



# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients



# Gábor Lakatos

Department of Oncology, St. Istvan and St. Laszlo Hospital, Budapest  
Hungarian Pancreatic Study Group

## Pancreatic Cancer Registry

**12th November 2016**  
**Budapest**



# Pancreatic Cancer Introduction



Pancreatic cancer remains a major health problem

## Incidence

### -Worldwide (2008)

- new cases: 279 000
- deaths: 266 000

### - Hungary (2010):

- new cases: 2373
- deaths: 1837

## Prognosis - unfavourable

1-year survival: 19%

5-year survival: 0,4-4%



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## Pancreatic cancer

Major health problem

**5 year survival** rate < 5%

Management of PC remains a **big challenge**

**Treatment options** in metastatic disease:

- Folfirinox
- nab-paclitaxel
- MM398

**Neoadjuvant** treatment: still controversial



# Pancreatic Cancer Introduction



## Central Europe – limited information

- **Worse prognosis** compared to western countries
- **Increasing incidence and mortality (1.)**  
(Romania, Albania, Croatia, Serbia)

## Possible explanation:

### Differences:

- the use and access of **diagnostic tools** and **treatment modalities**
- changes in the **incidence of risk factors** (for example smoking)

(1.) Hariharan D et al



# Pancreatic Cancer

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## Registry for Pancreatic Patients (RPP)

Est.: 2012

- **Web-based electronic** data collection method
- 1600 patients, more than 1300 blood samples in the Biobank.
- 34 Hungarian centers, 23 centers from abroad

### cohort studies:

- acute pancreatitis
- chronic pancreatitis
- **pancreatic cancer**
- pediatric pancreatitis



# Pancreatic Cancer

## The importance of cancer registries



### Objective (SEER):

Collect **accurate** and **complete cancer data** that can be used for

- cancer control and epidemiological research,
- public health program planning,
- patient care improvement.

### Types of registries:

- Hospital-based
- Population-based



# Pancreatic Cancer

## The importance of cancer registries



### Practical application

- Environmental risk factors - **preventive measures** can be taken
- Identify the **causes** of cancer - detect **earlier** – find a **cure**
- Maximize the effectiveness of limited public health funds,  
- implementation of **screening programs**
- **Follow-up** to determine whether the **treatment has worked**

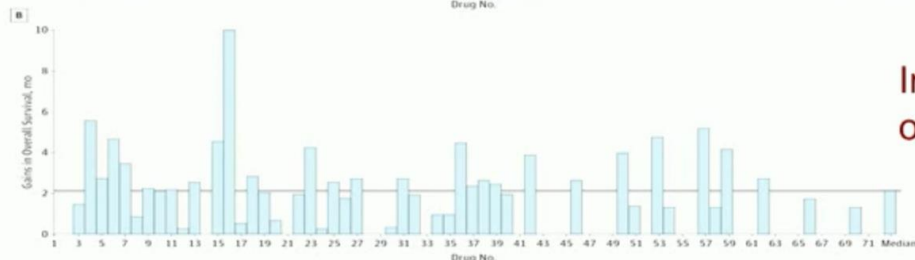
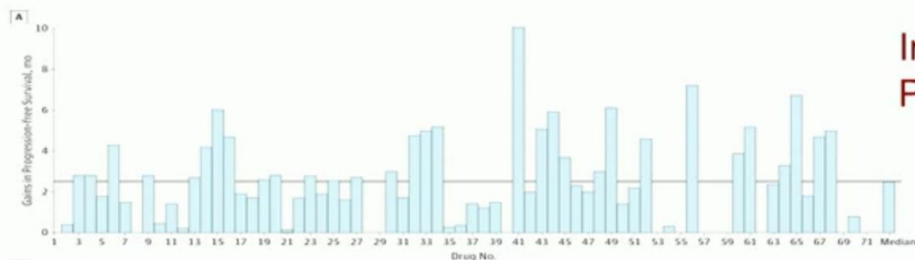
# Pancreatic Cancer

## The importance of cancer registries

### Economic considerations

- The **explosion** of innovation in **oncology**
- **dramatic** increases in **costs** – increase in **survival**?

