



# Pancreatic Cancer Registry

Registry supervisor: Dr. Gábor Lakatos  
HPSG Chair: Prof. Dr. Péter Hegyi

Andrea Szentesi

PancreOS Kick-off meeting, 17th March 2016, Madrid

# Pancreatic Cancer Registry

## Introduction



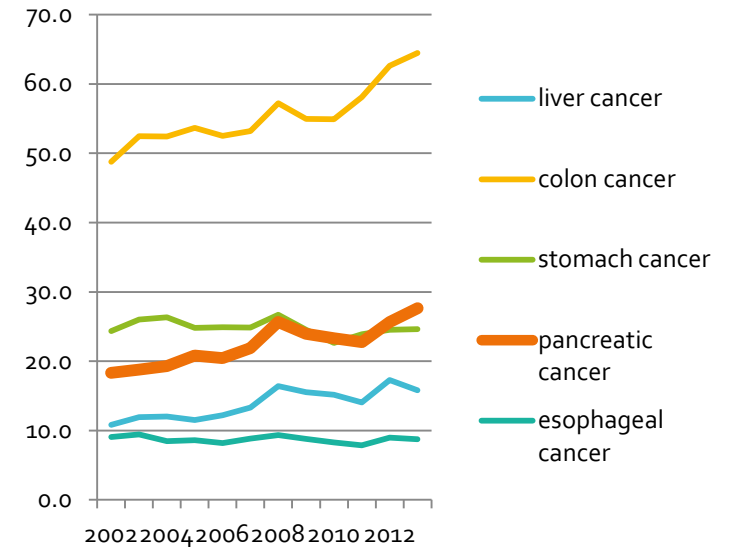
## Pancreas cancer worldwide



- 338.000 new cases in 2012
- 7th among cancer deaths worldwide
- 4% of all cancers diagnosed
- 5 year survival less than 5%
- Higher incidence in more developed countries

Source: GLOBOCAN 2012

## Pancreas cancer in Hungary



- 2545 new cases in 2012
- 5th among cancer deaths in Hungary
- Increasing incidence
- 5 year survival less than 5%

Source: National Cancer Registry

# Pancreatic Cancer Registry

## Introduction



## Eastern and Central Europe

- Worse prognosis compared to western countries
- Increasing incidence and mortality (Hungary, Romania, Albania, Croatia, Serbia) (1,2)

## Possible reasons

- limited access of diagnostic tools and treatment modalities (long waiting lists for CT and MRI)
- lack of evidence based guidelines
- financing problems

## Aim

- Prospectively collect and analyse data in the Hungarian (and Central and Eastern European) population that can serve as a basis for evidence based guidelines and further trials

(1.) National Cancer Registry, Hungary  
(2.) Hariharan D et al.

# Pancreatic Cancer Registry

## Development



### Starting the Registry – 2011-2012

- Research plan
- Financing (sponsors, grants)
- Ethical approval
- Biobank permission and set up
- CRF discussion
- Informatics (eCRF)
- Involving centres
  - Who is going to fill the forms (doctor, study nurse, administrator-partly?)
    - Motivation (financing, authorship)
- Data management and quality control
  - Administrative and professional control
  - Trainings

# Pancreatic Cancer Registry

## Development



## Data handling and analysis

### Secrecy

- Everyone can see only his/her own data unless otherwise agreed among participants
- In case of research projects permission is asked for using data (co-authorships)

### Transparency

- The registry head has the right to publish the first cohort
- Anyone may propose a research plan based on the registry data
  - The research plan is approved by the HPSG (to avoid duplication)
  - The researcher defines the first and last author
  - The HPSG may ask to name further co-authors and sponsors in the acknowledgement

