ROADMAP FAQs for Investigators and Participating Sites

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SITE PARTICIPATION

1. 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.

2. 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.

3. 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.

ROADMAP is also collecting isolates from Platform participants for a ROADMAP PJI isolate repository and potential future studies. The process for the collection, storage and transportation of isolates to the central repository at HMRI has now been established and is documented in the Microbiology appendix, link.

4. INFORMATION VIDEOS

Q: How are the information videos accessed?

A: Videos are located on the website www.roadmaptrial.com which can be accessed either directly on the ROADMAP website, or via a QR code on the PICF. They can be viewed using any electronic device (participant's phone, iPad, ward computer etc). The videos provide useful and concise information for patients, participants and ROADMAP site team members so they can better understand the ROADMAP trial.

5. 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.

6. 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.

7. 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).

8. 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.

9. SCREENING PATIENTS – DATABASE LOCKOUT

Q: Why won't the screening page let me complete entries? 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. Screening needs to be completed within 7 days of commencing an entry. After this point the database locks automatically and prevents further entering of data. If a screening entry times out, please contact your monitor or tmg@roadmaptrial.com to arrange the entry to be deleted.

ENROLMENT

10. TIME LIMIT FOR PLATFORM ENROLMENT AFTER CONSENT

Q: If a patient has just had their first of a two-stage revision and has 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. The randomisation will only be revealed if and when they have had the 2nd stage and subsequently meet domain eligibility criteria. If they do not have the second stage within 6 months, this will time out.

11. 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.

12. SURGICAL DOMAIN CONSENT TIMING

Q: Can you clarify the timing of consent for the surgical domain? Is it prior to index surgery? Is recruitment prior to surgery?

A: For surgical domain the patient needs to be approached for the study and consented prior to surgery for randomisation to either DAIR or revision. They can also be consented to the antibiotic domains as well.

Key point: Once the *definitive* initial surgery has been done, they become ineligible for the surgical domain. This means a formal DAIR or revision (or other salvage operation such as a Girdelstone's or amputation). This does NOT include a temporising operation – e.g. washout or debridement of the joint without replacement of modular parts. So, if they've had an arthroscopic or temporising washout and are planned to have their proper operation sometime in future, they can be assessed for surgical domain eligibility.

For the platform in general, if the patients already had their definitive index surgery, they still may be eligible for the platform in antibiotic domains with consent post-surgery dependent on whether DAIR or revision has been performed.

The Surgical poster is designed to put ROADMAP into the minds of registrars when a patient presents with PJI so consideration prior to surgery is done.

13. PARTICIPANT CONSENT AND DEATH OF PARTICIPANT.

Q: If a patient consents to participate in the trial and then dies before commencing trial allocated treatment, would his prior consent allow his data to be retained and used for Registry purposes?

A: If the patient consented to participation, then his data will be retained and they become a "Platform only" participant which will require completion of CRFs. Anyone that enters the trial as a platform participant is automatically entered into the registry. If the participant prior to their death consented to potential future data linkage, then this consent is retained and require the participant identifiers to be recorded in the ROADMAP REDCap database.

14. WAIVER OF CONSENT FOR DECEASED PJI PATIENTS

Q: If a patient meeting eligibility criterion for trial dies before participation consent is received, how are they included in the trial and what data is collected?

A: Where permissible under local requirements, a waiver of consent will be sought for the inclusion of patients with PJI meet the core eligibility criteria however die during their index hospitalisation prior to being approached for consent. In the case of a patient entered into the ROADMAP registry under a waiver of consent, no individual patient identifiers will be collected, therefore data linkage will not occur. A "ROADMAP Informed Consent Record 1 -Waiver of Consent Registry" form needs to be completed for each patient entering the Registry as well as additional RGO reporting in Western Australia.

The data collected will be of a minimal dataset only:

1. Demographic data collected for registry analyses including:
   - Patients' sex
   - Date of birth for derivation at age in years, or simply age in years at registry entry
   - Dates of diagnosis and index hospital admission (for calculation of outcome landmarks)
2. Prognostic variables used for casemix adjustment will including:
   - Patient's age at PJI diagnosis (derived variable)
   - Selected co-morbidities (e.g. Diabetes, CKD, liver cirrhosis, cancer, dementia)

ELIGIBILITY

15. 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).

16. PATIENTS RE-PRESENTING WITH NEW SYMPTOMS

Q: Are people who have had a previous prosthetic joint infection and then are re-presenting with new symptoms eligible or they need to be a first-time PJI?

