

# Spanish Cooperative Group for the Treatment of Digestive Tumors



## History

Spanish Cooperative Group for the Treatment of Digestive Tumors , has been working in the design and development of protocols in the field of gastrointestinal tumours since 1986.

## Objectives

- ✓ Develop clinical research protocols
- ✓ Introduce quality into healthcare through the improved oncological training of its members.
- ✓ Work at the heart of a cooperative group.
- ✓ Publish work on the studies performed to create an international impact

# The TTD Group in figures



303 members

140 hospitals

## Research Activity:

- **Clinical: 1986-2015**
  - ↙ N° trials: 82
  - ↘ N° patients: 8.936
- **Basic: 2008-2015 (n=2.328)**
- **Publications:**
  - ↙ Journals: 80
  - ↘ Conferences: 179

## Educational and Training Activity:

- **Consensus documents : 9**
- **Sponsorship of scientific activities (2006-2015): 75**
- **International meetings: 23**
- **Collaboration with patients' associations :**

2006: Adjuvant treat. colon Ca.  
2007: Colorectal Ca. liver Mets.  
2009: Gastric Ca.  
2010: Hereditary colorectal Ca.  
2011: Metastatic colorectal Ca.  
2012: Hereditary pancreatic Ca.  
2013: Peritoneal Carcinomatosis (I)  
2014: Exocrine pancreas  
2015: Peritoneal Carcinomatosis (II)

## PILOT STAGE

50-70 patients

7 centers (4 months)

To examine the feasibility of this registry and propose modifications, if relevant

## SECOND STAGE

600 patients

15 centers (3 years)

Data collection

### AEMPS

Jan 15- April 15 (study classification)



### EC

April 15- July 15 (favorable opinion)



### PATIENTS

- First: July 15
- Last: October 15



**FASE I FINAL REPORT**

### CENTER

- 1 H. Ramón y Cajal (Madrid)
- 2 H. Univ. Central de Asturias (Oviedo)
- 3 H. Universitario Reina Sofía (Córdoba)
- 4 H. Gregorio Marañón (Madrid)
- 5 H. Marqués de Valdecilla (Santander)
- 6 H. General Universitario (Valencia)
- 7 H. Universitari Vall d'Hebrón (Barcelona)

### TOTAL

### PTS

- 12  
5  
12  
12  
10  
3  
13  
**67**

Patient Visit Blank Page Blank page Reason DATE OF SIGNING THE INFORMED CONSENT FORM: 

## INCLUSION CRITERIA

- Signed and dated informed consent before any study specific procedures will be performed  Yes  No
- Suspect pancreatic cancer pathologically confirmed or not (any histology, any stage)  Yes  No
- Male or female subjects any age  Yes  No

## SOCIO-DEMOGRAPHIC DATA:

Date of Birth  (dd-mm-yyyy) Gender  Male  Female Blood group\*  Weight lost in last year\*  kg

\*Choose from picklist

\* From Informed Consent date. Choose the appropriate range of kg from the picklist

Postal code  If it is not known or not available, complete the fields:Patient location (town)  Province\*  \*Choose the appropriate one from the picklistToxic habits  Yes  No If Yes, complete: Smoking habit\*  \*Choose the habit from the picklist If smoker/ex-smoker: Pack/year\*\* 

\*\*Pack/year will be calculated multiplying the number of packs smoked per day by the number of years smoking/smoked

Examples: 1 pack/day during 20 years= 1\*20=20 packs/year; 2 packs/day during six months (0.5 year) = 2 \* 0.50 = 1 pack/year;

1 pack/week during 5 years= (1/7) \* 5 = 0.7 packs/year

1 pack= 20 cigarettes. If smoking consumption changes in a same patient, the accumulated consumption

will be reported (smoked packs in each period of time will be added): 20+1+0.7= 21.7 packs/year

Use of alcohol  Yes  No If Yes tick as appropriate:  Daily  Weekly  OccasionallyQuantity  Equal or more than 1 wine bottle or 2 beer bottles or 1/4 liqueur bottle (aprox. 3 or 4 cups) Less than 1 wine bottle or 2 beer bottles or 1/4 liqueur bottle (aprox. 3 or 4 cups)Study CRF page



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**CANCER FAMILY HISTORY**

Yes  No If Yes, please complete information for all family members affected:

Grade (1)	Kinship (2)	Other kinship, specify	Type of cancer (3)	Other, Specify	Age at diagnosis (4)

- (1) GRADE: Choose one option per line from the picklist linked to the field
- (2) KINSHIP: Choose one option per line from the picklist linked to the field
- (3) TYPE OF CANCER: Choose one option per line from the picklist linked to the field
- (4) AGE AT DIAGNOSIS: If it is not known, please report 'UK'

