



Welcome to the ARTnet newsletter in which we highlight latest progress and outline our planned future activities.

ARTnet EXECUTIVE COMMITTEE UPDATE

Dr Paul Thomas, as AANMS representative, and Dominic Mensforth, representing ANZSNM, have recently commenced as ARTnet Executive Committee co-Chairs. The Executive Committee is responsible to the oversight and strategic planning for ARTnet. Tremendous thanks to the previous Executive Committee Co-Chairs, Paul Roach and Liz Bailey, for their excellent leadership since ARTnet's inauguration in April 2014.

ARTnet SCIENTIFIC COMMITTEE UPDATE

The Scientific Committee of ARTnet has continued to meet quarterly over 2017 by teleconference and in person at the ANZSNM ASM in Hobart. The Committee has made significant progress this year, in particular with PSMA PET initiatives, and with the progress of the ARTnet site initiation program. More details are provided below.

Committee members

Many thanks to the following outgoing Scientific Committee members for their excellent contribution to ARTnet activities: Dr Martin Cherk and Prof Dale Bailey.

We would like to welcome two new Scientific Committee members:
Prof Chris Rowe, Nuclear Medicine Specialist, Austin Health
Dr Daniel Badger, Medical Physicist, The Queen Elizabeth Hospital

ARTnet SCIENTIFIC UPDATE

ARTnet has been active in 2017 in supporting and promoting research in clinical trials involving radiopharmaceuticals. There has been significant progress and we are pleased to share these achievements with you. We invite everyone to the ARTnet session at WFNMB in April 2018, where we will further expand on the current trials and we hope for active discussion on future trial ideas.

Key achievements of ARTnet over the last 12 months include:

- collaboration with leading clinical trials groups including ANZUP, TROG, USANZ, COGNO
- support of multicentre clinical trials, including ProPSMA and TheraP trials (see below)
- development of the ARTnet phantom camera calibration program
- publication of our first ARTnet supported clinical trial
- support for successful grant funding
- accepted for full membership of ACTA (Australasian Clinical Trials Alliance)

Please see below for more detailed updates on all of these activities. If you would like any further information or would like to discuss how to be involved, have feedback or ideas related to ARTnet scientific activities, please contact us at: scientific.chair@artnet.org.au

Clinical trials – update

A/Prof Michael Hofman summarises the progress of two Australian prospective clinical trials below:

ProPSMA Study: a prospective randomised multi-centre study of the impact of Ga-68 PSMA-PET/CT imaging for staging high risk prostate cancer prior to curative-intent surgery or radiotherapy

Principal Investigator: A/Prof Michael Hofman (Peter Mac, Melbourne)

This study evaluates the role of PSMA-PET/CT for patients with newly diagnosed high risk prostate cancer. Patients enrolled are randomly allocated to receive either conventional scans (CT + bone scan), or a PSMA-PET/CT scan, which is being evaluated. Patients cross-over to second-line DI (crossover to other arm) unless the more than 2 sites of distant metastatic disease are identified. The primary endpoint of the study is accuracy, determined by using follow-up information available up to 6 months after entering the study. Secondary end-points include management impact, utility of second-line imaging, radiation dose, reporter variability, a health economic analysis and safety of PSMA PET. The study is funded by a grant from the Prostate Cancer Foundation of Australia (PCFA) with funding from Movember, and coordinated by Centre for Biostatistics and Clinical Trials (BaCT) at Peter Mac.

Nine sites are now actively recruiting patients including Peter MacCallum Cancer Centre (Prof Michael Hofman, VIC), Sir Charles Gairdner (A/Prof Ros Francis, WA), Austin Health (Prof Andrew Scott, VIC), Hunter New England Imaging (Dr Natalie Rutherford, NSW), Royal North Shore (Dr Edward Hsiao, NSW), St Vincent's Hospital (Dr Kim Taubman, VIC), Royal Adelaide Hospital (Dr Ian Kirkwood, SA), SAHMRI (Dr Michael Kitchener, SA), Royal Brisbane and Women's Hospital (A/Prof Paul Thomas, QLD) with Monash Health (Dr Ramdave Shakher) due to be activated shortly. Study recruitment is ahead of schedule with over 115 patients randomised to date.

