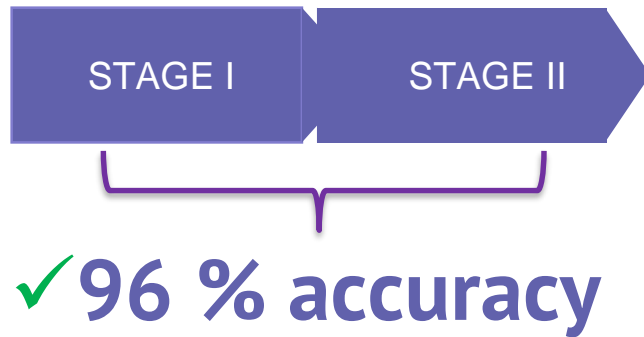
# EUR 3.7bn addressable market EU&US





# IMMray™ PanCan-d

## 96% accuracy stage I and II patients



JOURNAL OF CLINICAL ONCOLOGY

BIOLOGY OF NEOPLASIA

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

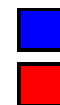
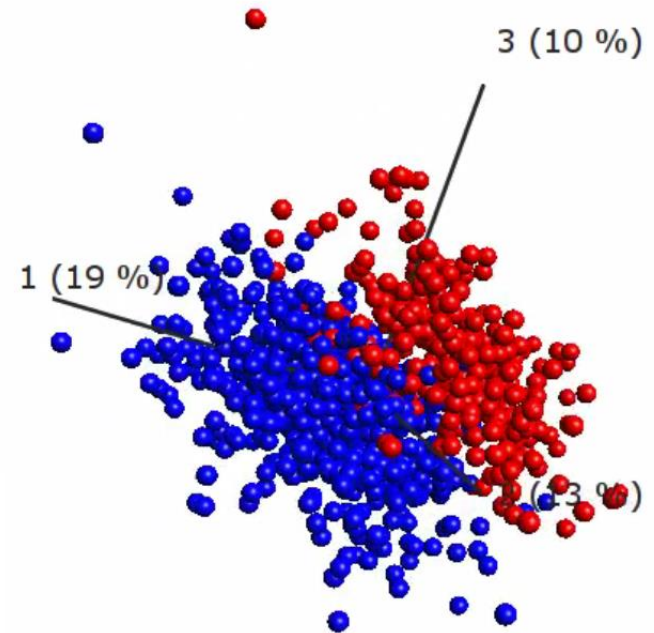
Linda D. Mellby, Andreas P. Nyberg, Julia S. Johansen, Christer Wingren, Borge G. Nordestgaard, Stig E. Bojesen, Brecana L. Mitchell, Brett C. Sheppard, Rosalie C. Sears, and Carl A.K. Borrebaeck

#### A B S T R A C T

##### Purpose

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



Healthy

PDAC Stage I and II

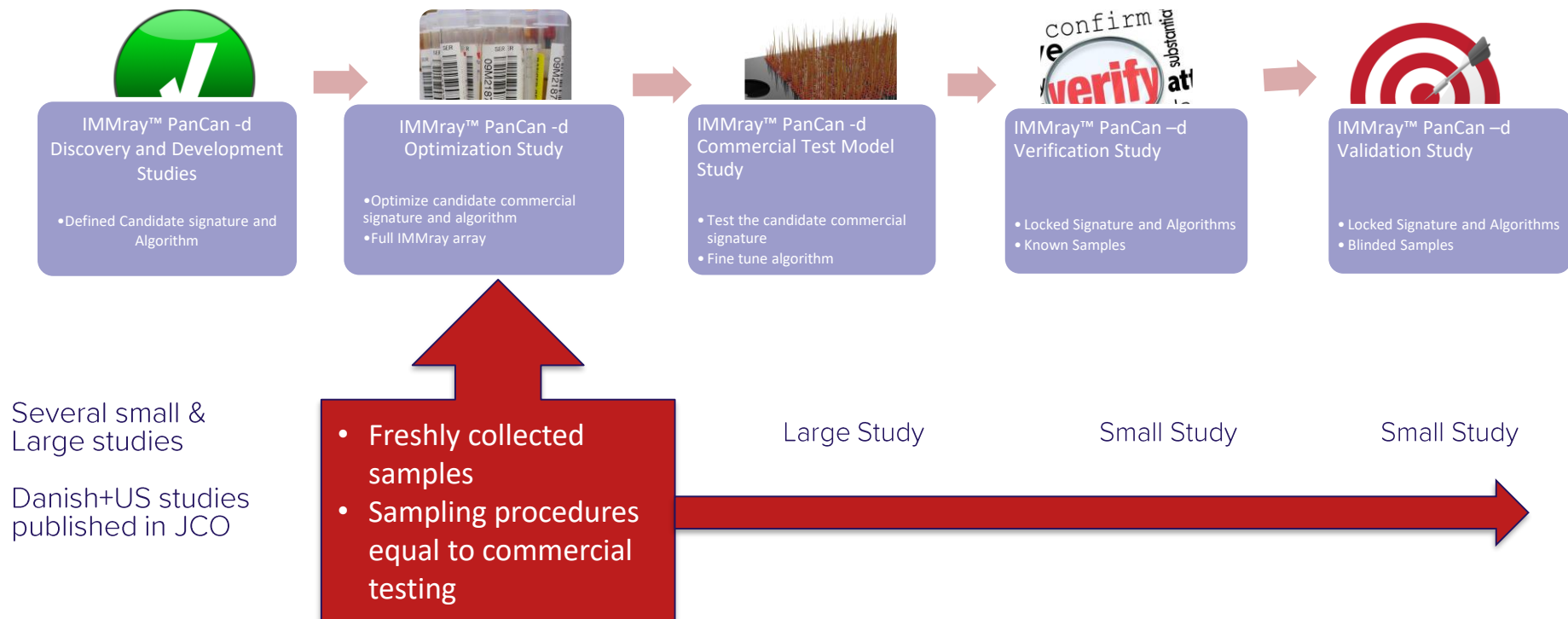
Author affiliations and support information (if applicable) appear at the end of this article.