A: A second PJI in the same joint is not of itself a platform exclusion. However, such patients may be ineligible for other reasons, including previous enrolment in the platform for the index joint at any time or previous enrolment in the registry for the index joint in the past 24 months. Also, if they have had a revision previously in the index joint (whether it was for infection or not), they will not be eligible for the surgical domain but could be considered for any of the antibiotic domains.

17. 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

18. 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 A's – BUT you also need to have one or more criteria from categories B or C. Having more than one "A" criterion only counts once.

In the "confirmed" category, there is only one A criterion (sinus or prosthesis on show). In the "likely" category, there are 5 but whether the patient meets, 1,2,3,4 or all 5 of these, it still only counts once for fulfilling the A criteria. To be counted as "likely" the patient would also need to mee at least one of the B or C criteria.

19. 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) and infected shoulders both left and right.

A: For the platform:

If multiple joints (treated with curative intent) are infected at the same time:

- Index joint = the joint with the earliest onset of symptoms

If onset is simultaneous:

- Site PI chooses the most appropriate joint for randomisation

For the registry:

Participants with concurrent PJIs of any large joints 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.

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

20. 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 they would not be eligible.

21. 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 are 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. The list of medications which are absolutely and relatively contraindicated are provided in the antibiotic choice DSA and the Handbook.

22. 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.

23. 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.

24. 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: Once a patient has had a DAIR, they automatically become ineligible for the antibiotic duration domain part A (one stage revision). This is because this domain requires the initial definitive procedure to be a one stage revision. If the patient has a DAIR but then has a 2-stage completed within 6 months of platform entry, they could potentially be eligible for the antibiotic duration part B domain.

You only need to fill in the eligibility CRFs for antibiotic duration domain A if the patient has a one-stage revision, and for part B if they have completed a two-stage revision.

25. 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.

26. RANDOMISATION ALLOCATION CHANGING

Q: What happens if randomised to a DAIR or a first stage, and during operation and it changes due to clinical reasons or what you find?

A Clinician discretion is allowed with understanding that operations may change, and the randomisation is no longer considered to be in the best interest of the patient. If the change is due to a clinically indicated decision, no protocol deviation is required. The patient will still be analysed in the allocated group by the intention to treat principal but will not be in the per-protocol analysis for the surgical domain. Data are collected in the CRF about what operation they ended up having.

27. CURATIVE INTENT CHANGING POST RANDOMISATION

Q: How do you deal with treatment changes for curative intent after randomisation has occurred?
For example, a DAIR was performed with curative intent, and the patient is randomised into the platform, and then a month later, or two weeks later, the surgeon says, "I've changed my mind, it's not with curative intent?"

A: Once a patient is entered into the platform, they stay in the trial unless the patient wants to withdraw. In the above case, we would continue to collect data and follow up on this patient, as well as continuing treatment that may have been allocated in other domains. If they were eligible at the time of eligibility assessment, they stay in.

To retrospectively exclude someone based on post-randomisation events would violate key statistical principles.

28. PARTICIPANT DIES POST RANDOMISATION

Q: What do you do when a patient that has been consented and randomised to the platform and the participant dies prior to implementation of allocation?

A: Once a patient is entered into the platform, they stay in the trial as a " Platform only" participant. Data will be collected as usual with the participants death recorded in Day 100 and Day 365 CRFs.

29. PARTICIPANT PATHOLOGY RESULT CHANGE POST RANDOMISATION

Q: A patient's initial preliminary microbiology report showed Gram-positive organisms and they met all other eligibility criteria and entered into the trial as a participant. Their subsequent microbiology report showed Vancomycin Resistant Enterococcus with limited oral treatment options meaning they no longer met the eligibility criteria. What should we do?

A: The participant was entered into the trial based on the available information. Once a patient is entered into the platform, they stay in the trial as a "Platform only" participant. Data to reflect the change in participant microbiology will be collected as usual with the participants in Day 100 and Day 365 CRFs.

If the participant was randomised to rifampicin, and if this was not implemented, then the change will be captured in the CRFs Day 100 and Day 365. The status change to randomisation should also be documented in the patient's medical record.

30. REVISION DEFINITION

Q: Is there a strict definition of a revision, which everything that's in there has to be removed?