## 71 drugs for all solid cancers approved by the FDA from 2002 to 2014



Fojo T et al. *JAMA Otolaryngol Head Neck Surg.* 2014; 140: 1225-1236

Hungarian Pancreatic Study Group – Eastern and Central European Pancreatic Study Groups



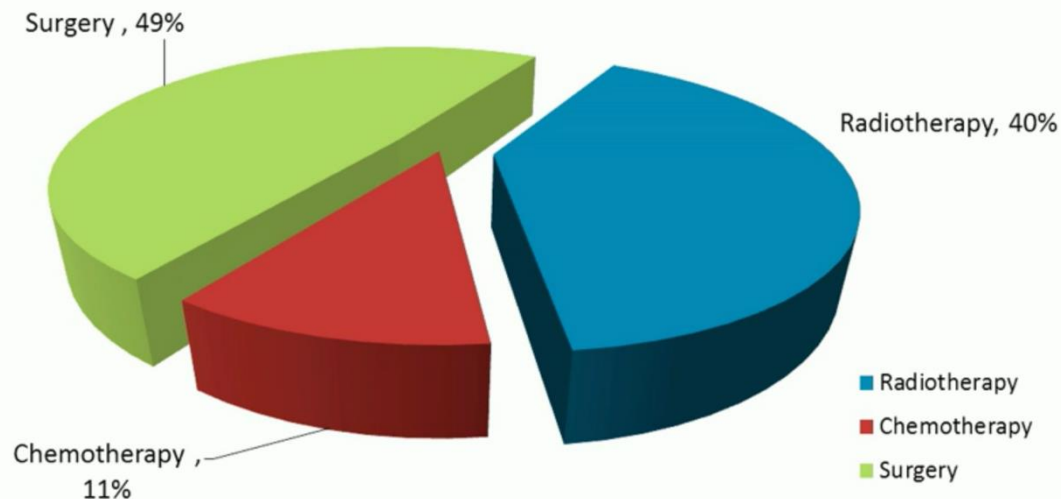
# Pancreatic Cancer

## The importance of cancer registries

### Economic considerations

- Worldwide, **drugs** associated with **cancer care** - **\$40 billion** per year
- 100** new **molecules** are in **phase III** trials

### Curative treatments for all cancers





# Pancreatic Cancer

## The importance of cancer registries



- Cancer is a **major burden**
- Impossible to **finance** all treatments.
- **Registries** can offer:
  - Transparency and control
  - Results from the „real world setting” vs. clinical trials

### National Health Insurance Fund

- Application of expensive therapies using **registries**:
  - **Colorectal** cancer: bevacizumab, regorafenib etc.
  - **Breast** cancer: trastuzumab
  - **Lung** cancer: erlotinib
  - **Pancreatic cancer**: nab paclitaxel, MM398 ????



# Pancreatic Cancer RENEWED REGISTRY FOR PANCREATIC CANCER



**2015** – the registry for pancreatic cancer has been **completely renewed**

## **Main changes:**

- The **content** of the questionnaire was fully **updated**
  - possibility of **more detailed** data collection
- The registry is available in **two languages** -
  - *Hungarian*
  - *English*
- International data collection** is now possible.

