A METHOD FOR EARLY DIAGNOSIS OF PANCREATIC CANCER

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Well-known victims of pancreatic cancer

Luciano Pavarotti (1)
diagnosed 2006, died 2007

Patrick Swayze (2)
diagnosed 2008, died 2009

Steve Jobs (3)
diagnosed 2004, died 2011

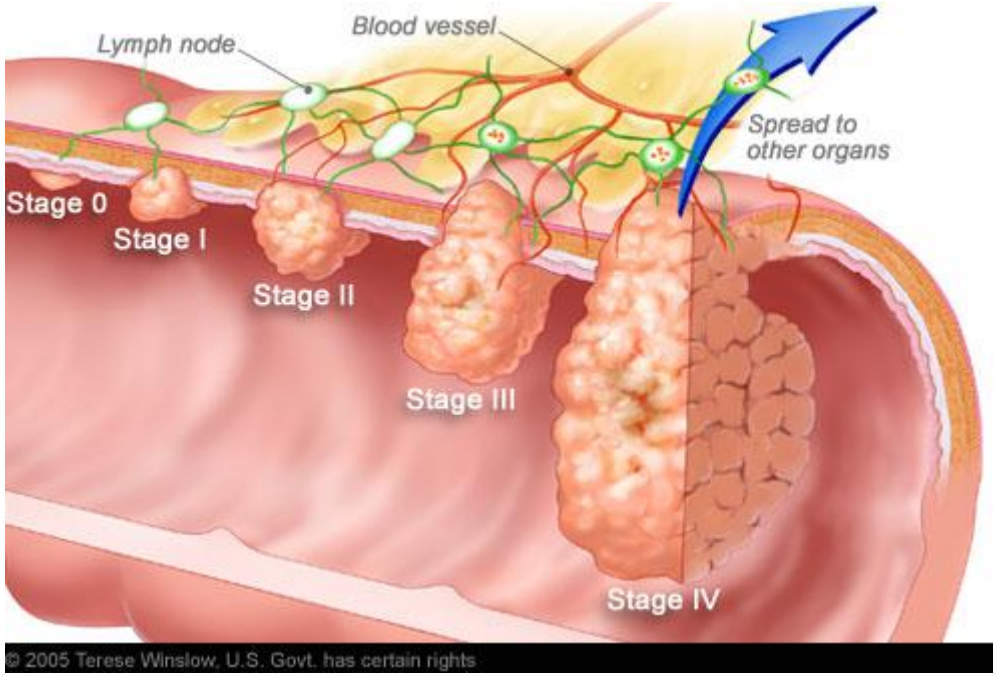
91% of pancreatic cancer patients die – Diagnosed in an Advanced and Incurable Stage!!

Screening tests for breast cancer, prostate cancer, colon cancer have saved millions of lives over the last 20 years.

Highly Sensitive and Specific Screening Tools URGENTLY NEEDED!!

