



An Expression of Interest (EOI) is the first stage of the review process for all new proposals (including use of the isolate repository). The study lead(s) will be required to complete the new study proposal EOI template and return the completed form to the ROADMAP Management Team (TMG@roadmaptrial.com).

1. STUDY INVESTIGATOR DETAILS	
Name of Project Leader (<i>lead person</i>)	
Email Address	
Institution & Region	
Other Study Collaborators	
Do you or any study collaborators have any conflicts of interest to declare?	☐ Yes ☐ No
If yes, please state details of the perceived conflict(s)	
Have you discussed this proposal with a member of the ROADMAP GTSC? If so whom?	☐ Yes ☐ No Name: _____
Does the planned study involve students?	☐ Yes ☐ No
2. STUDY PROJECT DETAILS	
Title of project:	
Proposed Short Title of Project (<i>if available</i>):	
Proposed Study Category <i>(See New Study Process document for further detail)</i>	☐ Nested trial (New domain, new intervention or other) ☐ Adjunct Prospective Observational Study ☐ Secondary use of data and/or specimens
Proposed Regions	☐ Any regions interested in participating ☐ Specific Regions (<i>please specify</i>): _____ _____
ROADMAP Enrolment	☐ Platform Patients Only ☐ Registry Patients Only ☐ Both Platform AND Registry Patients
ROADMAP Participants (select all that apply)	☐ Adults ☐ other specific new-study participant <i>(please specify):</i> _____
Timeline for the project: <i>(Include recruiting start and data collection finish dates)</i>	



RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial (ROADMAP)

3. STUDY PROPOSAL OUTLINE (no more than 1000 words)

Use the following headings in the order below:

1. Background and Rationale
2. Hypothesis/research questions
3. Methods
4. Project Endpoints/Outcomes
5. What data points and/or specimens are required or brief schedule of events

4. STUDY REVIEW CRITERIA – (GTSC USE ONLY) <i>GTSC members: Please provide a brief justification/response to each of the following points.</i>		GTSC Use Only
Trial Integrity - Does this study require access to data that could threaten trial integrity? - Does this study plan to report on trial outcomes prior to the ROADMAP Trial results paper? - Does the study wish to report on study outcomes by treatment allocation prior to the ROADMAP Trial results paper? - Other potential trial integrity issues?		☐
Harmony with ROADMAP Protocol - Does the study require a significant amount of data/sample collection outside of standard care or ROADMAP trial protocols? - Are the sample/data collection harmonised with the ROADMAP core protocol and other ROADMAP studies?		☐
Adoption of the Pragmatic Trial Approach - Does this study place a significant additional burden on the participant or the site study team? - Does the proposal include only the necessary data collection to answer the research question?		☐
Feasibility - Is the sample size reasonable and achievable? - Will the research question be able to be answered recruiting only ROADMAP Trial participants?		☐
Global Application - Has the investigator considered the ability for the study to be conducted in other regions/countries? - Is the protocol applicable to other countries/regions?		☐
Funding - Has funding for this study been considered or obtained? - Are there any grants the investigator is intending to apply for to cover the costs of the study? - Has a proposal been put forward to the central team for covering some or all of the costs?		☐
Sample Collection, Analysis & Shipping - Will samples be collected for this study and shipped to an external location? - Has the shipping and storage of these samples been considered? - Has a plan for the analysis been generated?		☐

5. GTSC REVIEW (GTSC USE ONLY)

Date of GTSC Review:	
GTSC Decision: ☐ Approved	☐ No further detail required ☐ Proceed to Full Protocol
GTSC Decision: ☐ Not Approved	☐ Revise EOI & Respond to GTSC Comments & resubmit proposal (<i>Section 6 below</i>) ☐ Study will not proceed further at this time
GTSC additional Comments for Response (<i>if applicable</i>):	

6. RESPONSE TO QUERIES (*please complete this section upon resubmission of your EOI if required*)

Query 1:	Query 1 Response:
Query 2:	Query 2 Response (repeat as required):