

UNISoN Trial News

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Welcome to the first UNISoN newsletter

Since opening our first sites in November, 15 patients have already been enrolled on this important trial, exceeding our projections and expectations. Thank you to the teams at Calvary Mater Newcastle, Box Hill, St George, Royal Brisbane and Women’s Hospital, Flinders Medical Centre, Northern Cancer Institute, Ashford Cancer Centre, Tamworth Hospital, Port Macquarie Base Hospital, Campbelltown Hospital and St Vincent’s Hospital for all your hard work and support in opening your centres. With our remaining sites working tirelessly through the ethics and governance processes, we hope to continue the hard work needed to help us reach our target of 85 patients ahead of our planned milestones.

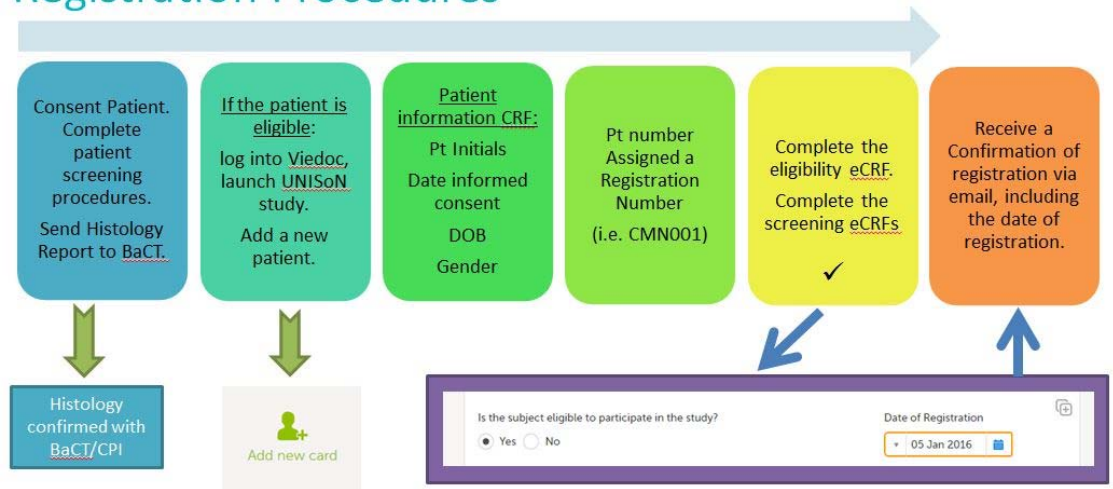
UNISoN is a collaboration between ANZUP and BaCT



Six-step registration

Once your site is activated and you’re ready to enrol your first patients, use this checklist as a guide (it can be found in section 5 of the UNISoN start-up pack).

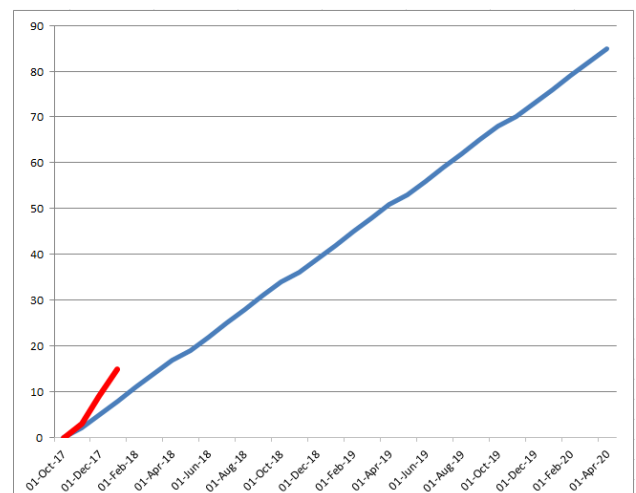
Registration Procedures



Site	Patients
Adelaide Cancer Centre	2
Box Hill	4
Calvary Mater Newcastle	2
Royal Brisbane and Women’s	2
Northern Cancer Institute	2
St George	2
Campbelltown Hospital	1
Total	15

Current recruitment

Congratulations to Ian Davis and his team at Box Hill for being our highest recruiter to date with 4 patients. Adelaide Cancer Centre, Calvary Mater Newcastle, Royal Brisbane, Northern Cancer Institute and St George are all close behind with 2 patients each.



Tissue is the issue

The UNISoN translational studies offer a unique opportunity to understand which patients with metastatic variant-histology renal cell carcinoma do, and do not benefit from treatment.

We are investigating the association between clinical outcomes and biomarkers in particular immune-related biomarkers. Novel therapies such as nivolumab and ipilimumab have benefit in some people, but not in others. To do this, adequate tissue samples are essential. **Only patients with a suitable tumour specimen can be enrolled in UNISoN.**

- If an archival primary tumour sample is available
- Identify the pathology facility storing the sample, send the Pathology Request Letter and seek release of block
 - If not available, consider a core biopsy, send the Pathology Request Letter and seek release of block
 - Ship block to Central lab



Hot tips

These best practice tips will help you administer the protocol and avoid data queries and protocol deviations:

Tip #1: Send de-identified histopathology reports to BaCT, for centralised review by the UNISoN team, as soon as a patient provides consent (a response will be provided within 24 hours)

Tip #2: Ensure Viedoc training is completed by site staff prior to site activation to alleviate delays when it comes to registering patients

Tip #3: Screen failures are not to be entered into Viedoc, use the UNISoN paper-based screening log provided

Tip #4: Ensure de-identified source documents are sent to BaCT in a timely manner, as per the UNISoN Source Data Plan

Tip #5: A CT brain is only required at baseline

Tip #6: No question is a silly question! Feel free to ask anything!



ANNUAL SCIENTIFIC MEETING
8-10 JULY 2018
 HYATT REGENCY
 SYDNEY

Putting People First

CELEBRATING ANZUP'S 10TH ANNIVERSARY

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