ANZUP 1301

ANZUP Cancer Trials Group Limited

BCG+MM Trial News

www.anzup.org.au

Welcome to the 9th edition of the BCG+Mitomycin Study Newsletter

Recruitment closed a year ago and many participants are now completing the Follow-Up stage.

Thank you to all Investigators, Clinicians and Study staff (past and present) for your continued efforts on the trial.

Please continue to complete data entry in a timely manner. Overdue data reminders will be sent regularly. For any questions, please contact **BCGMM.study@sydney.edu.au**

Study accrual

Recruitment is closed as of 17 May 2023
Final recruitment: 501

Study accrual by site

Site Name	State	Investigator	Activation Date	Recruited
Fiona Stanley Hospital	WA	Dickon Hayne	2 Dec 2013	127
GenesisCare North Shore	NSW	Laurence Krieger	11 Feb 2014	70
Austin Health	VIC	Joseph Ischia	18 Mar 2015	58
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	43
The Tweed Hospital	NSW	Ratnesh Srivastav	18 Nov 2015	38
Nottingham University Hospital	UK	William Green	29 Apr 2021	33
The Alfred Hospital	VIC	Jeremy Grummet	12 May 2014	23
Frankston Hospital	VIC	Emma Beardsley	11 Mar 2015	21
Southside Cancer Care Centre	NSW	Patricia Bastick	28 Jul 2017	21
John Hunter Hospital	NSW	Alison Blatt	29 Nov 2019	19
Westmead Hospital	NSW	Manish Patel	17 Mar 2017	12
Concord Repatriation General Hospital	NSW	Andrew Mitterdorfer	28 Jul 2014	12
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	10
Epworth HealthCare (Richmond)	VIC	Shomik Sengupta	23 Jan 2016	8
Nepean Hospital	NSW	Matthew Winter	27 Oct 2020	4
Footscray Hospital	VIC	Conrad Bishop	21 Aug 2014	1
SAN Clinical Trials Unit	NSW	Gavin Marx	25 Feb 2015	1
Flinders Medical Centre	SA	Alexander Jay	09 Dec 2022	0
			Total	501

"Getting close to the end - almost there! Let's get it done."

Study Chair
Professor Dickon Hayne

Data Management

Collection and Entry

Thank you for your ongoing efforts in entering the BCG+ Mitomycin trial data in a timely manner. Please continue to ensure data has been entered for all completed study visits to date. This is particularly important for the tracking of disease-free survival events, the primary endpoint for this study, as they occur.

A regular reminder email will be sent to site coordinators to flag overdue data and open queries in InForm.

Site coordinators – Please make every effort to address open queries in the database within two weeks of the query being issued.

Data entry and data collection guidance documents have been provided to all sites previously and are available upon request:

1. BCGMM eCRF completion generic guidelines, v3.0 14Feb2018
2. BCGMM eCRF Training slides, v4.0 14Feb2020
3. BCGMM QOL instructions, v1.0 12Nov2013

Timing of Pre-Progression and Post-Progression Follow-Up Visits

The expected dates for Pre-Progression Follow-Up visits are calculated from the participant's randomisation date, not the end of treatment date or most recently completed study visit. The expected date of Pre-Progression Follow-Up Visit 1 is 15 months (+/- 1 month) from the date of randomisation.

If a participant meets criteria for progression, the date and details of progression should be recorded in InForm. The participant is then expected to follow the Post-Progression visit schedule, as per the protocol schedule of assessments. The expected dates for Post-Progression Follow-Up visits (6, 12 and 24 months, +/- 1 month) are calculated from the date of documented progression, not the most recently completed study visit.

A visit calculator tool which can assist in scheduling future study visits has previously been provided to all sites. A blank template is available upon request.

Data Management, cont….

Missed Visits in Follow-Up

Any Follow-Up visits as per the protocol schedule of assessments, that are not conducted, are still expected to be recorded in InForm. To record these, create a Follow-Up visit with the expected visit date and timepoint, apply a 'Not done' form-level comment to the STATUS form within the visit folder, and add a comment noting the reason the visit was not conducted. This also applies to any Follow-Up visits missed due to treatment and EOM cystoscopy delays.

For all data entry questions, please contact **BCGMM.study@sydney.edu.au.**

Mortality Data Collection

A clarification that participant mortality data only needs to be collected up until two-year post disease progression follow-up OR the five-year follow-up has been completed.

OncoTICE® Study Allocation

We would like to thank MSD Australia once again for their ongoing support of the BCG+Mitomycin Study. MSD Australia have continued to assist by providing participating study sites access to OncoTICE® each month.

Safety

Serious Adverse Event Reporting

Please ensure Serious Adverse Events (SAEs) are reported to the BCG+Mitomycin team within 24 hours of you becoming aware of the event.