A: Definition of "revision" (ROADMAP – Surgical DSA):

- A revision is defined as an operation with ALL of the following:
  - Open procedure (arthrotomy)
  - Comprehensive synovectomy
  - Exchange of all prosthetic material
  - Reimplantation of new prosthetic material

Additional clarifications:

- Includes both:
  - One-stage revision
  - Two-stage revision
- Key concept:
  - Complete removal and replacement of the prosthesis (not partial)

Contrast (important):

- NOT revision (i.e. counts as DAIR):
  - Partial component exchange (e.g. tibial only)
  - Debridement without full prosthesis exchange

Bottom line:

- Revision = full prosthesis removal + new implant placement (open, with synovectomy)
- Anything less = not revision in ROADMAP terms

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31. 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.

32. ELIGIBILITY OF HEMIARTHROPLASTY PATIENTS

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

A: Yes

33. ELIGIBILITY OF MEGAPROSTHESES PATIENTS

Q: Are megaprostheses eligible for ROADMAP?

A: The exclusion of PJI patients with megaprostheses and a definition of megaprostheses is a planned additional exclusion criterion in the major amendment protocol V 3.0 which will be finalised soon. In the meantime, please do not include such patients in the platform and select "enrolment not in patient's best interest" as the platform exclusion. They are currently and will remain eligible for the registry.

34. ELIGIBILITY OF GMRS PATIENTS

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

A: These are megaprostheses – see the answer to question #33 above.

35. ELIGIBILITY OF PATIENTS THAT HAVE A "KIWI PROSTHESIS" PROCEDURE

Q: Are patients that have had a KIWI (PROSTALAC system, a specialised 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 but would not be eligible for the surgical domain. The KIWI date of insertion would be considered the date of the initial definitive surgery. If there is a plan for a 2nd stage, they are still eligible as above, but the Kiwi would be considered the first step of a 2-stage revision.

36. HITH & OPAT PATIENTS

Q: Are HITH and OPAT (IDAC ID ambulatory care) patients eligible for enrolment into ROADMAP?

A: Yes, platform recruitment is allowed if the patient is in HITH / OPAT, are otherwise eligible, and are accessible for consent, data collection and follow up.

37. PATHOGEN CONSIDERATION IN STUDY DESIGN

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

A: Yes. Data on causative organisms is recorded and will be reported in any papers/analyses. Some domains have particular pathogen exclusions, including:

- **i)** "Difficult to treat" organisms (such as fungus or extensively drug-resistant bacteria) are excluded from the antibiotic duration part B (post 2-stage revision) domain
- **ii)** Monomicrobial Gram negative infections are excluded from the antibiotic choice domain.

38 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: The index prosthesis is the one in situ at the time the PJI is diagnosed.

BASELINE

39 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.

40. 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."

41 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.

42. 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.

43. ANTIBIOTIC USE BEFORE PLATFORM ENTRY

Q: A participant received antibiotic therapy prior to platform entry which resulted in an acute kidney injury (AKI) however, there is no place to enter this data. Should this information be included within the Baseline data?

A: In this trial AKI is secondary endpoint, defined as a rise in creatinine of 1.5 times or more from the baseline value at platform entry. It is measured over 100 days following platform entry. Because platform entry is the point of randomisation, anything that happens before this (including antibiotics and any resulting renal injury) is pre-randomisation and would already be captured in the baseline creatinine value. There is no protocol requirement to record pre-platform-entry antibiotics or associated adverse events.

44. ANTIFUNGAL USE

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.

45. 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).

46. RECORDING OF ALT & AST

Q: AST is not a standard part of liver function testing (LFT) at our site, therefore this value cannot be recorded in spinnaker in the Baseline or Day 100. What do we do?

A: The protocol specifies ALT and/or AST and/or Bilirubin. ALT alone is sufficient. If AST is not performed, then select "Not done/ done but not available" option in spinnaker CRF.

47. BLOOD RESULTS WINDOW AT BASELINE

Q: Are Baseline blood results a prerequisite for randomisation

A: Baseline CRF is not completed until after day 1 and are NOT a prerequisite for randomisation. The =/- 2 day window is included for practical flexibility.

48. 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: These joint scores were validated for chronic stable joints. The score applies to the average over the 4 weeks preceding the relevant date (date of diagnosis or follow up).

49. QOL EQ-5D-5L SCORE

Q: IS EQ-5D-5L scored as an average over 4 weeks as in Oxford score or as currently.

A: Please record the score from current assessment (TODAY). We want to measure the effect of the fact that they have an infection currently and compare with outcome at DAY365.

50. SINUS SILO

Q: What silo does a patient that had a sinus evident during surgical management categorised to, and how do you enter the dates of "first symptom" to fit silo categorisation.

