Adaptative Platform Trial

SNAP
Staphylococcus aureus
Network Adaptive Platform

ROADMAP TRIAL

RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial – Synopsis

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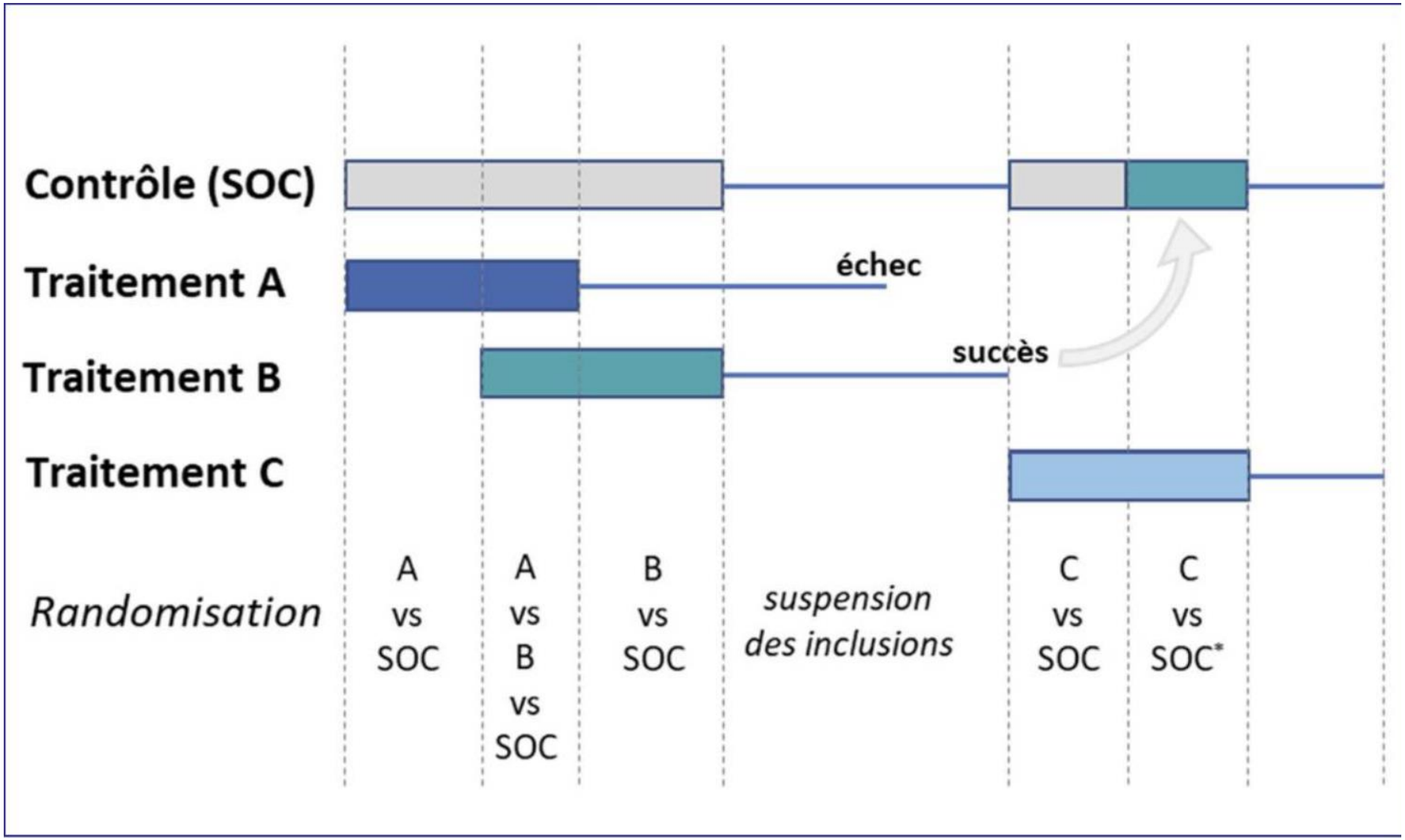

Roustit et al. Therapies 2023

SNAP

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1.1 Overview of initial trial design (given only as an example, at initial trial launch)

SILOS	DOMAINS			
	Surgical Rx	***Antibiotic duration***	***Antibiotic choice***	***Future domain***
Early* PJI	No randomisation options[1]	For one stage: Total 6 weeks versus 12 weeks post the one-stage For two-stage – 7 days versus 12 weeks post 2nd stage	Backbone regimen with or without adjunctive oral rifampicin	A vs B *(e.g. choice of irrigation fluids; adjunctive vitamin C; antidepressants)*
Late acute* PJI	DAIR versus revision[2]			
Chronic* PJI	One stage versus two stage revision			

