

# UNISoN Trial News

[www.anzup.org.au](http://www.anzup.org.au)

## Welcome to the third UNISoN newsletter

Since opening our first site in October 2017, 52 patients have already been enrolled into this important trial, far exceeding our recruitment projections and expectations, and clearly demonstrating that this study is facilitating an unmet need in the non-clear cell renal cell carcinoma landscape.

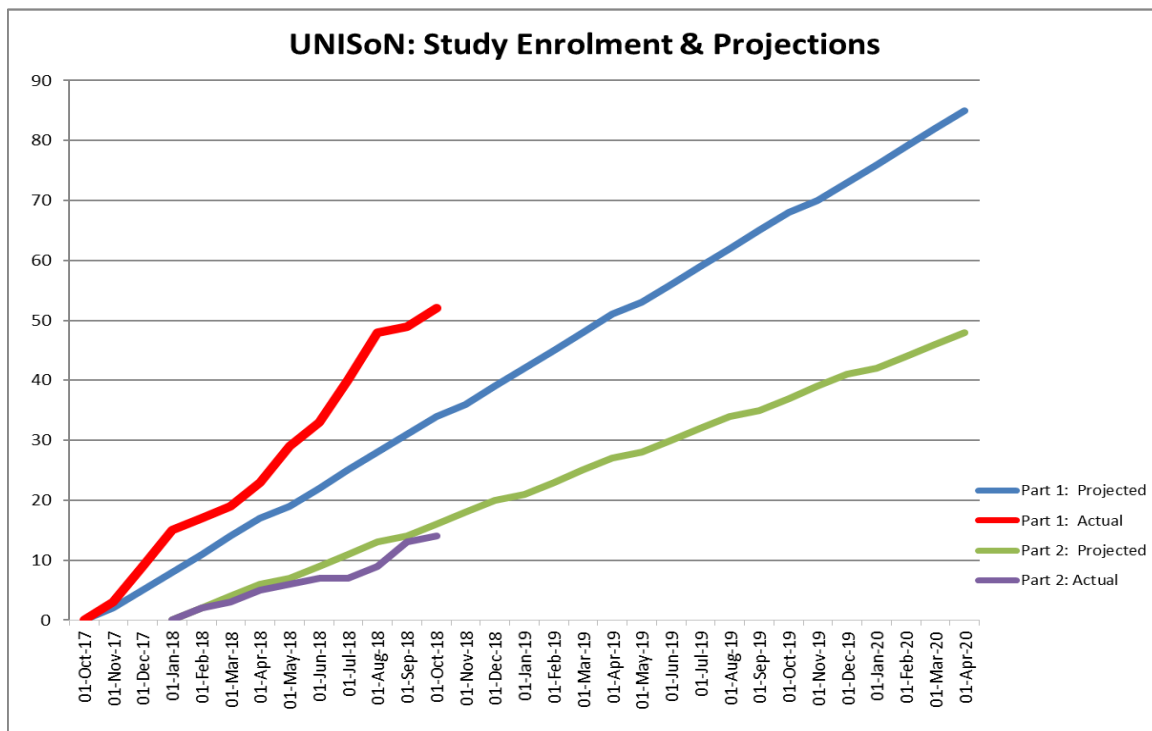
Thank you to the teams across all 19 participating sites for all your hard work and support in opening your centres. All participating sites are open and actively screening, enrolling and cross-referring patients.

We have recruited 52 patients (61%) into Part 1 of the study, across 16 sites, with 14 (29%) of these patients transitioning onto Part 2 of the study. Over the last two months we have seen an increase in recruitment into Part 2 of the study. We hope to continue the hard work needed to help us reach our target of 85 patients ahead of our planned milestones.

## Current recruitment

Ian Davis and his team at Box Hill still lead the recruitment race with 10 patients enrolled to date. Royal Brisbane Hospital has also been very successful enrolling 6 patients. Adelaide Cancer Centre, Flinders Medical Centre, Northern Cancer Institute and Westmead Hospital are all close behind with 4 patients each. Lastly, congratulations to Thomas Ferguson and the team at Fiona Stanley Hospital for enrolling their first two WA patient into the study.

*UNISoN is a collaboration between ANZUP and BaCT*

## Recruitment by site

Site No.	Site	No of Patients Screened	# Patients Registered Part 1	# Patients Registered Part 2
1	ACC	4	4	1
2	BMO	5	3	1
3	BOH	0	0	0
4	BXH	13	10	2
5	CAM	4	3	0
6	CMN	5	3	2
7	COL	5	1	1
8	FMC	4	4	0
9	FSH	3	2	0
10	MON	1	1	0
11	NCI	5	4	2
12	PMQ	2	1	1
13	POW	1	1	0
14	RBWH	11	6	2
15	SCU	1	0	0
16	STG	7	3	1
17	SVH	1	1	0
18	TAM	1	1	0
19	WES	4	4	1
	<b>TOTAL:</b>	<b>77</b>	<b>52</b>	<b>14</b>

### \*\*\*IMPORTANT REMINDER ABOUT DRUG ACCOUNTABILITY\*\*\*

Sites must maintain drug accountability logs (both bulk and individual) for review by BaCT and ANZUP at the end of the study.

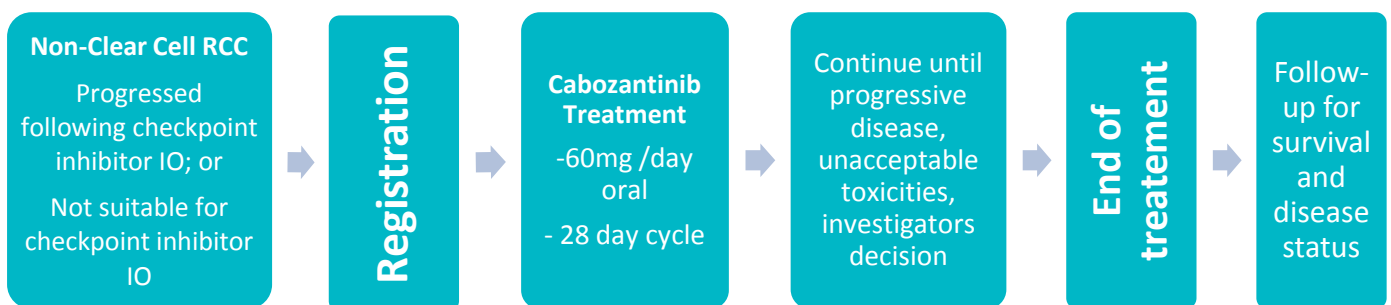
The logs (refer to Appendix 1 and 2) are to be filed in the UNISoN Pharmacy Folder throughout the trial and will be made available for review by BaCT and/or ANZUP on request.

The UNISoN Pharmacy Folder is provided to sites just prior to site activation

A friendly reminder that it is the responsibility of the sites and sites Pharmacy Departments to monitor and maintain stock levels.

If you need any further information, please contact Clinical Trial Operations on the details below.

## Introducing UNICAB



### UNICAB: Non-clear cell post Immunotherapy CABozantinib.

A Phase II trial of single agent Cabozantinib in patients with locally advanced or metastatic non-clear cell renal cell carcinoma post immunotherapy or who are unsuitable for immunotherapy (ANZUP 1802).

UNICAB is a clinical trial of second-line cabozantinib in non-clear cell kidney cancers for patients who have been failed by immunotherapy or for whom immunotherapy is unsuitable. The aim of UNICAB is to determine the objective response rate associated with cabozantinib.

UNISoN is rapidly recruiting, and currently there are no suitable follow-on treatment options for patients who progress on immunotherapy. Cabozantinib as a second line treatment option may be a useful opportunity for these patients. Patients with a non-clear cell RCC who have taken immunotherapy outside of the UNISON trial are also potentially eligible.

This follow-on study from UNISoN is currently in development with HREC submission planned for November 14th 2018. Selected sites have been contacted by ANZUP and BaCT. Please contact **Laura Galletta** BaCT Clinical Trial Manger to find out more about this promising study.

## 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: As patients are now transitioning to Part 2 of the study, please ensure that adequate supplies of both Ipilimumab and Nivolumab are available at sites prior to scheduled dosing. Pharmacists are kindly reminded that it can take up to 14 business days for drug orders to reach sites and careful monitoring at sites is required.*

*Tip #3: Mid ipo/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, be aware of pseudo-progression, which is rare with PD1 alone but more common with ipilimumab I-E treat beyond progression if pseudo-progression is suspected.*

## Viedoc User Guide

*PI Oversight of Data: As per Section 14.6 of the UNISoN protocol, Site Principal Investigators are required to confirm the accuracy of completed eCRFs by routinely logging into Viedoc (the UNISoN electronic data capture (EDC) system) and signing completed forms on a quarterly basis.*

*Outstanding Training: To date, there are still a number of site investigators yet to complete the mandatory online training in order to gain access to Viedoc.*

*Training links will be re-sent to these investigators again via email. Please check your inboxes and click on the link provided to gain access to the training module.*

*EDC training takes only 15 minutes to complete. Once completed, complete and sign page 1 and 2 of the attached EDC User Policy and Authorisation Form and return to Laura Galletta, UNISoN Clinical Trial Manager, for processing.*

*Sign-Off of Patient Data: Investigators whom have already completed EDC training have been provided with a username and password. If you cannot locate your username or password, please contact Laura Galletta, UNISoN Clinical Trial Manager, to arrange for your username and password to be re-sent to you.*

## UNISoN key contacts

- Clinical trial operations, BaCT E: [laura.galletta@petermac.org](mailto:laura.galletta@petermac.org) T: +61 3 8559 7529
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- ANZUP ClinTrial Refer app available for download from [iTunes](#) and [Google Play](#)

