REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Australia and New Zealand
Co-enrolment and Competing Studies Policy

REMAP-CAP Co-enrolment and competing studies policy version 1 dated 26th November 2018

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1. CO-ENROLMENT

1.1. Permitted co-enrolment

In Australia and New Zealand co-enrolment is permitted with the following studies for the Antibiotic domain, corticosteroid domain and macrolide duration domain.

1.1.1. Unconditional co-enrolment

Intensive nutrition therapy compared to usual care in critically ill adults: A randomised pilot trial

Liberal glucose control in critically Ill patient with pre-existing type 2 diabetes (LUCID): a phase II multicentre randomised controlled trial

Pre-hospital anti-fibrinolytics for traumatic coagulopathy and haemorrhage

Paramedic Antibiotics for Severe Sepsis: a phase 2 study of pre-hospital intravenous ceftriaxone in patients with severe sepsis

The Plasma-Lyte 148® vs Saline study

Randomised evaluation of active control of temperature vs. ordinary temperature management

STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre, Randomized, Controlled Trial

A cluster randomised controlled trial of the clinical effectiveness and cost-effectiveness with a contemporaneous study of the ecological impact of selective decontamination of the digestive tract in critically ill patients treated in intensive care units

Treatment of invasively ventilated adults with early activity and mobilisation

Prophylactic Melatonin for Delirium in Intensive Care

1.1.2. Conditional co-enrolment

Co-enrolment between these studies is permitted with the following guidance.

1.1.2.1. BALANCE RCT

Bacteremia Antibiotic Length Actually Needed for Clinical Effectiveness: A Pilot RCT

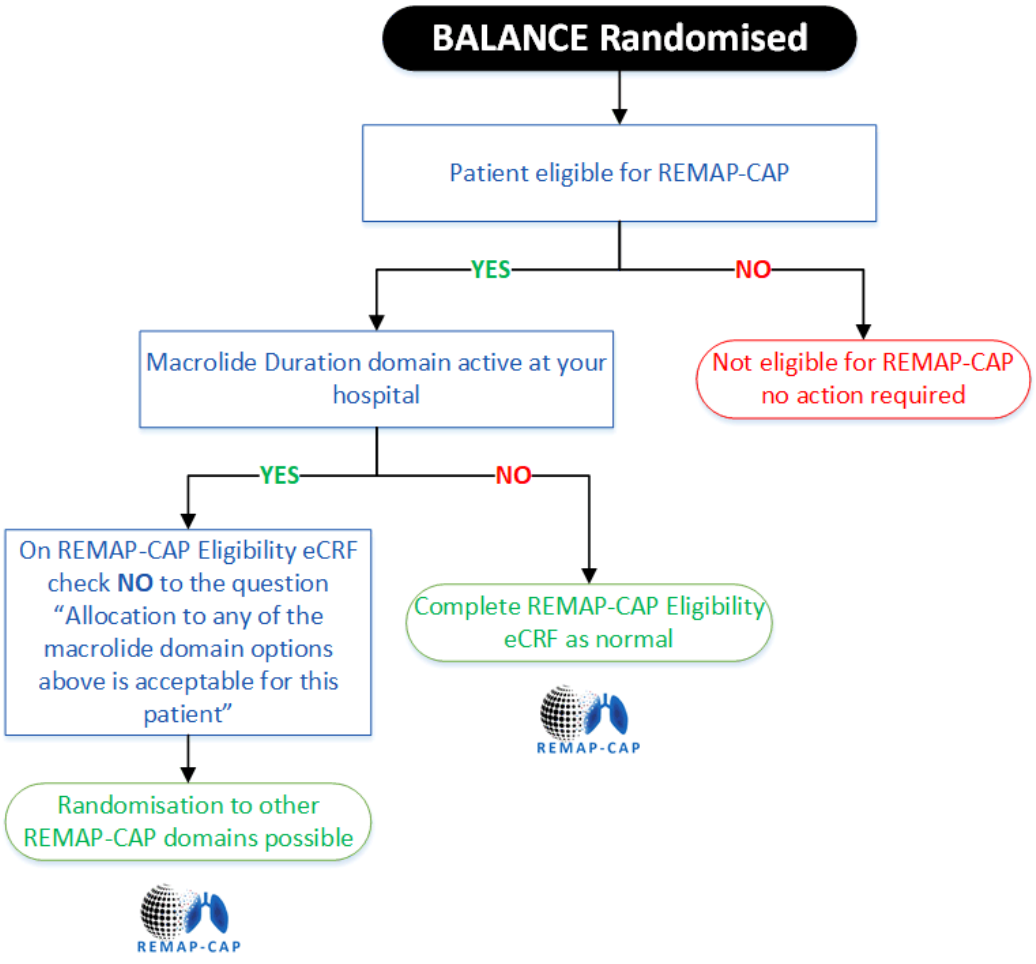
To co-enrol a patient in **BALANCE and REMAP-CAP** refer to the following figures as appropriate.

