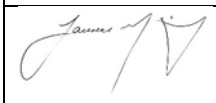
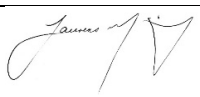
ROADMAP NEW STUDIES GUIDANCE DOCUMENT

VERSION 2.0, DATED 05 JUNE 2026

DOCUMENT APPROVAL

VERSION NUMBER	DATE	CREATED BY	APPROVED BY	SIGNATURE OF APPROVAL
2.0	05June 2026	TMG	Joshua Davis Laurens Manning	 
1.0	04 March 2025	TMG	Joshua Davis Laurens Manning	 
2.0	05June 2026	TMG	Joshua Davis Laurens Manning	 

This document has been reviewed by all members of the ROADMAP Trial Global Trial Steering Committee (GTSC) and has been signed by the Chief Investigators, on behalf of the GTSC.

1 TABLE OF CONTENTS

2 INTRODUCTION

Data collected in the ROADMAP Platform and the associated ROADMAP Registry are a rich resource for secondary analyses and new study projects. This document outlines the requirements and processes for the application and integration of new studies to the ROADMAP Trial. This includes the process for ratification of new study proposals through the Global Trial Steering Committee (GTSC), and the subsequent initiation, ethical review, and data access requirements for integrating a new study into the core platform.

This document also discusses the key aspects to consider when submitting a new study for review, including the criteria for review of new studies, data access and release considerations and things to consider prior to submitting a new study for review.

The ongoing and adaptive nature of the ROADMAP Trial means that extreme care is required before releasing any participant data from the platform database, even for small subsets or site-specific requests.

See the following documents for more information about data access and sharing for ROADMAP new studies:

- Data Sharing Policy
- Data Management Plan and
- Authorship and Publication Policy

If you have any questions about the new study process, please do not hesitate to contact the ROADMAP Trial Management Team (TMG) email: TMG@roadmaptrial.com

3 DEFINITIONS

The definitions related to the ROADMAP Trial are defined below. All definitions will be referenced by their acronyms throughout this document.

These definitions are consistent with the National Health and Medical Research Council (NHMRC) definitions, as specified in the guidance documents The *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) and the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) (2016).

Term	Description
Global Trial Steering Committee (GTSC)	The global steering committee responsible for overall decision making related to the ROADMAP trial.
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations, and regulatory requirements pertaining to Independent Ethics Committees may differ among countries but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline. ROADMAP Trial (AUST) – IEC = Human Research Ethics Committee (HREC)
Institution / Trial site	Any public or private entity where clinical trial-related activities are conducted
Institutional Review Board (IRB)	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial

	protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Regulatory Authorities	Bodies having the power to regulate. In the ICH GCP Guideline, the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.
Sponsor (Global)	An individual, company, institution, or organization which takes overall responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor (Regional)	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial in a given region.

4 NEW STUDY CATEGORIES

Proposed studies will be categorised as:

1. **Platform-nested clinical trial**
   This includes new domains, new interventions within an existing domain, and other clinical trials that sit under the ROADMAP core protocol. This type of study uses the existing ROADMAP core protocol and infrastructure. Generally, the study will use existing ROADMAP database and statistical model, however there may be some exceptions to this. This study will require an ethics and consent amendment, a domain specific appendix, and additional funding.
   Full study review process will need to be completed.

2. **Adjunct Prospective Observational Study**
   May include additional collection of samples or clinical data and can include platform and/or registry participants. This study will require a full study protocol and may or may not require additional ethics review and approval (IEC, HREC) of study and consent for additional study procedures (which may be broadly covered by existing approvals including ROADMAP Isolate Repository). This study may or may not require additional funding, which may be provided as "in-kind" support by new study investigators.
   Full new study review process will need to be completed.

3. **Secondary use of Data and/or specimen Analyses**
   This type of study makes use of samples (bacterial isolates) or data that has already been collected. Will likely require a study protocol but may not require additional ethics approvals (IEC, HREC) and generally **will not** require additional consent. Additional funding may be required, which may be provided as "in-kind" support by new study investigators.
   This type of proposal requires sign-off by the Global GTSC but may not need to go through the full new study review process.

5 NEW STUDY REVIEW CRITERIA

New study proposals will be judged on the following criteria for integration into the ROADMAP Trial. If a study does not fulfil the criteria below, the proposal may be recommended for co-enrolment, data sharing, or meta-analysis.

