



PCR MIB Trial News

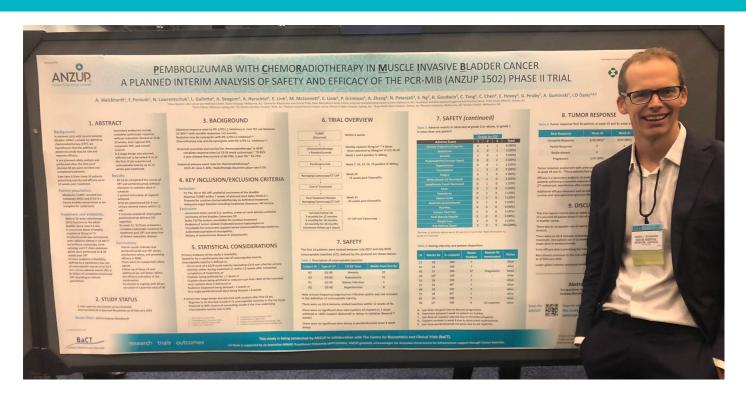
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Welcome to the fifth PCR MIB newsletter

From Andrew Weickhardt, PCR MIB Study Chair:

"PCR-MIB has recruited a total of 20 out of planned 30 patients. We presented a safety update from the first 10 patients at ASCO-GU with favourable coverage given the results suggest safety and activity of the combination. The results were discussed in a poster walk session with the audience eager to see the trial completed and follow up of patients. Please consider this trial as an option for patients suitable for bladder preservation.

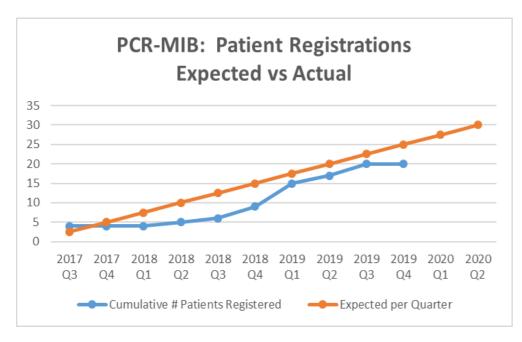
With only 10 patients required to complete recruitment we are nearly there!"



Andrew Weickhardt, PCR MIB Study Chair, presenting a Trials in Progress and preliminary results poster as ASCO GU in San Francisco in February 2020.

PCR MIB (ANZUP 1502)







Recruitment by site

| | # Patients Pre- | # Patients | # Patients |
|--------|-----------------|------------|------------|
| Site | Screened | Screened | Registered |
| AUS | 0 | 9 | 6 |
| COL | 3 | 6 | 3 |
| LIV | 0 | 0 | 0 |
| POW | 1 | 6 | 2 |
| SCG | 4 | 10 | 6 |
| RNS | 1 | 12 | 3 |
| TOTAL: | 9 | 43 | 20 |

Current Recruitment

At present, 20 patients have been registered to the study. We have surpassed the 70% mark! In Q3 of 2019, 3 patients were registered. A fantastic achievement given recruitment for the study has been low. Congratulations to Sir Charles Gairdner and Austin Hospital on registering the most amount of patients to date.

Thanks again to all our sites for helping us reach the 70% target. *Please remember to encourage colleagues to refer any eligible patients to this study.*

Interim Analysis

The next interim analysis is proposed in mid-April 2020. Recruitment to the study will be 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.

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

ADELAIDE CONVENTION CENTRE 19-21 JULY 2020



PCR MIB key contacts

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