ROADMAP FAQs for Investigators and Participating Sites

Version 1.3, Dated 02 February 2026

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SITE PARTICIPATION

➢ DOMAINS

Q: Does a site have to be included in all Domains of the trial?

A: To reach definitive answers to the questions posed in ROADMAP it is preferred to have all Domains active at each site however, it is recognised that some sites will opt out of Domains for different reasons.

Sites can elect to participate in all domains including the Registry or select which domains they have the capacity to be involved with and which domains the Infectious diseases and orthopaedic teams are comfortable enrolling participants into.

➢ PRIVATE HOSPITALS

Q: Can private hospitals be involved in ROADMAP as a participating site?

A: Yes. Both public and private hospitals and clinics can be participating sites if they meet the criteria listed previously. A caveat may be, if fees for Research Governance are considered by the regional trial steering committees (TSC) to be outside budget capacity. This is due to ROADMAP being a collaborative group trial sponsored and funded within strict grant guidelines in each regional area.

➢ LABORATORY REQUIREMENTS

Q: Do ROADMAP sites need a local laboratory to be formally involved?

A: ROADMAP is designed to be an embedded comparative effectiveness trial that does not request any assessments other than normal good clinical practise. The ROADMAP specific database will ask for results recorded in the participants medical file to be entered into the ROADMAP database; however, no specific testing is required.

In the future, ROADMAP plans to collect isolates for a ROADMAP PJI biobank and a potential sub-study however, the process for this has not been established. It is likely that the process will involve local laboratory storage of frozen isolates till batch sending is requested to the biobank.

SCREENING

➢ SCREENING PATIENTS USING DATABASE VS PAPER

Q: If a patient was screened using a paper screening form, believing that the patient would be eligible for ROADMAP, however subsequently it was decided this patient will not be enrolled. Should we screen this patient to the online spinnaker database? Or is the paper screening form sufficient?

A: Yes, please add this patient on the database. It's important that we see the numbers of patients that are "screening failures", and the reason they're not making it into the platform/registry. Doing so also gives us a better idea of the number of patients presenting with PJIs at each site.

➢ SCREENING PATIENTS – RETROSPECTIVELY FOR REGISTRY

Q: Can a site 'retrospectively' approach patients in the outpatient clinic setting to consent to Registry?

A: Yes, they can be approached as long as they are still being managed for the current active episode, and you can access them for consent and data collection.

➢ SCREENING PATIENTS AND SCREENING LOG INCLUSIONS

Q: If a site identifies a patient retrospectively for Registry inclusion, however, does not approach for Registry participation are they still to be included on the screening log.

A: Yes, all PJIs you become aware of and check for eligibility should be screened in the database, but only if the meet the inclusion criteria (regardless of exclusions or approached for consent or not).

➢ SCREENING PATIENTS – DATES

Q: If including retrospective outpatient clinic patients, what date is used i.e. time of admission or date of screening?

A: Date of Screening would be the date you are entering data.

ENROLMENT

➢ TIME LIMIT FOR COMPLETING ENROLMENT

Q: Do all enrolment forms need to be completed on the same day? Can I start eligibility/inclusion and complete consent later?

A: All eligibility and consent steps should be completed as soon as possible on the same day to prevent the patient forms from timing out. Currently there is a 48-hour screening window, meaning that when a patient is first entered, they need to be randomisation within 48hrs otherwise the database will consider them ineligible.

➢ TIME LIMIT FOR PLATFORM ENROLMENT AFTER CONSENT

Q: If a patient has just had their first of a two-stage revision and have been consented to the AB Duration domain (Part B) only, do they need to be randomised in Spinnaker immediately given that domain-specific eligibility cannot be assessed yet.

A: The participant should be enrolled and randomised in the trial as soon as possible once they have provided consent. Currently there is a 48hr window so they at least need to be entered into Spinnaker within that time otherwise they will be deemed ineligible for the platform. The domain specific eligibility CRF can be completed once the 2nd stage of the revision operation has been completed.