Published at [jco.org](http://jco.org) on August 14, 2018.

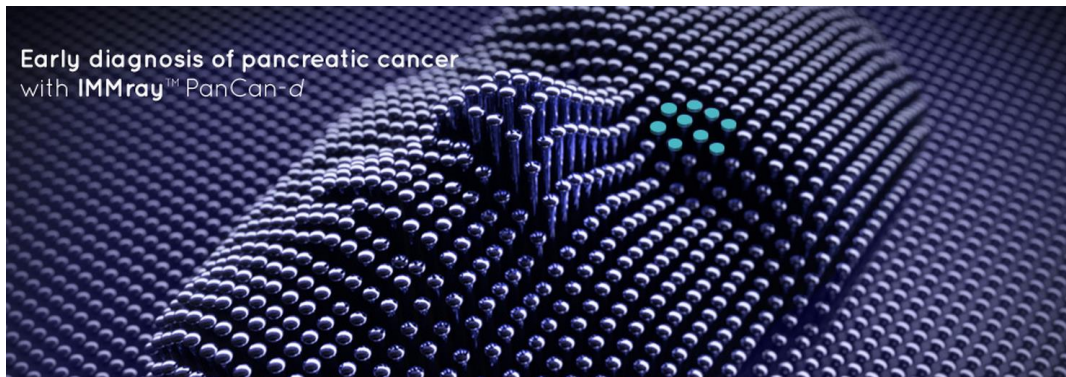
Clinical trial information: NCT03311776.

Corresponding author: Carl A.K. Borrebaeck, DSc, Department of Immunotechnology and CREATE Health Translational Cancer Center, Lund University, Medicin Village Bldg. 406, SE 223 81 Lund, Sweden; e-mail: carl.borrebaeck@immun.lth.se.

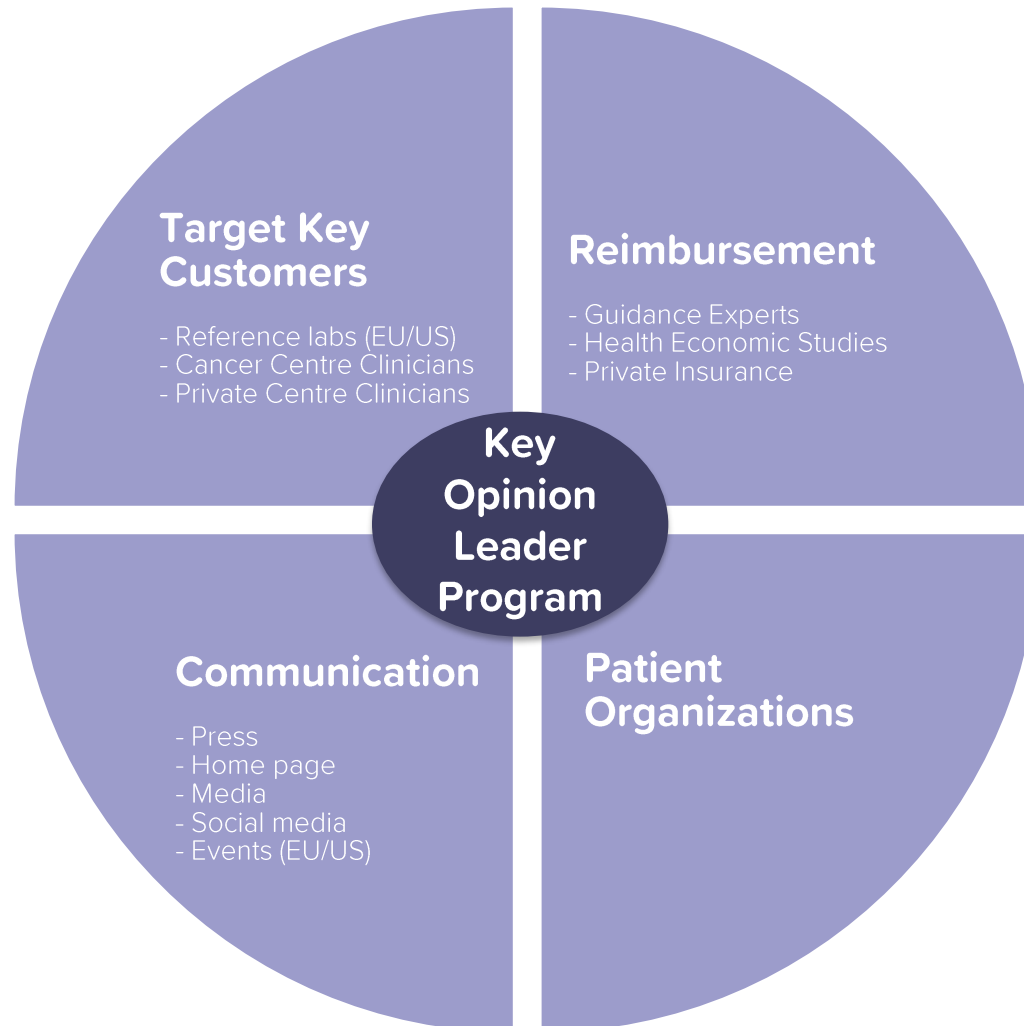
# Development and Accreditation Steps to Market



