

# Objective of PancreOs

PancreOs kick-off meeting. Madrid, 17th March 2016

- Improve information on pancreatic cancer
- Ensure appropriate sustainable collection of clinical data, comparability issues, exchange of data and information within and between European countries
- **Build a common European infrastructure for standardized information exchange in pancreatic cancer care**

The main outcome of the PancreOS project will be a **permanent and sustainable online standardised exchange of data**, through the use of a common dataset, to produce global indicators on the clinical management of pancreatic cancer in Europe... to identify areas of improvement.

The main advantage of starting PancreOs in several European centres at the same time is that the methodology (data collection, software use, data analysis and ethics) will ensure direct comparability.

# Round-table: Consensus on variables

# Consensus on variables (I)

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## PancreOs Variable list

### Personal details and socio-demographic variables; lifestyle factors

Date of birth, gender, weight in last 5 years (habitual), height

**Smoking:** yes/no (pack years)

**Alcohol:** yes/no (frequency and type of beverage)

Pathology confirmed: yes/no

Date of the interview

### Medical history

**History of other diseases:** for all previous illnesses (date of diagnosis, type of drug/treatment, duration)

**History of cancer:** cancer type, type of relative and date (age) of diagnosis

**Family history of cancer:** no/yes for each relative (grade, type of cancer, age at diagnosis)

\*other PDAC-related diseases are collected in the surgery section

### Physical examination

first physician and oncologist assigned

### First symptoms

in addition: whether the case was presented/discussed in hospital committee; whether clinical trial was offered

Weight and height

ECOG scale

### Diagnostic procedures and results

**Tumour markers:** CEA and CA19.9

### Clinical diagnosis:

Diagnostic method and date

Pancreatic mass found: yes/no, and location

Metastases: yes/no, and location

Drainage: yes/no

Date of diagnosis, procedure (imaging/pathology):

# Consensus on variables (II)

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## Histology:

- Diagnostic sample obtained
- Biopsy or cytology
- Location

## Tumor stage:

Date of diagnosis, procedure (imaging/pathology):

### cTNM and pTNM

**disease status** (resectable, potentially resectable, advanced-local, metastatic)

**histological type** (if pathology, verification is available),

grade

surgery: yes/no

**metastatic disease diagnosis** (date, procedure)

## Treatment-surgery

Date, type of intervention/surgery (e.g. partial pancreatectomy, etc.)

margin status (negative, residual, not evaluable)

invasion: venous, lymphatic, perineural

\*pTNM included in the previous section

additional pathological findings: chronic or acute pancreatitis, PAN, other lesions

**post-surgery:** hospitalization duration, complications (yes/no)

psychological, nutritional, pain treatment support: yes/no

# Consensus on variables (III)

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## Treatment-radiotherapy

Yes/no

Date, dose (Gy), duration, irradiation fields, number of sessions, setting (resectable, potentially resectable, unresectable, metastatic)

## Treatment-chemotherapy

Yes/no

intent (adjuvant, neoadjuvant, metastatic: first or second line), type of drug, duration,

**Response:** complete, partial, stabilized, Progression, not evaluated), end of treatment (progression, deterioration, etc)

**Progression/relapse:** date, location (local, distant, liver and other organs... if metastases were found)

## Supportive/palliative treatment

sent to palliative unit: yes/no

**Clinical trials:** yes/no

## Follow-up

Status: alive, lost to follow-up, dead (date of death)

Main cause of death: disease progression, disease-related complications (to be specified), toxicity, not related recurrent events (to be specified), other

# Consensus on variables (IV)

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☐ All variables **needed to evaluate adherence to clinical guidelines (ESMO 2015)** will be collected. New variables to be implemented are:

- Number of involved LN/number of examined LN
- Diagnostic method: EUS, MRI, etc.
- Whether potential metastases were evaluated
- Palliative therapy (more detailed)

Except, follow-up every 8 weeks (not feasible!)

