



NEWSLETTER

Edition 4: June 2025

Dear ROADMAP Community,

Welcome to another ROADMAP trial newsletter. **We're thrilled to share the most exciting development since our last update – the ROADMAP trial has officially commenced!** The first site opened on the last day of March 2025, and the first patient was randomised on that day.

We are now working hard to open more sites in Australia as quickly as possible – but a lot of this depends on you! Before sites can begin recruitment, site investigators and their teams will need to attend a virtual Site Initiation Visit (SIV) and fill in some paperwork (e.g. training and delegation logs) before they get a “green light” and are activated on the database. And this all happens after local site approval (called the SSA process in Australia). So, if you are in Australia, please look out for emails from the ROADMAP team and attend to these ASAP so you can start recruiting patients!

Looking ahead, we are hoping to activate sites in New Zealand later this year, with other regions to follow depending on funding.

A big thank you to the central ROADMAP Trial Management Group for their work thus far to get the trial up and running, and to all of you for being willing to contribute your time to answering important questions in the management of PJI.

– Josh Davis



Professor Joshua Davis
Co-ordinating Principal
Investigator for ROADMAP



Professor Laurens Manning
Co-ordinating Principal
Investigator for ROADMAP



Professor Ian Harris
Orthopaedic Surgeon (AUS)
and member of the ROADMAP GTSC

Thank you, Professor Ian Harris

The ROADMAP team would like to extend our sincere thanks and gratitude to Professor Ian Harris for his dedication in promoting the ROADMAP trial across hospital sites in recent months. His visits and presentations have been instrumental in engaging orthopaedic departments and infectious diseases teams.

"I've had good support from orthopaedic departments during my meetings over the last few months. The ID physicians at each hospital have also been influential in getting the local surgeons on board."

We're so grateful for Professor Harris' leadership and to all collaborating clinicians who are helping to bring the ROADMAP trial to life.

ROADMAP Resources: The GTSC have finalised and approved several key integrity documents, including the Data Management Plan, Data Sharing Policy, and Sub-study Guidance Document. These are now accessible on the ROADMAP Trial website under the [Resource Documents](#) section.

Presentations: The TMG have created a set of PowerPoint presentations for potential sites and investigators explaining the ROADMAP trial overall and each domain. These are available if you need to present to colleagues about ROADMAP – please contact TMG@roadmaptrial.com.

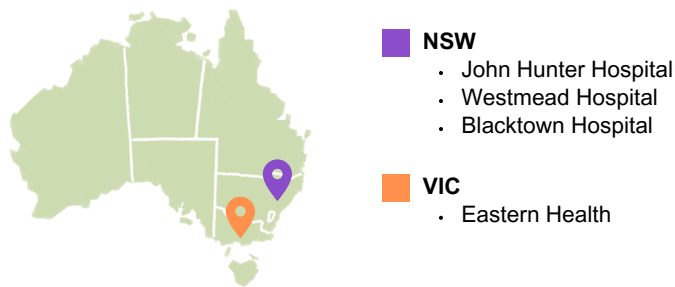
Key ROADMAP Updates

There's been exciting progress in the ROADMAP trial, both in Australia and Internationally, as momentum builds across multiple sites and countries.

Site Activation and Recruitment

Four sites are now activated in Australia and actively recruiting participants. A further five sites have been approved with local research governance and site activation is expected soon. At **John Hunter Hospital in NSW**, three participants have been enrolled in the platform and 15 have joined the registry. **Eastern Health in Victoria** received green light approval in May and has commenced recruitment, with one participant in the platform and one in the registry participant. **Westmead and Blacktown Hospitals in NSW** have received green light approval to commence recruitment in the first week of June.

Several Site Initiation Visits (SIVs) have been completed since March and will continue until all participating sites have been activated.



Trial Governance and Site Expansion

Australia has full HREC approval, and New Zealand has submitted and presented to its HRC with provisional approval given.

Within Australia, 34 sites are now listed under HREC, with ongoing exploration of private hospitals to boost recruitment potential.

International Developments

International expansion continues to progress with interest growing as a result of international conference and meeting presentations by the CPIs and other GTSC members.

- In the **UK**, the trial has entered the next stage of its grant submission, focusing on strategies to ensure ethnic diversity and provide simulation statistics. UK and Australian statisticians are collaborating on this effort.
- **Canada** has secured some seed funding, with a grant resubmission in progress. The team plans to employ a Canadian Research Manager to facilitate ethics submission and site recruitment in anticipation to commence recruitment in 2026.

- In **New Zealand**, agreements have been finalised and are now pending signatures.
- In **Europe**, Dr Johan Courjon (France) has submitted two grants, both of which have reached the second stage.
- **Ireland** has submitted a grant to the national funding body and a number of other countries teams and networks are either in the process of preparing grants, gaining support or by the time this newsletter is circulated may have submitted.

A European coordinating centre for the trial has not been decided as yet and will be through internal European discussions once applications are accepted and grants awarded. **Additional countries expressing interest or progressing funding applications include Sweden, Finland, India, Italy and the USA.**

ROADMAP Database

User Acceptance Testing (UAT) for the trial database was completed mid-February. A total of 13 testers from both medical and non-medical backgrounds evaluated the database's language, usability, functionality, and system logic using a variety of dummy cases. This process helped identify and resolve any database bugs, and the test environment was updated in response to the feedback received. Additional in-house testing was conducted to ensure optimal performance and readiness.

The live database was launched on 25 March and is now fully operational. To date, 20 patients have been enrolled across two sites in Australia, and we are actively working to onboard additional sites. We are continuously monitoring the live environment and implementing incremental improvements to ensure the system remains efficient, and user-friendly.