# Road to Market



# Road to Market - Main Programs



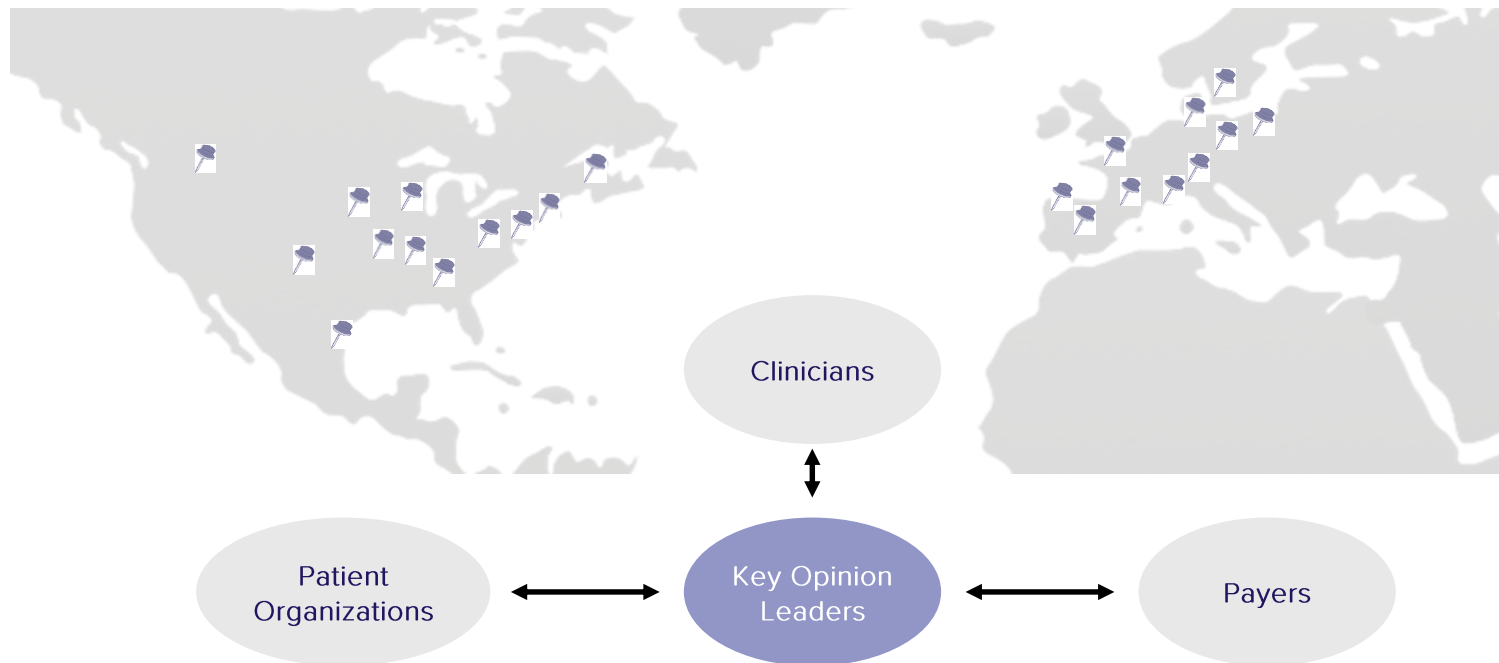
# Key Opinion Leader Network

Crucial for commercialization













**22 sites** from Europe and USA part of

3 large pancreatic cancer clinical studies: PanFAM-1, PanSYM-1 and PanDIA-1

Totally covering **>10 000 high risk subjects**



# IMMray™ PanCan-d prospective studies

	PanFAM-1	PanDIA-1	PanSYM-1
Risk group	Hereditary/Familiar	Type II Diabetes after 50	Early Symptoms
Character and population	Multicenter study ongoing	Large prospective study ongoing	Patient sampling in Pilot Study at UCL ongoing
Study read outs and results	Interim readout: Early 2020 Results: 2021	Interim readout 2020 Results 2021	Interim pilot: 2019 Results: 2020
Countries	US, CA, UK, ES, SE	SE: Ongoing DK, US: Initiating	UK US initiating
Selected partners	      	   	