☐ Variables inefficiently collected in the pilot be removed (e.g. ABO blood group, etc.).

clinical practice guidelines

Annals of Oncology 23 (Supplement 7): vi33–vi40, 2012  
doi:10.1093/annonc/mds224

**Pancreatic adenocarcinoma: ESMO–ESDO Clinical Practice Guidelines for diagnosis, treatment and follow-up<sup>†</sup>**

T. Seufferlein<sup>1</sup>, J.B. Bachet<sup>2</sup>, E. Van Cutsem<sup>3</sup> & P. Rougier<sup>4</sup>, on behalf of the ESMO Guidelines Working Group\*

ESDO, European Society of Digestive Oncology

<sup>1</sup>Department of Internal Medicine I, University of Ulm, Ulm, Germany; <sup>2</sup>University Paris XI, Paris, France; <sup>3</sup>Department of Digestive Oncology, University Hospital Gasthuisberg, Leuven, Belgium; <sup>4</sup>University of Versailles UVSQ, Paris, France

# **Round-table : Data sharing (variables and standardization)**

# Data sharing

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- ✓ **High quality data** = accurate, complete, up-to-date data at time of release, coherent (internal consistency)
- ✓ **Multidisciplinary team involved in data collection:** oncologists, surgeons, pathologists, etc.
- ✓ **Data protection policy:** PancreOS has to maintain the **privacy of the data subjects and confidentiality** to ensure that operations comply with the data protection regulation, using:
  - *Anonymised data:* identifiers removed so that there is no reasonable possibility to link data back to individual persons to whom data relates
  - *Encrypted data:* data rendered unintelligible to any person who is not authorized to access it



# Variables standardization

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Manual of protocols and procedures

→ Is being formalized under ENCR guidance

Data/variables definitions: data documentation files

→ Is being formalized under ENCR guidance



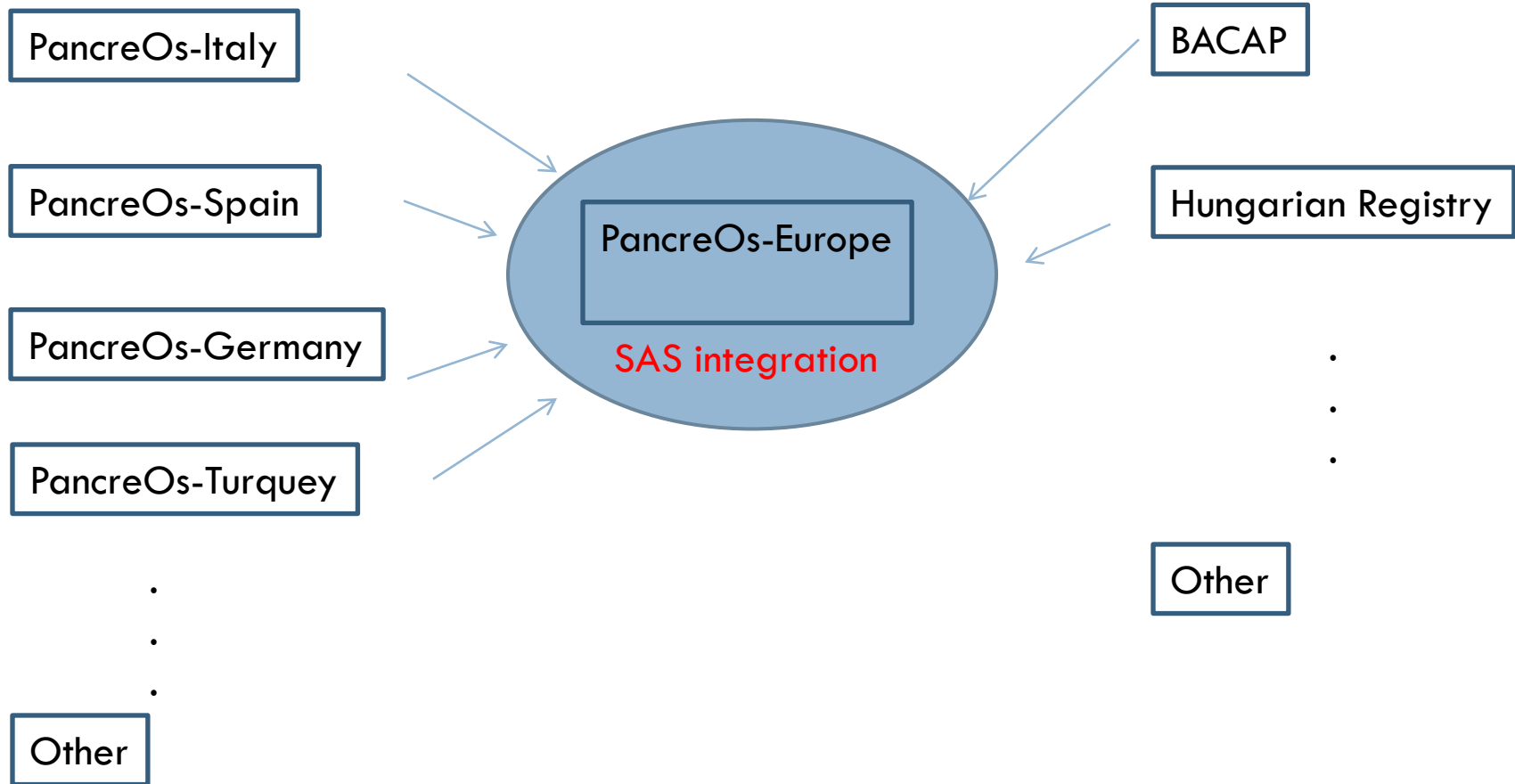
## **To facilitate data integration/harmonization:**