ARTnet has played a pivotal role in the design and running of the trial. As part of site activation and to ensure standardisation across all sites, ARTnet provide a validation certificate to sites after completion of a number of quality control activities. As part of this, all sites are sent an ARTnet phantom to fill with Gallium-68, which is analysed by a core laboratory to ensure accurate performance including quantitation. Initial testing demonstrated underestimation of SUV by an average of 15% on 10 of the 14 PET systems tested. Analysis demonstrated that inaccurate measurement by dose calibrators was the cause and calibrator settings for Gallium-68 was subsequently adjusted in order that reconstructed images produced accurate values. This finding has significant clinical implications and a manuscript has been accepted by the Journal of Nuclear Medicine summarising these results.

TheraP Study: A randomised phase 2 trial of 177Lu-PSMA617 theranostic versus cabazitaxel in progressive metastatic castration resistant prostate cancer

Principal Investigator: A/Prof Michael Hofman (Peter Mac, Melbourne)

This randomised multi-centre study compares Lu-177 PSMA617 to cabazitaxel chemotherapy. This trial may be suitable for men who have progressive disease after hormonal treatment and docetaxel chemotherapy. The study was awarded through a new concept grant from the ANZUP Clinical Trials group in conjunction with the Prostate Cancer Foundation of Australia (PCFA). This was supported by preliminary data from a phase II study at the Peter MacCallum Cancer Centre demonstrating high activity in men who progressed on conventional therapies, and was presented at the European Medical Oncology Society (ESMO) as a plenary session in

September. It has the additional industry support from ANSTO and Endocyte, and will be co-ordinated through the NHRMC Clinical Trial Centre.

ARTnet has played a pivotal role including review of the protocol and development of standardised trial protocol nuclear medicine guidelines. ARTnet will provide site certification for Ga-68 PSMA PET/CT and Lu-177-PSMA617. 10 sites around Australia will participate in the study. An investigators meeting, co-ordinated by ANZUP, was held in October 2017 and attended by medical oncology and nuclear medicine principal investigators from sites around Australia. The study has officially commenced recruitment at Peter Mac from 29 Jan 2018, with the other trial sites expected to open shortly following completion of trial study set-up requirements and local governance procedures.

Further information can be obtained from the ANZUP website:

<https://www.anzup.org.au/content.aspx?page=lutetiumprostatecancertrial>

Publication Success - Ga68 PSMA PET Management Impact Study

The results of ARTnet's first multicentre trial have been published! Congratulations to all investigators involved.

Paul J Roach, Roslyn Francis, Louise Emmett, Edward Hsiao, Andrew Kneebone, George Hruby, Thomas Eade, Quoc Nguyen, Ben Thompson, Tom Cusick, Michael McCarthy, Colin Tang, Bao Ho, Philip Stricker, and Andrew Scott. The impact of ⁶⁸Ga-PSMA PET/CT on management intent in prostate cancer: results of an Australian prospective multicenter study. J Nucl Med 2018 59:82-88.

Abstract:

⁶⁸Ga-PSMA PET/CT scanning has been shown to be more sensitive than conventional imaging techniques in patients with prostate cancer. This prospective Australian multicenter study assessed whether ⁶⁸Ga-PSMA PET/CT imaging affects management intent in patients with primary or recurrent prostate cancer. Methods: Before undertaking ⁶⁸Ga-PSMA PET imaging, referring medical specialists completed a questionnaire detailing relevant demographic and clinical data as well as their proposed management plan. A separate follow-up questionnaire was completed after the ⁶⁸Ga-PSMA PET/CT scan results were available to determine whether the management plan would change. Results: A total of 431 patients with prostate cancer from 4 Australian centers had pre- and post-⁶⁸Ga-PSMA management plans completed. Scans were obtained for primary staging of intermediate- and high-risk disease in 25% of patients and for restaging/biochemical recurrence in 75% of patients. Overall, ⁶⁸Ga-PSMA PET/CT scanning led to a change in planned management in 51% of patients. The impact was greater in the group of patients with biochemical failure after definitive surgery or radiation treatment (62% change in management intent) than in patients undergoing primary staging (21% change). Imaging with ⁶⁸Ga-PSMA PET/CT revealed unsuspected disease in the prostate bed in 27% of patients, locoregional lymph nodes in 39%, and distant metastatic disease in 16%. Conclusion: ⁶⁸Ga-PSMA PET/CT scans detect previously unsuspected disease and may influence planned clinical management in a high proportion of patients with prostate cancer. The impact was greater in patients with biochemical recurrence. These results demonstrate the potential clinical value of ⁶⁸Ga-PSMA PET/CT in management of prostate cancer.