Trial Integrity

1. Does this study require access to data that could threaten trial integrity?
2. Does this study wish to report on trial outcomes prior to the ROADMAP trial results paper?
3. Does the study wish to report on study outcomes by treatment allocation prior to the ROADMAP trial results paper?
4. Other potential trial integrity issues?

Harmony with ROADMAP Protocol

1. Does the study require a significant amount of data/sample collection outside of standard care or ROADMAP trial protocols?
2. Are the sample/data collection harmonised with the ROADMAP core protocol and other ROADMAP new studies?

Adoption of the Pragmatic Trial Approach

1. Does this study place a significant additional burden on the participant or the site study team?
2. Does the proposal include only the necessary data collection to answer the research question?

Feasibility

1. Is the sample size reasonable and achievable?
2. Will the research question be able to be answered recruiting only ROADMAP trial participants?

Global Application

1. Has the investigator considered the ability for the study to be conducted in other regions/countries?
2. Is the protocol applicable to other countries/regions?

Funding

1. Has funding for this study been considered or obtained?
2. Are there any grants the investigator is intending to apply for to cover the costs of the study?
3. Has a proposal been put forward to the central team for covering some or all of the costs?

Sample Collection, Analysis & Shipping

1. Will samples be collected for this new study and shipped to an external location?
2. Has the shipping and storage of theses samples been considered?
3. Has a plan for the analysis been generated?

Integration with the statistical model

1. Will this new study require integration into the overall ROADMAP statistical model?

6 NEW STUDY GTSC REVIEW PROCESS

The GTSC will review all new study proposals to determine if the new study is suitable for integration into the ROADMAP Trial. The new study proposal will be judged on the criteria described in Section 5, as well as overall scientific merit.

If a proposed new study is planned to only occur in a single region, it should be assessed and approved by the regional trial management group and the regional trial steering committee *prior to* submission for GTSC approval.

If it planned for multiple regions, each regional TSC and regional TMG will have the opportunity to approve it or not in their region, *after* the overall study is approved by the GTSC

New study proposals will be judged in 2 stages:

1. Expression of interest – 1-5 pages
2. Full protocol

At each of these stages, the GTSC will be provided the opportunity to raise questions and comments for the proposal lead(s) to respond to, prior to proceeding to the next stage. All comments/questions will be returned to the new study lead(s) within two weeks of the GTSC review.

Please see **Appendix 2 below for a flowchart overview of the new study process*

6.1 EXPRESSION OF INTEREST

An Expression of Interest (EOI) is the first stage of the review process for *all* new studies. This simple, 1-5 page outline will be assessed for scientific merit (including significance and impact, and quality of methods) and feasibility (including available support, sample size, data collection methods, and funding). The EOI will be presented by a GTSC representative at the next suitable GTSC meeting, and any comments or questions will be returned to the new study proposal lead(s).

At the end of the GTSC meeting, the committee will provide a consensus decision for:

- The proposed study to be approved with no further details required
- The proposed study to be approved and proceed to full protocol development and GTSC review
- The proposed study not to be approved and the study lead(s) to revise the EOI & provide a response to queries raised during the meeting
- The proposed study not to be approved and proceed no further, as deemed unsuitable for the ROADMAP trial at this time

6.2 FULL PROTOCOL

The full protocol is the final stage of the GTSC new study review process; if the full protocol is ratified, the new study will be integrated into the ROADMAP Trial. This is the final document outlining the design of the new study, and describes the objectives, methodology, detailed statistical plan, and overall organisation of the research to be carried out within the ROADMAP Trial. This protocol will be submitted for ethical review (where applicable) and will be provided to participating sites to conduct the new study.

The full protocol will be discussed/noted at the next suitable GTSC meeting, and the GTSC will have the opportunity to return comments for amending the protocol prior to operationalisation.

Unless any major issues have arisen, the default position is that the new study will be ratified and proceed to integration. At the end of the GTSC Meeting, the committee will provide a consensus decision for:

- The new study protocol to be ratified with no further queries, or
- Request for a revised protocol & response to queries raised by the GTSC

All final protocols will undergo review by the central ROADMAP Trial Management Team, who will provide additional feedback from an operational perspective (See Section 8.0).

6.3 GTSC REVIEW OUTCOMES

The outcome of the new study GTSC review process will be communicated to the new study lead(s) by the ROADMAP Global Trial Management Group.

