

**PAN1:** A randomised phase II study evaluating potential predictive biomarkers in the treatment of metastatic pancreatic cancer.

**Overview:** To prospectively evaluate hENT1 as a predictive marker of benefit from gemcitabine treatment in metastatic pancreatic cancer.

**Study Chair:** Dr Yu Jo Chua, Medical Oncologist, Canberra Hospital

**Open Date:** 22nd July 2011

**Accrual:** 0/80 patients

**Trial Management Committee Members:**

Yu Jo Chua	Canberra Hospital	ACT
Andrew Biankin	Garvan Institute of Medical Research	NSW
Chris Karapetis	Flinders Medical Centre	SA
Craig Underhill	Border Medical Oncology	VIC
Louise Nott	Royal Hobart	TAZ
David Goldstein	Prince of Wales Hospital	NSW
Michelle Cronk	Nambour Hospital	QLD
George Laking	Auckland Hospital	NZ
Val GebSKI	NHMRC CTC	NSW
Katrin Sjoquist	NHMRC CTC	NSW
Nicole Wong	NHMRC CTC	NSW

**Study Progress:**

- Received funding from the Avner Nahmani Pancreatic Cancer Research Fund.
- 20 sites are planned and 17 have been selected to date.
- 11 sites are activated to date.
- Protocol approved by Cancer Institute NSW Ethics Committee on 25/01/2011.
- Central pharmacy and oxaliplatin sourced for Australian and New Zealand sites.
- Biological testing process designed and contracts in place.
- PAN1 INFORM database designed, tested and launched live at active, participating sites.
- Internal PAN1 processes and documentation in place for site use and direction.
- Providing ongoing guidance and direction in the screening of any potential, eligible patients.
- Focus on working with New Zealand sites for additional, supplementary funding to support the conduct of the study in New Zealand.
- PAN1 AGITG Annual Scientific Meeting (ASM) presentation at the 2010 and 2011 ASMs.
- PAN1 Trials In Progress Abstract submitted to ASCO 2012 and has been accepted.
- Monthly screening logs collected from all sites for ongoing monitoring of patient screening.
- Trial Management Committee (TMC) formed.
- TMC meeting held on 21 February 2012 to discuss status of the trial and recruitment strategies. Next TMC meeting scheduled for 1 May 2012.
- The working group met on 13<sup>th</sup> March to further discuss revising the eligibility criteria of the PAN1 study. It has been proposed that locally advanced pancreatic cancer patients be included on the PAN1 study, in addition to metastatic pancreatic cancer patients. This discussion is still in process. Next meeting scheduled for 13<sup>th</sup> April.

## Site summary:

Site Name	Activation Date	Recruitment
Canberra Hospital	22/07/2011	0
Tweed Hospital	27/07/2011	0
Royal Hobart	28/07/2011	0
Nambour	31/08/2011	0
Border Medical Oncology	22/09/2011	0
Geelong Hospital	27/09/2011	0
Townsville	27/09/2011	0
Royal North Shore	03/11/2011	0
Port Macquarie	23/11/2011	0
Flinders Medical Centre	12/12/2011	0
Royal Perth	17/01/2012	0
Christchurch Hospital	-	-
Auckland Hospital	-	-
Prince of Wales	-	-
Queen Elizabeth	-	-
Austin	-	-
Calvary Mater	-	-

## Screening logs: 36 patients screened to-date. 2 patients in screening.

Site	# of Pts screened	Reasons not recruited to trial
Canberra Hospital	6	<ul style="list-style-type: none"> <li>- The patient was ineligible for the trial as they had a previous cancer diagnosed within the past 5 years.</li> <li>- 2 patients did not have adequate liver function tests. The tissue for 1 patient was sent for hENT1 testing.</li> <li>- 1 patient had non-measurable metastatic disease.</li> <li>- 1 patient had non-measurable disease and unable to biopsy primary tumour. Also declined chemotherapy.</li> <li>- 1 patient did not have metastatic disease.</li> </ul>
Tweed Hospital	6	<ul style="list-style-type: none"> <li>- 2 patients were eligible however did not want to join the study.</li> <li>- 1 patient had elevated bilirubin results.</li> <li>- 1 patient too unwell to join the study.</li> <li>- 2 potential patients in screening.</li> </ul>
Border Medical Oncology	6	<ul style="list-style-type: none"> <li>- 1 patient did not have a core biopsy available and did not agree to have a core biopsy of their cancer;</li> <li>- 1 patient had symptomatic coronary or cardiac insufficiency;</li> <li>- 2 patients did not have metastatic disease;</li> <li>- 1 patient had bowel cancer and not pancreatic cancer;</li> <li>- 1 patient had disease recurrence within 6 months after completion of previous chemotherapy.</li> </ul>
Townsville	6	<ul style="list-style-type: none"> <li>- 1 patient did not have metastatic disease;</li> <li>- 1 patient did not have adequate liver function tests;</li> <li>- 1 patient had already commenced chemotherapy;</li> <li>- 1 patient had had previous chemoradiotherapy which was not radio-sensitiser dose chemotherapy.</li> <li>- 1 patient did not have a core biopsy available and did not agree to</li> </ul>

		<ul style="list-style-type: none"> <li>have a core biopsy of their cancer.</li> <li>- 1 potential patient, but did not end up attending clinical appointments.</li> </ul>
Royal Hobart	3	<ul style="list-style-type: none"> <li>- 1 patient did not have metastatic pancreatic cancer.</li> <li>- 2 patients were not suitable based on clinician advice.</li> </ul>
Nambour	7	<ul style="list-style-type: none"> <li>- 4 patients had a previous cancer diagnosed within the past 5 years.</li> <li>- 1 patient had elevated bilirubin results.</li> <li>- 2 patients did not have a core biopsy available and did not agree to have a core biopsy of their cancer.</li> </ul>
Geelong	2	<ul style="list-style-type: none"> <li>- 1 patient had had previous chemoradiotherapy which was not radio-sensitiser dose chemotherapy.</li> <li>- 1 patient did not have metastatic pancreatic cancer.</li> </ul>

\*Active sites not listed in table have confirmed that they have not seen any metastatic pancreatic cancer patients\*