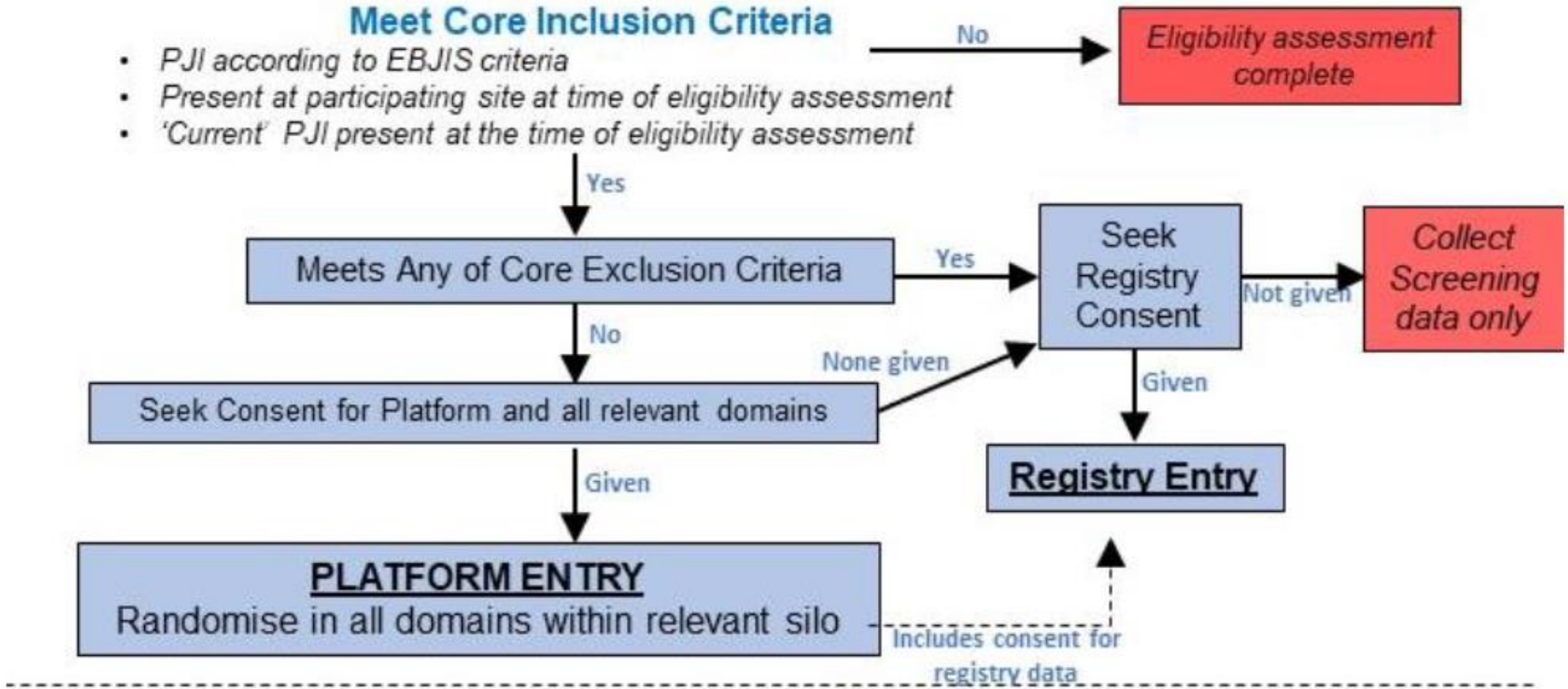
**Early = <30 days post implant. **DAIR=Debridement, Antibiotics and Implant Retention. "Late acute" = >30 days post implant and <=21 days of symptoms at diagnosis. "Chronic"= >30 days post implant AND a sinus or >21 days of symptoms 1. Those who are not eligible or consenting for the domain will be treated at clinicans' discretion, which will be DAIR for the majority, but will include revision in a small proportion. 2. If randomised to revision, it will be at the discretion of clinicians/patients whether the revision is one or two stage.*