# Pancreatic Cancer

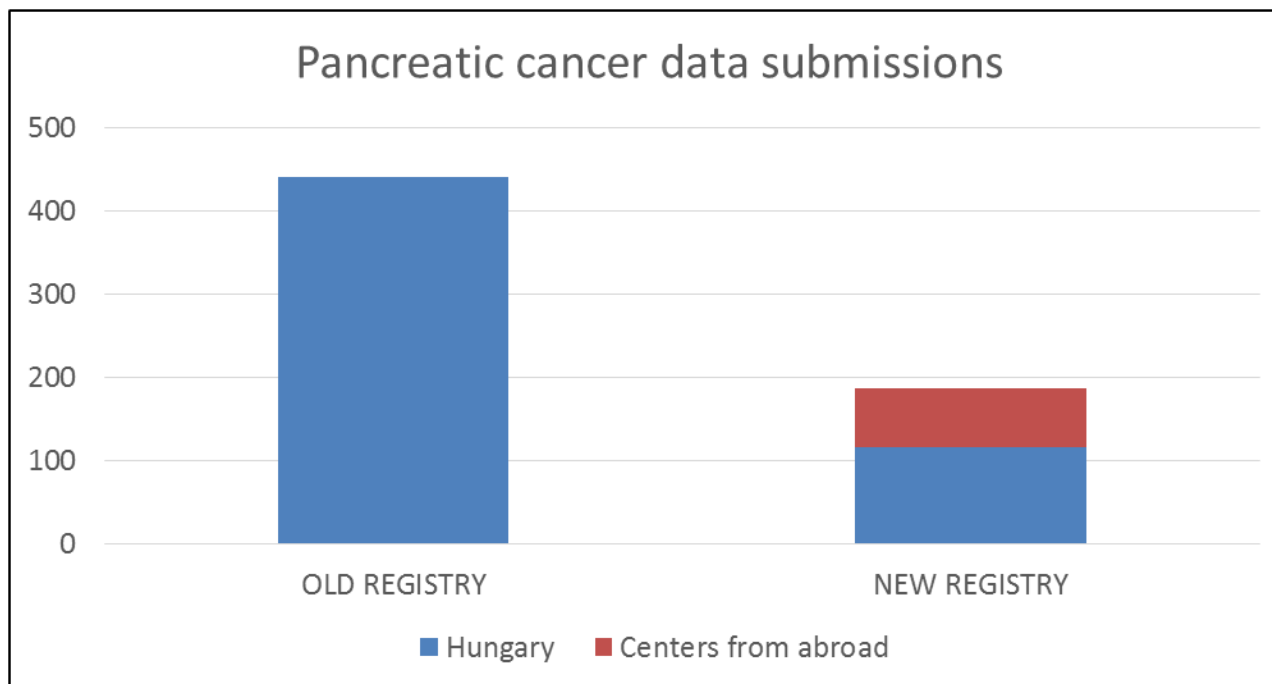
Biobank and Registry for Pancreatic Patients

## Data submissions

**2012-2015** – old registry: 440

**2015 -** new registry: 187

**Centers from abroad: 72 !!!**





# Pancreatic Cancer RENEWED REGISTRY FOR PANCREATIC CANCER



## Pancreatic cancer registry – CONTENT

- Patient personal details
- Details from the medical history
- Symptoms and signs
- Patient related data
- Tumor-related data
- Oncological therapy
- Supportive treatment

**HPSG-EDAS**  
Registry for Pancreatic Patients - Electronic Data Administration System

Magyar Hasnyálmirigy Munkacsoport Hungarian Pancreatic Study Group

Home » Forms

### Submit Pancreatic Cancer Form A

**Patient Form Pancreatic Cancer**

**1. Patient personal details**

Insurance number \*

Name \*

Date of birth \* -Year -Month -Day

Gender \* ☐ female ☐ male

Race - None -

Date of interview 2015 Oct 25

**Institute**  
Egyesített Szent István és Szent László Kórház - Rendelőintézet, Budapest

**Orvos kód**  
LG

**Blood sample code**

**Date of blood sampling**  
-Year -Month -Day

**Concent form** is available on the webpage

- Data recording
- Blood sampling

## The management of pancreatic cancer:

- **Multidisciplinary approach**

1. Pathologist

2. Radiologist

3. Gastroenterologist

4. Surgeon

5. Oncologist

- Data are usually submitted by: 3.-4.-5.
- **Heterogenous** data collection
- Too many missing data should be avoided
- Please **follow up** your patients!

