



Joshua Davis

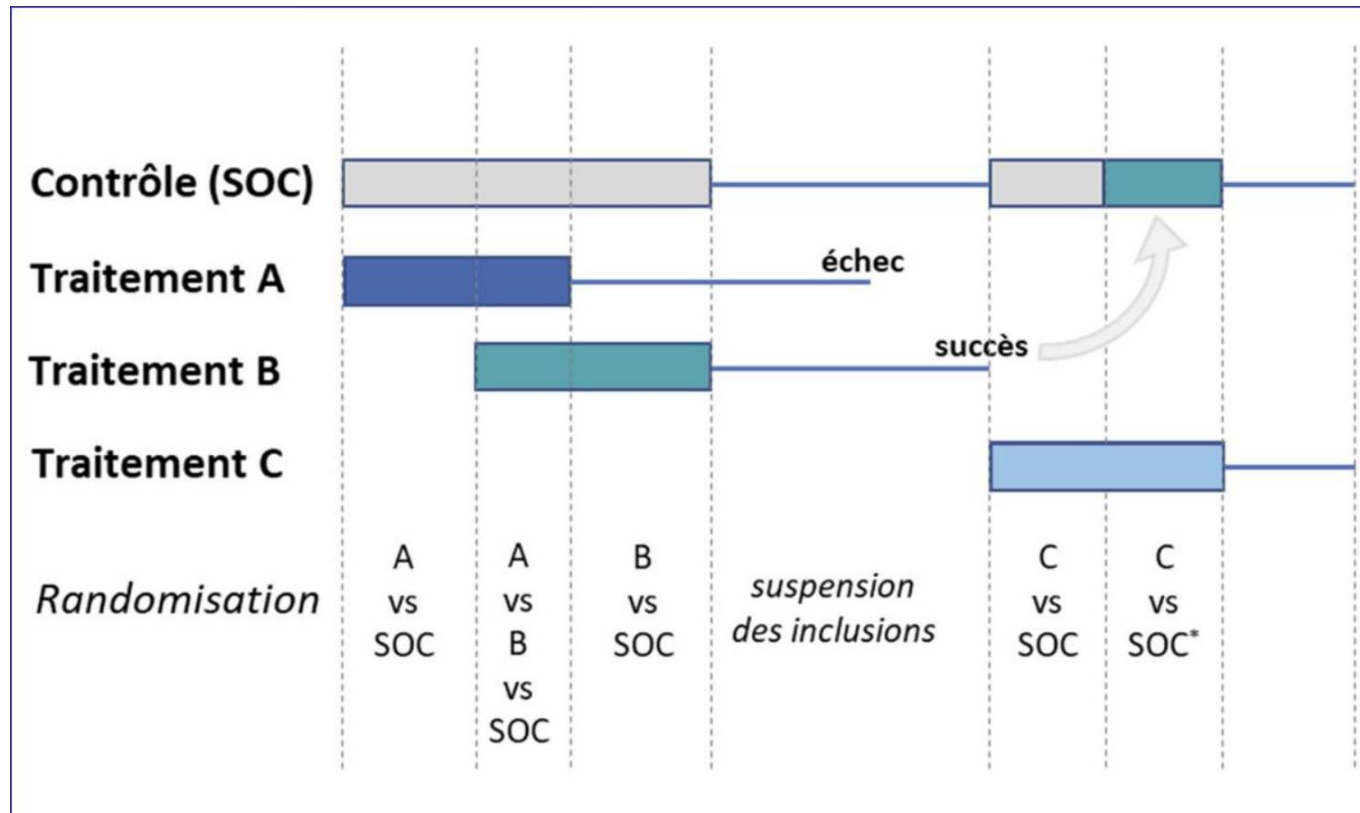


RandOmised Arthroplasty infection worlDwide

Multidomain Adaptive Platform trial

J. Courjon, A. Dinh, pour les CRIOAc et le RENARCI







No. of Participants Recruited

4600

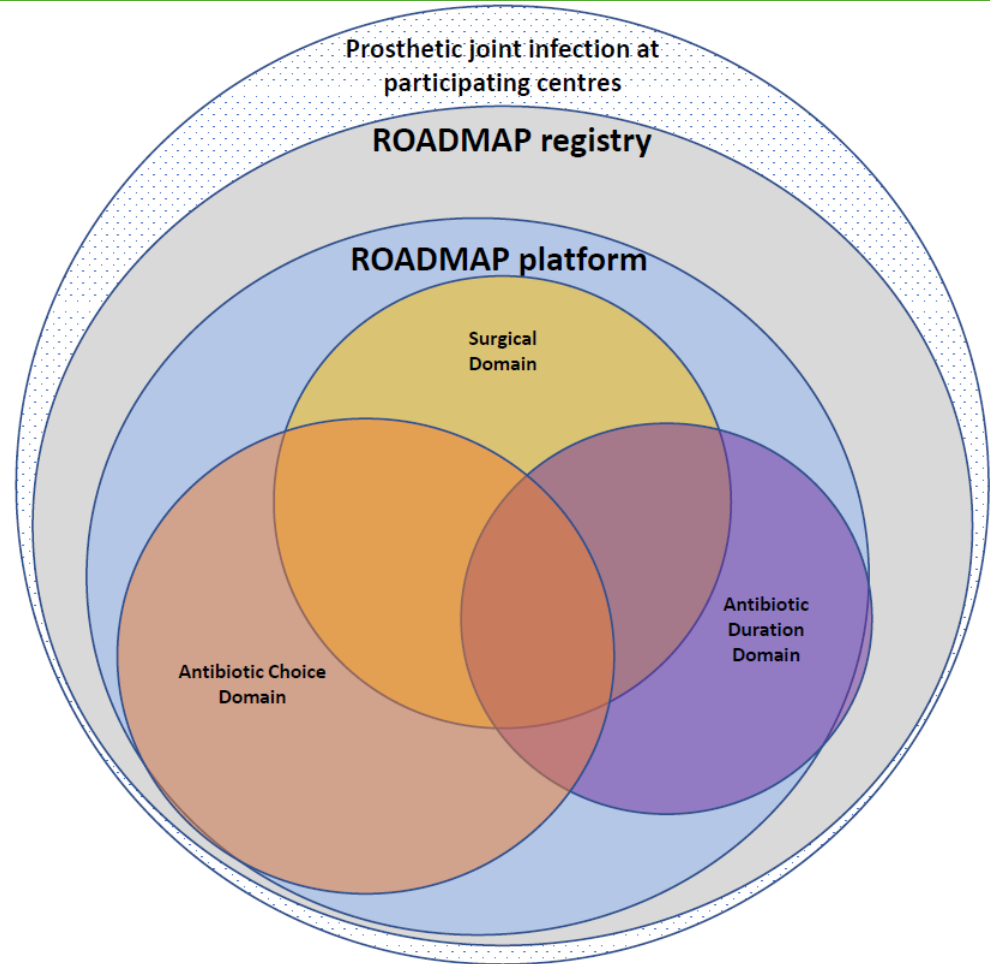
FIRST PATIENT RECRUITED - 17 FEBRUARY 2022

ROADMAP design

SILOS	DOMAINS		
	Surgical management	Antibiotic duration	Antibiotic type
Early PJI	Clinicians' choice (DAIR recommended)	For <u>DAIR</u> – Clinicians' choice	Backbone antibiotic regimen with
Late acute PJI	DAIR versus revision	(12 weeks recommended) <u>For one stage</u> : Total 6 weeks versus 12 weeks <u>For two-stage</u> – 7 days versus 12 weeks post 2 nd stage	<u>adjunctive rifampicin</u> versus Backbone antibiotics alone
Chronic PJI	Clinicians' choice (Revision recommended)		



- ❖ Nested within an observational registry
- ❖ Participants can be in one or more domains



Core eligibility criteria

❖ Inclusion

- “Current” PJI as per EBJIS criteria

❖ Exclusions

- 1) Known previous participation in the randomised ROADMAP platform for the index joint
- 2) Treating clinician believes that death is imminent and inevitable
- 3) Treatment is not with curative intent
- 4) Patient is not classifiable into one of the three defined silos
- 5) Unlikely to be accessible for follow up over the 12 months following platform entry
- 6) Treating team deems enrolment to any domain of the platform is not in the best interests of the patient

