

A Message from our Co-Chairs

Welcome to another edition of the ROADMAP Newsletter. We're well and truly in a growth phase, with new sites and countries coming online in rapid succession.

There are now 11 sites green-lit in Australia, with Aotearoa New Zealand sites set to begin recruitment in the coming weeks. The Canadian team is expected to start in early 2026, and our French colleagues have been successful with funding and will commence later in 2026. Participant recruitment in Australia is also accelerating.

The big 'operational announcement' is that version 2.0 of the protocol has been approved! The Trial Management Group have been working with Australian sites to help with the bureaucratic admin associated with this new version – so please keep an eye out for emails from the ROADMAP team.

Additional building blocks of the ROADMAP ecosystem are progressing well. Our statistics and microbiology working groups have been busy refining plans for the statistical analyses and isolate repository, and we now have an independent Data Safety Monitoring Committee established – to keep us honest! And at the same time, ROADMAP investigators are already looking ahead to potential future domains and research questions as the trial evolves.

So as the end of the year and the festive season rapidly approaches, we'd like to thank you all for your being part of the ROADMAP Trial. We look forward to maintaining this great momentum into 2026. *Cheers, Laurens*



Professor Laurens Manning
Co-ordinating Principal
Investigator for ROADMAP



Professor Joshua Davis
Co-ordinating Principal
Investigator for ROADMAP

Key ROADMAP Updates

Protocol Updates & Major Amendment

The ROADMAP protocol is now at version 2.0, with ethics approval obtained. Sites are in the process of securing updated governance approvals.

A major amendment submitted in August received record turnaround for approval – a huge thank you to Dr. Marline Squance for her exceptional leadership and persistence throughout this process. Teams are currently updating trial and site documents, and revised resources will continue to be uploaded to the ROADMAP website.



New Online Regional Resources

The ROADMAP website now includes a region-specific resources section with site SOPs and key operational documents. Access is password-protected – please contact the TMG for your regional password.

ROADMAP Resources:

[Approved ROADMAP Documents](#)
[Patient Videos & Conference Recordings](#)

Growing Site Activity & Recruitment

ROADMAP continues to gain momentum, with 11 active sites across Australia. To date, 113 participants have been screened – 30 into the Platform, 72 enrolled into the Registry, and 7 not enrolled in either.

John Hunter Hospital (NSW) and Fiona Stanley (WA) have currently recruited the most participants in both the Platform and Registry.

Recruitment has been slowed with the temporary closing of the Antibiotic Choice domain at most active sites, due to a shortage of Rifampicin.

Thank you to all teams for their ongoing effort and healthy competition driving progress forward.



Screening of Patients

Teams are encouraged to screen all eligible patients, even if participation seems unlikely. Each screening contributes valuable information to help refine future enrolment strategies and ensure comprehensive data capture.

Registry Enrolment

Registry enrolment numbers remain below expectations. Tip is to present both Platform and Registry Patient Information and Consent forms to the patients – if participation to the Platform is declined, suggest Registry-only participation.

Antibiotic Choice Domain & Rifampicin Supply

Global shortages of rifampicin continue to impact recruitment. However, some sites have reopened recruitment to the domain after securing new stock. Full resolution is anticipated in early Q1 2026. This is welcome news, as reopening this domain across all sites will support stronger recruitment and further strengthen trial data.

Surgical Domain Recruitment Support

Recruitment in the Surgical Domain continues to face challenges – from case timing and consent complexity, to variation in surgical practice and limited capacity at smaller sites.



To support engagement:

- A promotional poster has been developed to raise awareness among orthopaedic registrars.
- A new quarterly **Surgeons Town Hall** has been established for Australian and New Zealand orthopaedic Surgeons. The next session is scheduled for 3 December 2025. All orthopaedic colleagues in these areas are encouraged to attend and share experiences and insight into how recruitment flow may be improved.

Data Safety & Monitoring Committee

The Data Safety & Monitoring Committee (DSMC) held its first meeting in August and now includes five members (all based in the US): two infectious disease physicians and two orthopaedic surgeons, in addition to the Chair. While interim analyses are not yet required, the committee will meet every six months to maintain oversight of trial integrity and participant safety.

Introducing Jacinta

We're delighted to welcome **Dr. Jacinta Martin**, who joined the global ROADMAP Trial Management Group (TMG) in July, taking over from Róisín Griffin.



Jacinta has bravely taken on dual roles as Data Coordinator and Isolate Repository Coordinator.

A belated warm welcome and thank you for your contributions so far!

Meet the rest of the ROADMAP family by visiting the Team Page on our website: roadmaptrial.com/about/our-team

“Kia ora” from New Zealand

We are pleased to announce that ethics approval for the ROADMAP study in New Zealand was successfully obtained in June 2025!

This milestone marks the beginning of an important new phase as we activate sites across the country.

The ROADMAP database is currently being adapted to ensure that consent and data collection procedures align with the New Zealand requirements.



North Shore Hospital, New Zealand
(Waitematā Health District)

Georgia Fowler, our Lead NZ ROADMAP coordinator, has been hard at work organising all the trial-related documentation and supporting sites through their activation processes, and ROADMAP investigator Dr. John Mutu-Grigg (Ngāti Kahu, Te Rarawa) has outlined the additional support he will provide to Māori participants on their ROADMAP journey.