➢ DATABASE – PATIENT DUPLICATION OR SITE LOCATION ERRORS

Q: How should a site manage a patient that has been entered twice into the spinnaker database or has been entered as a participant of an incorrect site?

A: If this occurs, please contact your monitor or tmg@roadmaptrial.com to notify us of the error before re-entering the patient as a new participant. Please complete a Note to File (NTF) marking the error and participant number affected and send this to your monitor so that error can be amended by the central team in the database prior to analysis. Note: re adding the participant will alter randomisation algorithms and participant numbers will be incorrect.

ELIGIBILITY

➢ APPROACHING PATIENTS FOR CONSENT BASED ON KNOWN ELIGIBILITY

Q: If it is known that a patient is not eligible for any domains in ROADMAP (e.g., their PJ was not an index joint and therefore are excluded from the Duration Domain), should we still obtain Platform consent and monitor them, or just seek Registry consent?

A: If it is known that the patient is not—and will not become—eligible for any available domains, they should not be enrolled in the Platform. Instead, approach the patient for **Registry consent only.**

However, if the patient is eligible for Platform enrolment or may become eligible for one or more domains, then **Platform consent** should be sought. Patients should go into the platform if they are likely (or even possible) to be eligible for >=1 domains at some stage – even if that is not a sure thing.

Please note: PJI plus adjacent fracture fixation device is still eligible for either platform or registry (but for platform only if treated with curative intent)

➢ APPROACHING PATIENTS FOR REGISTRY CONSENT

Q: When should patients be approached for consent for registry only

A: Patients should be approached for Registry only consent if they:

1) Have a PJI in a large joint according to EBJIS
2) Have not previously entered into the registry for the same index joint within the past 24 months
3) Have not previously entered into the randomised platform for the same index joint at any time
4) Not eligible for the platform (e.g. not treated with curative intent)
5) Eligible for the platform but not likely to be eligible for any domains
6) Eligible for the platform and >=1 domains, but do not consent for platform

➢ MEETING EBJIS DEFINITION

Q: To meet the EBJIS definition of a prosthetic joint infection (PJI), is it possible to have two positive 'A's? Will it still fit the criteria of a confirmed joint infection?

A: Yes, it is possible to have multiple As.

➢ PARTICIPANTS WITH CONCURRENT PJIS

Q: How should we screen, enrol, and collect data for participants who have concurrent PJIs in more than one joint? E.g., a participant with an infected left TKR treated with DAIR (likely curable) and a concurrent infected right THR with a periprosthetic fracture and extensive fixation (likely not curable).

A: Participants with concurrent PJIs can be included in the registry for more than one joint, provided eligibility criteria are met for each joint.

- Each infected joint should be entered as a separate registry entry.
- A single patient may appear in the registry more than once if they have PJIs affecting different joints.
- Data collection, screening, and eligibility assessment should be performed independently for each joint.

Exclusions to note: A patient will be excluded from the registry for a specific (index) joint if, at the time of eligibility assessment, they meet any of the following criteria:

1. They have previously been entered into the registry for the same index joint within the past 24 months; or
2. They have previously been entered into the randomised platform for the same index joint at any time.

Key point: Eligibility and exclusions apply per joint, not per patient. Concurrent joint infections do not automatically exclude a participant from the registry.

➢ AB CHOICE DOMAIN |SURGICAL TREATMENT

Q: If a patient has had an initial surgical treatment of a superficial fascia debridement would the participant be eligible for antibiotic choice domain?

A: No, Initial surgery for antibiotic choice domain is anything where the joint was opened. If the debridement included a capsulotomy, then that would be considered initial. If it was just a wound debridement or a needle arthrocentesis, then not.

➢ AB CHOICE DOMAIN EXCLUSION | RIFAMPICIN USE RESTRICTIONS

Q: Are patients excluded from antibiotic choice Domain if rifampicin is contraindicated?