PANCREATIC CANCER IN NUMBERS / American Cancer Society

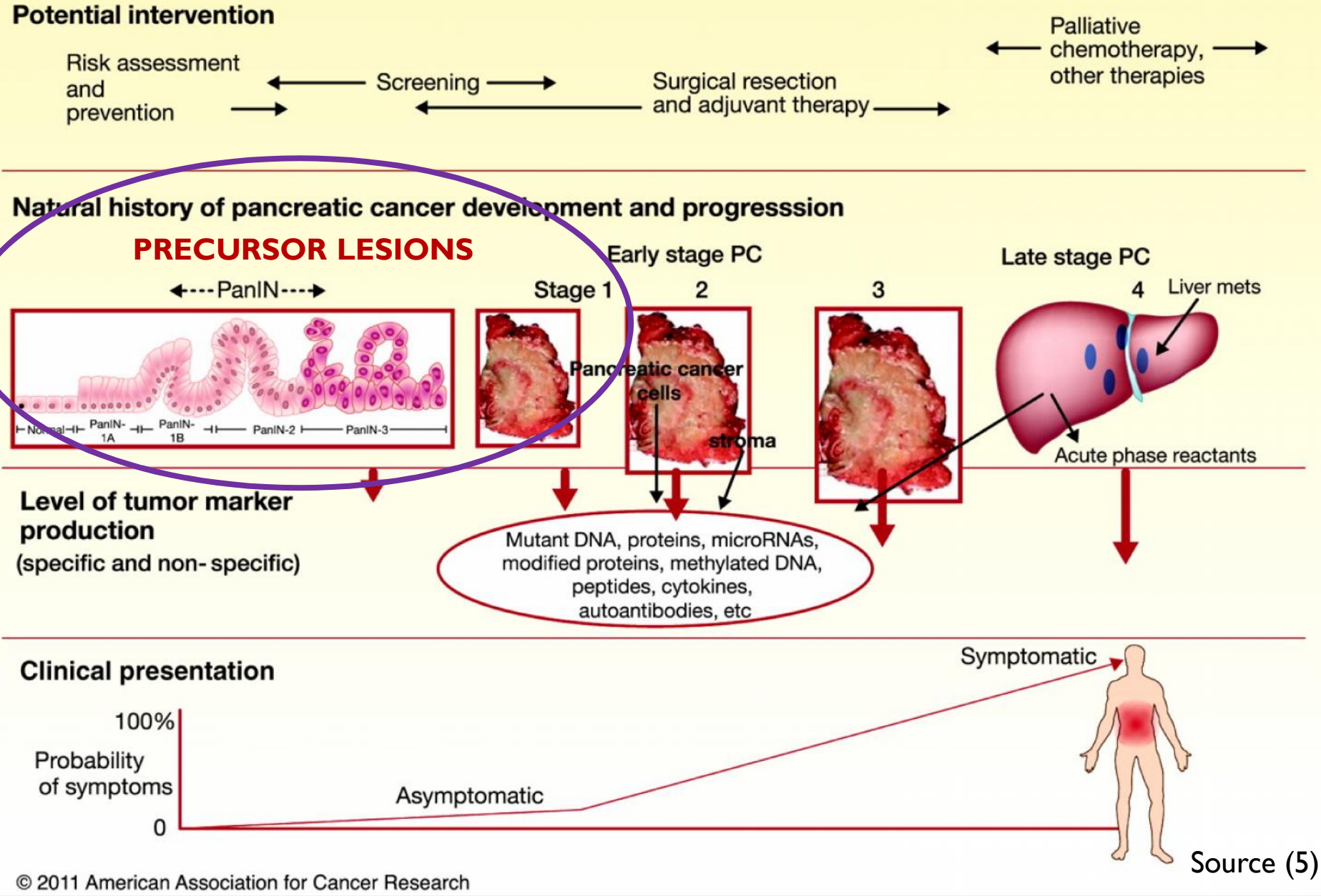
- **91%** mortality rate; **2,019,863 people died of PC** since 1971
- Estimated new cases in US, 2018 - 55,440 people
- Estimated deaths in US, 2018 - 44,330 people
- Average PC 5-year survival is <5%



Stage	Diagnosed	5 Year Survival Rate
Stage 0	**7%**	**20% +**
Stage I	**7%**	**20% +**
Stage II	26%	8.2%
Stage III	26%	8.2%
Stage IV	52%	1.8%

Source (4)