Observational Phase

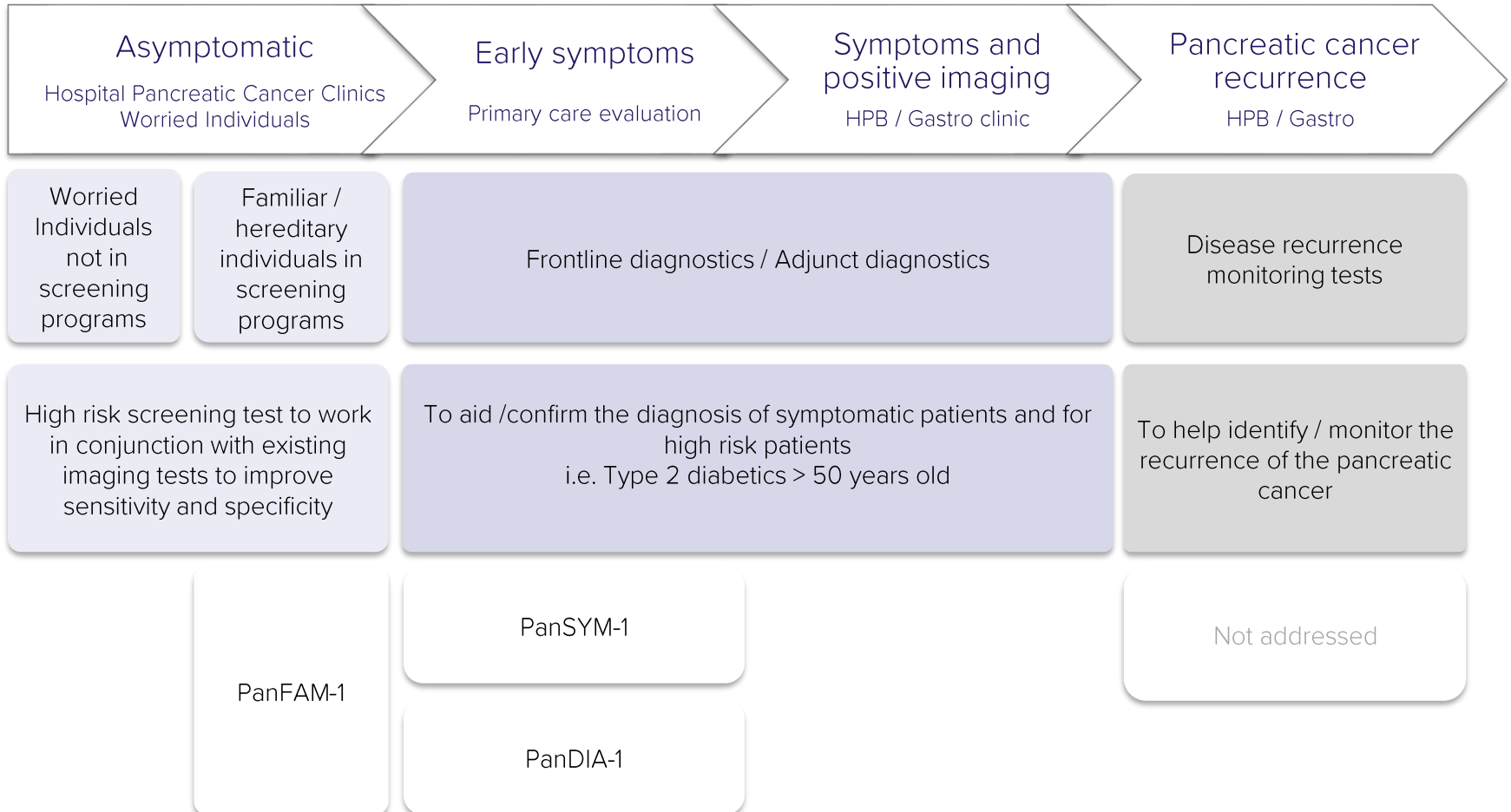
Interim Readout

Interventional Phase



# Positioning IMMray™ PanCan-d

Disease progression



# 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
3. Canada
3. DACH
4. Benelux
4. France

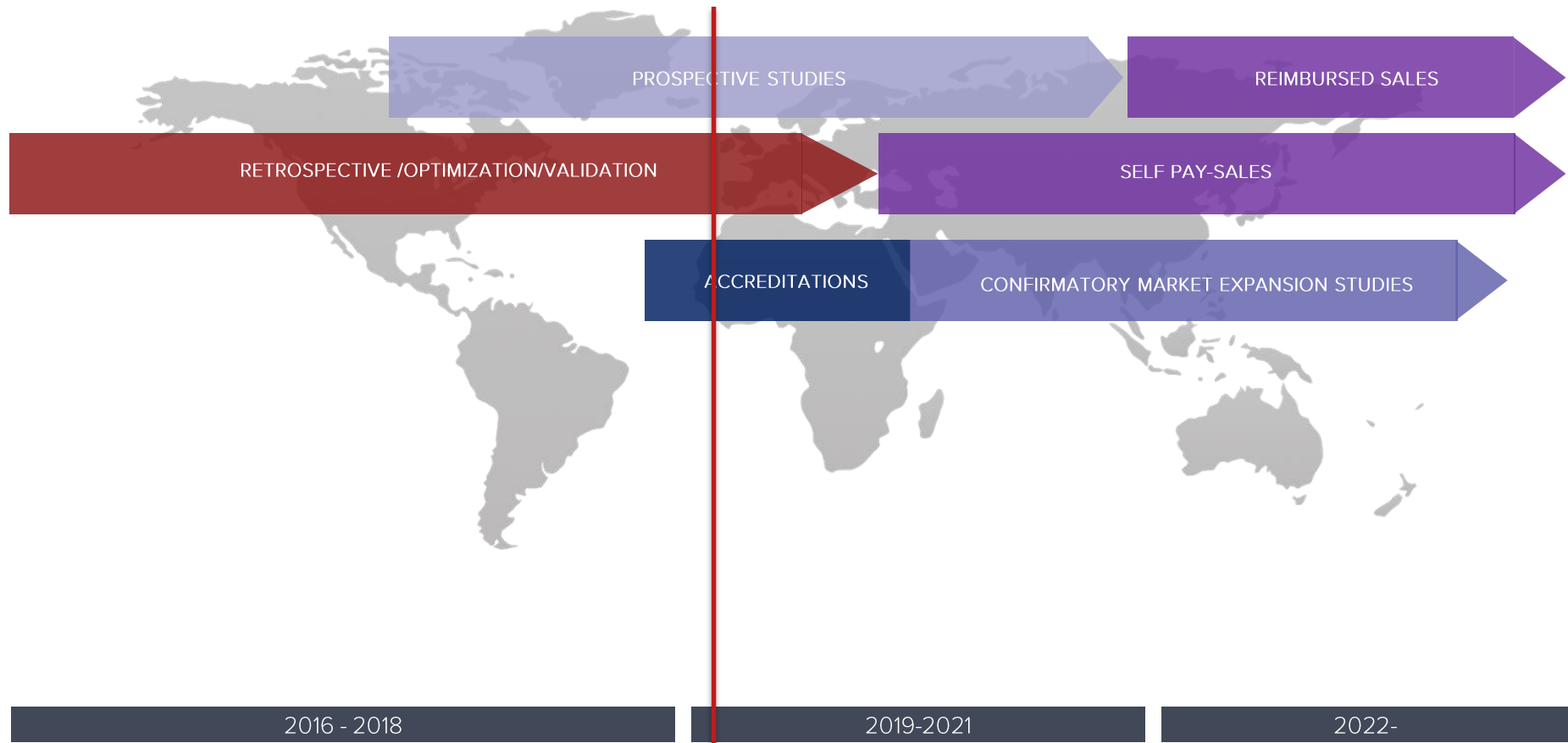


# Sales force development and marketing strategy 2019-2021

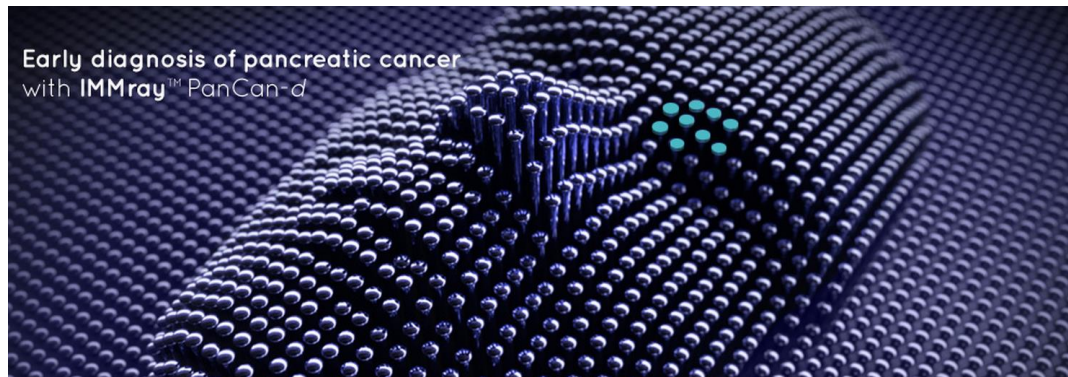
## Immunovia Key Account Management in place 2019-2020

Risk Group	Early symptoms 			Hereditary / Familial 			Type II Diabetes after 50 		
	Sales force			Target cancer centres with existing screening programs through KAMs			Start sales activities after interim results from PanDIA-1 Target key early adaptor centres		
	Focused Campaigns & Awareness			Patient Organization Partnerships, Meetings country wide with risk persons and clinicians DTC activities for worried individuals			Implement educational programs for gastro depts., primary care, diabetes patient organisations Web and social media		