A: Unfortunately, they are excluded if there is a contraindication and known intolerance. However, can be included if in the case of a drug interaction it is possible and ethical to cease or withhold or to switch the interacting drug to an acceptable alternative.

➢ DISTINGUISHING ACTIVE INFECTION FROM POST-SURGICAL SYMPTOMS

Q: Does a patient need to have active infection at the time of assessment to be eligible? For example, if symptoms are starting to subside a few days post-surgery, but infection is still present, how do we determine whether symptoms are related to the current infection or are simply post-operative?

A: There must be evidence of current PJI. As long as there are some signs and symptoms consistent with PJI, patients remain eligible.

➢ SURGICAL RANDOMISATION | ELIGIBILITY IF 12 WEEKS IV REQUIRED

Q: Can patients be randomised to DAIR vs. staged Revision if they require 12 weeks of IV antibiotics?

A: Patients can be randomised as long as they don't meet the exclusion criterion of "difficult to treat organism" such as fungus or extensively drug-resistant bacteria.

➢ SURGICAL DAIR RANDOMISATION & ANTIBIOTIC DURATION CRF

Q: A patient has consented to all domains and is randomised to receive a DAIR. Since the patient is not eligible for the antibiotic duration domains, what do I do with the Antibiotic Duration (AD) Eligibility CRFs in Spinnaker?

A: Although the patient may be randomised in the surgical domain to receive a DAIR, they still may have a revision at some stage in future, meaning they may then be eligible for the AD domain at that time (dependent on meeting other exclusion criteria). Therefore, unless the patient has had a revision, these CRFs should be left blank.

➢ INITIAL SURGICAL TREATMENT DEFINITION

Q: If a patient had a washout and then a DAIR where the joint was surgically opened and cleaned out, which is considered to be the "initial surgery"?

A: Initial surgical treatment would be the date of the definitive surgery where the wound was opened, and joint space entered not the first washout or superficial debridement.

➢ AB CHOICE DOMAIN | IMPACT OF PRE-DAIR PROCEDURES ON ELIGIBILITY

Q: If a patient had debridement/washout (but without mobile parts exchange) before a formal DAIR, can the patient still be enrolled in the Antibiotic Choice Domain?

A: Yes. Eligibility for the Antibiotic Choice domain should be timed from the first *definitive* surgical procedure for this PJI—i.e., temporising procedures do not count.

➢ ELIGIBILITY OF HEMIARTHROPLASTY PATIENTS

Q: Are patients with a hemiarthroplasty (hip) eligible for enrolment into ROADMAP?

A: Yes

➢ ELIGIBILITY OF GMRS PATIENTS

Q: Are patients with a global modular replacement system (GMRS) of the knee or hip eligible for ROADMAP?

A: As these are generally revision prostheses, they are platform eligible but excluded from the surgical domain.

➢ ELIGIBILITY OF PATIENTS THAT HAVE A "KIWI PROSTHESIS" PROCEDURE

Q: Are patients that have had a KIWI (PROSTALAC system, a specialized antibiotic-loaded cement spacer) inserted as part of their management of PJI eligible for Platform entry or are they to be ineligible for platform and be considered for Registry only participation?

A: In the ROADMAP protocol a KIWI with no definitive date for 2nd stage revision, is considered to have had a one stage revision operation and therefore is eligible for both platform and registry participation. In particular the Antibiotic duration domain. The KIWI date of insertion would be considered the definitive prosthesis.

➢ PATHOGEN CONSIDERATION IN STUDY DESIGN

Q: Is the pathogen considered in the study domains and approach?

A: Yes. Pathogen must not be considered to be a "difficult to treat organism" such as fungus or extensively drug-resistant bacteria. For the Antibiotic Choice Domain, growth of a Gram-positive organism is required. Detailed consideration can be found in the domain specific appendices however an excerpt of microbial consideration can be found here.