- Selection of standard datasets and terminology to facilitate local and cross-border exchange: e.g. ICD for coding cancer sites

→ Is being implemented under ENCR guidance

# Data sharing process

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# Round-table: Ethical and legal issues

# Ethical & legal issues (I)

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- ✓ A patient registry can be established using either of two legal instruments:
  - 1) explicit consent of the data subject
  - 2) based on law, in particular cases (e.g. population-based cancer registries)
- ✓ **The explicit consent**, where the data subject approves the processing of his/her personal data, will be the primary ethical instrument in PancreOS, under two assumptions: The protection of patient's privacy and Confidentiality
- ✓ However, **this is case-specific** and require in-depth ethical evaluation → Contact the local Ethical Committee concerning the ethical issues of PancreOS establishment in your country to start the evaluation process
- ✓ PancreOS-Spain has already obtained Ethical Approval.

**Both ethical approval and the patient's informed consent need to specify an informed indication on data sharing across the PancreOS-Europe framework.**

→ PancreOS will provide documentation (standard informed consent + study protocol)

# Ethical & legal issues (II)

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## Considering Legal Aspects and Confidentiality

Most important European law affecting patient registries': **Data Protection Directive (95/46/EC)** that regulates the collection, processing and distribution of personal data.

But the implementations and interpretations of the Data Protection Directive vary between countries → contact the data protection authorities in your country (surely needed if personal data is being collected)

### **Data ownership and access:**

**Registry holder:** Multi-stakeholder platform (Pancreatic Cancer Europe)

List of data providers: all participating PancreOS centers/countries

Legal basis for establishment

Legislation and standards (privacy, national, international) that PancreOS must adhere to

→ Policy document will be formalized

# Ethical & legal issues (II)

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## Data protection authorities and contact details

