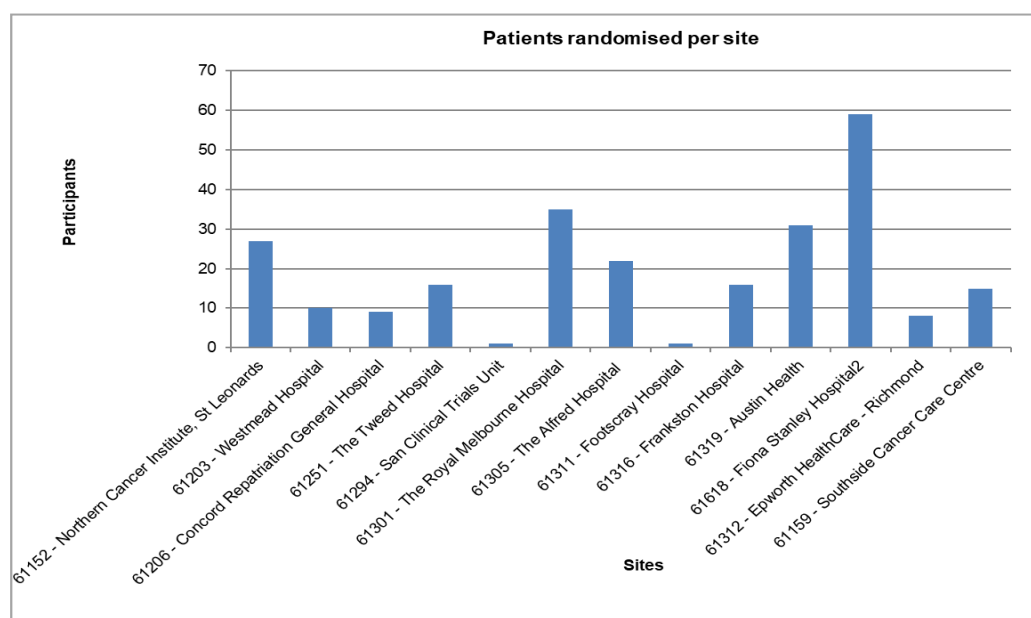


BCG+MM Trial News

www.anzup.org.au

Welcome to the first BCG + Mitomycin trial newsletter – halfway milestone reached!

This is an opportunity for us to keep you informed of the progress of the BCG + Mitomycin study, and to express our appreciation to Principal Investigators, Sub-Investigators, Study Coordinators and research team for your continued support to the study, which has *reached the halfway recruitment milestone!*



BCG+MM is being led by ANZUP Cancer Trials Group in collaboration with the NHMRC CTC



Halfway milestone reached!

We are very pleased to announce that we have **reached the halfway recruitment milestone** (250/500 patients). Congratulations and thank you to everyone for your hard work and continued support. Special congratulations to the teams from our top 4 recruiting sites: Fiona Stanley Hospital, The Royal Melbourne Hospital, Austin Health and Northern Cancer Institute.

New Sites

Welcome to John Hunter Hospital (NSW) who was activated on 29 November 2019.

Sites in start-up:

- Nepean Hospital (NSW)
- Nottingham University Hospitals (UK)

These sites will be activated as soon as the required approvals are obtained.

BCG shortage

Reminders:

- For sites who are solely reliant on trial allocation, please email bcgmmc@ctc.usyd.edu.au prior to randomising patients.
- Allocations from MSD are valid only for that month, i.e. allocations must be submitted to MSD by end of month or they will be considered void.
- If your site pharmacy is looking into alternative strains (such as RIVM) or changes to dosing schedules, we urge sites to use these alternatives for non-trial patients, and where possible utilise BCG OncoTICE for the BCG + Mitomycin study patients.

Protocol and PICF Amendment

We recently received HREC approval for an updated version of the Protocol and PICF. If you haven't already, please email your site-specific PICF's to bcgmmc@ctc.usyd.edu.au for review, prior to submitting to you RGO or local HREC (as required).

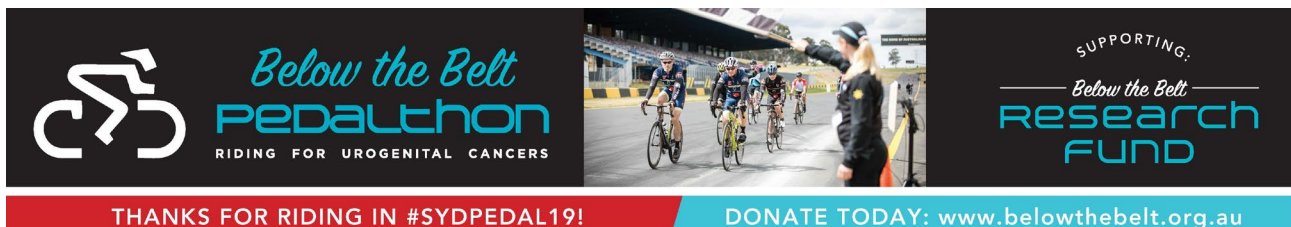
Christmas Closure

The NHMRC Clinical Trials Centre will officially close from Monday 23rd December 2019 and will re-open on Tuesday 7th January 2020. A memo will be distributed to sites closer to the date.

Variation to Clinical Trial Agreement

Please note a fully executed variation agreement is required to be eligible for the increased site payments.

For sites whose variation agreements are still in review stage or partially executed, we would greatly appreciate if you could assist us by liaising with your contracts team to ensure we have the agreements fully executed by December 2019.



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BCG+MM key contacts

- ANZUP - lead collaborative group: anzup@anzup.org.au
- Clinical trial operations: bcgmmc@ctc.usyd.edu.au
- Coordinating PI - Dickon Hayne: dickon.hayne@uwa.edu.au
- Trial information: <https://www.anzup.org.au/content.aspx?page=trials-bcgmmc>