

UNICAB Trial News

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Welcome to our first UNICAB newsletter

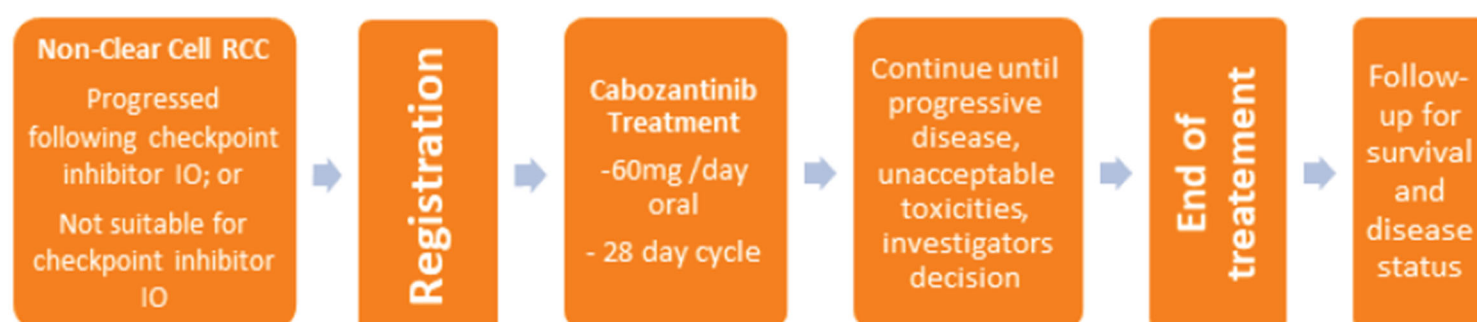
The study is currently open at 10 of 11 sites across Victoria, NSW, QLD and SA. Thank you to all the trial teams from the open sites who continue to actively screen patients, and to Border Medical Oncology for registering the first UNICAB patient on 23 September 2019.

Site	Site Activated	Number Registered
Border Medical Oncology (NSW)	15/4/2019	1
Campbelltown Hospital (NSW)	18/9/2019	0
Calvary Mater Newcastle (NSW)	26/6/2019	0
Northern Cancer Institute (NSW)	Q4 2019	0
St George Hospital (NSW)	19/9/2019	0
Macquarie University (NSW)	1/8/2019	0
Royal Brisbane & Women's Hospital (QLD)	28/8/2019	0
Adelaide Cancer Centre (SA)	11/4/2019	0
Flinders Medical Centre (SA)	28/8/2019	0
Box Hill Hospital (VIC)	17/9/2019	0
Monash Medical Centre (VIC)	29/5/2019	0
Total:	10/11 sites	1

UNICAB is a collaboration between ANZUP and BaCT



As we complete recruitment for the UNISoN study, and enter the follow-up period, this is a reminder that patients who have progressed or are unsuitable for immunotherapy, should be considered for Cabozantinib on the UNICAB study.

