ROADMAP TRIAL
DATA SHARING POLICY AND ACCESS PROCEDURE

Version 1.0, DATED 24 April 2025

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1.1 ABBREVIATIONS

Term	Definition
CIHR	Canadian Institutes of Health Research
DAAF	Data Access Application Form
DDict	Data Dictionary
DSP	Data sharing policy
DTA	Data Transfer Agreement
GCP	Good Clinical Practice
GTSC	Global trial steering committee
HRC	The Health Research Council of New Zealand
NHMRC	National Health and Medical Research Council
PJI	Prosthetic Joint Infection
ROADMAP	RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial
UK MRC	United Kingdom Medical Research Council
UON	University of Newcastle

1.2 DEFINITIONS

Term	Definition
Data Sharing Agreement	Legally binding document that delineates the terms, conditions, and responsibilities associated with the exchange of data between parties. It defines the scope, purpose, confidentiality measures, to ensure secure and compliant data sharing
Data requesters/Investigator	Individual, entity, or system that formally seeks access to and use of specific data, typically governed by legal or contractual agreements
Data custodians	Individual or entity responsible for safeguarding and managing the security, access, and integrity of a specific dataset or database
De-identified data	Information from which all personally identifiable elements have been removed or altered to prevent the identification of individuals
Data access application form	Document used to formally request authorisation for accessing specific datasets, detailing the purpose, scope, and intended use of the requested data

2 INTRODUCTION

The objective of data sharing is to enhance the value of datasets, making them more valuable for research in various areas. Additionally, it encourages collaboration among researchers, promoting further research opportunities. By sharing data, researchers can avoid redundant efforts, saving time, and resources that would otherwise be invested in reproducing existing datasets. Furthermore, sharing data is essential for rapidly translating research outcomes into knowledge and procedures that lead to better human health outcomes.

The approach to disseminating scientific data must be responsible and consider various factors, including legal, regulatory, ethical, and commercial constraints. The National Statement on Ethical Conduct in Human Research,2023, outlines the requirements for the collection, use, and management of data and information pertaining to research with human participants. Unless there is a valid reason for doing so, researchers are strongly encouraged to share data generated by their research. In the context of clinical research involving individual participants, considerations must be given to:

- Participants having provided informed consent to have their data shared
- The risk of participant re-identification from shared de-identified datasets
- The risk of data being misused or misrepresented
- Data security measures and protection laws
- Fostering transparent communication with the participant regarding how their data will be shared.

Furthermore, Good Clinical Practice (GCP) emphasizes that researchers must engage in data management planning for their research studies, encompassing arrangements for sharing or providing access to published data. The Australian Code for the Responsible Conduct of Research 2018 defines transparency in research and research data management as declaring interests and reporting the methodology, data, and findings applicable to all research studies involving these aspects. This involves sharing and communicating research methods and findings openly, accurately, and in a responsible manner.

This data-sharing policy (DSP) ensures ROADMAP has transparent processes in place to enable the appropriate sharing of ROADMAP-related data in a research culture that increasingly encourages access to publicly funded research data.

The ROADMAP trial is managed by the global trial management group (GTMG) and regional trial management groups (RTMG) on behalf of the global sponsor (the University of Newcastle) and regional sponsors. In the rest of the document, the abbreviation "ROADMAP" will be used to mean the ROADMAP GTMG and the ROADMAP investigators.

3 ROADMAP DATA SHARING PRINCIPLES

This DSP pertains to all datasets and analyses which form part of the ROADMAP platform, registry or sub studies, and is guided by the principles of responsible data sharing in clinical trials established within the University of Newcastle (Australia), and national research and research funding bodies such as the National Health and Medical Research Council (NHMRC), The Health Research Council of New Zealand (HRC), United Kingdom Medical Research Council (UK MRC), Canadian Institutes of Health Research (CIHR), and the European Union. Furthermore, this DSP applies to all members of the ROADMAP trial community: all trial committees and working groups, trial management teams, and the broader ROADMAP trial group (site teams and investigators). The guidelines outlined in this policy apply to requests for sharing data, both for ongoing studies and those that have been completed.

This data dissemination serves the purpose of encouraging physicians, patients, and healthcare providers to make well-informed treatment decisions and to foster advancements in scientific understanding that have a positive impact on society at large. Our commitment lies in ensuring that our clinical study information is accessible to patients, medical practitioners, and researchers, all while upholding the principles of patient privacy and safeguarding trial integrity.