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### PATIENT PRIOR MEDICAL HISTORY

DIABETES MELLITUS  Yes  No If Yes, please complete:

Diagnosis date  DM type  Choose the type from the picklist

Did the patient take treatment for DM?  Yes  No  Unknown If Yes, tick the treatments:

Oral  For how long?\*  Years

Insulin  For how long?\*  Years

Other  Specify  For how long?\*  Years

\* For how long? (Treatment duration): From Start date to End date. For intermittent treatments, the average length will be included. If it is not known, report 'UK'

SIGNIFICANT DISEASES  Yes  No If Yes, please complete:

Significant diseases*	Date of diagnosis	Additional information

\*Do not forget report all chronic pancreatitis and allergies suffered by the patient.

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PATIENT PRIOR CANCER HISTORY (other neoplasms):  Yes  No  Unknown If Yes, please complete:

Diagnosis Date (1)	Type of cancer (2)	Other type, specify

(1) DIAGNOSIS DATE: If it is not known, report 'UK' (2) TYPE OF CANCER: Choose one option per line from the picklist

PATIENT PANCREATIC CANCER HISTORY

Information

Who was the first physician to see the patient?

Who sent the patient to the Medical Oncologist?

What was the first symptom? (Check below all present at the beginning)

Abdominal pain  Back pain  Anorexia  Weight loss  Asthenia  Nausea and vomiting  Coluria  Hypo/acolia  Itching

Constitut syndrom  Jaundice  Mental disorders  Abdominal mass / distension  Hepatomegalia  Ascites  Others (specify)

Was the patient history presented in a multidisciplinary committee before starting any treatment?  Yes  No  Unknown

PHYSICAL EXAMINATION AND CLINICAL LABORATORY TEST AT FIRST ONCOLOGY VISIT

Weight  kg Height  cm BSA  ECOG PS  CEA\*  ng/mL CA 19.9\*  IU/mL

*(Autocalculated)* *\*If values are not available at first visit, report the ones before treatment. If any of them are unknown, report 'UK'*

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Patient Visit Blank Page Blank page Reason 

### DISEASE DIAGNOSIS

\*First diagnostic date: It will be the date of the FIRST anatomopathological/cytological diagnosis . If Hystological/cytological confirmation is not available, report the date of the FIRST Imaging test where pancreatic cancer was confirmed or suspected.  
For Procedure, Tumor stage, Disease status, Grade and Histologic Type fields, choose the appropriate option from the picklists.

\*\* Histologic type will be completed ONLY if Procedure is Pathology

#### INITIAL DISEASE DIAGNOSIS

First diagnostic date*	Procedure	T	N	M	Stage	Disease status	Grade	Histologic Type**
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					Autocalculated			

If Histologic type is Ductal, please tick all applicable options  
Only applicable if pathology

- |  |  |
|--|--|
| <input type="checkbox"/> Signet ring cell carcinoma  | <input type="checkbox"/> Adenosquamous carcinoma   |
| <input type="checkbox"/> Anaplastic carcinoma        | <input type="checkbox"/> Serous cystadenocarcinoma |
| <input type="checkbox"/> Mucinous cystadenocarcinoma | <input type="checkbox"/> Other, specify type:      |

#### METASTATIC DISEASE DIAGNOSIS

Tick only if diagnosis is the same as Initial diagnosis. If not, please report:

Metastatic date	Procedure	
<input type="text"/>	<input type="text"/>	Choose the appropriate option from the picklist

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 Patient 

 Visit 

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### DIAGNOSTIC PROCEDURE

Record all diagnostic procedures performed to the patient TAC, RMN, PET, ecoendoscopy, etc. If more than two procedures were performed, please insert a new VISIT PAGE (Diagnostic) in order to collect all of them.

Procedure*	Date	Pancreatic mass found	Metastases	HISTOLOGY Diagnostic sample obtained	Any drainage?
<input type="text"/>  If Other, specify: <input type="text"/>	<input type="text"/>	<input type="checkbox"/> If Yes tick all affected <input type="checkbox"/> Head <input type="checkbox"/> Uncinated process <input type="checkbox"/> Body <input type="checkbox"/> Tail	<input type="checkbox"/> If Yes tick all affected <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="checkbox"/> If Yes: Method* <input type="text"/> and Location: <input type="checkbox"/> Pancreas <input type="checkbox"/> Liver <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other**: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="text"/>  If Other, specify: <input type="text"/>	<input type="text"/>	<input type="checkbox"/> If Yes tick all affected <input type="checkbox"/> Head <input type="checkbox"/> Uncinated process <input type="checkbox"/> Body <input type="checkbox"/> Tail	<input type="checkbox"/> If Yes tick all affected <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="checkbox"/> If Yes: Method <input type="text"/> and Location: <input type="checkbox"/> Pancreas <input type="checkbox"/> Liver <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other**: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No