1. Participant randomised to BALANCE – possible REMAP-CAP domain(s) participation

Possible REMAP-CAP Domain eligibility

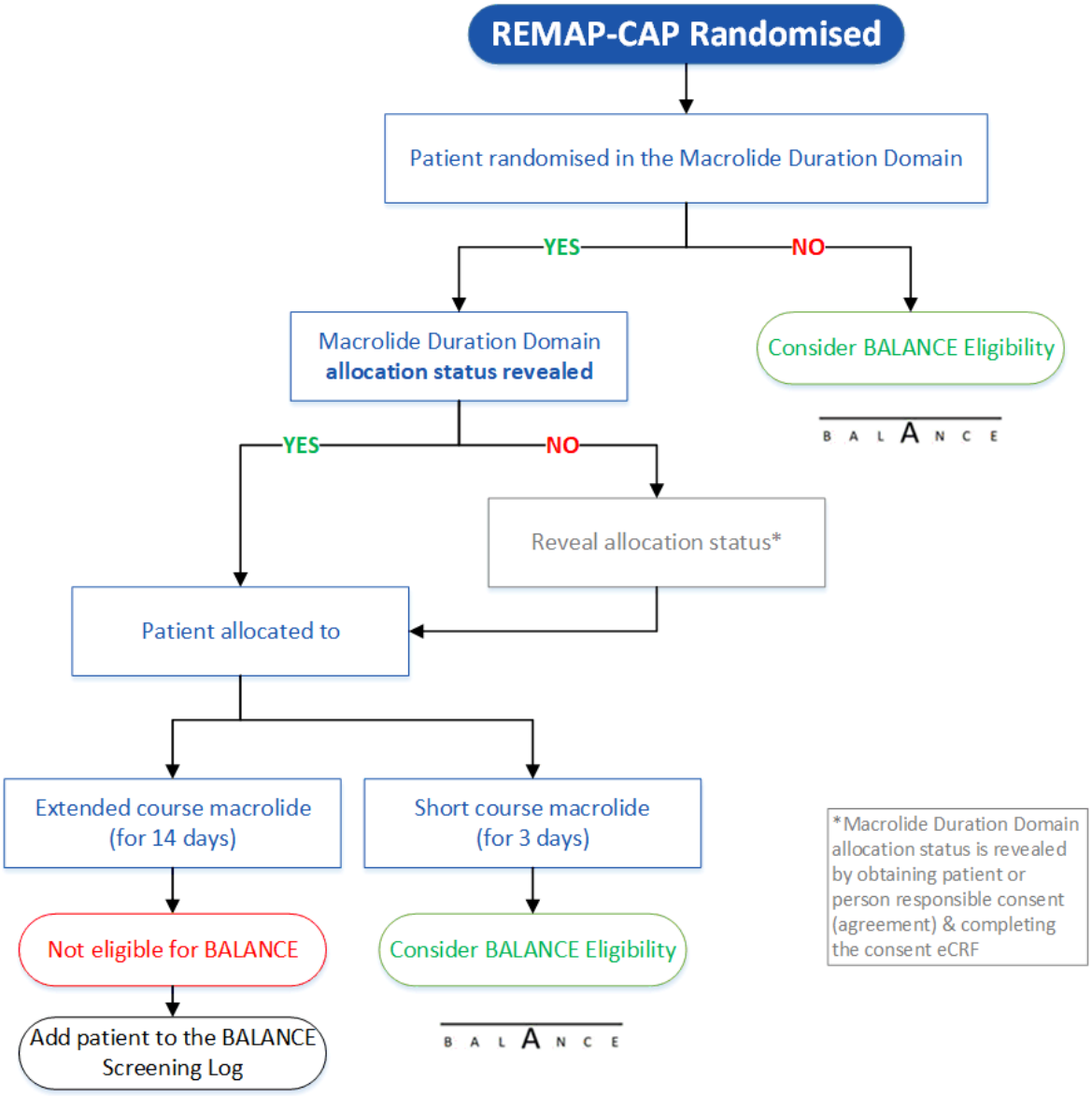
- Co-enrolment **is not permitted** in the Antibiotic and the Macrolide Duration Domains.
- Co-enrolment **is permitted** in the Corticosteroid Domain.