Achieving this objective involves productive collaborations with various individuals dedicated to promoting data-sharing initiatives. We strongly believe that disclosing our research results and data is instrumental in fully recognizing

The ROADMAP trial's key principles of data sharing include:

1. ROADMAP is committed to ensuring information generated in our studies is used for the benefit of patients and society.
2. ROADMAP takes all necessary steps to safeguard patient privacy, in compliance with the principles of GCP, GDPR and other applicable laws and regulations.
3. ROADMAP, as custodians of the data, have adopted a data sharing approach which is aligned with the guidelines and requirements of the University of Newcastle (UON), and national research and research funding bodies such as the NHMRC, HRC, UK MRC, CIHR, and the European Union.
4. ROADMAP reserves the right to protect our commercially sensitive information or that of third parties with whom we have contractual obligations.
5. ROADMAP collaborates with a range of organisations and individuals to support and advance the sharing of data and information.

It is with these principles in mind that we have designed this policy to guide the responsible sharing of data across diverse study designs, fostering the advancement of scientific knowledge while maintaining ethical and transparent practices.

4 DATA RESPONSIBILITIES AND OWNERSHIP

The ROADMAP Global Trial Management Group (GTMG) is directly responsible for implementing the Data Sharing procedures set out in this policy to ensure that data are shared appropriately in accordance with the research study requirements. This includes but is not limited to:

- ethical and other regulatory approvals,
- participant consent,
- ROADMAP Trial policies and requirements, and
- the terms and conditions of any funding agreements, where applicable.

Whilst the ROADMAP GTMG will be the initial point of contact for requests to access research data, the Global Trial Steering Committee (GTSC) are the data custodians and will ultimately oversee all requests for data access/transfers, and if applicable, define the circumstances under which the data will be shared.

The GTSC will:

- review, by way of approving or rejecting, all data access requests
- collaborate with external researchers to establish the scope, purpose, and duration of data sharing, aligning with ethical guidelines and legal regulations. Specific restrictions on data use, such as preventing re-identification and commercial use, are defined to protect participant privacy and trial integrity
- address issues of intellectual property and authorship to ensure proper credit for contributions

The ROADMAP regional trial management teams will be informed of the data request/s that pertain to region-specific patient data by the ROADMAP GTMG. This process is to ensure that the request aligns with the regional-specific policies regarding patient privacy and confidentiality, patient consent, regulations, and data-sharing agreements.

5 DATA SHARING AGREEMENT

Upon approval of the data request, the data requester/investigator must be familiar with the terms and conditions of data use and data sharing expectations outlined in this policy and adhere to the following conditions:

1. Data received can only be used for the approved research project (outlined in the Data Access Application Form [DAAF]). If the data requesters/investigators wish to use these data for a new project, a new data request application must be submitted.
2. Data requesters/investigators must acknowledge the ROADMAP trial and data source and ensure that individual participant data are kept confidential. These data can only be shared with data requesters/investigators included in the original data request (DAAF Section 5); requests from others should be directed to GTSC.
3. A fee may be applied where the dataset/s requested requires conditional formatting and other processing requirements outlined in the data request form.
4. ROADMAP's policies, including Privacy and Confidentiality, Clinical Data Transfers, and Informed Consent, apply to data use and transfer. Authorship details will be discussed before data release and should adhere to the policies outlined in the ROADMAP Authorship and Publication document.
5. A contract may need to be established between the ROADMAP sponsor and relevant parties for data release. This contract acknowledges compliance with collaborative agreements between ROADMAP and the data requester/investigator's institution.
6. If applicable, data requesters/investigators must disclose their funding sources, if any, for the proposed work, and must provide updates on any subsequent funding secured after receiving the shared data.
7. The data requesters/investigators, along with their research team, must not make any attempts to personally identify individuals from the provided data. If the requester/investigator, or any member of their research team inadvertently identifies an individual, they must report the instance to trial sponsors and are strictly prohibited from: recording such identifiable information; disclosing the identification to others; or attempting to contact the individual.