SELECTIVE SCREENING OF HIGH RISK INDIVIDUALS



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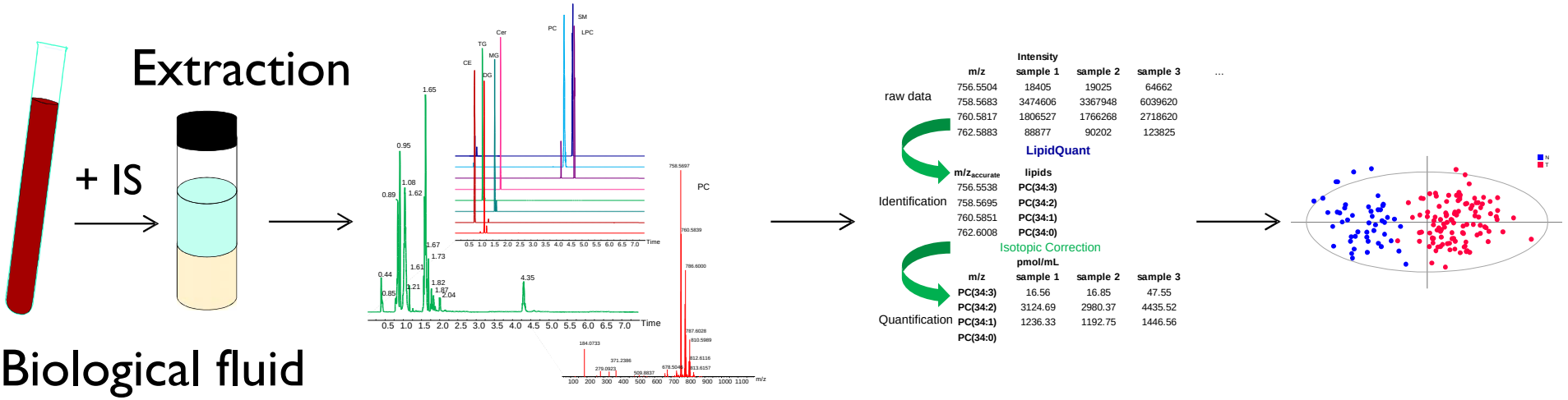
Source (5)