Figure 1: BALANCE participant considering REMAP-CAP eligibility



2. *Participant randomised to REMAP-CAP – possible BALANCE participation*

Figure 2: REMAP-CAP participant considering BALANCE eligibility



1.1.2.2. BLING III

BLING III

A phase III randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients

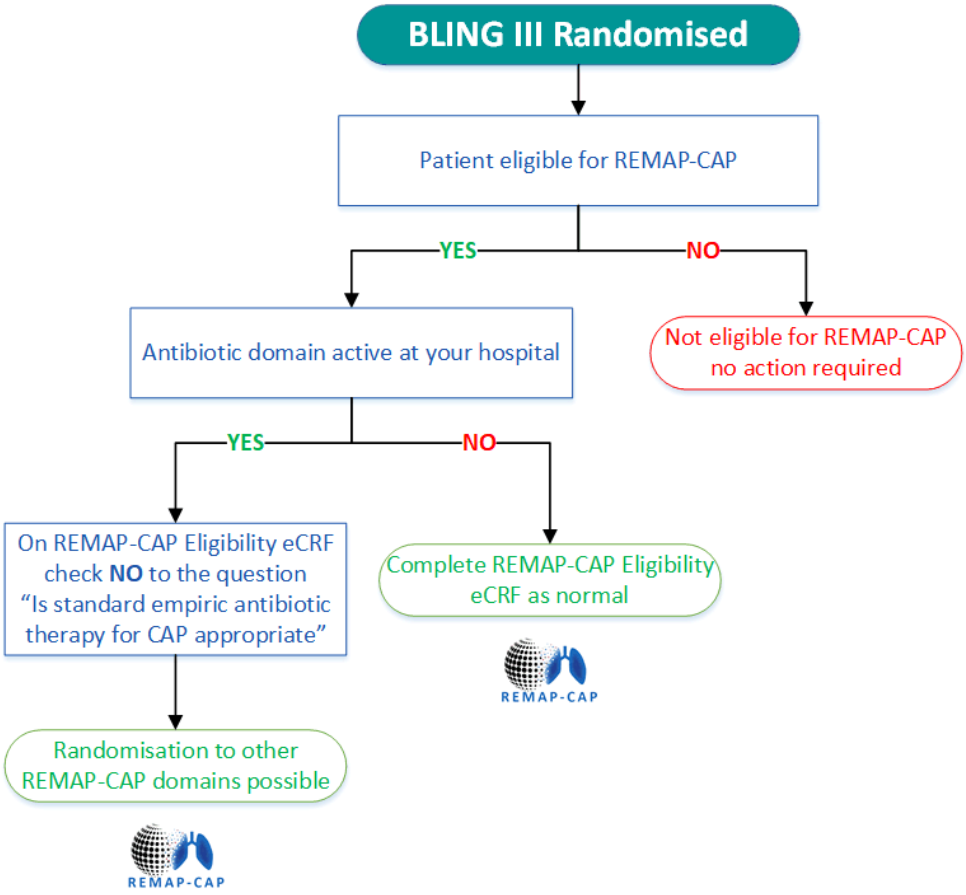
To co-enrol a patient in **BLING III and REMAP-CAP** refer to the following figures as appropriate.