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## General registry on pancreatic cancer:

- core database,

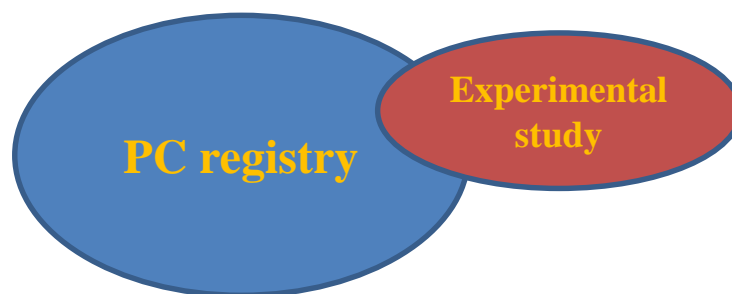
### *Aim:*

To collect all important information basically associated with

- epidemiology
- diagnosis and
- treatment

## Experimental studies

- specific issues on pancreatic cancer diagnosis or management





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## Details from the medical history

- Alcohol consumption
- **Smoking**
- Drug abuse
- History of infectious disease
- **Diabetes mellitus**
- Lipid metabolism disorder
- Familial pancreatic disease
- **Any disease of the pancreas**
- Medication taken
- Diet
- Weight/height
- **BMI**



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## Biobank and Registry for Pancreatic Patients

### Patient related data

#### - Date of diagnosis

- clinical
- histological

#### - Survival status

#### • Date of death

#### - ECOG PS status

#### - Tumor markers:

**CA 19-9, CEA**

#### 4. Patient related data

Date of clinical diagnosis  -Year ▼  -Month ▼  -Day ▼

Date of CT verifying the diagnosis first  -Year ▼  -Month ▼  -Day ▼  
or

Date of MRI verifying the diagnosis first  -Year ▼  -Month ▼  -Day ▼  
or

Date of ERCP verifying the diagnosis first  -Year ▼  -Month ▼  -Day ▼  
or

Date of EUS verifying the diagnosis first  -Year ▼  -Month ▼  -Day ▼

Hystological verification: ☐ yes ☐ no ☐ N/A

If yes: Date of hystological sampling  -Year ▼  -Month ▼  -Day ▼

Weight at the date of diagnosis  kg

Height at the date of diagnosis  cm

Body Mass Index (BMI)  kg/m2

ECOG status  - None -

#### Tumor markers at the date of diagnosis

CA 19-9  U/ml Date  -Year ▼  -Month ▼  -Day ▼

CEA  ng/ml Date  -Year ▼  -Month ▼  -Day ▼

Is the patient alive? ☐ yes ☐ no

If not: Date of death  -Year ▼  -Month ▼  -Day ▼

### Tumor related data

#### - Staging

- clinical
- pathological

#### - Resectability

#### - Surgical treatment

- type of surgical intervention

#### - Endoscopic treatment

#### - Radiological intervention

#### 5. Tumor-related data

##### Clinical stage

T

N

M

Tumor location

##### If histological verification is available

Please mark the tumor type

Type of sampling

Resectability at the date of diagnosis

Surgical intervention: ☐ yes ☐ no

If yes: Date of surgical intervention

Type of surgical intervention:

##### In case of palliative surgery:

Type of palliative surgery  
☐ biliary bypass ☐ enteral bypass ☐ macroscopic residual disease (R2 resection) ☐ other

If not: please provide the reason

### Tumor related data

#### - Staging

- clinical
- pathological

#### - Resectability

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- type of surgery

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#### - Radiological intervention

### 5. Tumor-related data

#### T categories

**TX:** The main tumor cannot be assessed.

**T0:** No evidence of a primary tumor.

**Tis:** Carcinoma in situ (the tumor is confined to the top layers of pancreatic duct cells). (Very few pancreatic tumors are found at this stage.)

**T1:** The cancer is still within the pancreas and is 2 centimeters (cm) (about ¾ inch) or less across.

**T2:** The cancer is still within the pancreas but is larger than 2 cm across.

**T3:** The cancer has grown outside the pancreas into nearby surrounding tissues but not into major blood vessels or nerves.

**T4:** The cancer has grown beyond the pancreas into nearby large blood vessels or nerves.

#### N categories

**NX:** Nearby (regional) lymph nodes cannot be assessed.

**N0:** The cancer has not spread to nearby lymph nodes.

**N1:** The cancer has spread to nearby lymph nodes.

#### M categories

**M0:** The cancer has not spread to distant lymph nodes (other than those near the pancreas) or to distant organs such as the liver, lungs, brain, etc.