OUR APPROACH = MS LIPIDOMIC QUANTITATION



Biological fluid

- **10-25µl** of sample

MS based analysis

- UHPLC/MS, UHPSFC/MS
- MALDI/MS
- Shotgun MS

Data processing

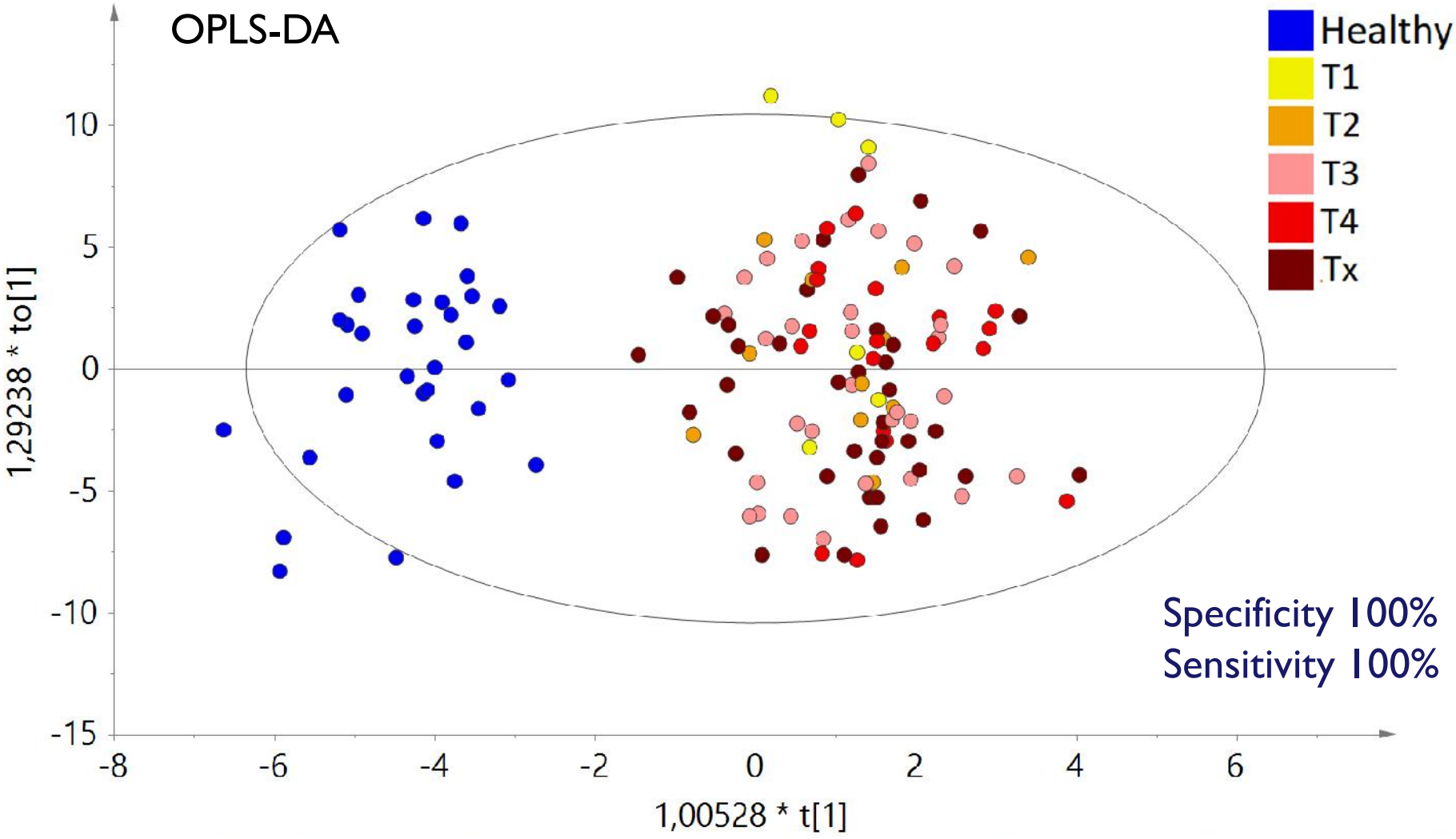
- own software
- MDA

Statistical Analysis

- **early stage** dysregulation – PanIN, T0

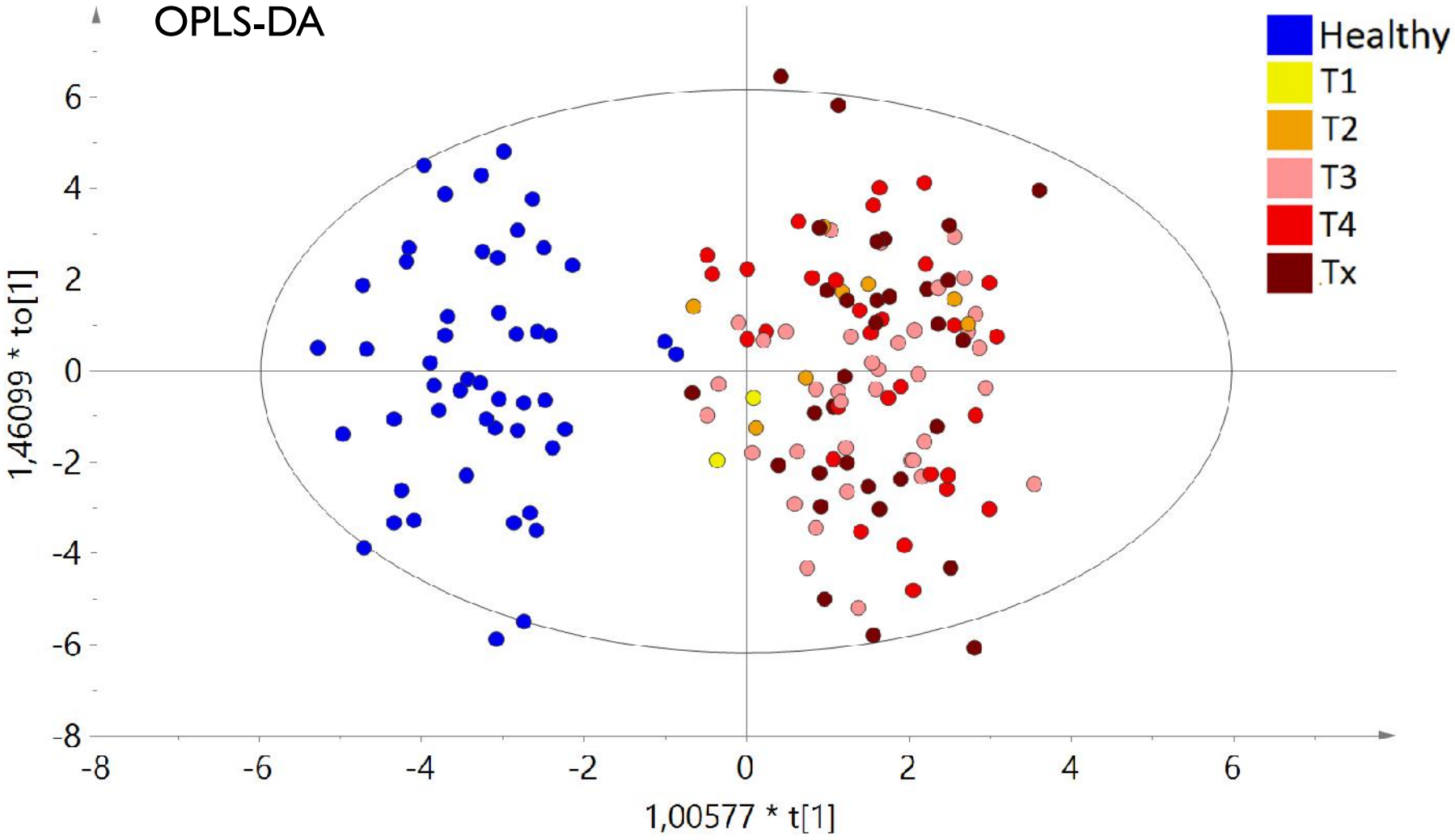
- lipidome dysregulation – up to **400 species**
- analysis time = **14 minutes**