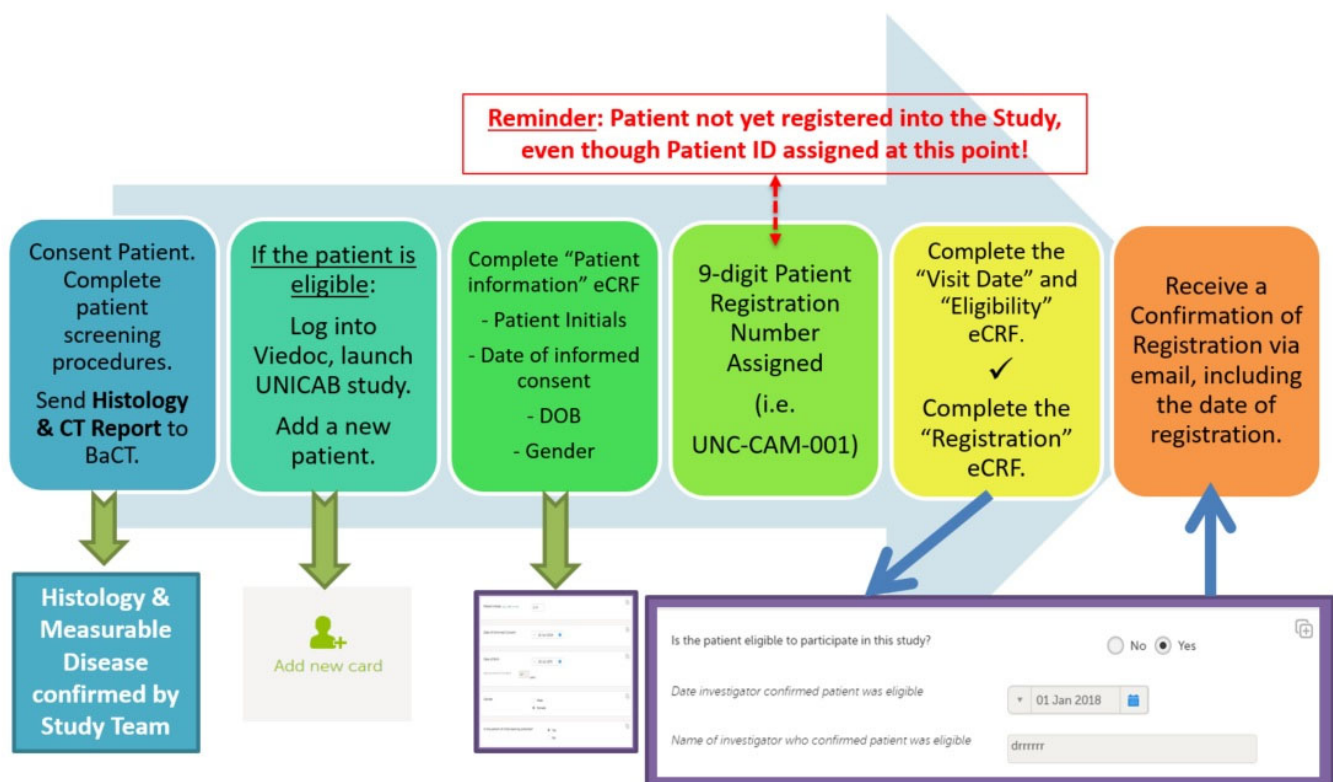


Registration Procedure

A reminder that UNICAB patient registrations are solely completed via the study database (Viedoc). There is no other method of patient registration.

If your patient has previously been enrolled into the UNISoN study, then central review of their histopathology report prior to patient registration (via Viedoc) does not need to be undertaken again.

****Added Pre-Registration Step:** The UNICAB Study Team are now also centrally reviewing baseline CT reports prior to patient registration. A reminder to forward de-identified baseline CT Reports to the UNICAB Clinical Trial Manager once patient consent is obtained so to confirm patient eligibility.



Where UNICAB and UNISoN Collide

Wherever possible, BaCT and ANZUP have aligned operational procedures of the UNICAB study with UNISoN. This is to allow the smooth transition of patients from one study to another and to minimise the change of on-site processes and study logistics for Study Coordinators and Site Staff.

In summary, the following study processes remain the consistent both UNICAB and UNISoN:

- The forwarding of de-identified histopathology reports to BaCT, for centralised review by the UNICAB team, post consent but prior to patient registration. *Note: this only needs to occur for patients which have not previously been enrolled into the UNISoN study.*
- The use of the same database platform (Viedoc) for UNICAB, minimising the needs for additional staff training or re-training or the need for navigating a new platform.

- The use of same on-site processing protocols/methods for the provision of patient blood samples for Translational Research.
- Sharing of archival FFPE tumour blocks between the two studies if UNICAB patients have previously been enrolled via UNISoN, reducing the need for Site Staff to request archival material during the screening period.
- The same process for reporting Serious Adverse Events (SAEs) and responding to queries raised by either the Ipsen Pharmacovigilance Team or Medical Reviewers (i.e. Reporting SAEs via email using an SAE form).
- The same BaCT Clinical Project and Data Management teams assigned to UNICAB, in order to maintain existing relationships established with participating sites and Site Staff.

Hot tips

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

1. Viedoc training is now mandatory for site staff the site PI to be completed **prior to site activation**. Sites will not be activated if Viedoc training has not been completed by the Site PI and the UNICAB EDC User Policy and Authorisation form returned.
2. Ensure de-identified source documents are sent to BaCT in a timely manner, as per the UNICAB Source Data Plan (SDP).
3. Please ensure patient eligibility has been completely confirmed prior to entering new patients into Viedoc. Screen failures are not to be entered into Viedoc. Use the UNICAB Screening Log provided.
4. Ensure you have access to SiteDocs (<https://sitedocsportal.com/auth/login>), as current study documents can be located and downloaded electronically at your convenience.

Clinical Pointers

1. A CT brain is required at baseline, subsequent brain scans as clinically indicated.
2. Whole Body Bone Scans (WBBS) are only required for patients with known bone metastasis.

UNICAB key contacts

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