6 DATA AVAILABILITY POLICY

A. Following publication of domain-specific results:

1. De-identified patient data may be made available. All requests for data must be accompanied by
    - A formal request (made via the Data Access Application Form [DAAF])
    - A study proposal with a clear statement of aims and hypotheses, and
    - A statistical analysis plan

    Requests for access to the dataset(s) relating to domain-specific results will be assessed by the GTMG on behalf of the Global Trial Steering Committee (GTSC). If a proposal is approved, a signed data transfer agreement will be required before data sharing.

B. Before publication of domain-specific results:

1. Regarding post-randomisation outcome data stratified by randomised intervention: The ROADMAP trial will not release data that includes post-randomisation outcomes stratified by intervention until a domain conclusion has been publicly declared for the relevant domain.
2. Regarding post-randomisation outcome data not stratified by intervention: As a default, the ROADMAP trial will

not release data that includes post-randomisation outcomes regardless of stratification by intervention.

However, where there is compelling justification, the GTSC may consider requests to release trial outcomes without stratification by interventions. Such requests will be evaluated on a case-by-case basis and must include a compelling justification, alongside clear risk mitigation strategies to protect trial integrity.

3. Data and analyses arising from registry-only participants may be accessed and published before publication of the primary clinical trial results. However, specific data requests must be reviewed and approved by the GTSC.
4. Regarding requests for a mixed dataset (platform and registry data): Platform considerations (1 & 2) will apply to these data requests.

7 DATA REQUESTS

7.1 APPLYING TO ACCESS DATA

Initial inquiries regarding data access should be directed to the ROADMAP GTMG. To formally request access, data requesters/investigators must submit a Data Access Application Form (DAAF), by either:

- Completing the PDF version (Appendix 12.3) and emailing it to TMG@roadmaptrial.com, or
- Completing the online version on REDCap https://redcap.hmri.org.au/surveys/?s=MK4P48DTYCPAF4LA

7.2 REVIEWING DATA ACCESS APPLICATION

Data sharing requests will be assessed based on the following criteria:

- **Scientific Value:** Contribution of the research proposal to medical science and/or patient care
- **Methodological Soundness:** Suitability of the proposed statistical analysis plan to achieve the scientific objective of the research proposal
- **Conflict of Interest:** Potential conflicts of interest and measures to mitigate them
- **Research Team Expertise:** Qualifications and expertise/experience of the research team
- **Resource Implications:** ROADMAP staff resources required to process the request
- **Privacy Risks:** Likelihood of participant re-identification, or privacy breaches
- **Data Security:** Capacity of the data requester/investigator(s) to maintain ensure secure data handling
- **Compliance History:** Previous adherence to ROADMAP data-sharing conditions
- **Reputational Risk:** Potential for data misuse that could misrepresent or undermine ROADMAP's scientific credibility

7.3 DATA RELEASE

Once a data sharing request has been approved, and the signed Data Access Application is received, the requested dataset should be released promptly, typically within two months.

The dataset will be provided as a Data Pack—a prepared package containing the requested data and metadata alongside the Data Dictionary (DDict) and the signed DAAF.

The Data Pack will be transferred via a secure channel (See Appendix 12.2 Data Information). Information and instructions on accessing and using the secure transfer system will be sent to the requester upon data release.

8 TIMELINE FOR REVIEWING AND ACKNOWLEDGING A DATA ACCESS APPLICATION

All data access applications will be reviewed at or before the next scheduled GTSC meeting from the date when the data access application was received. Data requesters who have submitted a Data Access Application will be notified of the outcome by the ROADMAP GTMG within 10 working days from the meeting date. The acknowledgment should indicate the decision (approved/rejected), or whether additional information is required from the data requester before a decision can be made.

Incomplete Data Access Applications Forms (DAAF): Incomplete DAAFs should be returned to the data requester with an instruction to complete and resubmit the form.

Accepting a Data Access Application: If the GTSC approves an access request, the data requester will be notified in writing, and a timeline provided for when and how the data will be made available. The outcome of the data request will be logged, and all approvals are subject to review. Where demand exceeds the availability of staffing resources to make the data available, access will be prioritised by the ROADMAP Trial management team on scientific merit.

Rejecting a Data Access Application: If the GTSC rejects a data access application, the data requester will be notified in writing and be provided an explanation/justification as to why the request was rejected.

Subsequent Data Requests Post Rejection: Based on any feedback provided, a data requester may amend their original data access request application and submit a new access request following rejection.