A list of all approved new studies and their status will be provided on the ROADMAP Website here: https://www.roadmaptrial.com

6.3.1 RATIFICATION

When a sub-study is ratified by the Global TSC, a formal email will be provided to the new study lead(s), informing them of this outcome.

This ratification may come with GTSC comments/queries that will need to be addressed prior to proceeding to document preparation and regulatory submission.

6.3.2 NEW STUDY NOT TO PROCEED

If the GTSC feel the new study proposal is not suitable for integration within the ROADMAP Trial, the new study lead will be formally notified by email that the proposal has not been approved.

A new study may not be approved to proceed if, for example:

- the full study protocol would be better as a standalone study, but which may be able to co-enrol with the ROADMAP Trial
- The full study protocol would be better suited to a separate, full study (data and/or sample collection, interventions, or sample size do not align), with an opportunity for meta-analysis
- The proposed new study is already planned or in progress. In this case, we would encourage the proposer to collaborate with the existing new study lead(s).

6.4 ADDITIONAL WORKING GROUP REVIEW

If required, the new study proposal and /or full protocol may undergo further review from additional ROADMAP working groups, including but not limited to:

- **Microbiology WG**
  Any new studies involving isolates, or the microbiological aspects of the ROADMAP Trial.
- **Statistics WG**
  Any new studies that intend to use the ROADMAP statistical model or may impact the statistical model.
- **Relevant Domain-Specific WG(s)**
  Any new studies that are nested within, or will have an impact on, a particular domain.
- **Health Economics WG**
  Any new studies that intend to collect additional health economic data.
- **Registry WG**
  Any new studies that intend to undertake a secondary analysis of parts of whole of the collected ROADMAP registry data.
- **Consumer Reference WG**
  All new studies occurring in that working group's oversight region.

7 ETHICAL & REGULATORY APPROVAL (RATIFIED NEW STUDIES)

This section outlines the documents required for integration of the new study into the ROADMAP Trial for ratified new studies. These documents will need to be prepared and collated for ethics and institution submission (where applicable in each region) and will be provided to participating sites who have opted into the new study.

Each new study protocol may require additional regulatory review and approvals. These additional reviews may include:

- National regulatory/governing bodies (for example, TGA, Health Canada)
- Ethics review in each region/country in which the new study will be made available
- Local Institutional Review at each site that will be participating in the new study

The new study lead(s) will be responsible for checking which reviews are required for the new study, in each region that is participating.

7.1 DOCUMENT PREPARATION

The following documentation may be required for your new study. Template documents are available from the ROADMAP Management team and/or regional lead(s). Please reach out with any questions you may have about whether these documents are required for your new study. TMG@roadmaptrial.com

- **New study Patient Information and Consent Form (PICF)**
  New studies that include tests, procedures, sample collection, or data collection that are *additional to the ROADMAP trial or to standard of care procedures* will require a separate Participant Information Sheet (PIS) or Participant Information Sheet & Consent Form (PICF) be provided to all eligible participants.

In jurisdictions where the simplified layered consent model has been approved, a simplified PICF will be used for new studies requiring additional consent. This simplified PIS/PICF will contain a brief overview of the new study, including a summary of *any tests, procedures, sample collection, or data that is additional to the ROADMAP trial or standard of care procedures*, and a synopsis of the shipping or storage of samples external to the ROADMAP Isolate Repository sample protocol.

- This document will reference the ROADMAP Website www.ROADMAPtrial.com and will provide a direct link for the participant to read more information if they wish.
- This template will be provided by the central management team to the new study lead(s) for completion.

A template simplified PIS/PICF has been created for new study adaptation. Please contact the ROADMAP Management Team to discuss this further. If possible, the PICF for prospective new studies and new domains will be integrated into the existing master versions (for example as additional tick boxes on the consent form).

***Please note:** Not all regions will be able to use the simplified model of consent, and can be discussed further on a case-by-case basis.*

- **New study website information**

  Each new study lead(s) will be required to provide additional new study website information for the ROADMAP website via the new studies page available here: https://www.roadmaptrial.com

  - This website information will be used to document all active and progressing new studies embedded within the ROADMAP Trial in once central location.
  - The website information can also be used to provide more in-depth information about each new study for the participant, if they choose to seek out further detail. This website information will be used for participants in regions that have approved use of the simplified consent model.
  - The new study lead(s) will also have the choice to provide an IEC/ HREC approved *additional short video* to summarise the new study. This video will be displayed with the new study information on the website. The development and production of new video content to be used as part of the consent process may incur an additional cost and will need to be a consideration in budgeting and funding of the study.