Team Update

We're excited to welcome Alana Di Giacomo as the newest member of our team! Alana joins us as one of our Clinical Trial Coordinators and Monitors in Australia and will be supporting sites in central Sydney (NSW), Western Australia, and Queensland.



Alana Di Giacomo
ROADMAP Data Manager

You can meet the rest of the ROADMAP family by visiting the [Team page](#) on the website.

ROADMAP ‘talking turkey’ in Istanbul

The ROADMAP Trial team, including Laurens Manning, Josh Davis, David Dewar, David Campbell, Andrew Toms (UK), Renjy Nelson, Bogdan Soloman, Craig Aboltins, Ben Clark and Andrew Fraval, represented the ROADMAP Trial investigators at the 3rd Meeting of the International Consensus Meeting (ICM) in Istanbul, Turkiye, May 8-10.



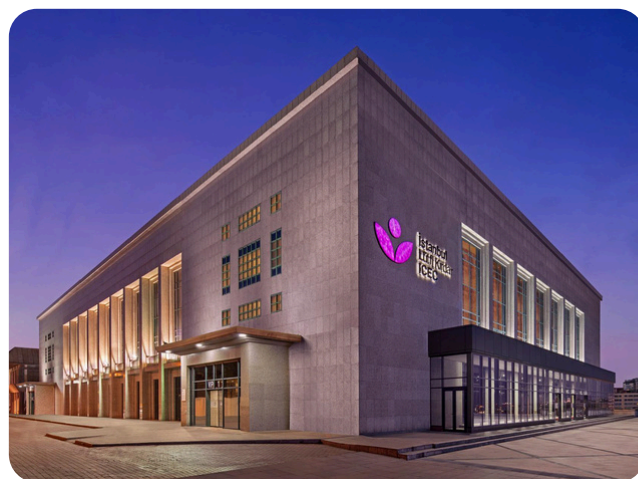
Laurens Manning, Ben Clark and Josh Davis waving a flag for ROADMAP

The meeting brought together around 1,000 delegates, including 800 orthopaedic surgeons and 200 ID/micro experts, to discuss advancements in prosthetic joint infection (PJI) management.

Over three intense days, more than 300 short PJI-related presentations were delivered by clinicians and researchers from more 100 countries, each followed by voting on a consensus statement. All current ROADMAP domains were presented as stand-alone questions and received strong, or very strong consensus supporting their inclusion in the Platform.

Key highlights included:

- **Surgical Domain:** The statement read “A DAIR is an acceptable option for patients who have acute haematogenous PJI. However, the procedure, on average, has a nearly 40% failure rate in this patient population”.
- **Rifampicin Domain (Antibiotic Choice):** It was highlighted that “well-designed randomised trials are needed before a clear recommendation can be given”.
- **Antibiotic Duration Domains:** Questions related to the antibiotic duration domains reinforced the need for a high-quality RCTs to inform clinical practice.



ICM Location: The Istanbul Lutfi Kirdar Congress Centre

We met the two Nico’s (Nicolas Cortés-Penfield and Nicolas Piuizzi, both from the US), who have kindly agreed to join Roger Berry on the Independent DSMC. ROADMAP generated quite a hubbub, with many clinicians and researchers from diverse settings expressing support for, or wanting to participate in, the trial. It even got a ‘shout-out’ in the final closing statement as the most efficient, modern and collaborative approach for generating new evidence required to change practice.

Away from the rinse and repeat cycles of PJI presentations, statement and voting, there was plenty of time to sample some spectacular Anatolian breakfasts, walk the Theodosian walls, sip drinks on an evening Bosphorus Cruise, drink Turkish coffee under the Aqueduct of Valens and marvel at the splendour of the Hagia Sophia.

The team looks forward to the 4th ICM, whenever and wherever that is; hopefully ROADMAP will be able to inform global practice and be seeking to answer the next tranche of PJI treatment dilemmas.

– *Laurens Manning*



Josh Davis and David Dewar enjoying a meal in Istanbul

Upcoming Meetings

The following meetings have been scheduled for ROADMAP working group and committee members.

These meetings are designed to keep everyone informed, connected, and engaged.

Please check your calendars for these dates and keep an eye out for email reminders and detailed agendas.

Antibiotic Working Group

Thursday 25th September 9:30am AEST

Global Trial Steering Committee

Tuesday 17th June 9am AEST

Tuesday 19th August 5pm AEST

Tuesday 21st October 10am AEDT

Microbiology Working Group

Thursday 26th June 10am AEST

(one more to be scheduled for 2025)

Surgical Working Group

Monday 23rd June 6pm AEST

Wednesday 15th October 11am AEDT

Registry Working Group

Thursday 2nd October 4pm AEST

Statistics Working Group

Monday 16th June 3pm AEST

(scheduled monthly)

Guess Who?

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.

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.

Who is this guitar-playing surgeon-scientist?



Look out for the reveal in the next ROADMAP newsletter!

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

Stay Connected with ROADMAP

Don't forget to visit the ROADMAP website for key trial information, [patient videos](#) and essential 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.



You can also follow ROADMAP on YouTube and BlueSky for video updates and ongoing discussions.

 **YouTube** www.youtube.com/@ROADMAP_Trial

 **BlueSky** [@roadmaptrial.bsky.social](https://roadmaptrial.bsky.social)

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

Chief investigators: Professor Joshua Davis & Professor Laurens Manning

Global Clinical Trial Manager: Dr Marline Sqaunce

Data Manager: Róisín Griffin

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

Administrative Assistant: Sandy Isles



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