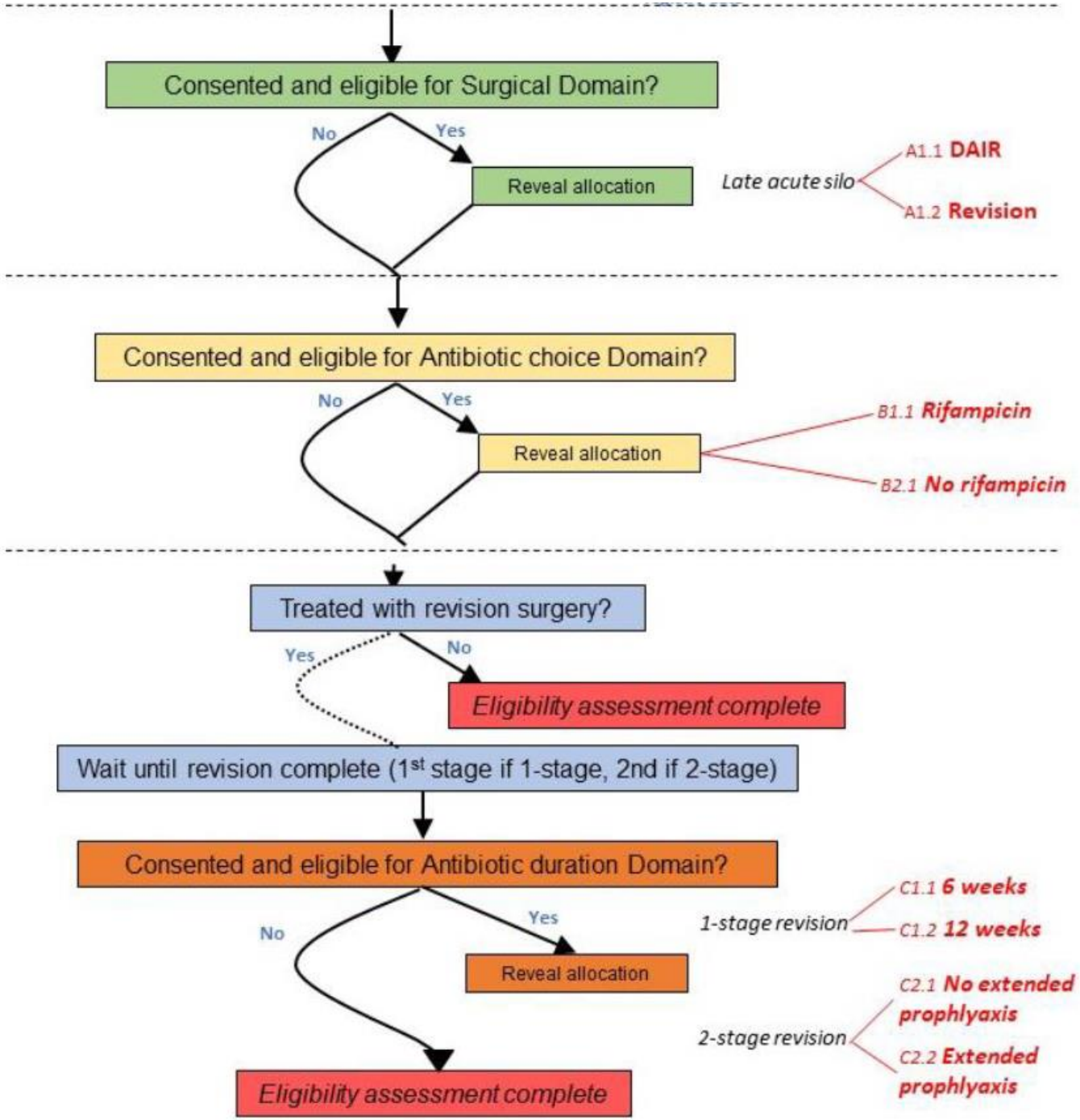
Open-label
Aim: 2500 patients

SITES	Aiming for 50-100 sites across Australia, Canada, NZ and UK, with more regions likely to be added. Each site should see >20 PJIs/year and have both ID and orthopaedic investigators and engagement

PLATFORM INCLUSION CRITERIA	1. "Confirmed" or "Likely" Prosthetic joint infection of hip or knee according to EBJIS criteria. 2. Physically present at participating hospital at time eligibility assessment 3. "Current" prosthetic joint infection, meaning symptoms and/or signs of the PJI are present at the time of eligibility assessment

CORE PRIMARY OUTCOME MEASURE	Treatment success at 12 months post platform entry, defined as all of: i) Alive; ii) Clinical cure (no clinical or microbiological evidence of infection); iii) No ongoing use of antibiotics for the index joint; and iv) "Destination prosthesis" (the prosthesis present after the initial management strategy is complete) still in place


Meet Core Inclusion Criteria
PJI according to EBJIS criteria
Present at participating site at time of eligibility assessment
'Current' PJI present at the time of eligibility assessment
No
Eligibility assessment complete
Yes
Meets Any of Core Exclusion Criteria
Yes
Seek Registry Consent
Not given
Collect Screening data only
No
None given
Seek Consent for Platform and all relevant domains
Given
Registry Entry
Given
PLATFORM ENTRY
Randomise in all domains within relevant silo
Includes consent for registry data


Consented and eligible for Surgical Domain?
No
Yes
Reveal allocation
Late acute silo
A1.1 DAIR
A1.2 Revision
Consented and eligible for Antibiotic choice Domain?
No
Yes
Reveal allocation
B1.1 Rifampicin
B2.1 No rifampicin
Treated with revision surgery?
Yes
No
Eligibility assessment complete
Wait until revision complete (1st stage if 1-stage, 2nd if 2-stage)
Consented and eligible for Antibiotic duration Domain?
No
Yes
Reveal allocation
1-stage revision
C1.1 6 weeks
C1.2 12 weeks
2-stage revision
C2.1 No extended prophlyaxis
C2.2 Extended prophlyaxis
Eligibility assessment complete

8.7 Participant timeline

Table 2. Schedule of visits, data collection and follow-up.

Platform Day	Day 1			Weekly during inpatient/HITH[1] stay	Day 90 (+/- 7 days)	12 months (+/- 30 days)
Eligibility screening	X					
Informed consent		X				
Randomisation			X			
Collect data as per CRFs			X		X	X
Check protocol compliance				X		
Collect PROMS[2]	X					X

1. Hospital in the home. 2. Patient-reported outcome measures

PHRC
ANRS MIE

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