\* For fields PROCEDURE and METHOD, choose one option from the picklist

\*\* If 'Other' is ticked in LOCATION, please specify it

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 CRF page

Patient 

 Visit 

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### SURGERY

 Did the patient suffer any surgery?  Yes  No

Date	Surgical*	Margins*	Invasion (1) (Only if there were resection)	Additional pathological findings (2)	Post-surgery complications
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Venous <input type="checkbox"/> Lymphatic <input type="checkbox"/> Perineural	<input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Intraepithelial neoplasia <input type="checkbox"/> Pre-neoplastic associated lesions <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Venous <input type="checkbox"/> Lymphatic <input type="checkbox"/> Perineural	<input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Intraepithelial neoplasia <input type="checkbox"/> Pre-neoplastic associated lesions <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Venous <input type="checkbox"/> Lymphatic <input type="checkbox"/> Perineural	<input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Intraepithelial neoplasia <input type="checkbox"/> Pre-neoplastic associated lesions <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No

\*SURGICAL and MARGINS: Choose the appropriate option from the picklist

(1) INVASION: Choose all options affected. This field will not completed if option chosen in Margins is NE or NA

(2) ADDITIONAL PATHOLOGICAL FINDINGS: Choose all findings observed

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 CRF page

Patient Visit Blank Page Blank page Reason 

### RADIOTHERAPY

Did the patient receive radiotherapy?  Yes  No If Yes, please complete:

Radiotherapy setting (1)	Radiation fields description (2)	If metastasis specify	Started date	Ended Date	Type (3)	Other type specify	Total Dose (Gy)	RT given at pat hospital (4)
								<input type="radio"/> Yes <input type="radio"/> No
								<input type="radio"/> Yes <input type="radio"/> No
								<input type="radio"/> Yes <input type="radio"/> No
								<input type="radio"/> Yes <input type="radio"/> No
								<input type="radio"/> Yes <input type="radio"/> No
								<input type="radio"/> Yes <input type="radio"/> No

(1) RADIOTHERAPY SETTING: Choose the appropriate option from the picklist: Resectable; Potentially resectable; Potentially unresectable or Metastatic disease (palliative).

(2) RADIATION FIELD DESCRIPTION: Choose the appropriate option from picklist: Primary or Metastatic. If Metastatic is chosen, specify Location in next field.

(3) TYPE: Choose the appropriate option from the picklist: Conventional or Other. If Other is chosen, specify it in next field

(4) RT GIVEN AT PATIENT HOSPITAL: Confirm if Radiotherapy was administered in patient hospital.

Study CRF page


 Patient 

 Visit 

 Blank Page 

 Blank page Reason 

### CHEMOTHERAPY

For fields: (1) INTENTION, (4) BEST REPOSE and (5) END TREATMENT, choose the appropriate option from the picklist added in each field.

(2) DRUGS: ID = Investigational drug; G = Gemcitabine; C/5FU +/- L = Capecitabine / 5FU +/- Leucovorin ; F = FOLFOXIRI; O = Oxaliplatin; N = Nabpaclitaxel; E = Erlotinib; Othr = Other

(3) DATES: Started date = First drugs of the combination; Ended date = Last drugs of the combination

(6) DATE: Progression date in case of METASTATIC DISEASE and Relapse date in case of NEO / ADJUVANT treatment. Also, mark all LOCATIONS affected

 Did the patient receive chemotherapy?  Yes  No

Row	Trt received Clin trial?	INTENTION		CHEMOTHERAPY DRUGS (2)								DATES (3)		ECOG		BEST RESPONSE	
		Intent (1)	Other line specify	ID	G	+/- L	F	O	N	E	Othr	Other drug, specify	Start Date	Stop Date	started	ended	Best Resp(4)
1	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Row	END TREATMENT		PROGRESSION/RELAPSE										
	End trt (5)	Other reason, specify	Date (6)	Local	Liver	Lung	Bone	Brain	Distal lymph nodes	Peritoneum	Other	Other, specify	
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	

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Patient

Visit

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### PATIENT STATUS

#### Patient survival status

- Alive Date of last known to be alive
- Lost to follow-up Date of last contact:
- Dead Date:

#### Main cause of death

- Disease progression
- Disease-related complication. Specify:
- Toxicity. Specify:
- Not related intercurrent events. Specify:
- Unknown
- Other (specify)

Was the patient sent to palliative unit?  Yes  No

Did the patient need support during the pancreas cancer?  Yes  No If Yes, please tick all supports needed:

- Psychological support
- Nutritional support
- Pain treatment support

### COMMENTS

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