  A template website information form will be provided by the ROADMAP management team to the new study lead(s) for completion.

7.2 ETHICAL REVIEW

Some new studies will need to undergo ethical review prior to being implemented. Depending on the nature of the new study, this ethics approval may be separate to the ROADMAP Trial or may sit within the overarching study approval of the ROADMAP Trial in the regions the new study will activate.

If ethical review of the new study is required, the new study lead(s) will be responsible for:

- Ensuring that ethical review is received by each regional ethics committee, as required
- Liaising with the ROADMAP management team and regional trial leads to prepare the required documents for submission

  Documents for submission may include:
  - Final new study protocol – *ratified by the GTSC*
  - Final PIS/PICF(s) and website information including videos – confirmed by the ROADMAP management team/ regional trial leads
    - Scripts for any patient facing videos
    - Factsheets
  - If the new study will be **implementing interventions, procedures, or treatments** that are additional to the ROADMAP trial protocol, further documentation for ethical review may be required. Please contact the ROADMAP management team to discuss further.

7.3 INSTITUTIONAL REVIEW (RESEARCH GOVERNANCE REVIEW)

A local institutional submission may be required for a site to participate in a new study. Again, depending on the nature of the new study, this approval may be separate to the ROADMAP Trial or may sit within the overarching institution approval of the ROADMAP Trial at the site.

If institutional review of the new study is required, the new study lead(s) will be responsible for:

- Ensuring that institutional reviews are conducted at each participating site, as required
- Liaising with the ROADMAP management team and regional trial leads to prepare the required documents for submission

  Documents for submission may include:
  - Approval letter & associated documents– *approved by the region-specific ethics committee*
  - Updated ROADMAP trial documents – *if applicable; updated to include the new study*
  - Localised new study PIS/PICF(s) and website information including videos – *if applicable, for the new study and site*
  - Site specific documents such as departmental approvals, radiation reports, etc. – if any additional procedures/interventions/tests are required as a result of the new study

The new study will only be activated at each site once the institution has provided authorisation.

7.4 AGREEMENTS & CONTRACTS

There are a few agreements that may be relevant to your new study. Template agreements are available from the ROADMAP TMG and/or regional lead(s). Please reach out with any questions you may have about which agreements are applicable to your new study.

- **New study agreement** – ***between new study lead(s) and sponsor(s)***

  This agreement will outline any additional sample collection/transfer, data access/transfer, and publication and payments that will be involved with the conduct of this new study within the ROADMAP Trial. Each new study will be required to complete this agreement prior to proceeding with any new study activities, and this agreement will be fully executed as part of the ethical review process.

- **Site specific contracts/contact amendments** – ***between participating site(s) and the relevant regional sponsor(s)***

  Each participating site will need to have their site-specific Clinical Trial Research Agreement (CTRA) updated to reflect any changes to the conduct of the ROADMAP trial at their site, as a result of their participation in one or more new studies. This updated contract will include any additional payments provided to the site, outline any additional sample or data collection obligations, and any additional intervention, procedure, or departmental commitments that will be required. Each site will be required to accept this updated agreement and have either a deed of novation or a CTRA letter of Variation (whichever is appropriate) fully executed by the sponsor and research site prior to proceeding with any new study activities.

- **Data sharing agreement** – ***between new study lead(s) and the ROADMAP data custodian(s)***

  A data sharing agreement is an agreement between two or more entities (most likely legal entities) that are providing and receiving data. It specifies the conditions under which the data will be shared and documents what can and cannot be done with the data, giving clarity and certainty to all parties.

  This agreement would be applicable where there is no existing new study contract or where jurisdictional regulations require an additional data sharing agreement.

7.5 REGISTRATION OF NEW STUDIES

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals.

Integrated clinical trials within the ROADMAP Trial should be registered on clinicaltrials.gov by the new study lead as a separate listing and should reference the ROADMAP Trial (NCT06771050) in the sections as below. Observational new studies may or may not be required to be registered on clinicaltrials.gov, with this decision made by consensus between the new study lead and the global TMG.