1. Participant randomised to BLING III – possible REMAP-CAP domain(s) participation

Possible REMAP-CAP Domain eligibility

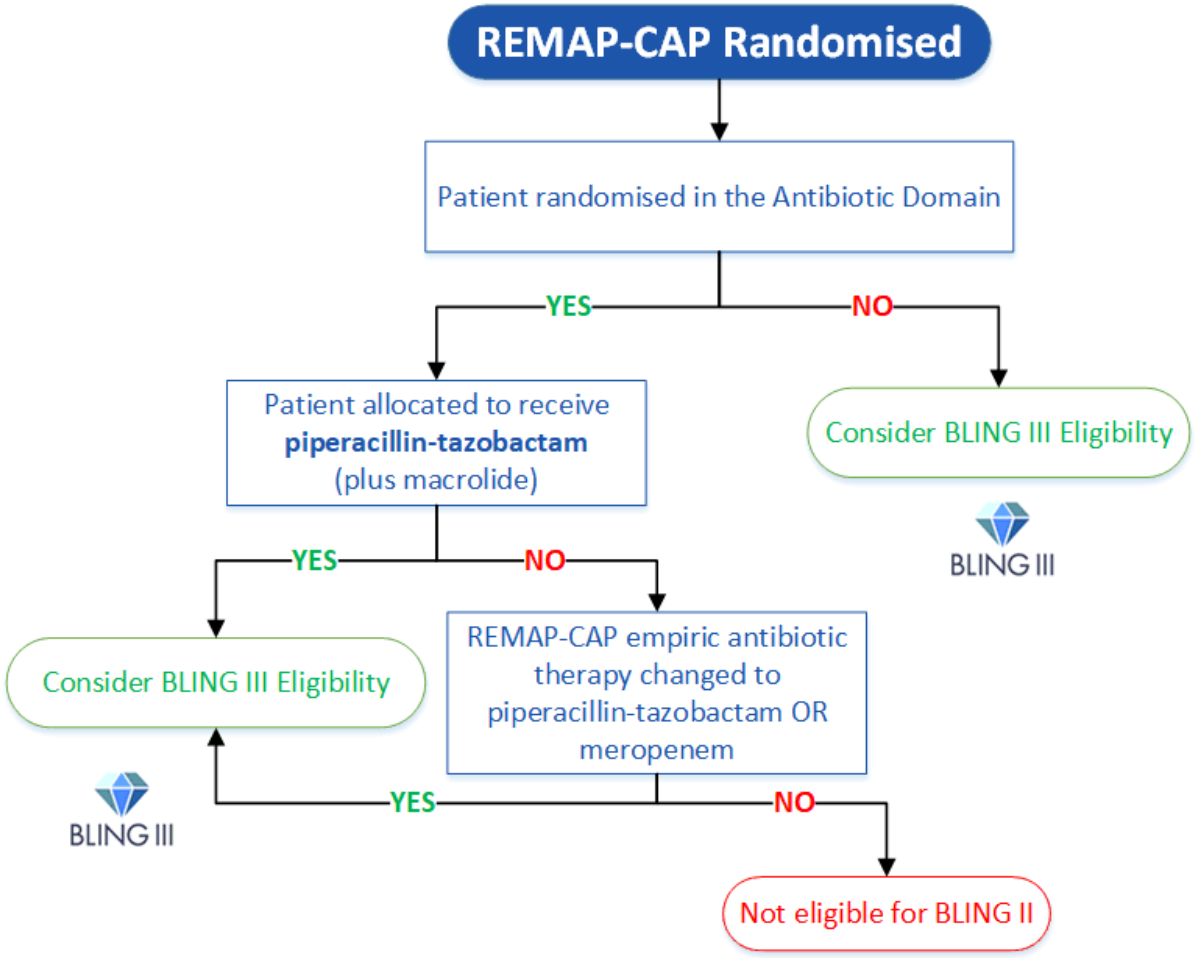
- Co-enrolment **is not permitted** in the Antibiotic and the Macrolide Duration Domains.
- Co-enrolment **is permitted** in the Corticosteroid Domain.

Figure 3: BLING III participant considering REMAP-CAP eligibility



2. *Participant randomised to REMAP-CAP – possible BLING III participation*

Figure 4: REMAP-CAP participant considering BLING III eligibility



1.1.2.1. VITAMINS Trial

VITAMINS Trial

The Vitamin C, Hydrocortisone and Thiamine in patients with septic shock trial (A Prospective, Feasibility, Pilot, Multicentre, Randomised, Open label controlled Trial)

1. *Participant randomised to VITAMINS Trial – possible REMAP-CAP domain(s) participation*

Possible REMAP-CAP Domain eligibility

- Co-enrolment **is not permitted** in the Corticosteroid Domain.
- Co-enrolment **is permitted** in the Antibiotic and the Macrolide Duration Domains.

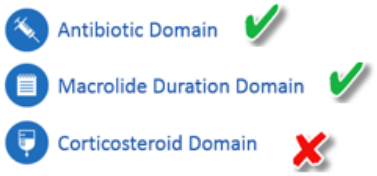
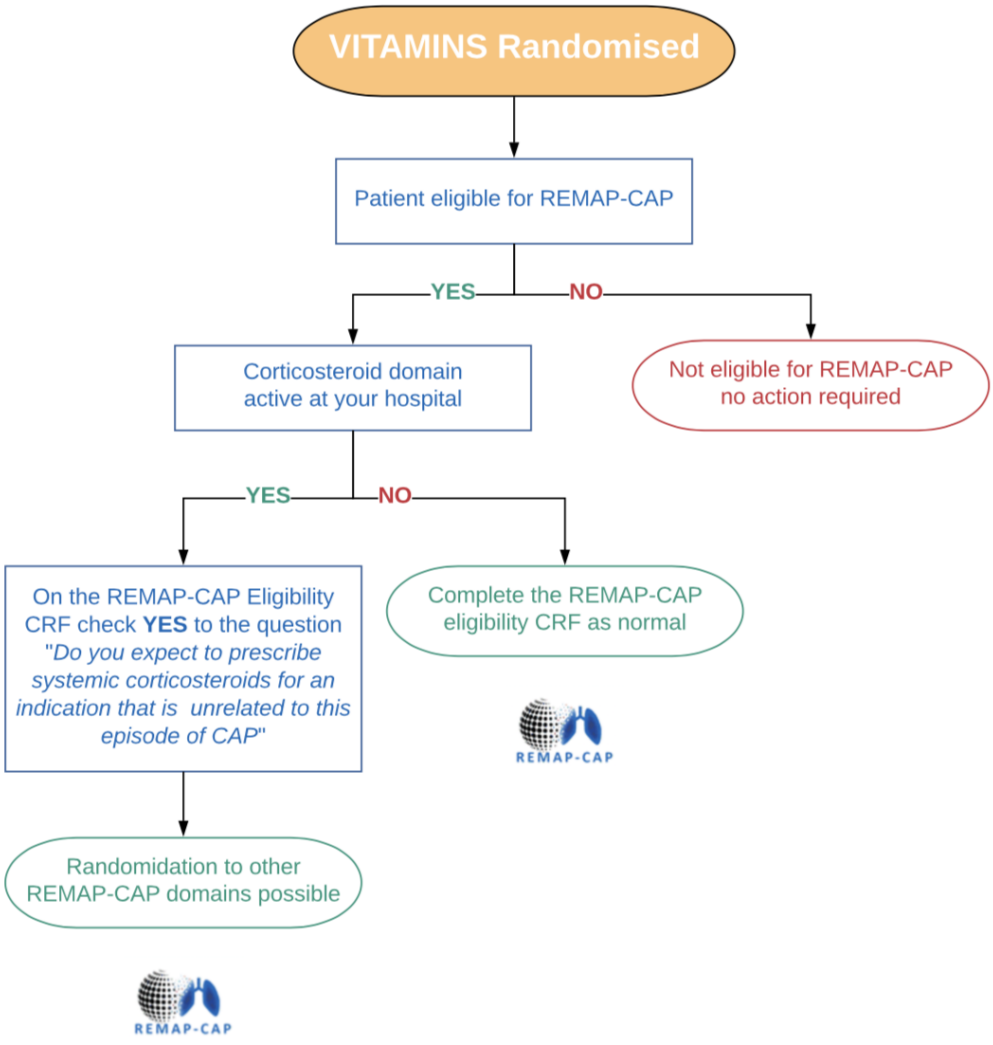
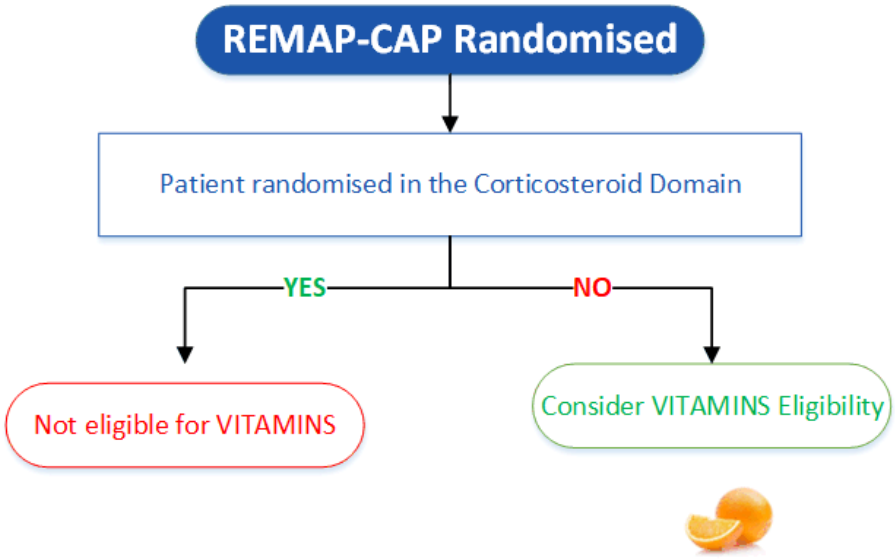


Figure 5: VITAMINS participant considering REMAP-CAP eligibility



2. *Participant randomised to REMAP-CAP – possible VITAMINS participation*

Figure 6: REMAP-CAP participant considering VITAMINS eligibility



1.1.3. Co-enrolment not considered

The following Australia and New Zealand Intensive Care Society – Clinical Trials Group (ANZICS-CTG) studies were not reviewed for co-enrolment. The study was either consider to be a study design which would not impact on co-enrolment or the REMAP-CAP Australia and New Zealand Regional Management Committee (ANZ RMC) considered it unlikely that a patient would be eligible for both studies.

ADRENAL Consent Substudy	A multicentre, prospective, observational study of the process of obtaining consent from potential participants or their substitute decision-makers in the adjunctive corticosteroid treatment in critically ill patients with septic shock (ADRENAL) Study
REACT Shock Study	Relative hypotension and acute kidney injury in patients with shock: A prospective multicentre cohort study
REVISE	The re-evaluating the inhibition of stress erosions trial
SPRINT-SARI	Short Period Incidence Study of Severe Acute Respiratory Infection
TAME	Targeted therapeutic mild hypercapnia after resuscitated cardiac arrest: A phase III multi-centre randomised controlled trial

1.2. Requesting co-enrolment

Prior to co-enrolling a REMAP-CAP participant in another study (and vice-versa) please ensure it has been approved for co-enrolment. If unsure, contact your local project manager to discuss specific studies.

To submit a study for co-enrolment review, send the Study Protocol (or Synopsis is a protocol is not available) to your local project manager and request the ANZ RMC consider co-enrolment.