9 DATA SECURITY, ENCRYPTION, AND ACCESS CONTROL

Data security, encryption, and access control are necessary for data sharing within clinical trials to safeguard sensitive patient information, ensure research integrity, and maintain regulatory compliance. The ROADMAP trial contains confidential health records, personal identifiers, and private research insights, where robust data security measures—such as encryption during transmission and storage—are required to safeguard this information from unauthorized access and potential breaches. Furthermore, ROADMAP implements access control mechanisms to establish strict permissions, ensuring that only authorized personnel can access, modify, or analyse the data.

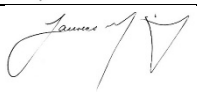
ROADMAP implements the following practices to safeguard patient information:

- **Automatic data de-identification and anonymisation**: Remove or replace identifying information from the dataset to ensure that individuals cannot be linked to their data
- **Residual Identifiability Prevention:** Anonymise data so that even if certain characteristics are present, they cannot be traced back to specific individuals
- **Limited Data Sharing:** Only share the minimum necessary data required for the intended research purpose
- **Access Controls and Authorisation:** Implement strong access controls to ensure that only authorized individuals or entities can access the shared data
- **Role-Based Access:** Use role-based access, where different levels of access are granted based on the user's role and need
- **Secure Data Transfer:** Use encryption protocols (such as SSL/TLS) during data transfer to prevent interception and unauthorized access
- **Encrypted File Sharing:** Use secure file transfer mechanisms and platforms to ensure data is transmitted safely

- **Data Encryption:** Encrypt data both during storage and transmission to protect it from unauthorised access
- **Secure Hosting Environments:** If data is hosted on a server, use secure hosting environments
- **Secure Disposal:** Ensure that any physical or digital copies of data that are no longer needed are securely disposed of to prevent accidental exposure

10 DOCUMENT HISTORY

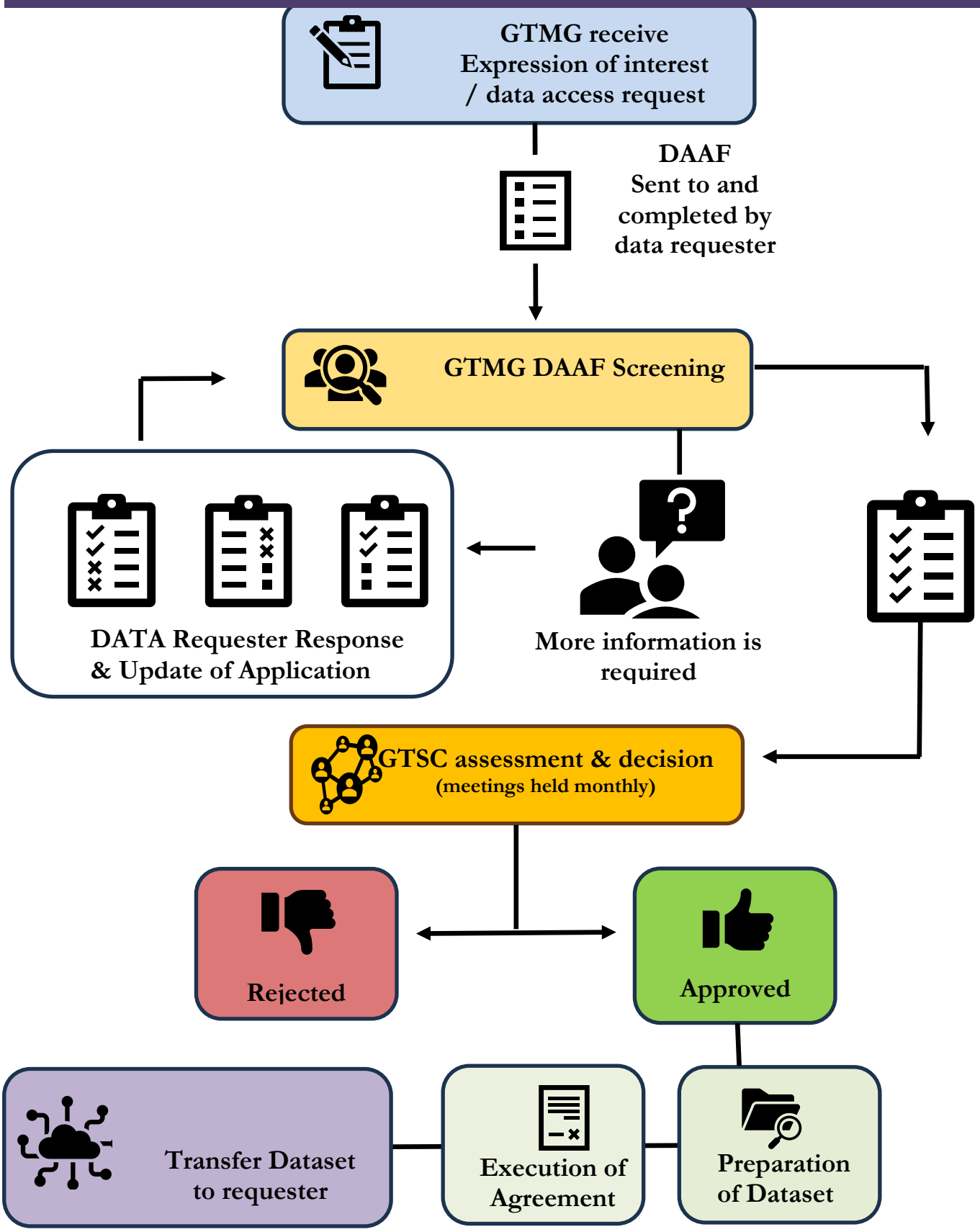
VERSION	DATE	REASON FOR REVISION
		Initial version