- **Brief summary**
  Please include the following sentence: *"This study is an approved new study of RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform (ROADMAP) trial ((NCT06771050)."*

- **Participation criteria**
  Please include the following sentence: *"The participant must fulfil all inclusion and exclusion criteria for the [ROADMAP Platform / ROADMAP Registry / ROADMAP Trial Platform or Registry] and the following inclusion and exclusion criteria to be eligible for this new study:"*

8 POST-APPROVAL & NEW STUDY INTEGRATION (RATIFIED NEW STUDIES)

8.1 DATABASE INTEGRATION

The ROADMAP Spinnaker database has the capacity to integrate new study data collection and/or keep track of participant enrolment into new studies.

- **New studies collecting data in the database** *– new studies that collect data using the ROADMAP Trial database infrastructure will be required to record participant enrolment using the Spinnaker database
- **New studies that impact the statistical model** – new studies that have an impact on the statistical model will be required to record participant enrolment using the Spinnaker database as per decision by the ROADMAP Statistical WG.
- **All other new studies** – it will not be mandatory to record participant enrolment using the Spinnaker database. However, this option is available for any new study lead that wishes to use this feature, as long as *sufficient time and funding* * is available to support the necessary changes to the Spinnaker database.

Costs for this integration will be passed along to the study team unless otherwise agreed upon by the new study lead the relevant ROADMAP RTMG

8.2 OPERATIONAL DOCUMENTATION

Below is a list of operational documents that are necessary for the development and implementation of new studies into the ROADMAP Trial. Depending on the type of new study, the following sections may or may not apply; please review the below points to ensure that the correct information is provided to the ROADMAP GTSC and Regional trial management group for live activation of the new study.

Templates are available for all documents listed in Section 7; please contact the ROADMAP Global TMG to obtain these template documents for completion. TMG@roadmaptrial.com.au

8.2.1 DATA COLLECTION SUMMARY

If not included in the new study contract, this completed should contain a summary of the datapoints required for the new study analyses including:

- Data collected in the ROADMAP Trial database that will be used for the new study
- Additional data required for additional collection as part of the new study

This document will also provide details about where and how the data will be collected, where the data collection tool will be hosted, and when the data will be requested.

This **data collection summary** will not be required for external studies approved for co-enrolment, and pre-planned analyses.

8.2.2 CRF DATA DESCRIPTION

If a new study plans to **collect any additional information within the ROADMAP Spinnaker database**, a **CRF Data Description** may be required to document any planned changes to the database.

- This must be discussed with the ROADMAP Management Team as soon as possible to confirm availability for these changes.
- The CRF data description should be completed with all datapoints and questions that are intended to be integrated into the Spinnaker platform.
- Consideration of costs associated with database changes, addition of CRFs or addition of datapoints should be made and may need to be reflected in budgets and funding of the new study. Please contact the ROADMAP Management Team for advice of complexity of changes and cost estimates if appropriate.

8.2.3 SCHEDULE OF EVENTS

If a new study plans on **collecting samples or requires the participant to undertake any procedures or attend study visits** that are additional to the ROADMAP Trial or standard-of-care, a new study **Schedule of Events** will be required, if not already included in the new study protocol.

- This schedule should outline all the samples/procedures/visits, and the timepoints at which they are required.
- Additional documentation may be requested if the procedures or tests require any additional regulatory review or approvals.

9 PUBLICATION, REPORTING & DATA RELEASE

To request data/samples from the ROADMAP Trial for new study analysis the following documents are required for completion at the time of new study completion:

- Data Access Request Form (DAAF)– *for any ROADMAP Trial data requests*
- Isolate Access Application Form (IAAF)– *for any ROADMAP Trial isolate requests*

See the following documents for more information about data access and sharing, and guidance on authorship citation for ROADMAP new studies:

- Data Sharing Policy
- Data Management Plan
- Authorship and Publication Policy

10 APPENDIX 1: RECORD OF CHANGES

VERSION NUMBER	DATE	SECTIONS AFFECTED	SUMMARY OF CHANGES	AUTHOR INITIALS
2.0	5June2026	-	Overall review and refinement of process Clarification of categories The word sub-study changed to new study throughout documents for clarification and to reflect the listed categories of proposed studies as either platform-nested, adjunct or secondary analyses.	JD MSq

11 APPENDIX 2: FLOWCHART OF ROADMAP NEW STUDY REVIEW, APPROVAL, AND INTEGRATION PROCESS