

# PCR-MIB Trial News

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

*From Andrew Weickhardt, PCR-MIB Study Chair:*

We are closing in to the final few patients required to complete the PCR-MIB study. We have 27 patients on study so far, with only 3 patients to recruit!! Well done everyone. Fantastic effort.

Some encouraging data from similar trials has been presented at ASCO 2021 in early June. Those studies shows similar outcomes to our initial results, and no additional toxicities from adding immunotherapy to radiation and chemotherapy for these patients.

## A couple of quick reminders

Please ensure that patients having their first 3 and 6 month cystoscopies have biopsies taken of the tumour base to ensure optimal designation of response rate.

If patients subsequently progress, it would be valuable to confirm this progression if possible with a biopsy. The analysis of biomarkers of progression will be undertaken in the future.

## Recruitment by site:

Site	# Patients Pre-Screened	# Patients Screened	# Patients Registered
Austin Hospital	0	10	7
Chris O'Brien Lifehouse	3	6	3
Liverpool Hospital	2	1	1
Prince of Wales	1	6	2
Royal North Shore	1	16	7
Sir Charles Gairdner Hospital	4	11	7
<b>TOTAL:</b>	<b>11</b>	<b>50</b>	<b>27</b>

*A/Prof Andrew Weickhardt  
PCR-MIB Study Chair*



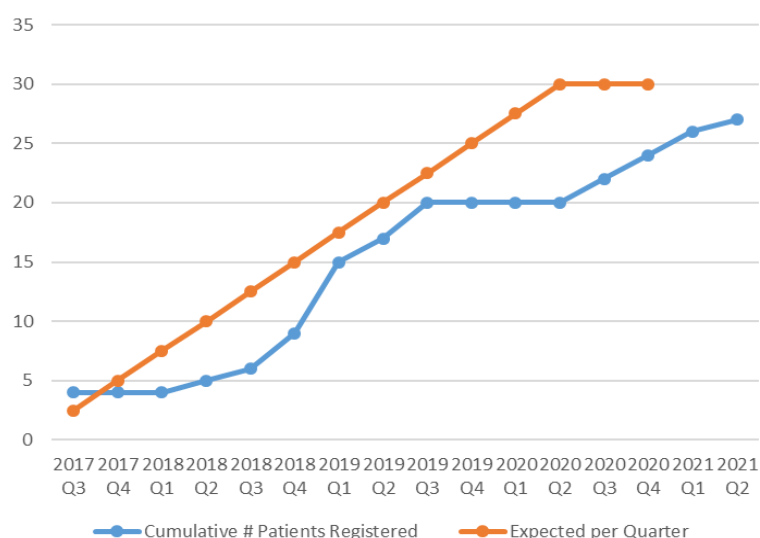
*PCR-MIB is a collaboration  
between ANZUP and BaCT*



## Interim Analysis:

The last interim analysis was done in November 2019 when 10 patients had completed 31 weeks of follow up after treatment. Recruitment to the study was not be halted during this time.

## PCR-MIB: Patient Registrations Expected vs Actual



### 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.

### 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 source 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.



### PCR-MIB key contacts

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