

PAN1 Study Trial Report

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

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

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

Open Date: 22nd July 2011

Accrual: 9 / 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 Clinical Trials Centre	NSW
Katrin Sjoquist	NHMRC Clinical Trials Centre	NSW
Nicole Wong	NHMRC Clinical Trials Centre	NSW
Fabyolla El-Tahche	NHMRC Clinical Trials Centre	NSW

Study Progress:

- The PAN1 study is coordinated by the NHMRC Clinical Trials Centre.
- Received funding from the Avner Nahmani Pancreatic Cancer Research Fund.
- 20 sites are planned with 12 sites activated to-date. QEH was initiated on 11-Jan-2013. NHMRC CTC is collecting the final documents and the site will be activated to begin recruitment this week. NHMRC CTC is currently finalising initiation date with SMDCC. Bankstown Hospital is submitting to their RGO this week. Once approved, they will also be ready for initiation.
- The latest PAN1 Trial Management Committee (TMC) meeting occurred on 27 November 2012. The next TMC meeting is scheduled for February 2013.
- Monthly screening logs are collected from all sites for ongoing monitoring of patient screening and review of ongoing recruitment at sites. The PAN1 TMC is providing ongoing guidance and direction in the screening of any potential, eligible patients.
- Nine (9) patients have been randomised onto the PAN1 study to-date. Of the patients considered for the PAN1 study, there have been 68 pancreatic cancer patients screened to-date, with 1 patient currently in screening at Prince of Wales Hospital. Please refer to the table below for more information.

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Site summary:

Site Name	Activation Date	Recruited	Screened
Canberra Hospital	22-Jul-2011	1	11
Tweed Hospital	27-Jul-2011	1	5
Royal Hobart Hospital	28-Jul-2011	1	10
Nambour General Hospital	31-Aug-2011	0	4
Border Medical Oncology	22-Sep-2011	1	4
Geelong Hospital	27-Sep-2011	0	4
Townsville Hospital	27-Sep-2011	0	11
Royal North Shore Hospital	03-Nov-2011	0	1
Port Macquarie Hospital	23-Nov-2011	0	6
Flinders Medical Centre	12-Dec-2011	1	2
Royal Perth Hospital	17-Jan-2012	1	1
Prince of Wales Hospital	29-Jun-2012	3	9
<i>Queen Elizabeth Hospital (QEH)</i>	<i>Initiated 11 Jan – Activation due this week</i>		
<i>Southern Medical Day Care Centre (SMDCC)</i>	<i>HREC Approved – To be initiated in Jan 2013</i>		
<i>Bankstown-Lidcombe Hospital</i>	<i>In Start-up: Awaiting RGO approval</i>		
<i>Royal Adelaide Hospital</i>	<i>In Start-up</i>		
TOTAL:		9	68