# Road to Market – Overview



# Immunovia pipeline Autoimmunity and Lung Cancer



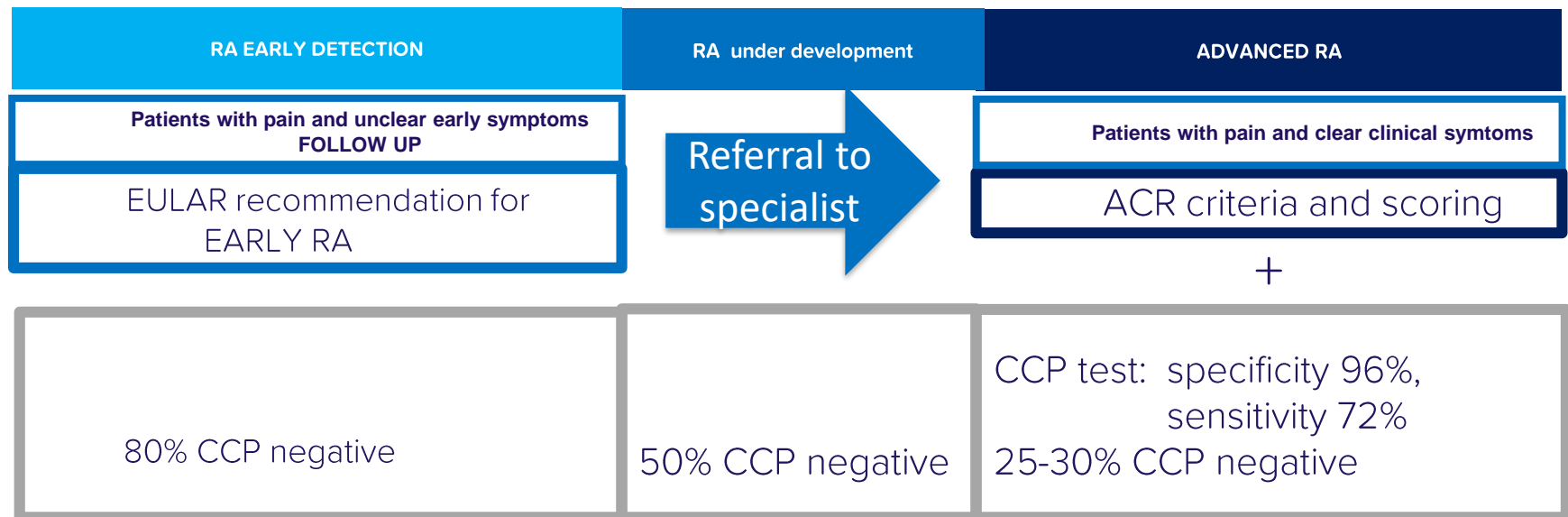
# Current RA diagnosis



Primary care



Rheumatologists





# IMMray™ RA-d Target Clinical Use



Primary care caregivers



Rheumatologists

## RA EARLY DETECTION

Patients with pain and unclear early symptoms  
FOLLOW UP

EULAR recommendation for  
EARLY RA

CCP testing: 80% CCP negative

2

EARLY RA

## RA under development

Referral to  
specialist

50% are CCP  
negative

## ADVANCED RA

Patients with pain and clear clinical symptoms

ACR criteria and scoring

+

CCP testing: specificity 96%,  
sensitivity 72%

25-30% patients are CCP  
negative

1

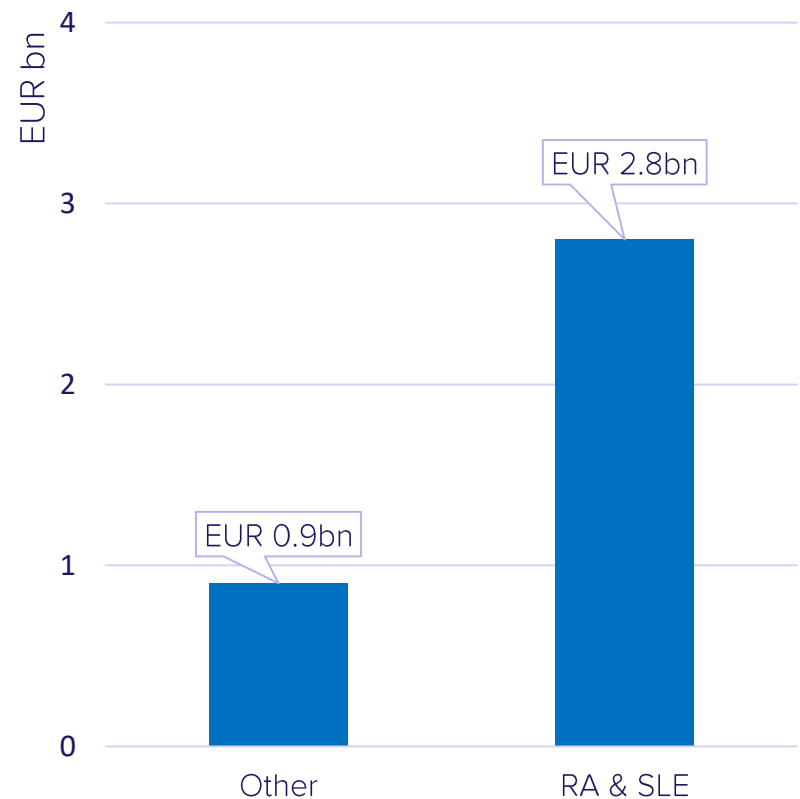
CCP negative  
patients

# IMMray™ pipeline autoimmunity market

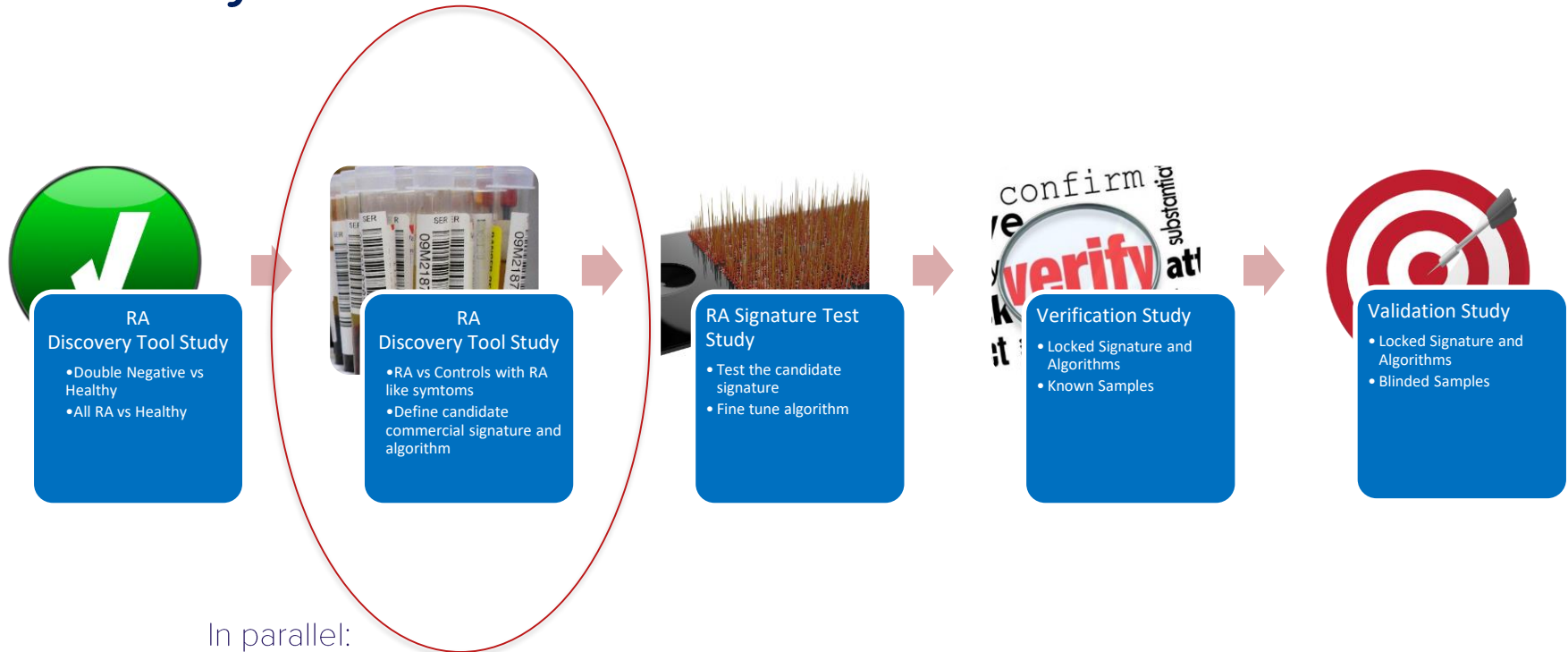
## Study readouts and commercial roll out

Study read outs	Validation & commercial roll out expected
Retrospective: 2019 Prospective: Interim read out: 2020 Prospective study: 2021	First product: 2021

## Global systemic autoimmune disease diagnostics market



# IMMray™ RA-d status



- Extend KOL network and interaction
- Patenting

# Two Separate Lung Cancer Opportunities

## 1. Early Diagnosis

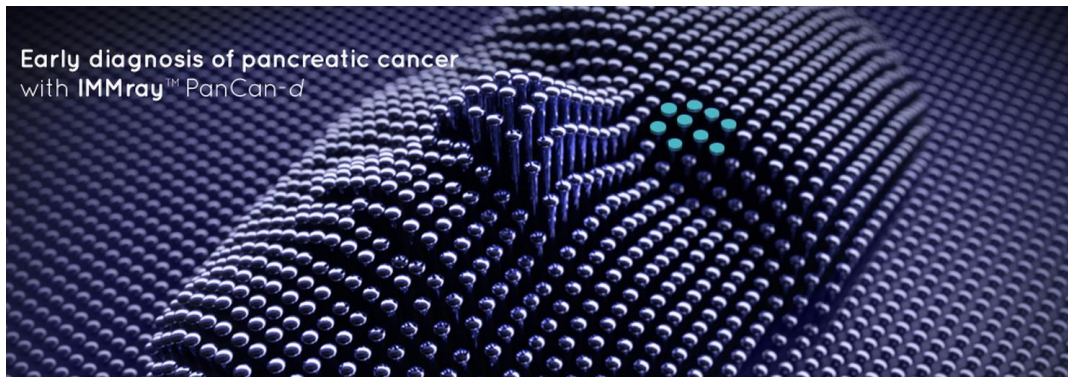
- Symptoms of lung cancer often at an advanced, non-curable stage
- Screening ongoing in US by LDCT\* in high risk people
- LDCT test has a low specificity, 25% false positive
- Clinical need 1: differentiate false and true positives after LDCT in US screening program
- Clinical need 2: screening of risk groups for early detection *before* imaging
- Retrospective study by Immunovia next step

## 2. Companion diagnosis (selection of patients for a specific therapy)

- Majority of pharmaceuticals target late stage (III + IV) lung cancer patients
- Clinical need: differentiate between Pharma's pharmaceutical responders and non-responders
- Activities has been initiated through the collaboration with a top 10 Pharma

\*Low Dose CT scanning

# Summary



# Immunovia Financial Targets

## Pancreas Cancer Sales

- Revenue 250-300 MSEK (30-36 MUSD) in 2022 based on self-pay for IMMray™ PanCan-d.
  - 5% penetration of familial/hereditary risk group
  - 1-2% penetration of early symptoms group
  - Confirmatory / Adjunctive use
- Revenue 800-1,000 MSEK (97-120MUSD) in 2024 for self-pay and reimbursement tests
  - 20% penetration of familial/hereditary risk group
  - 9% penetration of early symptoms group
  - Initial use in diabetes risk group
- Large New Onset Diabetes group opportunity penetration 2024 and onwards