**M1:** The cancer has spread to distant lymph nodes or to distant organs.

If not: please provide the reason

- Select a value -

base (R2 resection) ☐ other

# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients

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#### - Radiological intervention

#### 5. Tumor-related data

##### Clinical stage

T

N

M

Tumor location

##### If histological verification is available

Please mark the tumor type

Type of sampling

Resectability at the date of diagnosis

Surgical intervention: ☐ yes ☐ no

If yes: Date of surgical intervention

Type of surgical intervention:

##### In case of palliative surgery:

Type of palliative surgery  
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### Tumor related data

#### - Staging

• clinical

• pathological

#### - Resectability

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• type of surgical intervention

#### - Endoscopic treatment

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### 5. Tumor-related data

#### Clinical stage

T

N

M

**Resectability at the date  
of diagnosis**

N/A

resectable

„borderline” resectable

non resectable – locally advanced

non resectable – metastasis

Type of surgical intervention:

#### In case of palliative surgery:

Type of palliative surgery

☐ biliary bypass ☐ enteral bypass ☐ macroscopic residual disease (R2 resection) ☐ other

If not: please provide the reason

## Definition of resectability according to NCCN guidelines

### Borderline resectable disease:

#### Pancreatic head/uncinate process

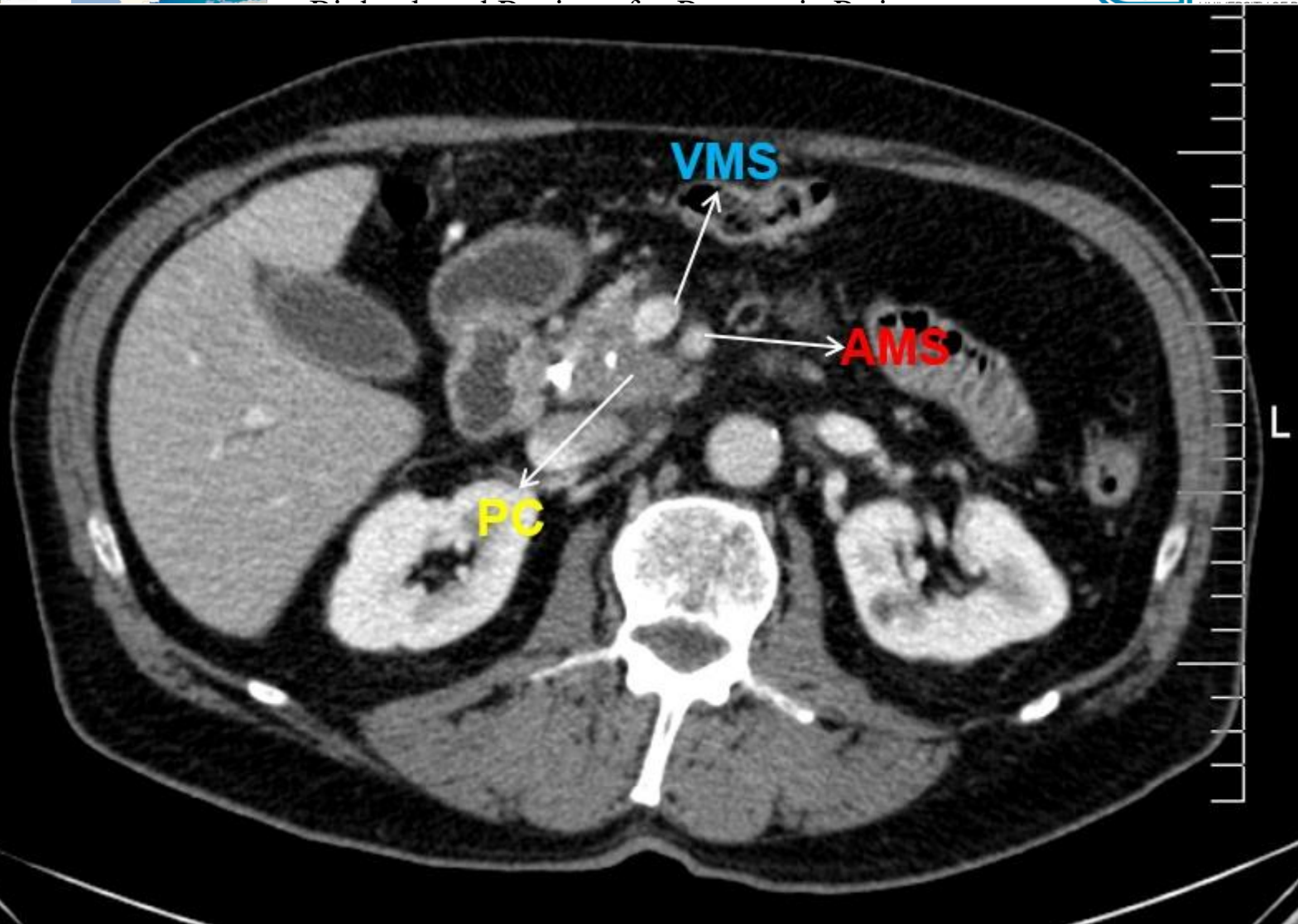
- Solid tumour with CHA without extension to coeliac axis or hepatic artery bifurcation allowing for safe and complete resection and reconstruction
- Solid tumour contact with the SMA  $\leq 180^\circ$
- Presence of variant arterial anatomy (e.g. accessory right hepatic artery) and the presence and degree of tumour contact should be noted if present as it may affect surgical planning
- Solid tumour contact with the SMV or PV of  $>180^\circ$ , contact of  $\leq 180^\circ$  with contour irregularity of the vein or thrombosis of the vein but with suitable vessels proximal and distal to the site of involvement allowing for safe and complete resection and vein reconstruction
- Solid tumour contact with the inferior vena cava (IVC)