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

Core secondary outcome measures

1. A “desirability of outcome ranking”
2. Patient-reported joint function (Oxford hip or knee score) at 12 months.
3. Patient-reported quality of life (EQ5D5L) at 12 months.
4. Direct health care costs.
5. All-cause mortality at 12 months after platform entry.
6. Microbiological relapse
7. Microbiological reinfection

Rank	Alive	Joint Function	Treatment Success	QoL
1	Yes	Good	Yes	Tiebreaker based on the EQ5D5L
2	Yes	Good	No	
3	Yes	Poor	Yes	
4	Yes	Poor	No	
5	No	N/A	N/A	

Enjeux Réflexions

- ❖ Ne pas regarder le train passer
- ❖ Positionnement européen
- ❖ Prioriser les essais français en cours
- ❖ Accès aux données françaises
- ❖ Challenger certaines pratiques

Premiers échanges avec 17 centres

- ❖ Amiens
- ❖ Besançon
- ❖ Bordeaux
- ❖ Brest
- ❖ Cochin AP-HP
- ❖ Lyon
- ❖ Marseille
- ❖ Nancy
- ❖ Nantes
- ❖ Nice
- ❖ Poitiers
- ❖ Raymond-Poincaré AP-HP
- ❖ Rennes
- ❖ Strasbourg
- ❖ Toulouse
- ❖ Tourcoing Lille
- ❖ Tours

	Lettre d'intention	Dossier complet déposé	Résultats
PHRC-N 2024	✓	✓	?
ANRS-MIE	✓	✓	?



Merci

Table 2. Recommended “backbone” antibiotic therapy

	Intravenous phase	Oral phase
<i>Single pathogen</i>		
MSSA	Preferred - Cefazolin Alternate – (Flu)cloxacillin	Preferred - Cefalexin Alternate - Doxycycline
MRSA	Preferred - Vancomycin Alternate – Daptomycin	Preferred - Doxycycline Alternate - Cotrimoxazole