

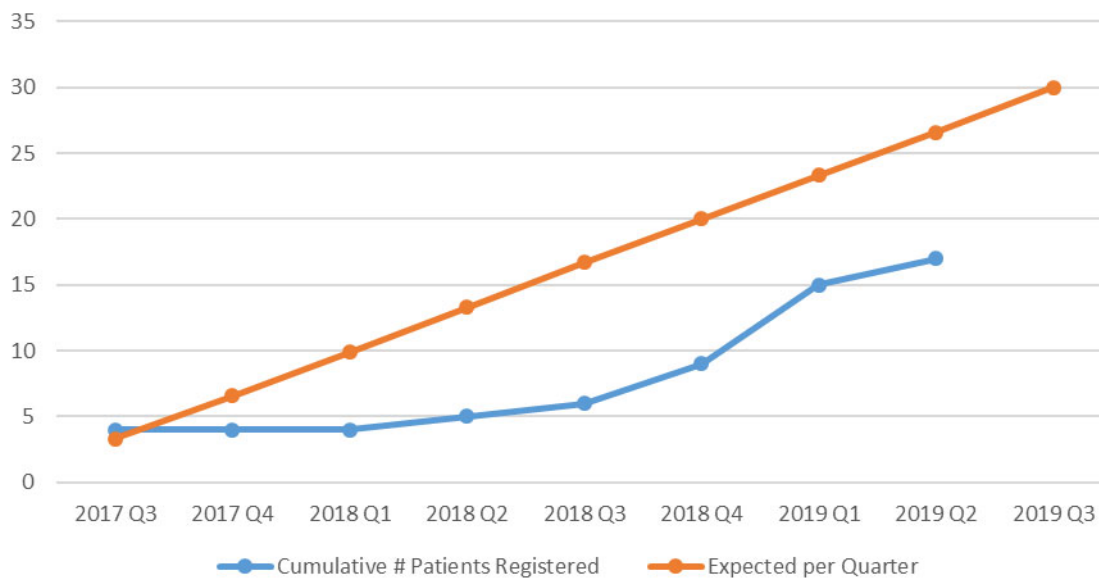
PCR MIB Trial News

www.anzup.org.au

Welcome to the fourth PCR MIB newsletter

At present, 17 patients have been registered to the study. We have surpassed the 50% mark! In Q1 and Q2 of 2019, 8 patients were registered. A fantastic achievement given recruitment for the study has been low. Congratulations to Sir Charles Gairdner on registering the most amount of patients to date with the Austin Hospital a close second. Thanks again to all our sites for helping us reach the 50% target.

PCR-MIB: Patient Registrations



PCR MIB is a collaboration between ANZUP and BaCT

BaCT
Centre for Biostatistics and Clinical Trials

Interim Analysis

The Interim Analysis for the study will be conducted once the 10th patient registered to the study completes their 31 week visit. The analysis is scheduled to take place mid-September 2019. Recruitment to the study will not be halted during this time.

SAE Reporting

Please remember to report SAEs on the SAE form to BaCT, ANZUP and Merck Global Safety within 24 hours of notification. Ensure one term is listed per SAE form. Multiple SAE forms can be used in cases where there are more than one term for the SAE.

Recruitment by site

Site	# Patients Pre-Screened	# Patients Screened	# Patients Registered
AUS	0	8	5
COL	1	4	1
POW	1	6	2
SCG	4	10	6
RNS	1	12	3
TOTAL:	7	40	17

PCR MIB Database

PI Oversight of Data - Site Principal Investigators are required to confirm the accuracy of completed eCRFs by routinely logging into Viedoc (the PCR MIB electronic data capture (EDC) system) and signing completed forms on a quarterly basis. Reminder emails are sent on a quarterly basis with instructions on completing the data sign-off.

Source Data Request – Congratulations to all sites for submitting data for the study in a timely manner. It has ensured that data management remains up to date and any issues can be addressed promptly.



ANNUAL SCIENTIFIC MEETING
21-23 JULY 2019 • HILTON, BRISBANE



PCR MIB key contacts

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- Trial information: <https://www.anzup.org.au/content.aspx?page=pcrmibtrial>
- ANZUP ClinTrial Refer app available for download from iTunes and Google Play

