

# Precision Panc: Advancing personalised medicine treatment strategies for pancreatic cancer

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<b>Registration date</b> 29/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/09/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

At present pancreatic cancer is the 3rd leading cause of cancer death in the western world with only 3% of patients surviving for 5 years or more. Therefore there is an urgent need to both optimise the use of current therapies by identifying responsive (or non-responsive) subgroups and to develop novel therapeutic approaches. The Precision Panc Master Protocol allows for the taking of either extra tissue from a patient's diagnostic biopsy or an additional specific trial biopsy as well as a blood sample. These samples are subjected to molecular profiling and allow for the patient to then be enrolled into a PRIMUS study.

### Who can participate?

Adults aged patients aged 16 and older who have a pancreatic mass and are willing to undergo a tumour biopsy.

### What does the study involve?

Patients with either suspected or confirmed pancreatic cancer are approached to take part in the study and given the Precision Panc Screening PIS. Participants are given time to consider trial participation and if they are willing to take part in the study they are screened onto the study. If the patient has suspected pancreatic cancer and are having a standard of care diagnostic biopsy, extra cores are taken at that time for the Precision Panc study. If pancreatic ductal adenocarcinoma is confirmed the patient are then given the registration PIS/consent which allows for molecular profiling to take place on the extra tissue taken for research. If the patient already has a diagnosis of pancreatic ductal adenocarcinoma they are asked to undergo and additional research biopsy for the study. All participants are also asked to provide a blood sample for research. The tissue (either the extra diagnostic tissue or the research biopsy) and blood sample are sent to Glasgow for molecular profiling and if enough tissue is available for profiling they may be eligible for an open PRIMUS study.

### What are the possible benefits and risks of participating?

It cannot be guaranteed that taking part in this study will benefit participants directly. This is because we cannot be sure that we will identify changes in participant's tumour make up that

will indicate that a specific treatment or clinical trial will work better than any other until the study is undertaken. However, participating in the first stage of Precision-Panc study, will enable the collection of tumour samples that can be studied in detail in the second stage of this study (if cancer diagnosis is made). This information from the tumour sample may help to determine which treatment or clinical trial is best suited to your specific cancer. Participants are invited to allow the study to take a further sample of tissue from participants pancreatic lesion or disease elsewhere such as liver or lung (if applicable), during your routine diagnostic procedure. Before a biopsy is carried out, the risks are discussed with participants directly by the clinical team who do the biopsy, and they obtain your consent for it (Screening Consent). They answer any questions that you may have about the biopsy. If you have been diagnosed with pancreatic cancer already, we will ask you to consent to undergo a new biopsy procedure to obtain samples for research use only. The biopsies can be obtained through interventional radiology procedure or endoscopic ultrasound. This has a few small risks due to discomfort with needles. Additional research samples are usually taken at the same time as participants diagnostic biopsy, so it should not cause you additional risk or inconvenience. However, there may be occasions where you are asked to have another biopsy if the previously obtained samples are not good enough for research purposes. There may be additional risks that we do not expect or do not know about.

Where is the study run from?  
Glasgow Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?  
April 2017 to March 2022

Who is funding the study?  
1. CRUK (UK)  
2. Celgene (UK)

Who is the main contact?  
Ms Judith Dixon-Hughes (Public)  
judith.dixon@glasgow.ac.uk

## Contact information

**Type(s)**  
Public

**Contact name**  
Ms Judith Dixon-Hughes

**ORCID ID**  
<https://orcid.org/0000-0002-5596-4400>

**Contact details**  
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G12 0YN

+44 141 301 7540  
judith.dixon@glasgow.ac.uk

## **Additional identifiers**

**Integrated Research Application System (IRAS)**  
184216

## **Study information**

### **Scientific Title**

Precision Panc Master Protocol: Personalising Treatment for Pancreatic Cancer

### **Acronym**

Precision Panc

### **Study objectives**

The overall framework of Precision-Panc aims to accelerate stratified therapeutic development through co-ordination, data sharing and aligned decision-making. This UK-wide Master Protocol will enable the screening and molecular profiling of patients with pancreatic cancer, embedded within the standard diagnostic pathway to subsequent enrolment in available Pancreatic cancer Individualised Multi-arm Umbrella Study (PRIMUS) studies. PRIMUS is the set of clinical trials where patients may be recruited to the most suitable treatment studies based on their molecular phenotype and/or integrated with biomarker discovery and validation approaches. We aim to create a patient-focused environment where attractive trial options are offered to as many patients and their treating clinicians as possible. The aim is to identify the right trial for the patient, rather than current approaches where we search for patients for a specific trial. By offering a range of attractive options for patients and clinicians, we envisage significant increases in recruitment. In addition, Precision-Panc will also provide a platform for drug development in partnership with industry, by screening and identifying subgroup of patients with candidate biomarker of therapeutic responsiveness.