# Going forward Top targets 2019

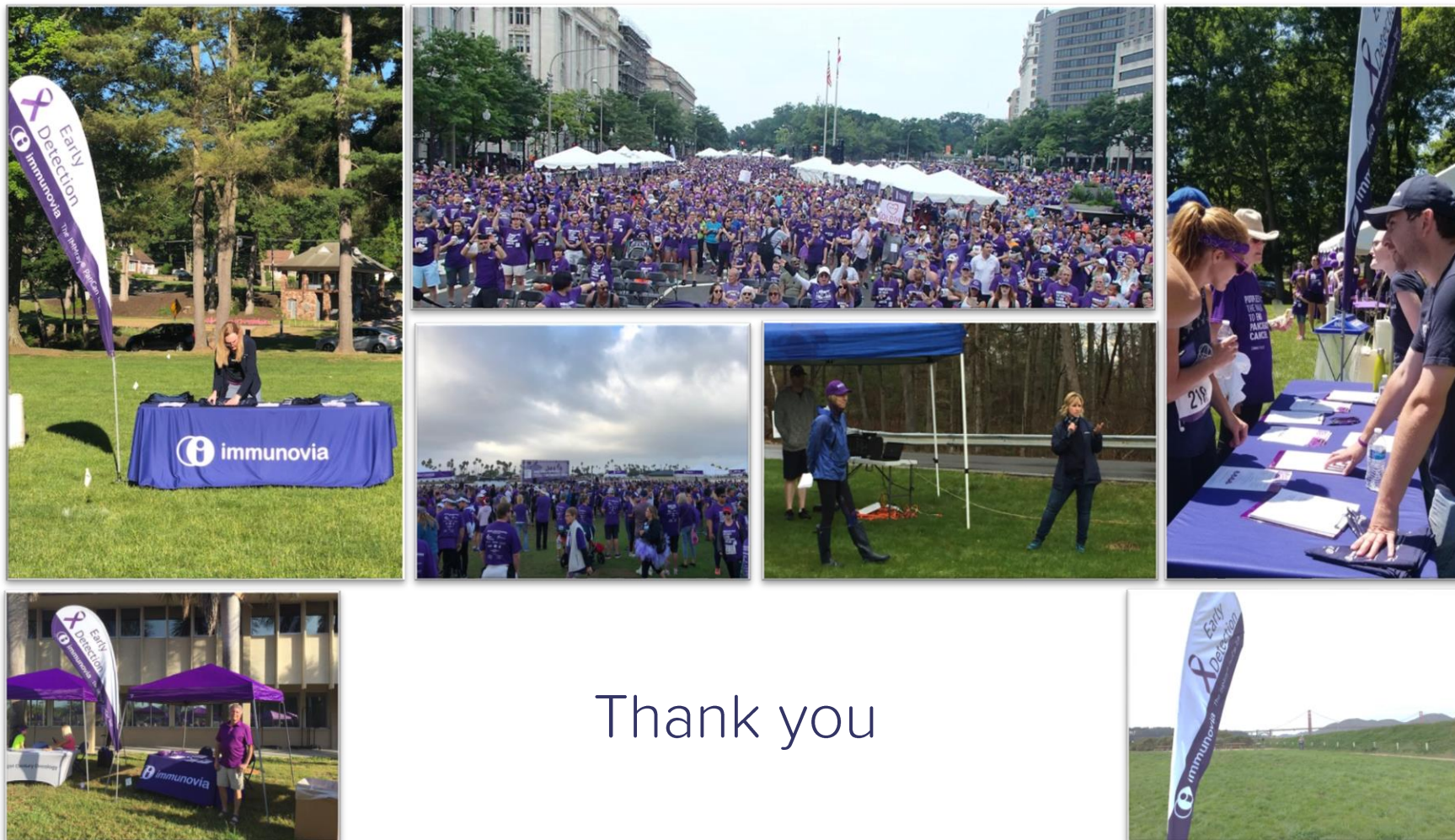
## Pancreas Cancer

- Complete IMMray™ PanCan-d for Sales Start
- Results of pilot prospective study PanSYM-1
- PanFAM-1 enrolment completion, interim results 2020
- Completion of PanDIA-1 agreements and sample collection for interim results 2020

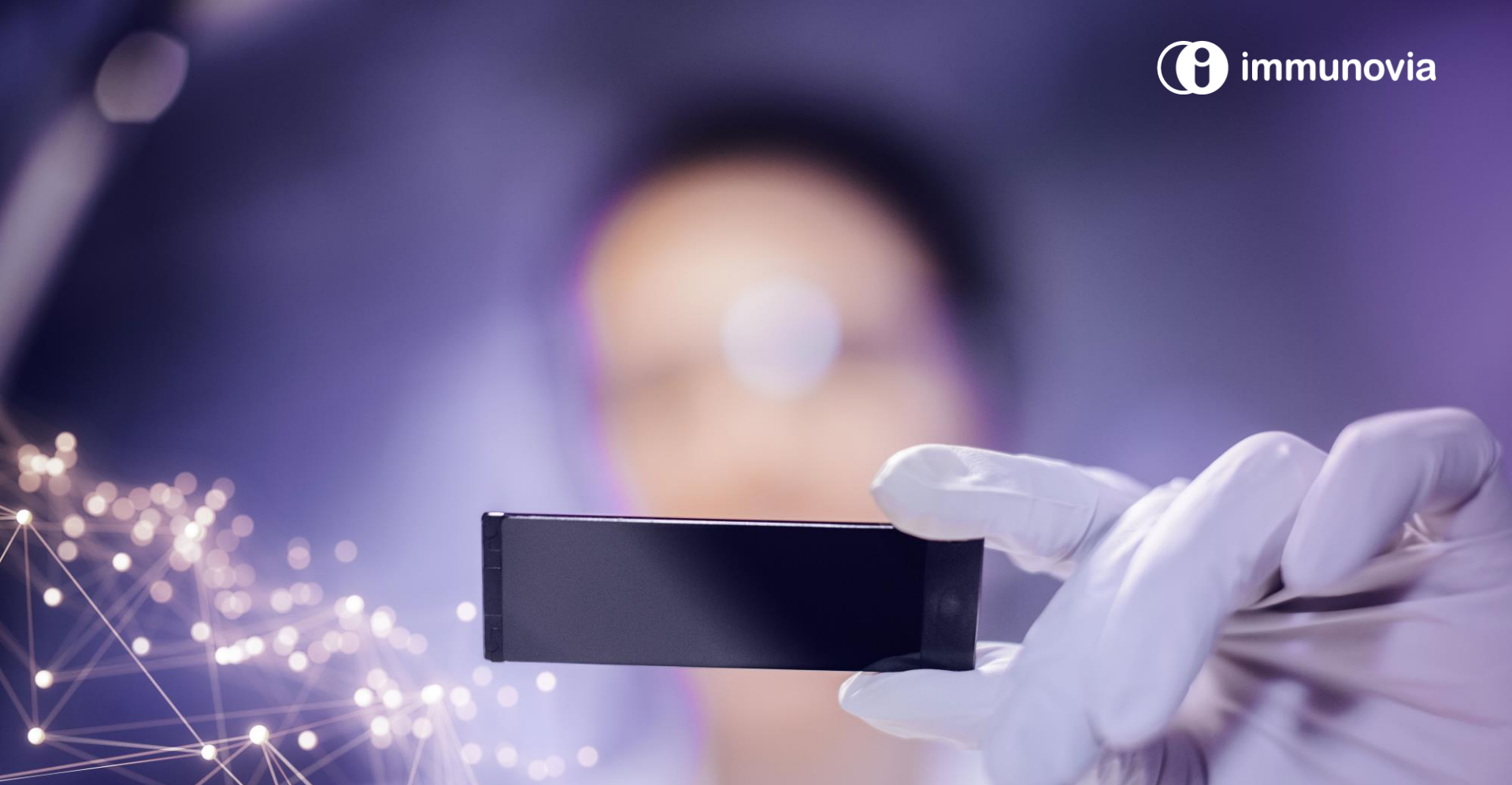
## Pipeline

- Results of Lung cancer Pharma study 2
- Results of Rheumatoid Arthritis vs Rheumatoid Arthritis like symptoms diseases

# Immunovia supporting pancreatic cancer walks



Thank you



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