<http://jnm.snmjournals.org/content/59/1/82>

Presentations were also made to EANM 2016 and SNM 2017.

Grant success - Prospective, multicentre trial of FET-PET in high grade glioma

Health Minister Greg Hunt has just announced that a grant submitted to the Medical Research Future Fund (MRFF) on "Prospective, multicentre trial of FET-PET in high grade glioma" has been successful, and awarded \$1.52 million over 5 years.

Led by Prof. Andrew Scott, and involving 19 investigators at sites across Australia, this clinical trial will explore FET-PET in newly diagnosed, and suspected relapsed patients with high grade glioma, and involve follow-up of all patients. This trial will be run under the auspices of ARTnet, as well as COGNO and TROG.

Australian Clinical Trials Alliance (ACTA) Full Membership

ARTnet has now been accepted as a Full Member of ACTA, whose mission is to help advance the role and value of investigator-initiated clinical trials and registries in Australia. As a Full member ARTnet is represented on the ACTA Advisory Council and has full voting rights. Prof Andrew Scott is the ARTnet representative for ACTA.

ARTnet Site Initiation Program

The ARTnet site initiation program was officially launched at the ANZSNM ASM 2016. This program utilises the ARTnet phantom to document PET or SPECT camera performance for clinical trials.

The ARTnet phantom assessment can be used for either:

- (i) a 'general' assessment of an imaging device (SPECT or PET camera) to document basic performance under standard conditions, not attached to any particular trial, or
- (ii) a 'specific' assessment designed to determine the suitability of imaging equipment for an individual clinical trial.

The general assessment might be performed to validate a site as a potential partner in future, unspecified clinical imaging trials, whereas the specific assessment would focus on the defined needs of a particular clinical imaging trial in question.

So far, fifteen PET systems have been evaluated at 9 PET facilities in Australia. Further details are available on the ARTnet website www.artnet.org.au

ANZSNM ASM Melbourne ARTnet session

Please join us at the ARTnet session of the ANZSNM ASM on **Friday April 20th, 3.30pm** immediately prior the Congress of the World Federation of Nuclear Medicine & Biology where further updates will be given on all of these initiatives.

Thank you to all who have contributed to these successful initiatives over the last 12 months. We look forward to keeping everyone updated with our activities.

Roslyn Francis (on behalf of ARTnet)
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Executive Committee members

Co-chairs: Dr Paul Thomas
Dominic Mensforth

AANMS Board Representative
ANZSNM Council Representative

Assoc Prof Ros Francis

Scientific Committee Chair

Janine Sargeant

Chief Executive Officer, AANMS

Dr Andrew St John

General Manager, ANZSNM Secretariat

Scientific Committee members

Chair:

Assoc Prof Ros Francis

Head of Department, Nuclear Medicine and WA
PET Service, Sir Charles Gairdner Hospital, WA
A/Prof Molecular Imaging, UWA

Dr Daniel Badger

Medical Physicist, The Queen Elizabeth Hospital,
Adelaide, SA

Ms Louise Campbell

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Assoc Prof Michael Hofman

Centre for Cancer Imaging, Peter MacCallum
Cancer Centre, Melbourne, VIC

Dr Stuart Ramsay

Royal Brisbane and Women's Hospital
Associate Professor in Medicine, James Cook
University

Prof Christopher Rowe

Director Molecular Imaging Research
Austin Health, VIC

Prof Andrew Scott

Director, Department of Molecular Imaging and
Therapy, Austin Health, VIC

Dr Douglas Smyth

Molecular Imaging & Therapy Research Unit,
South Australian Health & Medical Research
Institute (SAHMRI), SA

Mission Statement

To promote and facilitate innovative collaborative clinical research utilising radiopharmaceuticals for imaging or therapy.

Vision

- to develop a network of radiopharmaceutical imaging and therapy sites in Australasia with validated capabilities;
- to harmonise imaging protocols for research;
- to facilitate linkages with other clinical trials networks, the pharma industry and funding agencies for multicentre clinical trials;
- to support multicentre clinical trials with radiopharmaceuticals for imaging or therapy, including facilitating data collection, analysis and data management;
- to promote collaboration in clinical trials and outcome-based research with radiopharmaceuticals

www.ARTnet.org.au

The Australasian Radiopharmaceutical Trials Network is a collaboration of the

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