EU Member State	Data Protection Authority	email
Austria	<a href="#">Österreichische Datenschutzbehörde</a>	<a href="mailto:dsb@dsb.gv.at">dsb@dsb.gv.at</a>
Belgium	<a href="#">Commission de la protection de la vie privée</a>	<a href="mailto:commission@privacycommission.be">commission@privacycommission.be</a>
Bulgaria	<a href="#">Commission for Personal Data Protection</a>	<a href="mailto:kzld@cpdp.bg">kzld@cpdp.bg</a>
Croatia	<a href="#">Croatian Personal Data Protection Agency</a>	<a href="mailto:azop@azop.hr">azop@azop.hr</a> ; <a href="mailto:info@azop.hr">info@azop.hr</a>
Cyprus	<a href="#">Commissioner for Personal Data Protection</a>	<a href="mailto:commissioner@dataprotection.gov.cy">commissioner@dataprotection.gov.cy</a>
Czech Republic	<a href="#">The Office for Personal Data Protection</a>	<a href="mailto:posta@uouu.cz">posta@uouu.cz</a>
Denmark	<a href="#">Datatilsynet</a>	<a href="mailto:dt@datatilsynet.dk">dt@datatilsynet.dk</a>
Estonia	<a href="#">Estonian Data Protection Inspectorate</a>	<a href="mailto:viljar.peep@aki.ee">viljar.peep@aki.ee</a>
Finland	<a href="#">Office of the Data Protection</a>	<a href="mailto:tietosuojia@om.fi">tietosuojia@om.fi</a>
France	<a href="#">Commission Nationale de l'Informatique et des Libertés</a>	
Germany	<a href="#">Der Bundesbeauftragte für den Datenschutz und die Informationsfreiheit</a>	<a href="mailto:poststelle@bfdi.bund.de">poststelle@bfdi.bund.de</a>
Greece	<a href="#">Hellenic Data Protection Authority</a>	<a href="mailto:contact@dpa.gr">contact@dpa.gr</a>
Hungary	<a href="#">Data Protection Commissioner of Hungary</a>	<a href="mailto:peterfalvi.attila@naih.hu">peterfalvi.attila@naih.hu</a>
Ireland	<a href="#">Data Protection Commissioner</a>	<a href="mailto:info@dataprotection.ie">info@dataprotection.ie</a>
Italy	<a href="#">Garante per la protezione dei dati personali</a>	<a href="mailto:garante@garanteprivacy.it">garante@garanteprivacy.it</a>
Latvia	<a href="#">Data State Inspectorate</a>	<a href="mailto:info@dvi.gov.lv">info@dvi.gov.lv</a>
Lithuania	<a href="#">State Data Protection</a>	<a href="mailto:ada@ada.lt">ada@ada.lt</a>
Luxembourg	<a href="#">Commission nationale pour la protection des données</a>	<a href="mailto:info@cnpd.lu">info@cnpd.lu</a>
Malta	<a href="#">Office of the Data Protection Commissioner</a>	<a href="mailto:commissioner.dataprotection@gov.mt">commissioner.dataprotection@gov.mt</a>
Netherlands	<a href="#">Dutch Data Protection Authority</a>	<a href="mailto:info@cbpweb.nl">info@cbpweb.nl</a>
Poland	<a href="#">The Bureau of the Inspector General for the Protection of Personal Data</a>	<a href="mailto:sekretariat@uodo.gov.pl">sekretariat@uodo.gov.pl</a>
Portugal	<a href="#">Comissão Nacional de Protecção de Dados</a>	<a href="mailto:geral@cnpd.pt">geral@cnpd.pt</a>
Romania	<a href="#">The National Supervisory Authority for Personal Data Processing</a>	<a href="mailto:anspdc@dataprotection.ro">anspdc@dataprotection.ro</a>
Slovakia	<a href="#">Office for Personal Data Protection of the Slovak Republic</a>	<a href="mailto:statny.dozor@pdp.gov.sk">statny.dozor@pdp.gov.sk</a>
Slovenia	<a href="#">Information Commissioner</a>	<a href="mailto:gp.ip@ip-rs.si">gp.ip@ip-rs.si</a>
Spain	<a href="#">Agencia de Protección de Datos</a>	<a href="mailto:internacional@agpd.es">internacional@agpd.es</a>
Sweden	<a href="#">Datainspektionen</a>	<a href="mailto:datainspektionen@datainspektionen.se">datainspektionen@datainspektionen.se</a>
United Kingdom	<a href="#">Information Commissioner's Office</a>	<a href="mailto:casework@ico.org.uk">casework@ico.org.uk</a>
England	<a href="#">Information Commissioner's Office</a>	<a href="mailto:casework@ico.org.uk">casework@ico.org.uk</a>
Northern Ireland	<a href="#">Information Commissioner's Office</a>	<a href="mailto:ni@ico.org.uk">ni@ico.org.uk</a>
Scotland	<a href="#">Information Commissioner's Office</a>	<a href="mailto:Scotland@ico.org.uk">Scotland@ico.org.uk</a>
Wales	<a href="#">Information Commissioner's Office</a>	<a href="mailto:wales@ico.org.uk">wales@ico.org.uk</a>
EU	<a href="#">Data Protection Officer of the EU</a>	<a href="mailto:DATA-PROTECTION-OFFICER@ec.europa.eu">DATA-PROTECTION-OFFICER@ec.europa.eu</a>