A: There is a hierarchy of silo definitions (assessed at the time of eligibility assessment):

1) If it is <=30 days since the prothesis was implanted, it's "Early" regardless of whether there is a sinus or not, or the duration of symptoms
2) If it is >30 days then
    - If there is a sinus it's chronic regardless of all else
    - If there is no sinus and <=21 days of symptoms its late acute
    - If there is >21 days of symptoms, it's chronic

PROTOCOL DEVIATION

51. 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

52. 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.

53. 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.

54. 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 pathogen-directed prophylaxis (backbone antibiotic), not treatment (rifampicin).

MICROBIOLOGY

55 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.

56. 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.

57. 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.

58. ISOLATE COLLECTION

Q: Which isolate do I collect for storage and transport to the ROADMAP repository?

A: 1. Please liaise with the lab to confirm that PJI is confirmed and that the patient has consented to ROADMAP participation.

2. Let the lab know, that the patient is in the ROADMAP trial, complete ROADMAP request if your site has them so isolate is collected and stored.

3. The PI or ID physician will decide which single baseline isolate is the most representative and most important isolate. NOTE: There is a hierarchy of how to choose the most important isolate in the micro-appendix, please find link here.

59. CULTURE NEGATIVE SAMPLES

Q: Do isolates need to be collected if a sample was culture negative?

A: If there is nothing to culture and freeze down, then no isolate would be collected (because none exists!)

60. ISOLATE COLLECTION

Q: Do we collect isolates for both Platform and Registry participants?

A: No. Isolates are only collected for platform participants.

61. 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

62. 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".

63. 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.

64 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.

65. 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.

DATA MANAGEMENT PLATFORM ACCESS & TROUBLESHOOTING

66. SPINNAKER WILL NOT LOAD, OR THE PAGE IS BLANK OR SLOW. WHAT SHOULD BE CHECKED?

- Check whether other websites open.
- Try a different browser or a private/incognito window.
- If the problem continues, clear the Spinnaker site cache and cookies, close the browser and reopen the live link.
- Unsaved entries may be lost when refreshing or clearing site data.
- If other websites are also unavailable, contact local IT.

67. LOGIN IS NOT WORKING. WHAT SHOULD BE CHECKED?

- Check that the correct **ROADMAP live platform** is being used, rather than **staging** or an old bookmark.
- Open the approved live link and check the login details.
- For password, account or site-access problems, contact the site monitor or trial office.
- **Do not** use another staff member's account.

68. THE PLATFORM IS DOWN OR LOGIN STILL FAILS. HOW SHOULD THE ISSUE BE REPORTED?

- Lodge a ticket directly in Spinnaker Userback.
    - This gives Spiral project managers the issue details directly and helps them identify the cause faster.
- If Spinnaker cannot be opened, use the standalone Spinnaker Userback link.
- If Spinnaker Userback is also inaccessible, contact the monitor or tmg@roadmaptrial.com so the issue can be raised on the site's behalf.

69. WHAT INFORMATION SHOULD BE INCLUDED IN A USERBACK TICKET?

- The exact error message and the date, time and timezone.
- Whether the problem is on live or staging, and the affected page or form.
- The browser used, the action being attempted and the steps already tried.
- Whether the issue affects one staff member or several, and one record or several.
- A clear screenshot, with patient names and passwords excluded.

- Any deadline or time-sensitive activity being blocked.

70. A CRF WILL NOT SAVE. WHAT SHOULD BE CHECKED?

- Check highlighted mandatory fields, date formats and validation messages.
- If a correct value is rejected or the form still cannot be saved, lodge a Spinnaker Userback ticket with the form, affected question and exact error message.
- Do not change a correct value or enter a dummy value just to make the form save.

71. A TECHNICAL PROBLEM IS BLOCKING RANDOMISATION OR AN APPROACHING DEADLINE. WHAT SHOULD HAPPEN NEXT?

- Lodge a Spinnaker Userback ticket promptly and state the blocked activity and deadline, including the time and timezone.
- Notify the monitor or trial office at the same time so urgent support can be coordinated.

MISCELLANEOUS

72. IRRIGATION WASH-OUT FLUIDS

Q: Is there a prescription on what irrigation or washout fluids with or without antibiotics?

A: Irrigation fluids are known to be highly variable. In the PIANO study, we had more than 50 different regimens being used. No prescription is set currently, so surgeons can use whatever they choose.

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
1.4	16 APR 2026	Additional FAQs added	Marline Squance	16 Apr 2026
1.5	19 Oct 2026	Additional FAQs added and clarifications	Marline Squance	19 Oct 2026