➢ DOMAIN ELIGIBILITY CRFS IN SPINNAKER

Q: If I know a participant is not going to be eligible for a domain, do I still need to complete the eligibility CRF?

A: Yes. Even if you know the participant will not meet the inclusion/exclusion criteria, we would still like all the eligibility CRFs to be complete.

For example, if a participant is randomised to receive a DAIR, they would then not be eligible for the antibiotic duration domain (despite providing consent), we would still request that the antibiotic duration eligibility CRF be completed in Spinnaker so the data is complete, and we can determine why a participant has not been included.

➢ DEFINITION OF "INDEX' PROSTHESIS

Q: What is the definition of "index" in the Core Protocol "Early post-operative PJI Date of diagnosis is within 30 days of the index arthroplasty (i.e. the date that the index prosthesis was implanted"

A: It refers to the date that the currently infected prosthesis was implanted. i.e. If a patient has an acute, postoperative infection following (aseptic) revision arthroplasty, they would be eligible for the study.

BASELINE

➢ BASELINE DATA ENTRY

Q: How long do sites have to complete baseline CRF in spinnaker?

A: The baseline data should be completed within 7 days of enrolment into the platform.

➢ DEFINING SYMPTOM ONSET IN CHRONIC PJI

Q: For chronic patients, how should we define the 'Date of index symptom onset'? Should this refer to the onset of symptoms for the current flare/episode, or the very first symptoms of PJI—which may have occurred months or years ago? For example, in a case with long-standing knee swelling but recent fever and endocarditis, should the onset be based on the most recent exacerbation or the initial diagnosis?

A: For patients enrolled in the registry, it relates to the onset for the 'current' episode. However, for those enrolled in the platform, the date of symptom onset should be clinically determined. Core Protocol states "The duration of symptoms is counted from the first date that the patient clearly recalls having symptoms which, in the opinion of the site PI, specifically relate to the current episode of PJI. This date may be subjective and will be based on both patient history and the judgement of the site PI and/or treating team."

➢ HOSPITAL ADMISSION DATE

Q: For patients transferred from another hospital, which admission date should I enter—the date they first presented to any hospital, or the date they arrived at our hospital?

A: Enter the date the patient presented to *your* hospital for the current PJI episode or flare. For example, if the patient was admitted to another hospital on 03/01/2025 but transferred to your hospital on 05/01/2025, record 05/01/2025.

➢ ANTIBIOTIC USE

Q: When entering antibiotic use, if a participant received IV antibiotics as first line treatment, then swapped to oral antibiotics on the same day, should this be counted as 1 x day of IV antibiotics and 1 x day or oral antibiotics as the database states to count ½ days as full days?

A: This would be counted as 1 x day of IV antibiotics, and the oral antibiotic count commencing the following day.

➢ DATE WINDOWS IN CRFS | CALENDAR DAYS VS 24H BLOCKS

Q: When a CRF question specifies a ±2 day window (e.g., blood pathology results collected ±2 days of platform entry), is this based on calendar days or exact times? Some result can be wildly different (e.g., CRP).

A: It refers to calendar days—the exact time is not relevant (i.e., ±2 days means within two calendar days, before or after the reference date).

➢ OXFORD HIP AND KNEE SCORE

Q: When a patient is answering the initial Oxford Hip and Knee score, do we want to know the worst they were in the last four weeks or the average over the past 4 weeks e.g. if they have been healthy for 3 weeks and then had 1 week of extreme pain how would we want this answered?

A: Please record the worst they were over the last four weeks. We want to measure the effect of the fact that they have an infection currently.

PROTOCOL DEVIATION

➢ SURGERY AT ANOTHER HOSPITAL

Q: Does surgery at another hospital violate study protocol?

A: No, a study protocol violation will not be recorded as this is acknowledged as a possibility in some centres and has been allowed to occur within the protocol.

RANDOMISATION

➢ TRIAL DESIGN |LATE ACUTE INFECTION

Q: Does the trial include randomisation to DAIR or revision for late acute infection?