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# Round-table: Requirements to become a partner

# Requirements

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Terms	Request
Commitment: 2-3 years and exhaustiveness of case recruitment	Yes
Ethical approval requested (approval needed for data sharing), depending upon local rules. In addition, some centers may need to consider country-specific data protection laws.	Yes
Work under the PancreOs coordinating center guidance	Yes
Data quality controls: complete and consistent data needed	Yes
Collaboration established with population-based registries	Recommendable
Multi-disciplinary team involved	Recommendable

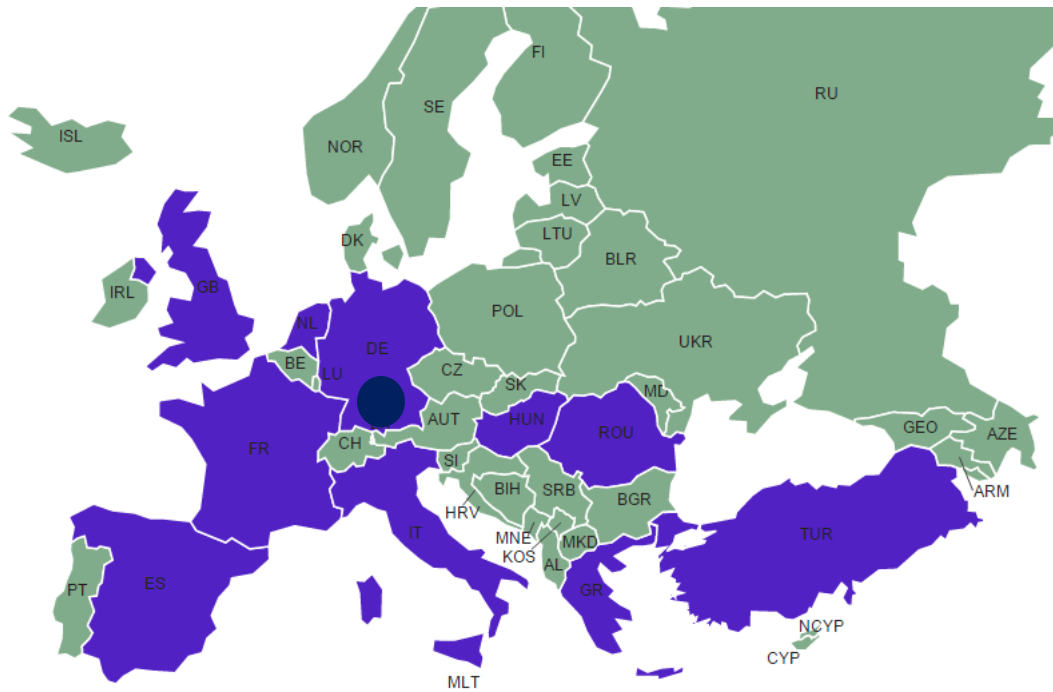


# How to become a partner

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## Need to involved more centers & countries

How to become a PancreOS collaborator? Contact **Alfredo Carrato & Núria Malats**



**Expression of interest,**  
describing setting,  
resources, etc.



Seek approval by  
PancreOs Steering  
Committee



Sign collaboration  
agreement to become an  
official "PancreOs center"