Congratulations to Waitematā for becoming the first site to be activated in New Zealand – a fantastic achievement and an encouraging sign of the momentum building around the trial. Meanwhile, Middlemore Hospital is preparing for its upcoming site initiation visit, and Auckland is also planning theirs soon. Tauranga and Christchurch are actively working through the necessary local approvals to join the ROADMAP study. With these sites coming on board, we are hopeful to recruit our first New Zealand participant before the end of the year. **Watch this space!**

“Bonjour” from France

After joining the SNAP project, French infectious disease specialists expressed their wish to also participate in the ROADMAP project, with Dr. Johan Courjon and Prof. Aurélien Dinh as co-investigators.

The project began more than a year ago, following an invitation to the French network of reference centres for complex bone and joint infections. The network currently brings together 33 centres where surgical, medical, and microbiological expertise is coordinated. Quite rapidly, about half of the centres indicated their interest in joining the project.

In 2024-2025, we submitted two funding applications, one of which was successful (€550,000). This funding will allow the project to begin; if successful, additional applications will be submitted to ensure its continuation.

The project is supported by the scientific board of the reference centres for complex bone and joint infections as well as by our national infectious diseases research network (RENARCI). The funding obtained is governmental, through ANRS Emerging Infectious Diseases.

The project was once again discussed during the French National Congress on Bone and Joint Infections, held in Bordeaux on September 18-19, 2026: discussions showed great interest and strong motivation to participate in this project, which has the potential to change our clinical practice.



Nice University Hospital, France



Sunnybrook Hospital, Toronto

Hello from Canada

ROADMAP in Canada remains in the administrative phase and have just submitted their ethics application.

The Canadian Steering Committee members have been finalised and had their first of a series of national investigator meetings on October 16 and 21 to discuss role out of the trial nationally.

Patient consent forms have been adapted for use in Canada according to Canadian guidelines. Unfortunately, a meeting with Health Canada on October 14 to discuss exemption of

labelling requirements for rifampicin resulted in the need to include labelling. Therefore, delaying start-up timelines. **We are hopeful to start in early Q1 2026.**

Other International Developments



United Kingdom:

The UK funding application was unsuccessful due to statistical concerns, pausing local activity for now.

We'd also like to acknowledge Philip Bejon for his contributions as former UK Lead and GTSC member, and welcome Maria Dudareva, who steps into this role.

Current Active/Pending Grants:

Ireland
Sweden

Other Interested Countries:

India
Japan
Netherlands
Spain
USA

Upcoming Meetings

The following zoom meetings have been scheduled for ROADMAP working groups, committee members and Australian sites. Keep an eye out for email notifications and reminders.

Site Initiation Visit (SIV) for new Australian sites: November date TBA

Australian Regional TSC: Friday 21 November, 2pm AEDT

Surgical Working Group: Friday 28 November, 10am AEDT

Statistics Working Group: Monday 1 December, 3pm AEDT

Surgeons Town Hall (Aus/NZ): Wednesday 3 December, 7pm AEDT

Preparations for 2026

The Trial Management Group is planning ahead for 2026 in collaboration with committee and working group Chairs. Meeting dates will be confirmed, and invitations sent out before the Christmas break.

Thank you to everyone across our ROADMAP network for your continued contribution throughout 2025. Your efforts have made tremendous progress possible. We look forward to welcoming more sites, more patients and more collaboration in 2026.

‘Guess Who?’ Reveal from Edition 4

As part of getting to know our ROADMAP community better, we like to examine closely the bios of our working group and committee members, highlighting their unique talents and personal interests.



CLUE: *When he's not leading pioneering research in joint replacement or chairing international surgical societies, you might find this orthopaedic professor performing with his rock band.*

ANSWER: *Richard de Steiger, Orthopaedic Surgeon, Australia*

Professor Richard de Steiger MBBS PhD FRACS FA OrthA is the Epworth, Victor Smorgon Chair of Surgery, The University of Melbourne, and for 17 years was the Deputy Director of the Australian Orthopaedic Association, National Joint Replacement Registry. He is also a member of the ROADMAP GTSC as well as the Surgical, Antibiotic and Registry Working Groups.

All ROADMAP working group members are listed on the [Governance page](#) of the ROADMAP website.

Publications & Highlights

Advancing the Management of Prosthetic Joint Infections

Burcu Isler, an Infectious Diseases Physician based in Brisbane, QLD – and a member of the ROADMAP GTSC – shares a review of recent and ongoing randomised controlled trials in PJI: <https://doi.org/10.1128/aac.00338-25>



Stay Connected with ROADMAP

Don't forget to visit the ROADMAP website for key trial information, patient videos and document resources.

The ROADMAP website is designed to educate and support investigators, trial sites, and patients affected by prosthetic joint infection (PJI). Content will be updated throughout the trial, and we welcome your feedback and ideas.

Visit www.roadmaptrial.com or scan the QR code to learn more.



Do you have something interesting to share in a future newsletter?

Please get in touch if you'd like to share a member or team profile, talk about a past or upcoming event, special achievement or interest. We'd love to hear from you!

ROADMAP Trial Management Group (TMG)

Chief Investigators: Professor Joshua Davis & Professor Laurens Manning

Global Clinical Trial Manager: Dr Marline Squance

Data Coordinator & Isolate Repository Coordinator: Dr Jacinta Martin

Trial Coordinators/Monitors: Mia Di Virgilio & Alana Di Giacomo

Administrative Assistant: Sandy Isles



Email: IMG@roadmaptrial.com

Website: www.roadmaptrial.com