A: Yes, the surgical domain does involve randomisation to DAIR or revision for late acute PJIs – although this domain is not essential for all sites to participate in. The Domain does include provision for surgeon's discretion based on the patient, patient history etc. The randomisation is a strong recommendation but if not adhered to will not be considered a PD. It will be dealt with in analysis.

➢ AB CHOICE DOMAIN | TIMING OF RANDOMISATION

Q: If a patient has consented to the antibiotic choice domain and once the definitive initial surgical treatment (DAIR or Revision) has occurred what is the timing of the antibiotic choice randomisation?

A: Once the initial definitive surgical management has occurred, then 2-7 days later you should screen for antibiotic choice eligibility assessment. If the patient meets criteria and enters the domain, the randomisation allocation is revealed. Liaise with treating team and chart the correct antibiotics.

➢ DURATION OF RIFAMPICIN TREATMENT

Q: If a patient receives a two-stage revision and is randomised to receive rifampicin (AB choice domain) and to receive extended antibiotics (AB duration domain part B), does that mean they would receive more rifampicin?

A: If they are randomised in the AB choice domain to receive rifampicin plus backbone therapy, then they will be administered this combination between the stages (after the 1st stage, before the 2nd stage), which may be any duration, but usually 6-12 weeks (there is no trial restriction/guideline on this duration).

If they are also randomised in the AB duration domain (Part B) to receive extended antibiotics post second-stage revision, they should not receive additional rifampicin. In the extended duration domain, they are randomised to extended prophylaxis (backbone antibiotic), not treatment (rifampicin).

MICROBIOLOGY

➢ LABORATORY REQUIREMENTS

Q: Do ROADMAP sites need a local laboratory to be formally involved?

A: ROADMAP is designed to be an embedded comparative effectiveness trial that does not request any assessments other than normal good clinical practise. The ROADMAP specific database will ask for results recorded in the participants medical file to be entered into the ROADMAP database; however, no specific testing is required.

In the future, ROADMAP plans to collect isolates for a ROADMAP PJI biobank and a potential sub-study however, the process for this has not been established. It is likely that the process will involve local laboratory storage of frozen isolates till batch sending is requested to the biobank.

➢ USING HISTORICAL CULTURES FOR CURRENT ADMISSION

Q: The patient has a chronic PJI, and no new swabs or cultures have been taken during this admission. Can I enter the causative organism from a previous admission?

A: This section refers to the current presentation only – i.e., the flare that brought the patient into hospital. If no microbiology has been taken during this admission, and the previously identified organism is still considered the presumed cause, you may enter the most recent organism grown from a prior admission.

➢ WHICH BLOOD RESULT SHOULD BE RECORDED

Q: What should I do if there are two identical blood test results for the same participant and outcome at Day 100? Which blood result should be recorded in the CRF

A: If two identical blood test results are available for the same participant and outcome at Day 100, please record the result closest to the relevant timepoint. When entering the data, ensure that the date recorded corresponds to the most recent test.

Example (AST MAX):

If two identical AST MAX results are recorded for a participant at Day 100, select the result from the test closest to the relevant timepoint.

For example, if AST MAX = 42 U/L was recorded on 12 March 2026 and again on 18 March 2026, record the AST MAX value from 18 March 2026 and enter 18 March 2026 as the test date.

➢ WHICH CAUSATIVE ORGANISMS SHOULD BE RECORDED

Q: The patient had a second stage revision performed and no organism has grown from the culture tissue collected during the surgery. However, the culture swab collected previously grew two organisms. Should the causative organism refer to the index surgery post randomisation, or should previous history also be included?

A: The causative organism relates to anything that is known at the time of platform entry that relates to the current episode and is considered to be clinically significant In this case, the culture sample collected pre-operation is related to this infection and should also be included.