Approval				
	Name	**Position**	**Signature**	**Date**
Author	Marline Squance	Global Trial Manager		24/04/25
Reviewed by	Róisín Griffin	Data Coordinator		18/03/25
Approved by:	Josh Davis	Chief Investigator		17/04/25
	Laurens Manning	Chief Investigator		24/04/25

Note: Document has been modified from the Data Sharing Policy of SNAP trial to make fit for purpose for ROADMAP trial

12.1 DATA ACCESS PROCEDURE (FLOWCHART)

12 APPENDIX



12.3 DATA ACCESS APPLICATION FORM (DAAF)

RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial

Data Access Application Form (DAAF)

Instructions for Data Requesters

1. Data Requesters should discuss their application with the ROADMAP Global Trial Management Group (GTMG) to understand the suitability, availability, and modes of collaboration and access to ROADMAP Trial data.

   The following ROADMAP trial documents should be read before completing this form:
   - Data Sharing Policy
   - Authorship & Publication Policy

2. Data Requesters must complete and submit this Data Access Application Form (DAAF) to the GTMG via the following email:
   TMG@roadmaptrial.com
   - Please also include relevant supporting information, including, where relevant: ethical approval and applicants/investigators' curriculum Vitae (CV).

3. The GTMG will review requests in order of receipt and will contact the Data Requester if more information is required. If the GTMG request further information or clarifications the Data Requester must update the DAAF and include additional supporting information as requested.

   Only DAAF's considered to be complete, with all questions and DAAF sections adequately answered will be submitted to the GTSC for assessment.

4. The GTSC will assess the request at the next monthly meeting for discussion and a data access decision based on the information provided and data request merit. The Data Requester will be notified of the GTSC decision of data access approval or non-approval by email. The GTSC can also make a request for further information if they feel it is needed to make an informed decision on granting data access.

5. If data access approval is given, a Data Transfer Agreement (DTA) must be finalised and executed by signature of the GTSC Chair(s), the Data Requester, and the Data Transfer Manager/ Coordinator prior to the transfer of any ROADMAP data and datasets.

Email completed Data Access Application Form (DAAF to:
TMG@roadmaptrial.com

The Data Access Application Form (DAAF) can be completed via this REDCap form link.

RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial

Data Access Application Form (DAAF)

Section 1: Applicant Details

Date of Application:	
Name of Applicant/Principal Investigator:	
Applicant Institution/Affiliation:	
Email:	
Other investigators (Names):	
With whom have you previously discussed this data request?	**ROADMAP Global Trial Steering Committee (GTSC) member/s Name/s:** And/or **ROADMAP GTMG member/s Name/s:**
Has this project already been approved by the GTSC? For example, a sub-study that has already undergone GTSC review and approval.	□ **Yes** **Date of Approval: --/---/----** □ **No**

Section 2: Ethics Review / Approval

PLEASE CONSIDER the following when determining if additional ethical approval via a separate ethics submission or by an amendment in the current ROADMAP trial approval is required:

Platform (randomised) trial dataset:
All secondary analyses of trial data will require additional assessment by the Trial Management Group (GTMG) to determine if additional ethics is required.