Report all treatment related SAEs, even if the event occurs 30 days after the final study dose specified in the current protocol. If in doubt, please contact the BCG+Mitomycin study team for assistance.

SAE reporting is completed through our electronic CRF (InForm). Please answer all fields prior to submitting an SAE report in InForm if possible. Once all available information has been entered, add an entry (Initial, Follow-Up or Final) under the Report Details section of the form then click the "Submit" button to ensure the CTC Team are notified of the SAE. Please also remember to submit an additional report (Follow-Up or Final) in the Report Details section whenever information is updated in an existing SAE.

If you do not receive an email from the BCG+Mitomycin team acknowledging receipt of your SAE report, please email **BCGMM.study@sydney.edu.au** to confirm the SAE was received. Include the participant ID number in your email.

If InForm is unavailable, a paper based SAE form should be completed and signed by a delegated investigator then sent to the BCG+Mitomycin study team.

Reminders and Updates

Updated Study Inbox Email Address

Please note that we have updated our study inbox email address to **BCGMM.study@sydney.edu.au** (previously **BCGMMC.study@sydney.edu.au**) to align more accurately with the study title. Any emails sent to the old email address will still be received by the BCG+MM Study Team.

Delegation of Authority Logs

Ensure an updated delegation log is sent to **BCGMM.study@sydney.edu.au** each time there is a change in staff at your site. This includes start/end dates for delegated coordinators, investigators and pharmacists.

Quality of Life Questionnaires

Please continue to email participant QOL forms to the BCG+Mitomycin study mailbox in a timely manner. Remember to check QOL Questionnaires for completeness/correctness prior to sending. In particular:

- Check the participant details written on the QOL matches the details entered in InForm at enrolment (i.e., pt ID, initials, DOB)
- Check all pages of the QOL have been scanned and are included in your attachment
- Enter the QOL details on InForm in the appropriate study visit tab

Follow-Up Visit Forms Not Appearing in InForm (Pre-Progression and Post-Progression)

Our Data team have been unable to resolve a database issue that is preventing Pre- and Post-Progression Follow-Up visit forms triggering automatically in InForm.

The study team manually activate Follow-Up forms in bulk on a regular basis as a workaround. Completion of the End of Treatment (EOT) form is a prerequisite for the activation of the Follow-Up forms.

If you require the Follow-Up visit tab for any participant and the EOT form has been completed, please notify the study team, and include the participant ID number in your email.

Primary Outcome Completion

Based on the current event rate, the expected completion date in terms of primary outcome is Q2 2025. This timeframe can be achieved with the timely completion of data entry which we thank all sites for their continued efforts.

ANZUP Cancer Trials Group Limited

Thank you for your ongoing support for the BCG+MM trial. If you have any questions, please feel free to contact the study team at BCGMM.study@sydney.edu.au or ANZUP at trials@anzup.org.au

BCG+MM is being led by ANZUP Cancer Trials Group in collaboration with The University of Sydney/NHMRC CTC.

NHMRC Clinical Trials Centre

We are grateful to Cancer Australia for their financial support for Stage 1 and the NHMRC funding support for Stage II.

Australian Government
Cancer Australia

We thank MSD for access to OncoTICE® for our trial patients.

MSD

We would also like to thank Omegapharm for the supply of Mitomycin.

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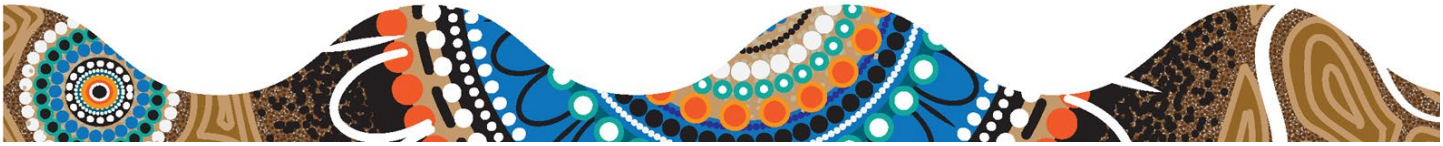
ANZUP Cancer Trials Group Limited

ANNUAL SCIENTIFIC MEETING 21–23 JULY 2024

GOLD COAST CONVENTION & EXHIBITION CENTRE • 'MAKING WAVES'



BCG+MM key contacts

- **ANZUP - lead collaborative group:** trials@anzup.org.au
- **Clinical trial operations:** BCGMM.study@sydney.edu.au
- **Coordinating PI - Dickon Hayne:** dickon.hayne@uwa.edu.au
- **Trial information:** https://anzup.org.au/clinical-trial/bcgmm-trial/