

RECOVERY and the NIHR Associate Principal Investigator Scheme



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Agenda

1. An introduction to RECOVERY
2. RECOVERY at the Bristol Royal Infirmary
3. How the Associate PI scheme works
4. Q&A

INTRODUCTION TO THE RECOVERY STUDY

RECOVERY



- RECOVERY is the UK national platform trial to investigate treatment of patients hospitalised for COVID-19
- Designed to be simple and to minimise disruption of busy clinical services
- Will deliver robust results which change clinical practice
 - e.g. dexamethasone is now standard care globally for hypoxic patients

Simple eligibility criteria



1. Hospitalised patient (of any age)
2. SARS-CoV-2 infection associated disease (clinically suspected or laboratory confirmed)
3. 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

Rapid randomisation procedure



- Online
- <5 minutes to complete
- Allocation delivered by prescription

Treating clinician

A1. Name of treating clinician

Patient details

A2. Patient surname

Patient forename

A3. NHS number

Tick if not available

A4. What is the patient's date of birth?

 / /

A5. What is the patient's sex?

Inclusion criteria

A6. Has consent been taken in line with the protocol?

If answer is No patient cannot be enrolled in the study

A7. Does the patient have proven or suspected SARS-CoV-2 infection?

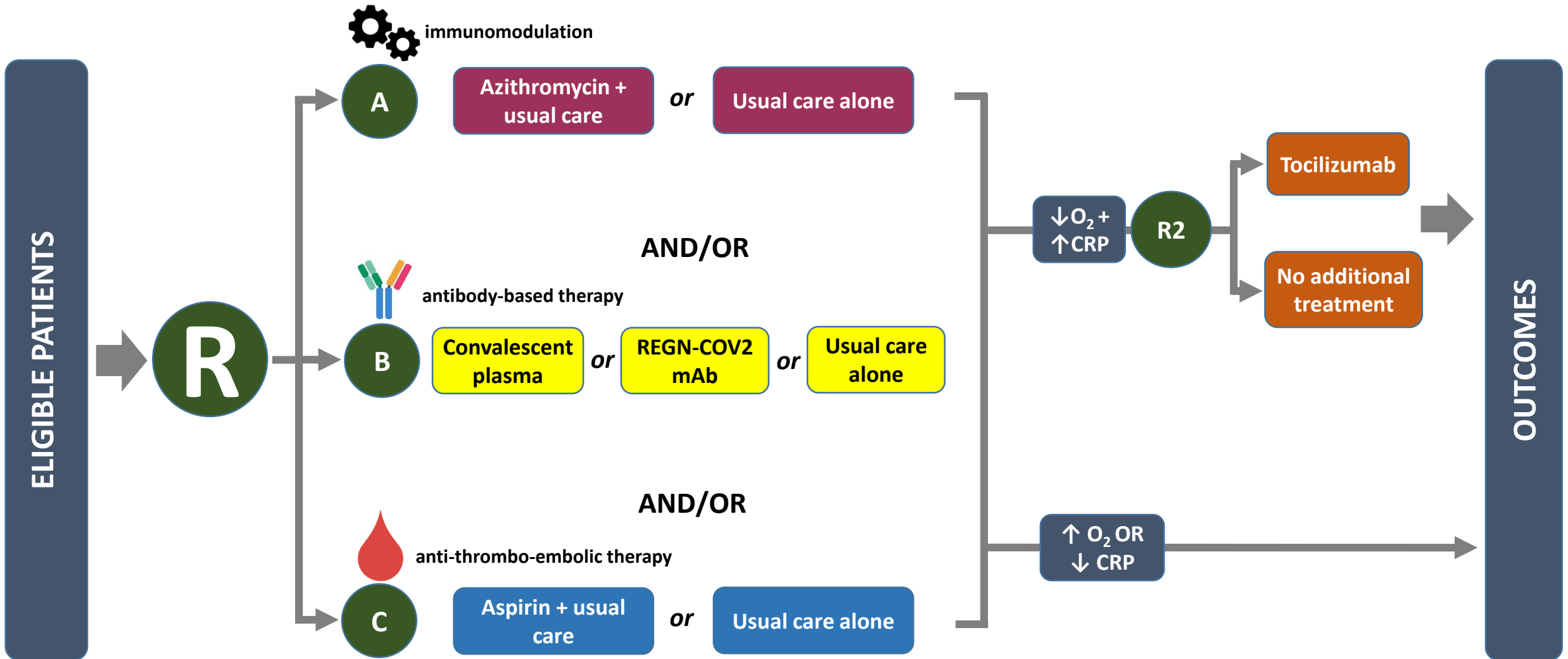
If answer is No patient cannot be enrolled in the study

A8. Does the patient have any medical history that might, in the opinion of the attending clinician, put the patient at significant risk if they were to participate in the trial?