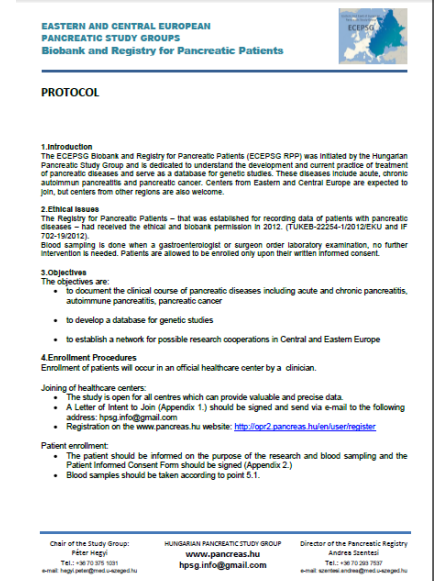
# Pancreatic Cancer Registry

## Development



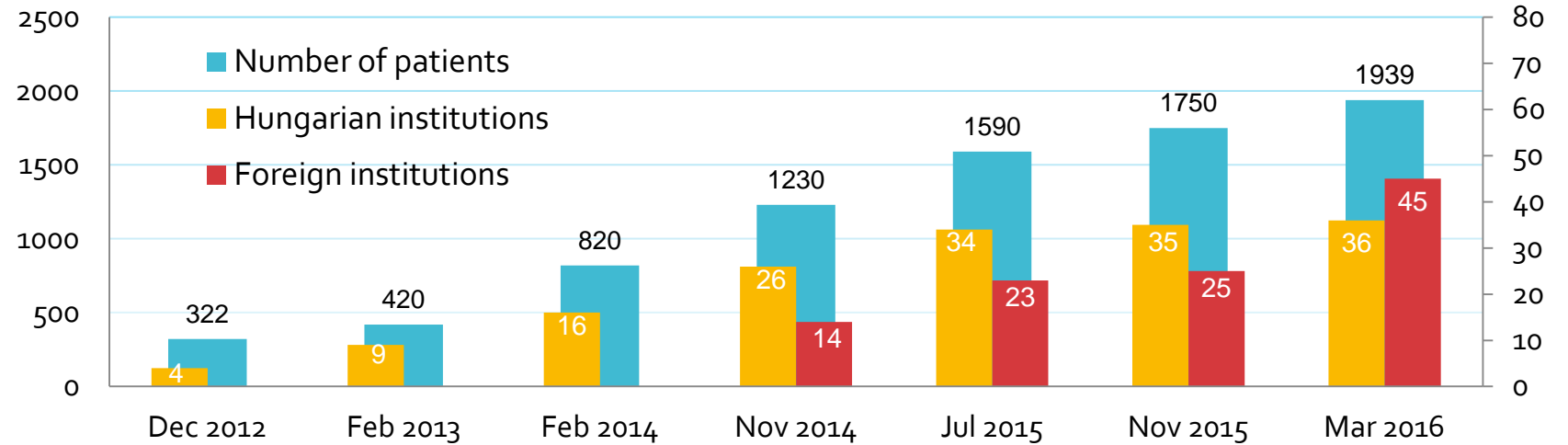
## Registry and Biobank for Pancreatic Patients

- started in 2012
- prospectively collected clinical data and blood samples
- web-based electronic data administration system
- acute pancreatitis (AP), chronic pancreatitis (CP), pancreatic cancer (PC), autoimmun pancreatitis (AIP)
- observational clinical trials in AP from 2015



# Pancreatic Cancer Registry

## Results



### Published genetic studies

- Genetic analysis of the bicarbonate secreting anion exchanger SLC26A6 in chronic pancreatitis
- SPINK1 Promoter Variants in Chronic Pancreatitis
- A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohorts

### Cohorts

- **Pancreatic cancer. Multicenter prospective data collection and analysis by the Hungarian Pancreatic Study Group.** – accepted in JGLD
- **Prospective, multicentric, nationwide clinical data from 600 cases of acute pancreatitis** – submitted
- Cohort in CP – under development

# Pancreatic Cancer Registry

## Results



## Observational Clinical Trials in AP

EASY

- Early Achievable Severity Index

Pre-study article: [J Gastrointestin Liver Dis](#), June 2015 Vol. 24 No 2

PINEAPPLE-P

- Pain in Early Phase of Pediatric Pancreatitis

Pre-study article: [Digestion](#). 2016;93(2):121-6. doi: 10.1159/000441352.

PINEAPPLE-R

APPLE-R

- Analysis of Pediatric Pancreatitis

Pre-study article: [Digestion](#). 2016;93(2):105-10. doi: 10.1159/000441353.

APPLE-P

### Under development:

- PREPAST - The role of preventive pancreatic stents in acute biliary pancreatitis - eCRF being developed

Pre-study protocol: [Pancreatology](#). 2015 Mar-Apr;15(2):115-23. doi: 10.1016/j.pan.2015.02.007.

### Planned in 2016:

- Interventional trials in AP
- 2 observational trials in CP



# Pancreatic Cancer Registry

CRF



## Pancreatic cancer registry – Content

- Date of birth, gender, race, date of interview
- Details from the medical history
- Symptoms and signs
- Patient related data
- Tumor-related data
- Oncological therapy
- Supportive treatment

# Pancreatic Cancer Registry

CRF



## 2. Details from the medical history

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

### 2. Details from the medical history

**Alcohol consumption:**  yes  no

If yes: frequency:  amount (per occasion):

for how many years:

---

If not: **Did you drink alcohol earlier?**  yes  no  N/A

If yes: frequency:

amount (g/occasion):

for how many years:

**Guide for estimation of the amount:**  
1 dl beer (4.5 vol. %) = ~3.5 g alcohol  
1 dl wine (12.5 vol. %) = ~10 g alcohol  
1 dl hard drink (50 vol. %) = ~40 g alcohol

---

**Smoking:**  yes  no

# Pancreatic Cancer Registry

CRF



## 3. Symptoms and signs

- Abdominal pain
- Nausea
- Vomiting
- Fever
- Loss of appetite
- Weight loss
- Jaundice

### 3. Symptoms and signs

Start date of symptoms

Abdominal pain at the time of diagnosis:

yes  no

If yes: since when:

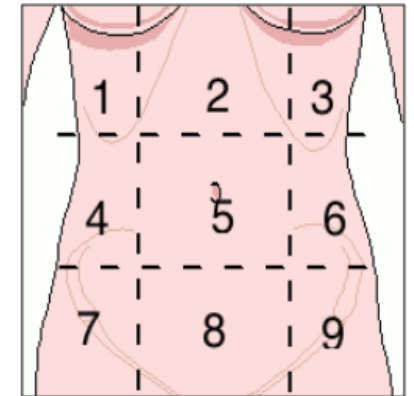
type:

intensity:

Location:

Specify location:

- |                            |                            |                            |
|----------------------------|----------------------------|----------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 |
| <input type="checkbox"/> 7 | <input type="checkbox"/> 8 | <input type="checkbox"/> 9 |



# Pancreatic Cancer Registry

CRF



## 4. Patient related data

### Diagnosis

- clinical
- histological

### Survival status

- (Overall survival time)

### ECOG PS status

- Tumor markers: CA 19-9, CEA

#### 4. Patient related data

Date of clinical diagnosis

Date of CT verifying the diagnosis first     
or

Date of MRI verifying the diagnosis first     
or

Date of ERCP verifying the diagnosis first     
or

Date of EUS verifying the diagnosis first

Histological verification:  yes  no  N/A

If yes: Date of histological sampling

Weight at the date of diagnosis  kg

Height at the date of diagnosis  cm

Body Mass Index (BMI)  kg/m<sup>2</sup>

ECOG status

#### Tumor markers at the date of diagnosis

CA 19-9  U/ml Date

CEA  ng/ml Date

Is the patient alive?  yes  no

If not: Date of death

# Pancreatic Cancer Registry

CRF



## 5. Tumor related data Staging

- clinical
- pathological

## Surgical treatment

- resectability
- type of surgical interven

## 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 Registry

CRF



## 6. 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

# Pancreatic Cancer Registry

CRF



## 7. Supportive treatment

- Pain management
- Pancreas enzyme substitution
- Nutritional supplements

### 7. Supportive treatment

#### Pain management

**Pain management**  none  minor analgesic  major analgesic  other

Medication	Dose	Duration of treatment
<input type="text"/>	<input type="text"/> mg/m <sup>2</sup>	<input type="text"/> week(s)
<input type="text"/>	<input type="text"/> mg/m <sup>2</sup>	<input type="text"/> week(s)
<input type="text"/>	<input type="text"/> mg/m <sup>2</sup>	<input type="text"/> week(s)

#### Pancreas enzyme substitution

**Pancreas enzyme substitution**  none  0 - 75 000 IU/day  > 75 000 IU/day

**Duration of treatment**  week(s)

#### Nutrition supplements

**Nutrition supplements**  none  Enteral formula 0-400 Kcal/day  Enteral formula 400-800 Kcal/day  
 Enteral formula >800 Kcal/day  Parenteral feeding

**Duration of treatment**  week(s)

# Pancreatic Cancer Registry

# Patient Enrollment

- Informing the patient, signed informed consent form

- Completing the patient questionnaire

- Collecting blood sample



- Uploading data to the electronic data administration system

## Source of data

- Patient questionnaire
- Electronic medical records
- Therapy information – usually paper-based





# Pancreatic Cancer Registry

## Data Quality Control



### In the electronic system

1. administrator or doctor
2. local doctor
3. central admin control
4. head of the registry

#51	(186)	finalized	19/18 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AL	delete
#50	(184)	draft	6/26 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	KZA	edit, delete
#48	(181)	draft	2/2 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	ES	edit, delete
#47	(180)	draft	2/1 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	ES	edit, delete
#45	(174)	draft	9/8 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	AL	edit, delete
#44	(168)	finalized	4/3 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	ES	delete
#43	(167)	finalized	9/9 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AL	delete
#42	(166)	finalized	4/3 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AL	delete
#41	(165)	finalized	6/5 +		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AL	delete



approved



rejected with a note

Informed consent forms, medical records – on site

Trainings – on site, on the HPSG conference

# Pancreatic Cancer Registry

## Results



### Genetic study

**“A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohort” – Anita Balázs et al.**

*Pancreas* 2016 Apr;45(4):541-5. doi: 10.1097/MPA.0000000000000539.

### First Hungarian cohort for PC

**“Pancreatic cancer. Multicenter prospective data collection and analysis by the Hungarian Pancreatic Study Group.” – Gábor Lakatos et al.**

- Study period:2012-2014
- 354 patients, 14 centers
- Manuscript accepted in [Journal of Gastrointestinal and Liver Diseases](#)

### Current patient and sample numbers

- 513 patients
- 420 blood samples

# Pancreatic Cancer Registry

## Recent Improvements and Plans



### What we have done recently

In 2015, the registry has been completely renewed

- Improvement of the **electronic system**
- The content of the **questionnaire was fully updated**
- The registry is available in Hungarian and **in English**

### Plans

- Need to further improve the **quality of data collection**
- Need to build up the **co-operation** along the patient's route in treatment (diagnosis, surgical treatment, oncological treatment)
- Need to **extend** the database to other Central and Eastern European countries.

# Pancreatic Cancer Registry



**Thank you for your attention!**

**THE HUNGARIAN PANCREATIC STUDY GROUP  
IS COMMITTED TO IMPROVING  
THE LIVES OF PATIENTS SUFFERING FROM  
PANCREATIC DISEASES!**