# Round-table : Other difficulties & challenges

# Difficulties & Challenges

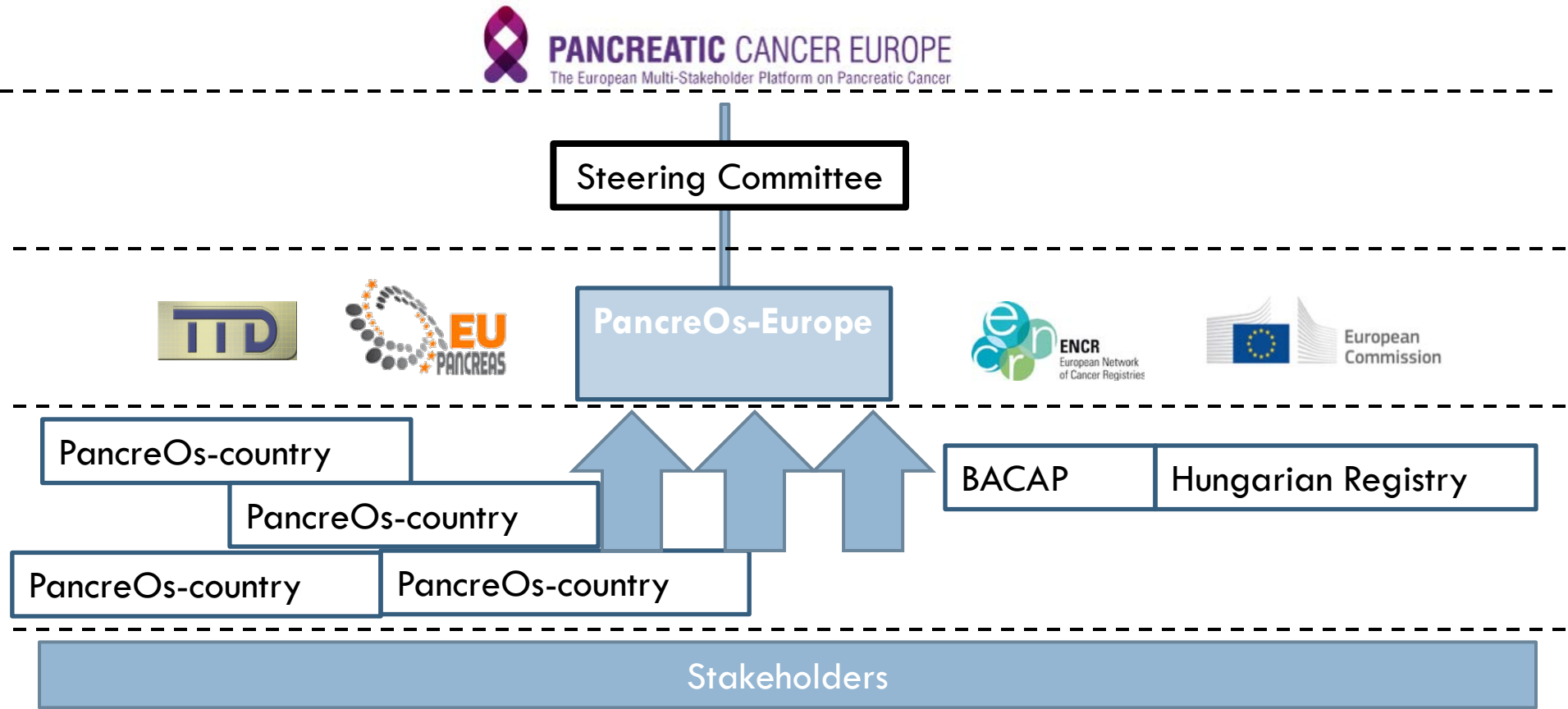
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- 1) **Legal issues** concerning registry set-up. Legal backgrounds differ greatly across Europe
- 2) **Involvement of stakeholders**
- 3) **Involvement of other centres and countries:** i) lack of centres in some Northern and Eastern European countries; ii) some countries are under-represented: more centres needed
- 4) Balance between accuracy and timelines
- 5) **Data quality and exhaustiveness:** need of a common quality control tool
- 6) **Registry transparency and openness for research purposes:** at local/national level, and at PancreOS-European level
- 7) **Reporting and Dissemination**
- 8) **Need of stable funding to ensure sustainability**

