Australasian Radiopharmaceutical Trials network

ARTnet Site Initiation Program – FAQ

What is the ARTnet site initiation program?

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.

Why is the site initiation / camera calibration process useful?

The main purpose of the ARTnet site initiation program is to facilitate standardisation of imaging data collected across sites in a multicentre clinical trial setting. By ensuring calibration of the cameras, this will allow the comparison of semi-quantitative data across sites.

What is the process if I would like my site assessed?

The process for organising to be involved is detailed below:

1. Fill in the 1 page **ARTnet site initiation form** which is available at artnet.org.au or at this link http://artnet.org.au/our-research-and-services/
2. Please send the completed form to scientific.chair@artnet.org,au
3. The ARTnet Project Officer will then contact you to organise the timing for delivery of the ARTnet phantom.
4. The ARTnet phantom will be delivered by courier to your site at the arranged date.
5. There are instructions included with the phantom, regarding how to prepare the phantom, how to perform imaging and how to upload the results. Please note that ARTnet does not supply the radioisotope for the phantom study.
6. Once you have completed imaging of the ARTnet phantom and uploaded your results, please organise return of the ARTnet phantom as per the instructions enclosed with the phantom.

What is the ARTnet phantom?

The ARTnet phantom uses a NEMA-NU2 (2007) IEC body phantom and is suitable for PET or SPECT camera validations. There are instructions included with the phantom that outline how to prepare the phantom, perform the imaging and upload data for analysis.

How is the analysis of the ARTnet phantom performed?

The data from the phantom study will be sent to the core imaging lab (PharmaScint) who will perform data analysis of the ARTnet phantom and provide a short report to ARTnet. ARTnet will then issue the certification statement to the site that has requested site initiation. ARTnet will hold the report data received from the core imaging lab for a minimum of 2 years.

What is the cost?

The cost of site initiation may vary depending on the specific requirements of a clinical trial. The fee that ARTnet charges is to cover direct ARTnet costs including transportation of the ARTnet phantom, co-ordination of the program and a fee for analysis of the data at the core imaging lab.

As an indicative cost, to perform camera calibration with the ARTnet phantom using FDG the standard cost is $1450 (incl. GST) plus courier costs per PET camera.

You will be informed of the cost for your individual request prior to proceeding with the site initiation program. Payment is requested within 4 weeks of being invoiced.

What information do I receive after my site has been assessed?

You will receive ARTnet certification for the camera that was assessed. This certification confirms that the camera meets calibration standards. If there are specific requirements for a clinical trial, this may also be noted in the certification. You will receive the certification within 4-6 weeks of upload of your data.

What do I do if my camera does not attain the accreditation requirement?

You will be contacted and given information on why the camera did not reach the accreditation standard. This may require repeating the ARTnet phantom study.

How long is the camera calibration valid for?

As a guide, ARTnet recommends re-certification every 2 years. If however there has been a major hardware or software upgrade to your camera that may influence semi-quantitative values, then the camera calibration may need to be repeated sooner than this. There may also be trial-specific requirements stipulated in the protocol of a clinical trial that may supersede these recommendations.

Do I need to repeat the process for each different clinical trial?

No – there should be no requirement for repeating the ARTnet phantom for each trial providing the camera and the isotope that was used in your original ARTnet calibration have not changed, and there has been no major change to the camera hardware or software since the ARTnet phantom study was performed. If you have a specific trial requirement and are uncertain if your current certification is valid, please contact us for further advice.

Can I get assistance with performing the site initiation?

If you do not have the resources to perform the testing within your facility but would still like to participate in the program, ARTnet can arrange for someone from the core lab to visit your site to perform the test. Travel costs and consulting fees will be charged at commercial rates for this service.