

UNISoN Trial News

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Welcome to the second UNISoN newsletter

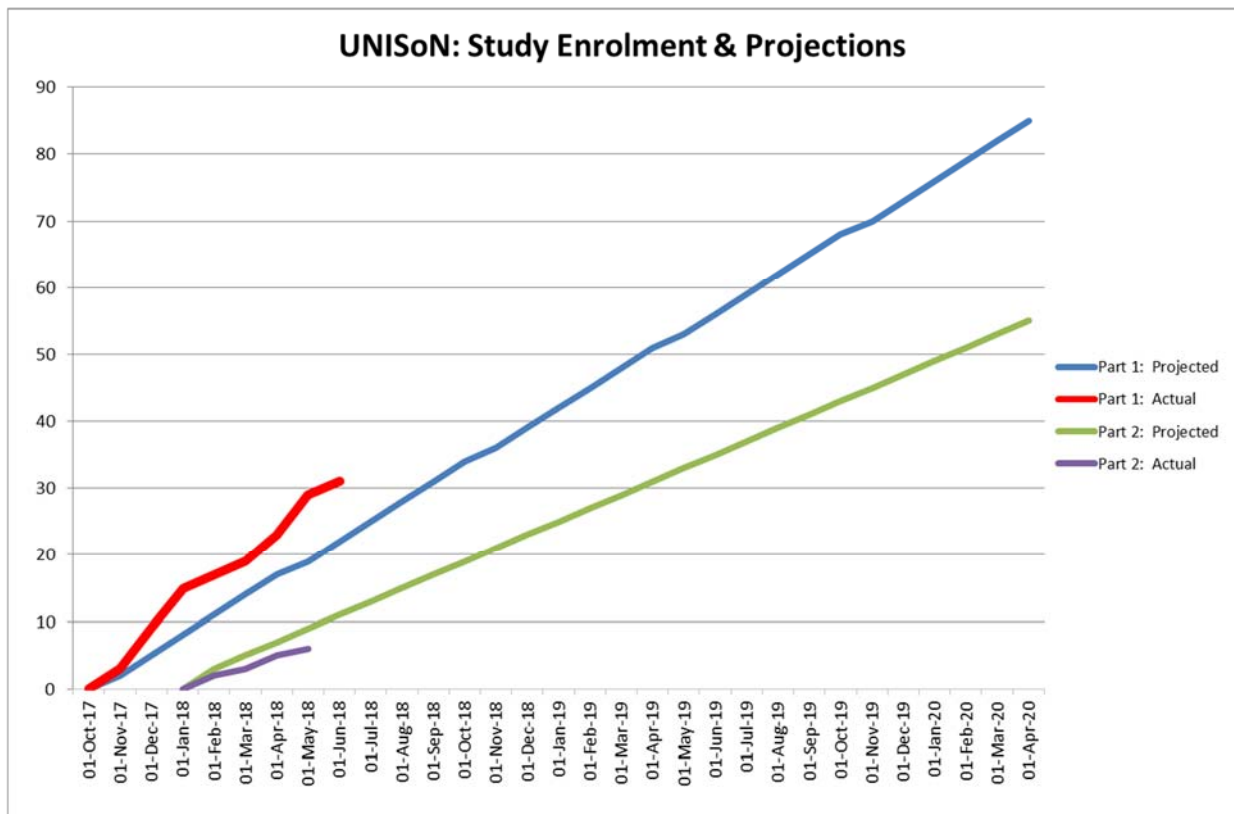
Since opening our first sites in October 2017, 31 patients have been enrolled on this important trial. This far exceeds recruitment projections and expectations, and clearly demonstrates a previously unmet need in the non-clear cell renal cell carcinoma landscape.

Thank you to all 19 participating sites for your hard work and support in opening your centres. All sites are now open, with Sunshine Coast University Hospital the final site to be activated on 18 June. We have recruited 31 patients across 11 sites with remaining sites actively screening and cross-referring patients. We hope to continue the hard work needed to reach the target of 85 patients ahead of our planned milestones.