# Steering Committee & Coordination Centres

# PancreOS organization

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# Steering Committee

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- ✓ 1 representative per country/initiative contributing with >> 5 centres
- ✓ 1 ENCR member
- ✓ 1 Pancreatic Cancer Europe
- ✓ 1 EUPancreas member
- ✓ 1 TTD member

**External expert opinion will be seek when needed**

# Strategic plans and timelines





# Dissemination

# Dissemination

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White Paper: PancreOS

Newsletters for the PancreOS community

Website at [www.pancreaticcancereurope.eu](http://www.pancreaticcancereurope.eu) & [www.eupancreas.com](http://www.eupancreas.com)



The screenshot shows the website [www.pancreaticcancereurope.eu/work-streams/registries/](http://www.pancreaticcancereurope.eu/work-streams/registries/). The page features the Pancreatic Cancer Europe logo and navigation menu. The main content area is titled "Registries" and includes a graphic of people holding hands around a globe. A sidebar on the right provides information about EUPancreas, including a list of member types and a map of Europe.

www.pancreaticcancereurope.eu/work-streams/registries/

**PANCREATIC CANCER EUROPE**  
The European Multi-Stakeholder Platform on Pancreatic Cancer

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## EUPancreas

EUPancreas is a COST Action (BM1204) that aims to unite pancreas cancer research groups across Europe and provides an innovative and unique platform for collaborating and sharing information, ideas and experience. We are 195 multidisciplinary members from:

- 22 EU countries
- 5 EU gov & non-gov institutions
- 3 Biotech companies (SME)
- 1 Pharma company

Registries



## Other issues

# Funding opportunities for sustainability

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## ***Public sector***

- ✓ At national/local level
- ✓ At international level: H2020

## ***Private sector***

Pharma companies (e.g. Celgene)  
Bank foundations

## ***NGOs (non-governmental organizations, i.e., charities)***

Patient organizations  
Scientific associations

→ Need to develop a funding strategy

# Resource planning

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## Human resources

- Project management
- Data management
- Epidemiology & statistical support
- Data dissemination
- Legal/data security & protection

PancreOS-Europe

## Each PancreOS centre will be responsible for resources on:

- Data collection
- Financial
- Legal/data security & protection

**Information Technology Resources** → PancreOS-Europe

# American Pancreatic Cancer registry

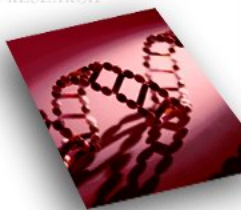
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← → ↻ pccrproject.com

## PANCREATIC CANCER

COLLABORATIVE REGISTRY PROJECT

CANCER RESEARCH



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### Pancreatic Cancer Collaborative Registry (PCCR)

PCCR is designed to unite centers with expertise in pancreatic cancer epidemiology, genetics, biology, early detection and patient care to facilitate rapid and uniform collection of critical information and biological samples to be used in developing prevention and treatment strategies against pancreatic cancer.

This resource is available to all participating institutions that desire the appropriate computing support. Institutional IRB approval and patient informed consent must be obtained.

The purpose of the project is to develop a national pancreatic cancer resource, the Pancreatic Cancer Collaborative Registry, which will include personal background information, medical, and family details, as well as dietary and environmental exposure history and a biospecimen registry from pancreatic cancer patients and their family members. One of the major goals of the PCCR is to help researchers identify what specifically causes pancreatic cancer, and possibly identify those individuals/families that are at increased risk for pancreatic as well as other cancers. Researchers may also identify those individuals who might benefit from screening measures to detect pre-cancerous changes at an earlier and potentially more treatable stage.



The PCCR is committed to protecting each individual's confidentiality/privacy online. Security issues are addressed using recommendations of the Healthcare Information and Management Systems Society (HIMSS) Privacy & Security Toolkit and the electronic information security standards regarding the collection, use, and retention of data mandated by the Federal Health Insurance Portability and Accountability Act (HIPAA).