#### Pancreatic body/tail

- Solid tumour contact with the CA of  $\leq 180^\circ$
- Solid tumour contact with the CA of  $>180^\circ$  without involvement of the aorta and with intact and uninvolved gastroduodenal artery (some members prefer these criteria to be in the unresectable category)



# Pancreatic Cancer





# Pancreatic Cancer

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## Neoadjuvant treatment:

**Reduce tumor size**

**Improve R0 resection rate and survival**

Treatment option mainly in **borderline resectable** cases

## ESMO guideline 2015:

*Treatment recommendation for borderline resectable disease:*

should be included in **clinical trials** wherever possible

In routine practice: period of **chemotherapy** (gemcitabine or FOLFIRINOX) **followed by chemoradiation** and then **surgery** appears to be the best option [IV, B]



# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients

### Tumor related data

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- pathological

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#### - Surgical treatment

- type of surgical intervention

#### - Endoscopic treatment

#### - Radiological intervention

#### 5. Tumor-related data

##### Clinical stage

T

N

M

Tumor location

##### If histological verification is available

Please mark the tumor type

Type of sampling

Resectability at the date of diagnosis

Surgical intervention: ☐ yes ☐ no

If yes: Date of surgical intervention

Type of surgical intervention:

##### In case of palliative surgery:

Type of palliative surgery  
☐ biliary bypass ☐ enteral bypass ☐ macroscopic residual disease (R2 resection) ☐ other

If not: please provide the reason

# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients

### Tumor related data

#### 5. Tumor-related data

##### Clinical stage

T

- None - ▼

##### Surgical intervention:

☒ yes ☐ no

If yes:

Date of surgical intervention

-Year ▼

-Month ▼

-Day ▼

Type of surgical intervention:

- Please select -  
- Please select -  
N/A  
pancreatoduodenectomy  
total pancreatectomy  
distalis pancreatectomy  
palliative surgery  
explorative laparotomy

##### In case of palliative surgery

Type of palliative surgery

☐ biliary bypass

☐ enteral by

ial disease (R2 resection)

☐ other

If not:

please provide the reason

- Select a value -

Type of palliative surgery

☐ biliary bypass

☐ enteral bypass

☐ macroscopic residual disease (R2 resection)

☐ other

If not:

please provide the reason

- Select a value -

# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients

## Tumor related data

### - Staging

- clinical
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### - Resectability