Current recruitment

Congratulations to Ian Davis and his team at Box Hill for being the highest recruiter to date with 8 patients enrolled. Royal Brisbane Hospital and Northern Cancer Institute are close behind with 4 patients enrolled and Adelaide Cancer Centre, Calvary Mater Newcastle and Campbelltown Hospital with 3 patients each. Of the 31 patients enrolled into Part 1 of the study, 6 patients have moved onto Part 2.

UNISoN is a collaboration between ANZUP and BaCT

Recruitment by site

Site	Patients screened*	Patients registered Part 1	Patients registered Part 2
ACC	3	3	0
BMO	1	1	0
BOH	0	0	0
BXH	11	8	1
CAM	4	3	0
CMN	4	3	2
COL	3	0	0
FMC	1	1	0
FSH	0	0	0
MON	0	0	0
NCI	5	4	1
PMQ	1	0	0
POW	0	0	0
RBWH	5	4	1
STG	3	2	1
SCU	0	0	0
SVH	1	1	0
TAM	1	0	0
WES	1	1	0
TOTAL	44	31	6

*Data obtained from UNISoN Screening Logs provided from sites in May/June 2018 and may not be an up to date representation of the number patients screened at each site

Protocol Version 2.0 – dated 15 February 2018

A minor protocol amendment which resulted in an update to the UNISoN Protocol and Main Master PICF was submitted in February 2018 to the lead HREC – Northern Sydney Local Health District (NSLHD).

The amendment focused on two main updates:

- a) Extending the Serious Adverse Event (SAE) reporting time-frame from 30 days post the last dose of study treatment to 100 days post last dose of study treatment.
- b) Minor administrative updates to various sections in the protocol to provide further clarification to sites regarding operational logistics.

This amendment was approved by the lead HREC (NSLHD) on 6 March 2018 and distributed to sites for submission to local RGOs (or equivalent) on 20 March 2018.

Thank you to all sites who have progressed this amendment to your RGO and provided evidence of RGO approval to BaCT. Remaining sites are reminded to please submit the amendment to RGO as soon as convenient and provide evidence of approval to BaCT.



ANZUP
Cancer Trials Group Limited

ANNUAL SCIENTIFIC MEETING
8-10 JULY 2018
HYATT REGENCY
SYDNEY

#ANZUP18

Putting People First

CELEBRATING ANZUP'S 10TH ANNIVERSARY

Hot tips

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

Tip #1: Please ensure patient eligibility has been completely confirmed prior to entering new patients into Viedoc. A reminder that screening failures are not to be entered into Viedoc, use the UNISoN paper-based screening log provided

Tip #2: Mid ipi/nivo scan has been left in place because patients are progressing on nivo, and you will want to keep a close eye on them, however, beware of pseudo-progression which is rare with PD1 alone but much more common with ipilimumab (that is treat beyond progression if pseudo-progression is suspected)

Tip #3: Ensure Viedoc training has been completed by site PIs - protocol requirement

Tip #4: PI Oversight of Data - As per Section 14.6 of the protocol, Site Principal Investigators are required to confirm the accuracy of completed eCRFs by routinely logging into Viedoc and signing completed forms on a quarterly basis. Reminders will be circulated to sites in June 2018

Tip #5: Reminder that CT scans completed out-of-window must be entered into Viedoc as Unscheduled Assessments, by selecting "Add a New Visit" and initiating an unscheduled Tumour Assessment eCRF

Tip #6: Provide copies of your RGO (or equivalent) approval to BaCT, relating to the version 2.0 protocol, so an updated version of the Viedoc database can be released for your site. This Viedoc update aligns the database with the changes in the protocol

Tip #7: Provide copies of your RGO (or equivalent) approval to BaCT, relating to the version 21 Ipilimumab IB update, for filing in the central site files

UNISoN key contacts

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- ANZUP ClinTrial Refer app available for download from [iTunes](#) and [Google Play](#)