The primary objective of the ROADMAP trial is to examine the effect of a range of interventions in patients with prosthetic joint infections (PJI) on treatment success at 12 months after platform entry.

The secondary objectives of the ROADMAP trial include:

- Examination of the effect of a range of interventions on several secondary endpoints including mortality, patient-reported outcome measures and healthcare costs.
- Establishment of a biospecimen repository of PJI isolates linked to clinical outcomes to elucidate the pathogen-specific characteristics that underlie responses to different therapies.
- Establishing an observational registry of patients presenting with PJI but who are ineligible for or do not provide consent for the randomised platform.

Registry dataset:
Analysis of the registry dataset has been considered and approved as part of the primary ROADMAP ethics application for the following purposes:

- **Monitoring the use of trial interventions among non-randomised patients**
  The registry dataset will be used to monitor the proportion of non-enrolled patients across participating sites who receive ROADMAP trial interventions as part of usual care. These results will be used to monitor changes in practice that occur during the lifetime of the trial, including the impact of site participation in the ROADMAP trial on usual care, and the implementation of findings declared at platform domain conclusions.

- **Assessing trial representativeness**
  The registry will also seek to describe the representativeness of patients enrolled into the ROADMAP trial by collecting epidemiological and disease-specific descriptors of patients with PJI who are not enrolled into the trial. These data will also be used to examine outcome differences between comparable randomised and non-randomised patients. Statistical comparisons will be made to accompany ROADMAP trial publications to inform these reports.

If your project intends to use/analyse data beyond the scope listed above, you may need additional ethics. Please discuss with your regional management team.

Has the Project/Study been submitted for ethical review and obtained approval?	**N/A (i.e. no additional approval required)** **□ Approved by ethics as:** **□ Amendment to the ROADMAP protocol, or** **□ Separate application** **Name of Ethics Committee:_____** **Reference number (if applicable): _____** **Date of approval: --/--/----** **□ Submitted, pending approval:** **Name of Ethics Committee:_____** **Reference number (if applicable): _____ Date of submission: --/--/----** **□ Not yet submitted for ethics approval**

Section 3: Project Summary

Applicant Project/Study Title:	

Provide a brief description of the project background, objectives, analysis plan, summary of any relevant data that supports the proposed study, and other supporting material/references. (Maximum: 1000 words)
□ Project/study protocol has been approved by the GTSC as part of the sub study approval process (please attach the approved protocol to this application).

Section 4: Data Request

The ROADMAP Global Trial Management Group (GTMG) at the University of Newcastle, Hunter Medical Research Institute (HMRI), New South Wales, Australia, wishes to acknowledge its explicit commitment to maintaining the confidentiality, safety, security, and integrity of all patient data. In adherence to relevant ethical principles and regulatory guidelines, we declare that no clinical trial data will be shared or disclosed to an external entity that could compromise trial integrity.

ROADMAP Trial – Data Sharing Overarching Policy

A. Following publication of domain specific results:

i. De-identified patient data may be available after publication of domain-specific results.
All requests for data must be accompanied by:

- A formal request,
- A study proposal with a clear statement of aims and hypotheses, and
- A statistical analysis plan.

Requests for access to the dataset/s relating to domain-specific results will be assessed by the GTSC. If a proposal is approved, a fully executed Data Transfer Agreement (DTA) will be required before data sharing.

B. Prior to publication of domain specific results:

i. Post-randomisation outcome data stratified by randomised intervention: The ROADMAP trial will not release data that includes post-randomisation outcomes stratified by intervention until a domain conclusion has been publicly declared for the relevant domain.

ii. Post-randomisation outcome data not stratified by intervention: As a default, the ROADMAP trial will **not** release data that includes post-randomisation outcomes regardless of stratification by intervention. However, where there is compelling justification, the GTSC may consider requests for the release of trial outcomes without stratification by interventions. Such requests will be treated on a case-by-case basis and will require strong and convincing justification and clear risk mitigation strategies to protect trial integrity.

iii. Data and analyses arising from registry-only participants may be accessed and published before publication of the primary clinical trial results. However, specific data requests will need to be reviewed and improved by the GTSC.