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Tumor location

##### If histological verification is available

Please mark the tumor type

Type of sampling

Resectability at the date of diagnosis

Surgical intervention: ☐ yes ☐ no

If yes: Date of surgical intervention

Type of surgical intervention:

##### In case of palliative surgery:

Type of palliative surgery  
☐ biliary bypass ☐ enteral bypass ☐ macroscopic residual disease (R2 resection) ☐ other

If not: please provide the reason

# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients

### Tumor related data

#### - Staging

• cli

• pa

#### - Re

#### - Su

• typ

#### 5. Tumor-related data

##### Clinical stage

T

- None - ▼

**Endoscopic intervention:**

☒ yes ☐ no ☐ N/A

If yes:

**biliary stent placement:**

☐ yes ☐ no ☐ N/A

If yes:

**material:**

- Please select - ▼  
- Please select -  
N/A  
metal  
plastic

**duodenal stent placement:**

☐ yes ☐ no ☐ N/A

#### - Endoscopic treatment

#### - Radiological intervention

##### In case of palliative surgery:

Type of palliative surgery

☐ biliary bypass ☐ enteral bypass ☐ macroscopic residual disease (R2 resection) ☐ other

If not: please provide the reason

- Select a value - ▼

## Oncological therapy

- Chemotherapy
- Radiotherapy
- Molecular targeted agents
- Somatostatin analogue
- Peptid receptor radionuclide Tx.

- Progression free survival
- Best response

### 6. Oncological therapy

#### a. In case of pancreatic adenocarcinoma

##### Radiotherapy:

☐ yes ☐ no ☐ N/A

If yes: Start date

End date

Intent:

Number of fractions:

Dose / fraction:  Gy

##### Chemotherapy:

☐ yes ☐ no ☐ N/A

If yes: Start date

End date

Intent:

##### Protocol

Type

Chemotherapeutic agent used

Dose  mg/m<sup>2</sup>

Dose reduction: ☐ yes ☐ no ☐ N/A

If yes: reason



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## Pancreatic neuroendocrine tumor (PNET):

- **different type of cancer**
- originates from the **endocrine cells** of the pancreas.
- **uncommon** tumors with increasing incidence.
- **better prognosis** vs. PDAC
- **different clinical course** and molecular patterns
- **different diagnostic** procedures and **treatment** strategies.



# Pancreatic Cancer

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- Increasing **incidence** and **mortality** of PC in Central Europe
- **Registries** are getting increasingly **important**:
  - research
  - prevention
  - clinical practice
  - financing
- **2015** – the registry for pancreatic cancer has been **completely renewed**
- **International** data collection



# Pancreatic Cancer

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## Centers contributing to the registry:

Dr. Bugyi István Kórház  
PTE KK I. sz. Belgyógyászati Klinika  
DEOEC Sebészeti Intézet  
SZTE I. sz. Belgyógyászati Klinika  
SZTE Sebészeti Klinika  
SZTE II.sz. Belgyógyászati Klinika  
CSMEK Makói Kórház  
Fejér Megyei Szent György Kórház  
Fejér Megyei Szent György Kórház  
PTE KK Sebészeti Klinika  
DEKK Belgyógyászati Intézet B. ép. Gasztroenterológia  
SZTE II-es Kórház

Petz Aladár Megyei Oktató Kórház  
SZTE Onkoterápiás Intézet  
Egyesített Szent István és Szent László Kórház  
Békés Megyei Pándy Kálmán Kórház  
Markusovszky Egyetemi Oktatókórház  
HM Honvédkórház  
SE I. sz. Sebészeti Klinika  
BAZ Megyei Kórház és Egy. Oktató Kórház  
Országos Onkológiai Intézet  
Bács-Kiskun Megyei Kórház  
Szent Imre Kórház  
Réthy Pál Kórház-Rendelőintézet

**Moscow Clinical Scientific Center**  
**Fundeni Clinical Institute, Bucharest**





# Pancreatic Cancer

## Biobank and Registry for Pancreatic Patients



# Thank you for your attention!

The hungarian pancreatic study group is committed to improving the lives of patients suffering from pancreatic diseases.

[www.pancreas.hu](http://www.pancreas.hu)

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