➢ RECORDING MULTIPLE CAUSATIVE ORGANISMS IN CRFS

Q: If a patient grows PSSA in 3 of 6 specimens at platform entry, and later grows MSSA and Corynebacterium on a repeat DAIR in Week 2, how should this be recorded?

A: PSSA should be recorded on the **Baseline form** as the initial causative organism. MSSA and Corynebacterium should be recorded on the **Day 100 form** as organisms identified after baseline.

If the patient is in the Antibiotic Choice domain, the backbone antibiotics should be adjusted as clinically indicated to cover all clinically significant organisms. Rifampicin (or no rifampicin) should be continued as per the original randomisation result (reveal outcome).

FOLLOW UP

➢ SECONDARY HOSITAL SURGERY | LIMITED FOLLOW UP ACCESS

Q: Can a patient remain in the trial if surgery is at a secondary hospital and data collection will be difficult to follow up?

A: It is the hope that the patient is accessible for data collection in relation for follow up and outcomes data collection at Day 100 and Day 365 however, if it is known at baseline that the patient is likely to be transferred to another hospital to which investigators have no access to records, the patient would meet the platform exclusion criterion "not likely to be accessible for follow up over the next 12 months".

➢ DEFINING 365 START POINT

Q: In the Registry, how should we determine the Day 365 entry point? For patients with a long history of PJI, the original diagnosis may have occurred years ago. Should the Registry and Platform use the same start date (e.g., date of current presentation) to calculate follow-up timelines?

A: For both Platform and Registry participants, the day of enrolment—defined as the day eligibility is confirmed, and consent is completed—is considered Day 1. All follow-up timepoints (e.g., Day 100 for Platform, Day 365 for both) are calculated from this date.

Site staff will be notified by email when a participant is approaching Day 365. If the Day 365 CRF is overdue, site staff will receive another email flagging that this CRF must be completed to avoid a protocol deviation.

➢ TIMING OF DAY 100 AND DAY 365 ANTIBIOTIC USE

Q: As a participant had a DAIR 4 days after platform entry, by the time DAY 100 the participant had received 104 days of antibiotics. This will mean that the noted days of antibiotic will also be out at DAY 365. How should we deal with this issue?

A: No need to do anything as the system will flag an alert to double check the data however it will still allow the data to be entered.

➢ RECORDING HOSPITAL DAYS

Q: Should inpatient rehabilitation days count as hospital days in CRFs? E.g. a patient was an inpatient in a hospital however was not receiving active antibiotic treatment at rehab.

A: Hospital admission includes ICU stays and rehabilitation stays (counted if directly following or is linked to the admission, even without active antibiotic treatment), but excludes Hospital in the Home (HITH). Count every full and partial day spent in the hospital or in each hospital unit. E.g. If a patient spends day 14 through to day 21 in the ICU, this counts as 8 total days.

➢ RECORDING USE OF ANTIFUNGALS IN THE DATABASE

Q: A participant received antibiotic therapy as well as antifungals (IV and/or oral). Should this information be included?

A: Yes. In this context, the term "antibiotics" is used broadly to refer to **antimicrobial agents in general**. This includes antibacterial agents, **antifungals** (both IV and oral), and other non-antibacterial antimicrobials.

All antimicrobial therapies administered to the participant should be recorded in the relevant fields. If an antifungal or other antimicrobial agent is not listed as a selectable option, please use the **"Other"** option and specify the agent accordingly.

DOCUMENT HISTORY

VERSION NUMBER	DATED	SUMMARY OF CHANGES	APPROVED BY	APPROVAL DATE
1.0	31 JUL 2025	This is version 1.0 of the ROADMAP Site FAQs	Marline Squance	31 Jul 2025
1.1	7 AUG 2025	Combined Investigator FAQs from website	Marline Squance	19 Aug 2025
1.2	20 Jan2026	Additional FAQs added	Marline Squance	20 Jan 2026
1.3	02 FEB 2026	Additional FAQs added	Marline Squance	02 Feb 2026