iv. Requests for a mixed dataset (platform and registry data): Platform considerations (i & ii) will apply to these data requests. **The data requester is responsible for protecting the confidentiality of the data and not sharing this data with third parties.**	
What data elements are required? Please attach a detailed description of the requested dataset/s to your application, including specific variables and any additional relevant information.	□ **Platform dataset only (randomised participants)** □ **Registry dataset only (non-randomised participants)** □ **Mixed dataset (platform and registry participants)**
Is data from all participants required or only from a subset?	□ **All participants OR** **Specific Domains:** □ **All Domains** □ **Surgical Domain** □ **Antibiotic Choice Domain** □ **Antibiotic Duration Domain (Part A)** □ **Antibiotic Duration Domain (Part B)** **Specific subsets:** □ **Subset, please specify:** □ **Hip PJI** □ **Knee PJI** □ **Region, please specify: _____** □ **Other, please specify: _____**
Does your request relate to specific data collection variable/s used in the ROADMAP trial? Please refer to ROADMAP data description for variables available, and list these accordingly.	□ **Yes** If yes, please refer to the data description and select the appropriate variables. □ **No,** I require all variables related to the dataset/s required above.
Frequency of data extracts:	□ **Once-off request** Landmark for data extract (date or other) _____ □ **Recurrent request** Landmark for first data extract _____ Frequency of subsequent extracts _____
Data Format:	**Datasets will be provided in .CSV file format** For other requirements, please discuss with the ROADMAP Trial Management Group (TMG).
Section 5: Data Security	
How and where will the data be stored?	
Names of individuals with authorised access to the data.	
What security measures will be in place to protect data?	
Describe the preferred method of data transfer (e.g., secure FTP, encrypted email, dedicated secure network):	

Detail any encryption methods used in the process of receiving the data:	
How long will the data be retained?	
And (if relevant) how will the data be securely and irreversibly destroyed?	
Provide any additional information or instructions related to data security not covered above:	

Section 6: Funding

Do you have funding for this research project?	**□ Yes** **□ No**
If yes, please provide details of the grant/award/funding body to support your proposed work:	
If No, outline how the project will be resourced, including whether the submission of a grant is anticipated:	

Section 7: Form Execution - Data Requester

The proposed protocol/study/project will be discussed by the ROADMAP GTSC, who will recommend ROADMAP investigators who should be included as authors for associated publications. These recommendations will be communicated to sub-study investigators for agreement prior to data transfer.

Please confirm that you have read and agree to comply with the ROADMAP Publication & Authorship policy.

□ Yes, I have read the ROADMAP Publication & Authorship policy.

As Principal Investigator:

- I agree to acknowledge the ROADMAP participants and research team as the source of data used in any publication or presentations of the research at any scientific meetings.
- I will forward a copy of any publication or presentation to the ROADMAP GTSC
- I confirm that I have completed all sections of the application form, read, and understood the Standard Conditions outlined above and that all required supporting documents have been provided.

Are the following supporting documents attached to this application? **Please check all that are attached.**	**□ Evidence of ethical review and approval** **□ CV & GCP of the Investigator** **□ Approved Protocol** **□ Additional documentation:**

_____ _____

Principal Investigator's signature **DATE (DD-MMM-YYYY)**

Section 8: Form Execution- Data Review/Transfer

Data must be accessed/shared following the study's Data Sharing and Access requirements, including all relevant ROADMAP policies and procedures, the ROADMAP Data Sharing Policy and Access Procedure, and must also be consistent with the Protocol, Patient Information and Consent Form (PICF) and the terms of any funding, collaboration agreements or other legal arrangements governing the project.

8a: Review by GTSC

Request reviewed by:	
Date of Review:	
Have the region leads been notified of data sharing where appropriate?	
Has the data request been approved?	**□ Yes, approved.**

	Comments: □ **No, not approved.** **Comments:**
Date applicant was notified of outcome:	
_____ _____ **GTSC representative signature** **DATE (DD-MMM-YYYY)**	

8b: Data Transfer

Name of the person who prepared the dataset for transfer: **Role:**	
Confirm data sharing agreement has been executed:	□ **Yes, date executed:** □ **No, reason:**
Additional Comments:	
Date of Transfer:	
Method of Transfer:	
_____ _____ **Data Transfer Coordinator signature** **DATE (DD-MMM-YYYY)**	