If you are interested in becoming a participating center or you are an individual/family interested in participating in this study and/or want more information regarding the PCCR please contact us.

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Publication:

Simon Sherman, Oleg Shats, Marsha A. Ketcham, Michelle A. Anderson, David C. Whitcomb, Henry T. Lynch, Paola Ghiorno, Wendy S. Rubinstein, Aaron R. Sasson, William E. Grizzle, Gleb Haynatzki, Jianmin Feng, Alexander Sherman, Leo Kinarsky and Randall E. Brand. PCCR: Pancreatic Cancer Collaborative Registry. *Cancer Informatics* 2011;10 83-91.

Developed by and hosted at the University of Nebraska Medical Center, Fred & Pamela Buffett Cancer Center



# Virtual biobanking for PancreOs?

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## Characteristics:

- Store samples in a decentralized manner (each center keeps its own samples)
- Apply the EUPancreas\_SOP
- Create a data repository, regularly updated
- Display data repository via a software or web portal

## An example:

### UK Prostate Cancer Sample Collection Database



#### Introduction

The two prostate cancer collaboratives which have been established in England have been working together for a number years. The two collaboratives are ProMPT and the Southern Collaborative. Both collaboratives have built up an extensive collection of human samples, derived bio-materials such as DNA and RNA, urine, fresh and paraffin embedded tissue materials.

We have established this joint database to highlight to the research community the facilities that are available potentially for collaborative studies with our respective groups. We hope you find this useful or more formal enquiries for access to samples and for research collaborations. We frequently release relatively small amounts of material for proof of principle studies but for larger studies, these go to our Scientific Advisory Committee to review quality.

Contributing organisations are responsible for making sure that samples are collected in accordance with the Human Tissue Act and are stored in HTA licenced premises.

Definitions for various terms can be found by placing the mouse pointer over the relevant word. For example point at this. A full list of terms and definitions can be found in the [glossary](#).

If you are a UK prostate researcher and you would like your collection of clinical prostate samples to be included on this database, please [contact us](#).

#### Collections

Name	Num Patients	Study Sample Type(s)	Study Type(s)
ProtecT	77223	TMA Core, TURP, Urine, Whole Prostate - Fresh, Whole Prostate - FFPE, Biopsy, Blood	Radiotherapy, TURP, Active Surveillance, Other treatments, Hormone Therapy, Prostatectomy
UK Genetic Prostate Cancer Study	10589	Blood	Genetics
ProMPT	3174	Whole Prostate - Fresh, Blood, Urine, Biopsy, TURP, Whole Prostate - FFPE, TMA Core	Non-cases, Hormone Therapy, Active Surveillance, TURP, Radiotherapy, Prostatectomy
TransAtlantic Prostate Group (TAPG) series	800	TMA Core	TURP
Wales Cancer Bank	662	Biopsy, Blood, TURP, Whole Prostate - Fresh, Whole Prostate - FFPE	Prostatectomy
Exeter Tissue Bank	569	TURP	TURP
Danish TMA	378	TMA Core	Prostatectomy
Active surveillance trial	292	Biopsy, TMA Core	Active Surveillance



COST  
EUROPEAN COOPERATION IN SCIENCE AND TECHNOLOGY



<b>Title</b>	Standard Operating Procedure (SOP) for Pancreatic cancer Fresh Tissue samples		
<b>Reviewers</b>	Irene Esposito	Esther Molina	Draft Date: 25th January 2016

#### I - PURPOSE

The purpose of this procedure is to describe the process for the collection and storage of pancreatic cancer patient tumour tissue in a biobank, so as to provide optimally preserved tissue that can be linked to relevant epidemiologic, genetic and/or clinical data.

#### II - SCOPE

This procedure is applicable to all individuals who want to perform a high quality collection and storage of pancreatic cancer fresh tissue that will be placed in a biobank.

**Questions ??**



# THANK YOU !!

## PancreOS kick-off meeting

Madrid

March 17, 2016