Pancreatic Cancer: UHPSFC + Shotgun (Males)



Model works well for all stages including early stages T1 and T2

Pancreatic Cancer: UHPSFC + Shotgun (Females)



Model works well for all stages including early stages T1 and T2

COMPARISON WITH EXISTING SOLUTIONS

recommended by International Cancer of the Pancreas Screening (CAPS) Consortium summit

Selective screening of individuals at increased risk based on their family history or identifiable genetic predisposition is considered very worthwhile, because pancreatic neoplasia detected early is potentially curable.
Further competitor method could be Immunovia´s IMMray™ PanCan-d test - platform based on antibody microarray analysis, still in validation.

Method	Invasive	Sensitivity	Specificity	Radiation or magnetic field exposure	Operator dependance	Price per test or analysis in Europe, US more expensive
EUS	✓	**95 %**	**80 %**	**x**	✓	**from 125 EUR**
MRI/MRCP	**x**	**>83 %**	**>8 %**	✓	**x**	**from 200 EUR**
MS Lipidomics	**x**	**>95 %**	**>95 %**	**x**	**x**	**expected below 40 EUR**

IP & DEVELOPMENT STATUS

- EP application was filed in January 2018. 2nd EP application in preparation, filing expected May 2018.
- current results derived from clinical validation covering about **1,000** human samples of healthy volunteers and cancer patients
- methodology could discriminate pancreatic cancer patients from healthy controls with >**95%** accuracy
- the sample throughput is **10,000 samples per year** and one MS system
- validated in line with recommendations of **FDA and EMEA**

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COMMERCIAL OPPORTUNITY

Worldwide Unmet Need

The global pancreatic cancer therapeutics & diagnostics market is expected to witness a CAGR 5.6% during the forecast period, 2018-2023.

Based on test, the market has been segmented into:

- Imaging test, Biopsy, Blood test

Based on end user, global pancreatic cancer diagnostics market is segmented into:

- Hospitals, Oncology Institutes, Diagnostic Centres

Icon created by Vectors Market – Flaticon.com

FURTHER DEVELOPMENT

3 months

Current model adoption by clinical lipidomic lab!

The methodology is available for licensing and further development.

Technology development, ERC CZ funding

2013 - 2018

2 mil EUR spent

Model improvements, further clinical validation, various effects on variability, model for further diseases, urine samples analysis, etc.

2018 - 2023

3 mil EUR expected costs

RESEARCH TEAM

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http://holcapek.upce.cz/

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SOURCES

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