The outcomes of the patients will be recorded on the Master Protocol or the PRIMUS studies. Precision-Panc Master Protocol will serve not only as a molecular profiling platform for PRIMUS clinical trials, but also a translational research platform. The molecular profiling data generated along with the outcome data will be essential in the delineation of molecular mechanisms important in the pathophysiology of pancreatic cancer. This in turn will provide significant opportunities to understand the molecular pathology of pancreatic cancer better, and to identify candidate biomarkers for available therapeutic options and define therapeutic targets for novel drug development.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

West of Scotland REC 1, 27/09/2017, ref: 17/WS/0147

### **Study design**

Interventional non randomised study

## **Primary study design**

Interventional

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Pancreatic Cancer

## **Interventions**

Patients with either suspected or confirmed pancreatic cancer are approached to take part in the study and given the Precision Panc Screening PIS. Participants are given time to consider trial participation and if they are willing to take part in the study they are screened onto the study. If the patient has suspected pancreatic cancer and are having a standard of care diagnostic biopsy, extra cores are taken at that time for the Precision Panc study. If pancreatic ductal adenocarcinoma is confirmed the patient are then given the registration PIS/consent which allows for molecular profiling to take place on the extra tissue taken for research. If the patient already has a diagnosis of pancreatic ductal adenocarcinoma they are asked to undergo and additional research biopsy for the study. All participants are also asked to provide a blood sample for research. The tissue (either the extra diagnostic tissue or the research biopsy) and blood sample are sent to Glasgow for molecular profiling and if enough tissue is available for profiling they may be eligible for an open PRIMUS study.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

To establish a mechanism and framework to recruit and screen patients with pancreatic cancer to perform molecular profiling, evaluation of circulating biomarkers and allow enrolment to Precision Panc PRIMUS studies. This will be measured by the number of patients screened and registered to the study and the number of patients where a molecular profile is obtained. The number of patients registered to Precision Panc who then go onto a PRIMUS study will also be measured

## **Key secondary outcome(s)**

1. To assess the overall survival (OS) in patients enrolled in Precision-Panc and relate this to molecular profile information
2. To assess the safety of obtaining tumour biopsies suitable for molecular profiling within a standard patient treatment pathway
3. To establish a central repository of molecular profiles with accompanying phenotypic data and accompanying biospecimens for further translational research
4. To establish a dynamic platform for evaluation of circulating biomarkers to subsequently inform design of subsequent clinical studies

## **Completion date**

30/03/2022

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (age >16 years)
2. With either:
  - 2.1. Presence of a hypodense pancreatic mass highly suspicious of primary pancreatic cancer with or without distant metastasis as assessed by a Pancreatic Multi-Disciplinary Team (MDT) or
  - 2.2. Histologically or cytologically confirmed pancreatic ductal adenocarcinoma and its variants
3. Patient is willing and able to undergo tumour biopsy aimed at obtaining sufficient tissue for molecular profiling
4. Patient is deemed suitable to receive chemotherapy and/or radiotherapy, and/or surgery pending stage of disease at presentation
5. Signed informed consent for screening research tumour biopsy (Consent 1)
6. Signed informed consent for Precision-Panc Master Protocol molecular profiling (Consent 2)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

There is no participant exclusion criteria.

**Date of first enrolment**

14/12/2017

**Date of final enrolment**

29/03/2022

**Locations****Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

**Study participating centre**

**Glasgow Royal Infirmary**

84 Castle Street

Glasgow  
United Kingdom  
G4 0SF

**Study participating centre**  
**Aberdeen Royal Infirmary**  
Aberdeen  
United Kingdom  
AB25 2ZN

**Study participating centre**  
**Royal Marsden Hospital**  
London  
United Kingdom  
SW3 6JJ

**Study participating centre**  
**UCLH**  
London  
United Kingdom  
NW1 2BU

**Study participating centre**  
**Addenbrookes Hospital**  
Cambridge  
United Kingdom  
CB2 0QQ.

**Study participating centre**  
**Christie, Manchester**  
Manchester  
United Kingdom  
M20 4BX

**Study participating centre**  
**Weston Park**  
Sheffield  
United Kingdom  
S10 2SJ

**Study participating centre**  
**Bristol Oncology Centre**  
Bristol  
United Kingdom  
S10 2SJ

**Study participating centre**  
**Imperial College London**  
London  
United Kingdom  
SW7 2BX

**Study participating centre**  
**Nottingham University Healthcare Trust**  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**  
**Royal Free London Hospital**  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**Ninewells Hospital**  
Dundee  
United Kingdom  
DD2 1UB

**Study participating centre**  
**St George's Hospital**  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**Southampton University Hospital**  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**Queen Elizabeth Hospital Birmingham**  
Birmingham  
United Kingdom  
B15 2WB

**Study participating centre**  
**King's College Hospital**  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Churchill Hospital**  
Oxford  
United Kingdom  
OX3 7LE

**Study participating centre**  
**Castle Hill Hospital**  
Cottingham  
United Kingdom  
HU16 5JQ

**Study participating centre**  
**Poole Hospital**  
Poole  
United Kingdom  
BH15 2JB

**Study participating centre**  
**Freeman Hospital**  
Newcastle

United Kingdom  
NE7 7DN

**Study participating centre**  
**Royal Bournemouth Hospital**  
Bournemouth  
United Kingdom  
BH7 7DW

**Study participating centre**  
**Royal Albert Edward Infirmary**  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**  
**Northern Ireland Cancer Centre**  
Belfast  
United Kingdom  
BT9 7JL

**Study participating centre**  
**Western General Infirmary**  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**Raigmore Hospital**  
Inverness  
United Kingdom  
IV2 3DZ

**Study participating centre**  
**Royal Liverpool Hospital**  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**Huddersfield Royal Infirmary**  
Huddersfield  
United Kingdom  
HD3 3EA

## Sponsor information

**Organisation**  
NHS Greater Glasgow and Clyde

**ROR**  
<https://ror.org/05kdz4d87>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
CRUK

**Funder Name**  
Celgene

**Alternative Name(s)**  
Celgene Corporation

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
For-profit companies (industry)

**Location**  
United States of America

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Judith Dixon at [judith.dixon@glasgow.ac.uk](mailto:judith.dixon@glasgow.ac.uk)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>		06/10/2017	02/04/2019	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes