Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

13th July 2020

Agenda

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1. Introductions
2. Update on progress
3. Recruitment
4. Future plans
5. Q&A

Introductions

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- One of the central study team will talk to the agenda
- If you have questions please enter them into the “Q&A” on the right side of your screen.
- Questions may be answered directly or to the whole group

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PROGRESS UPDATE

Current trial design

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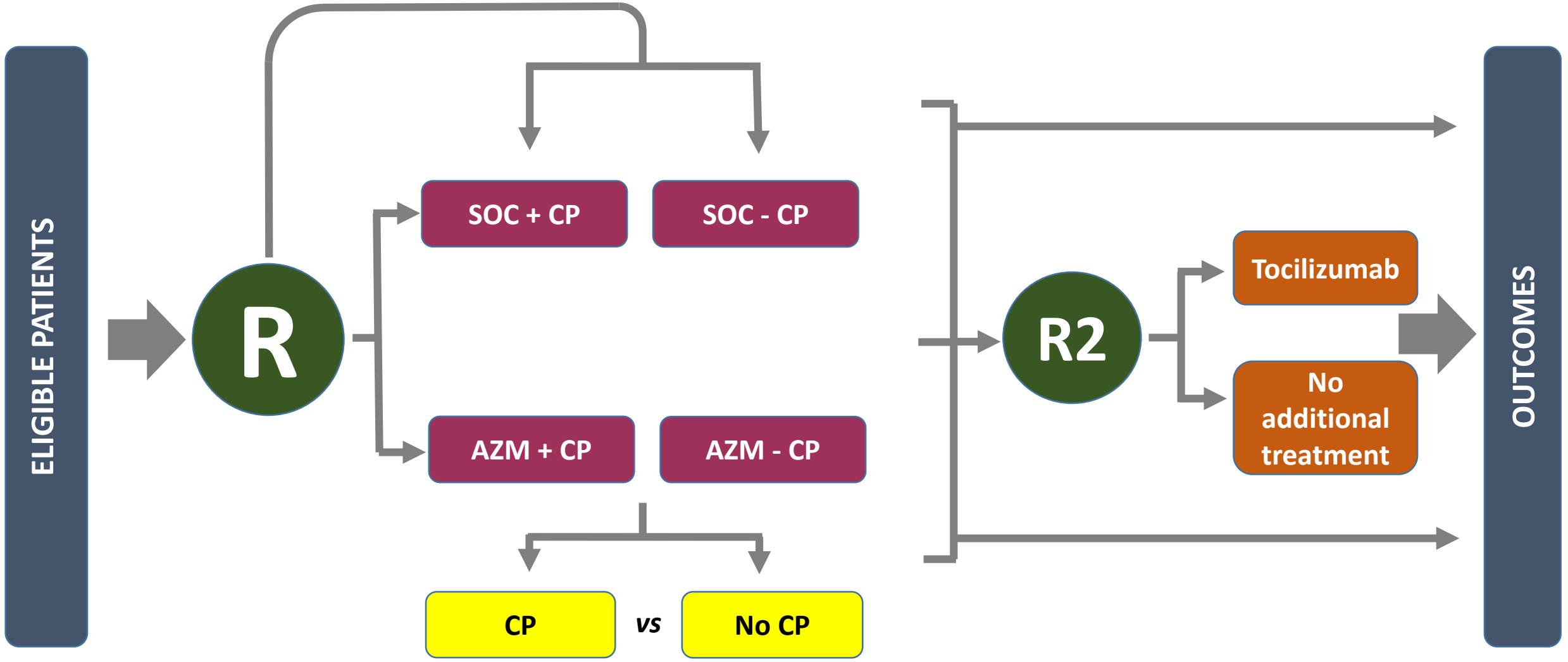

Recruitment by site and by time

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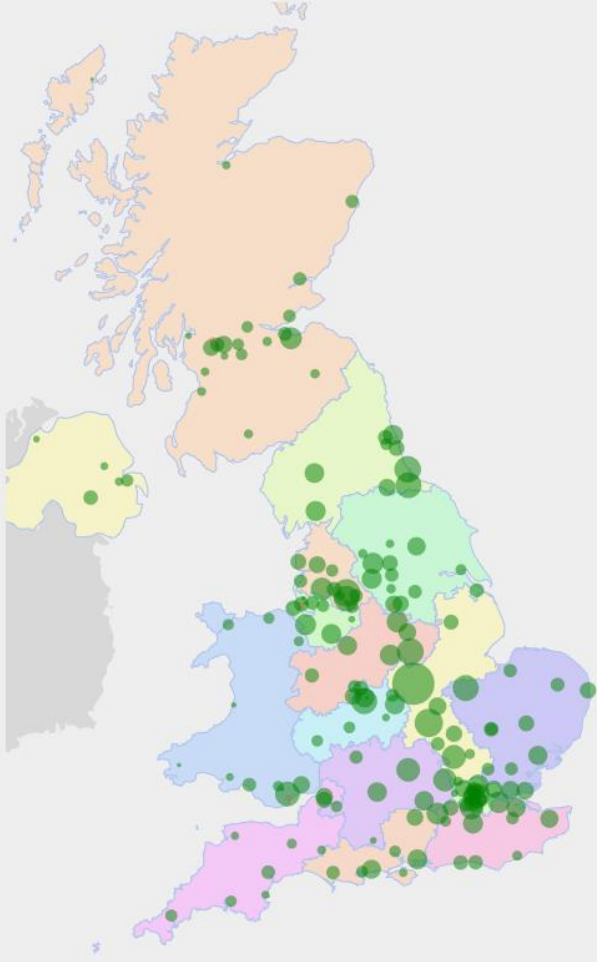
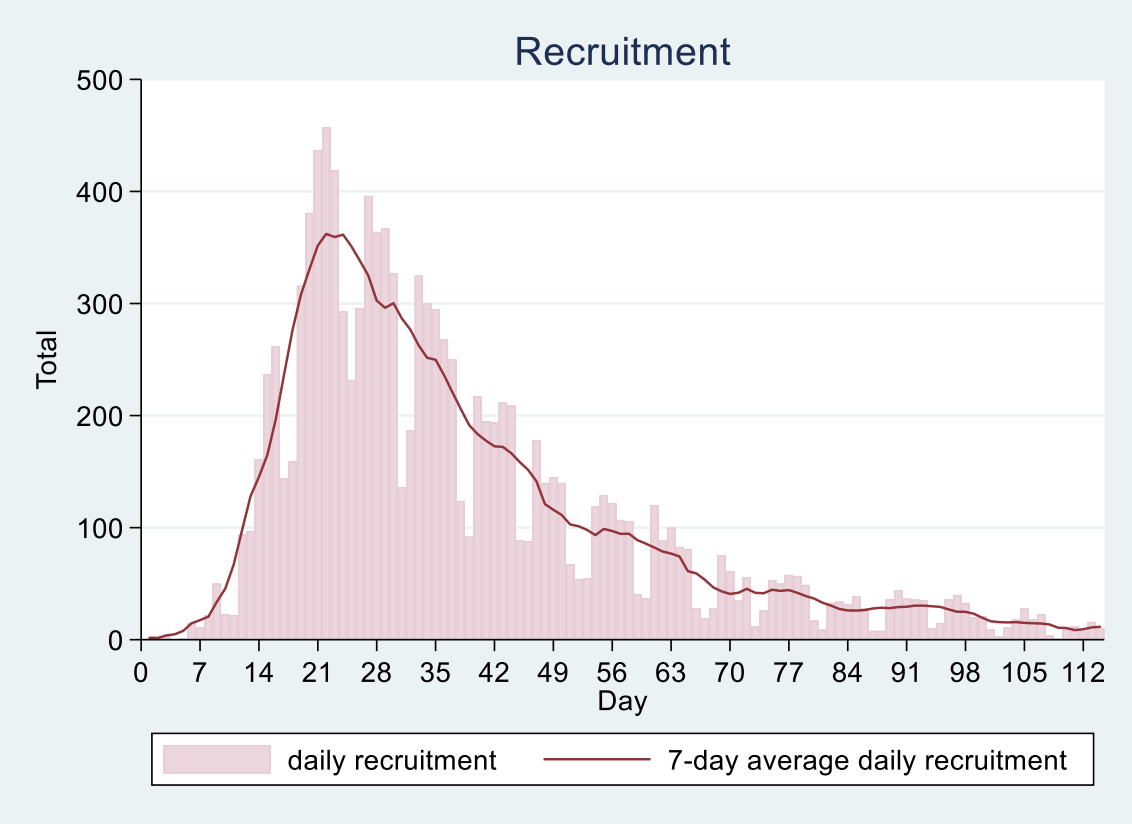
Active Sites	Recruiting Sites	Participants	Phase 2 rands.	Phase 3 rands.
176	172	12034	808	216





Recruitment proportion

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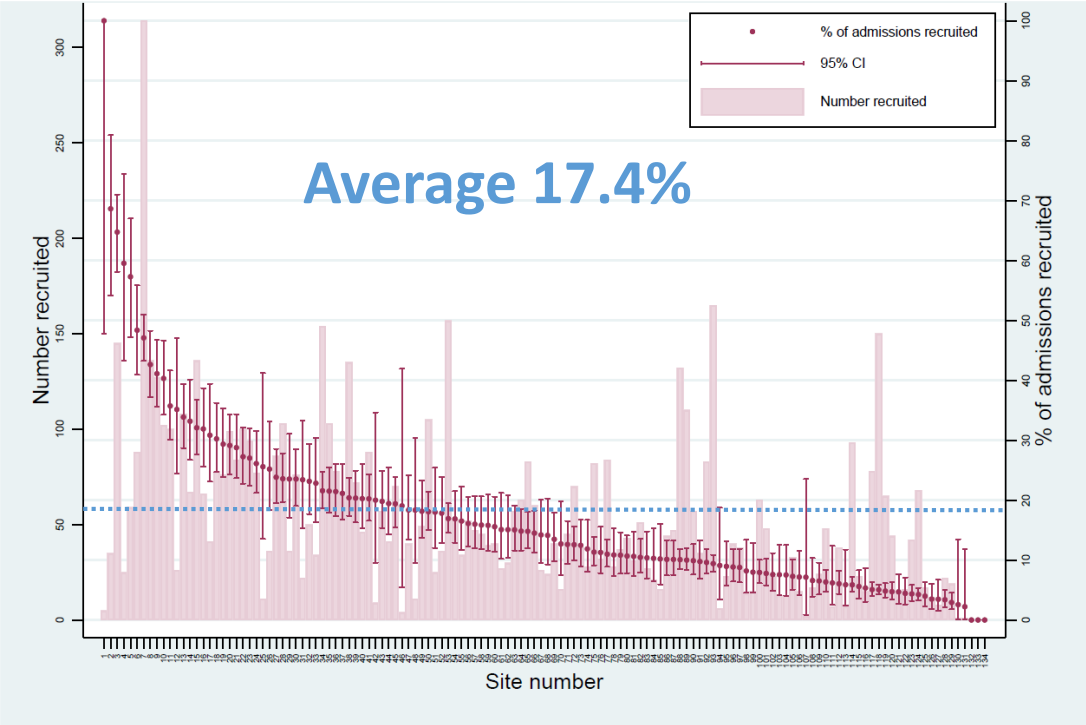
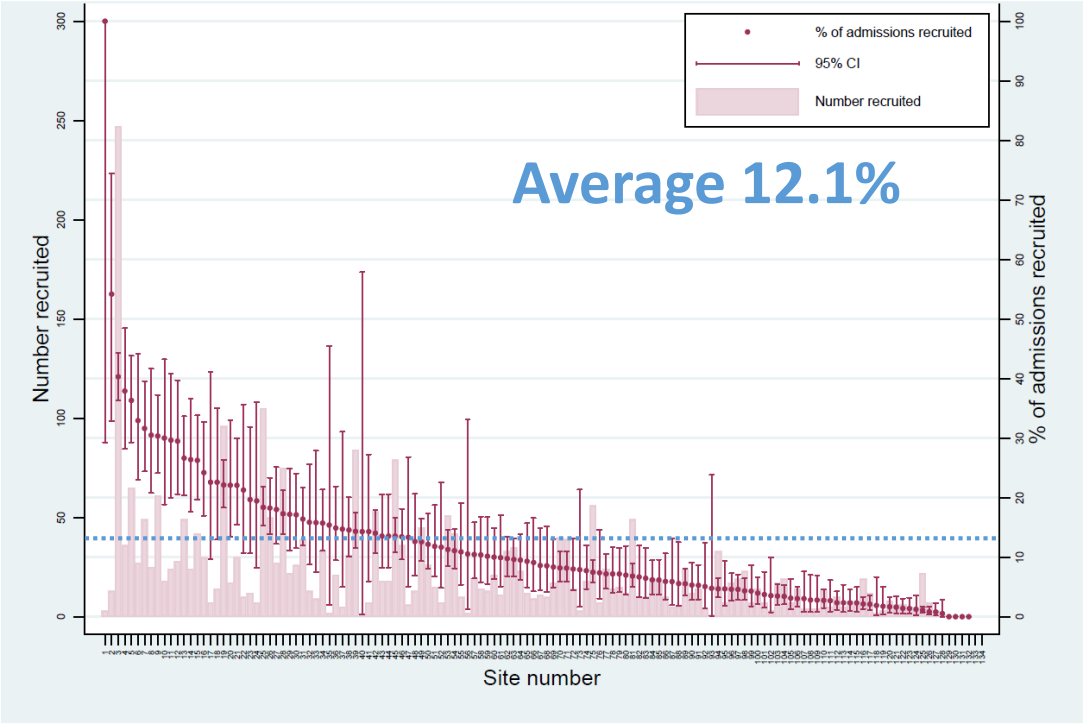
Proportion recruited 20 March – 30 April



Proportion recruited 30 April – 7 July



Recruitment proportion

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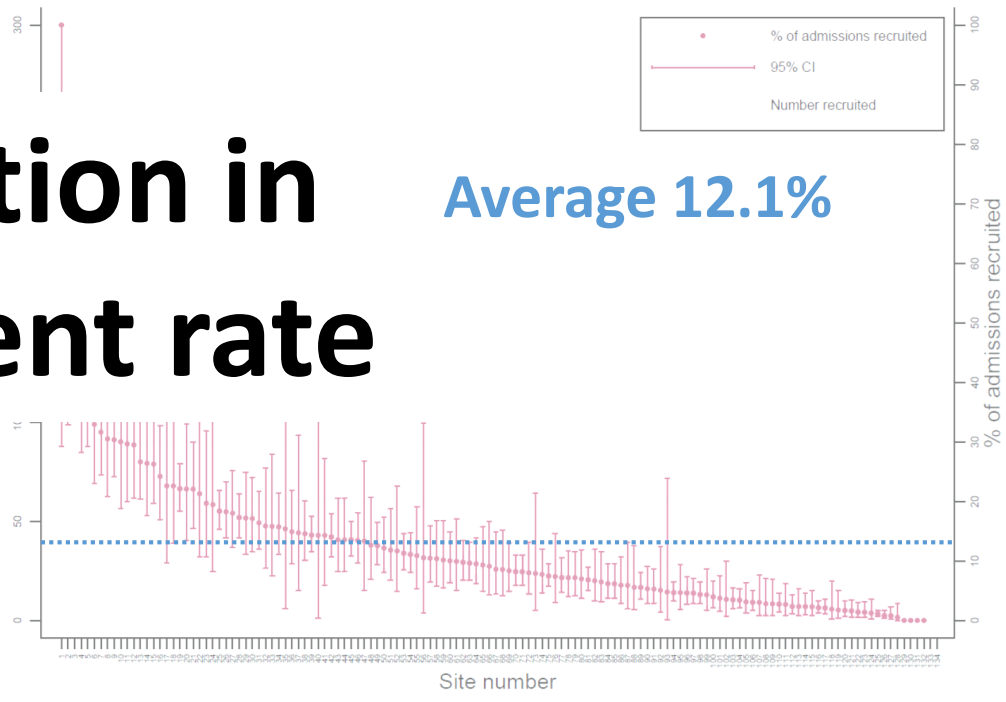
Proportion recruited 20 March – 30 April

Average 17.4%

⅓ reduction in recruitment rate

Proportion recruited 30 April – 7 July



Average 12.1%

Recruitment proportion: change in rate between two periods

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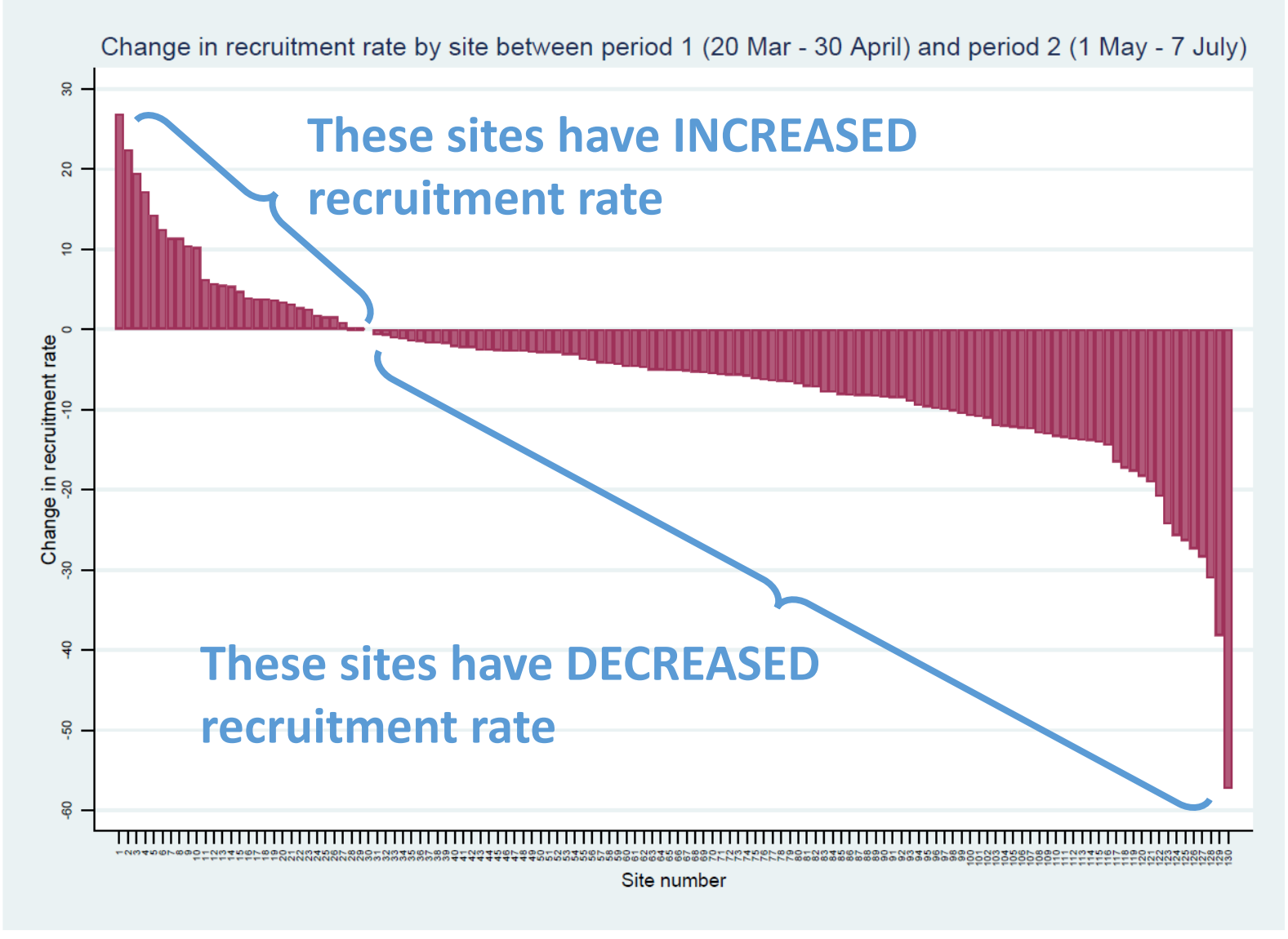

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TOCILIZUMAB

Tocilizumab

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- Added to protocol on 14 April as a second randomisation for deteriorating participants
  - Hypoxia (or significant systemic disease with persistent pyrexia in children)
  - Inflammation (CRP ≥75 mg/L)

- Two other tocilizumab trials due to present results at the end of July
  - COVACTA: Roche's own trial of 450 participants
  - BACC study: 243 participants

- If your site is not included yet but would like to be, please e-mail recoverytrial@ndph.ox.ac.uk

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FOLLOW-UP

Completeness is key

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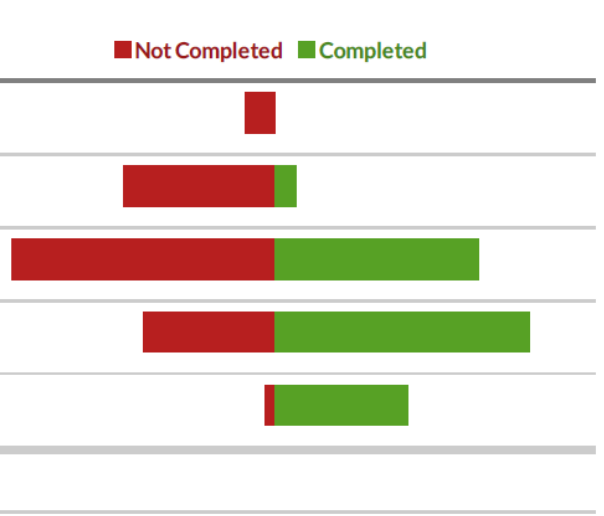
- Weekly reminders highlighting participants randomised >28 days ago without complete form **and also** those needing a Convalescent Plasma 72h safety form

- Please do complete these as soon as possible

Follow-up form completion summary

Days Since Rand.	FU Not Completed	FU Completed	Total Rands.
7 ≤ 14	3 (100.0%)	0 (0.0%)	3
14 ≤ 21	15 (88.2%)	2 (11.8%)	17
21 ≤ 28	26 (56.5%)	20 (43.5%)	46
28 ≤ 35	13 (34.2%)	25 (65.8%)	38
> 35	1 (7.1%)	13 (92.9%)	14
Total	**58 (49.2%)**	**60 (50.8%)**	**118**



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FUTURE PLANS

Current trial design

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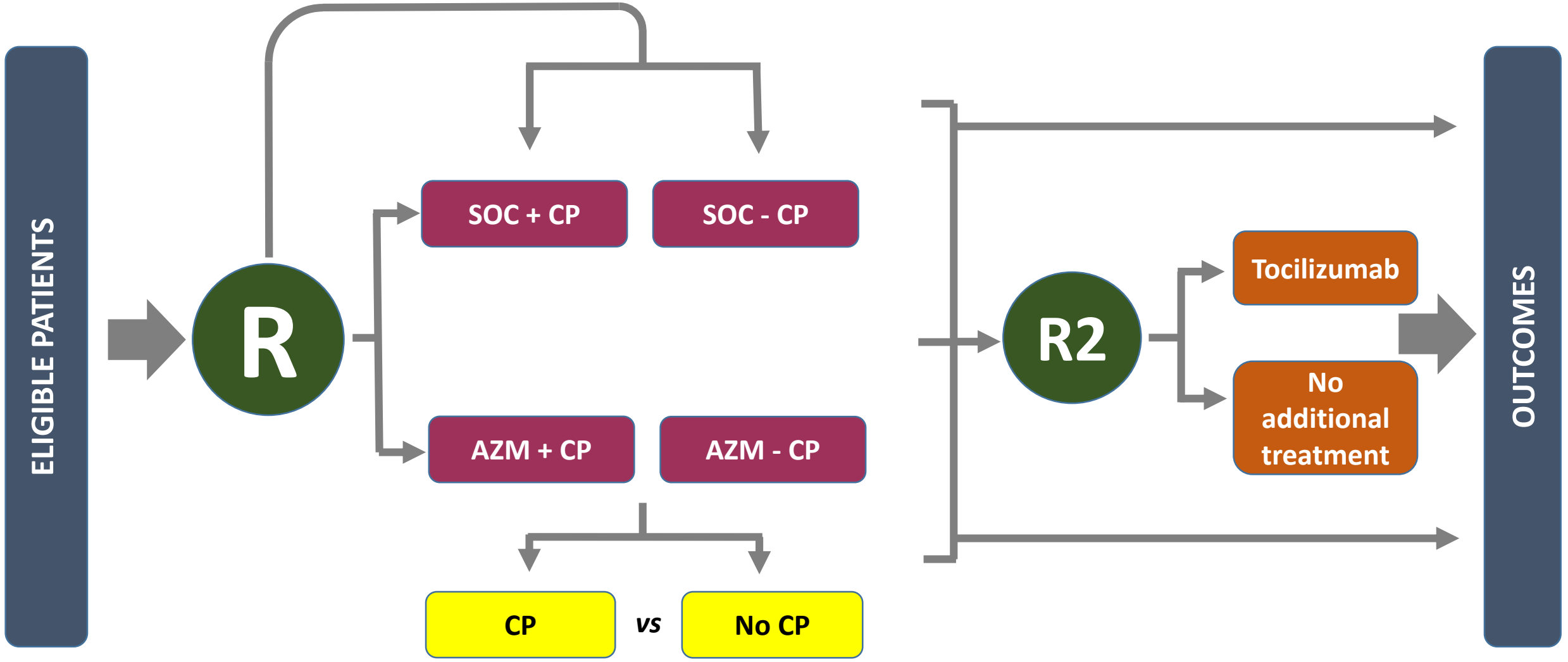

Protocol V8.0

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- Adds collection of serum sample at baseline for patients entering convalescent plasma comparison

- Standard serum sample (often ‘red top’) to be sent to transfusion laboratory **before** patient is randomised
- Will allow measurement of coronavirus and antibodies against it, to help assessment of effect of convalescent plasma

Protocol V8.0

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- Introduces treatments for PIMS-TS (Paediatric Multisystem Inflammatory Syndrome temporally associated with COVID-19)
  - High-dose methylprednisolone *vs*
  - intravenous immunoglobulin *vs*
  - usual care

Carry on recruiting!

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- Need to continue recruitment and collection of follow-up information to provide DMC with information about efficacy and safety of study treatments

- As admission rates fall, please focus efforts on recruiting as many admitted patients as possible

- Thank you!

RECOVERY - pregnancy

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Site teams

This page contains additional information for RECOVERY site team members. Follow these links for guidance on randomisat

RECOVERY Privacy Notice for Trial Staff

INTERVENTION INFORMATION

RECOVERY intervention sheet - dexamethasone (now only recruiting children)

RECOVERY intervention sheet - azithromycin

RECOVERY intervention sheet - tocilizumab

RECOVERY intervention sheet - assessing patients for risk of transfusion associated circulatory overload (TACO) prior to convalescent plasma transfusions

GUIDES FOR SPECIFIC PATIENT GROUPS

RECOVERY for paediatric patients

RECOVERY for patients with chronic kidney disease

RECOVERY for pregnant and breastfeeding women

RECOVERY for neonatal inclusion

RECOVERY and remdesivir

RECOVERY - pregnancy

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RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Catherine Williamson, Prof Marian Knight

	RECOVERY trial protocol	Adaption for pregnancy
Eligibility	Patients are eligible if all of the following are true: i. Hospitalised ii. SARS-CoV-2 infection iii. No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial	Same eligibility
Interventions	**First randomisation** • No additional treatment • Azithromycin • Convalescent plasma **Second randomisation** • Tocilizumab	Same interventions
Follow-up/ outcomes	Ascertained at the time of death or discharge or at 28 days after randomisation (whichever is sooner): ➢ Vital status (alive/ dead, with date and presumed cause of death, if appropriate) ➢ Hospitalisation status (inpatient/ discharged, with date of discharge, if appropriate) ➢ Use of ventilation (none/ previous/ ongoing, with days of use and type, if appropriate) ➢ Use of renal dialysis or haemofiltration (none/ previous/ ongoing)	Same follow-up and outcomes, with addition of UKOSS COVID-19 case number (for pregnancy and baby information) to allow later data linkage
		Adaptions for breastfeeding
		The same interventions should be used. UKOSS COVID-19 case number added if available.

RECOVERY - pregnancy

- 160 pregnancy leads identified, supported by research midwives
- Midwife champions on board

- 18 antenatal women recruited + more postnatal women

Carry on recruiting!

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- Thank you!