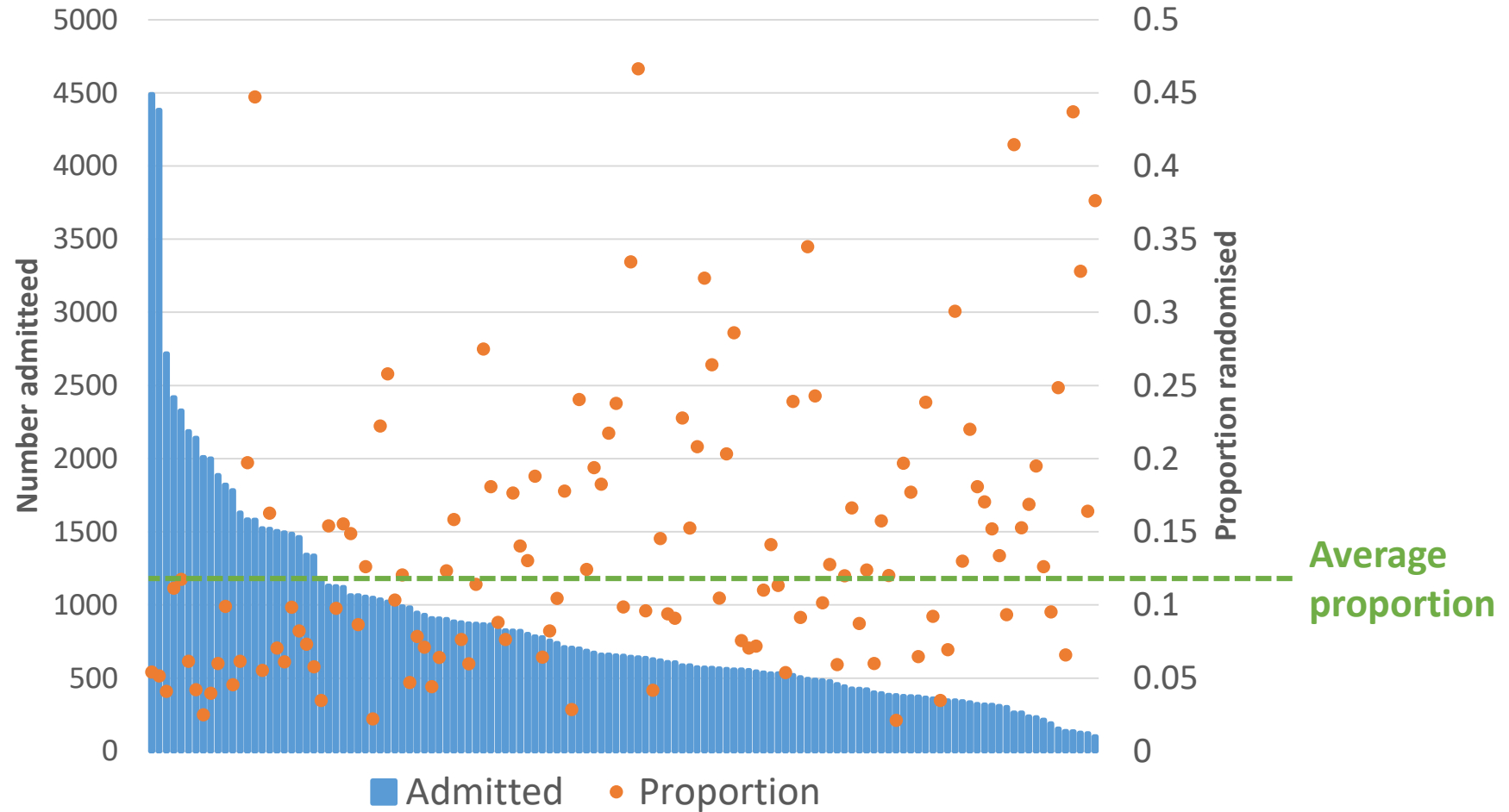
Follow-up

- Single case report form to be completed at earliest of death, discharge or 28 days after randomisation
- Simple outcomes:
 - Death
 - Need for ventilation
 - Major clinical events eg, significant cardiac arrhythmia, thrombotic event, bleed
 - Adherence with study treatment
- Some participants also require 72h early safety form (if in antibody-based treatment comparison)

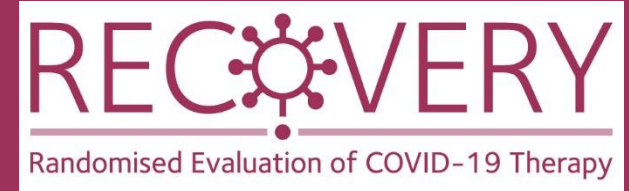
Design



Recruitment



Getting involved



- Volunteer to your local PI
- Complete relevant training online (<https://www.recoverytrial.net/for-site-staff/training>)
- Register for the Associate PI scheme

BRISTOL EXPERIENCE

Challenges

A silhouette of a person rappelling down a dark, jagged cliff face. The person is positioned in the upper left quadrant, holding a rope that extends vertically down the right side of the frame. The background is a soft, colorful sky transitioning from a pale yellow at the top to a deep purple at the bottom, suggesting a sunset or sunrise. The overall mood is one of challenge and perseverance.

- Rapidly adapting study design
- Rapidly developing situation
- Deployment of research staff
- Anxiety/uncertainty
- Patients on multiple wards/sites

1:1 recruitment training
Stepwise withdrawal of supervision



Recruitment of >50% of eligible
patients (mainly by junior doctors)



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Associate Principal Investigator Scheme

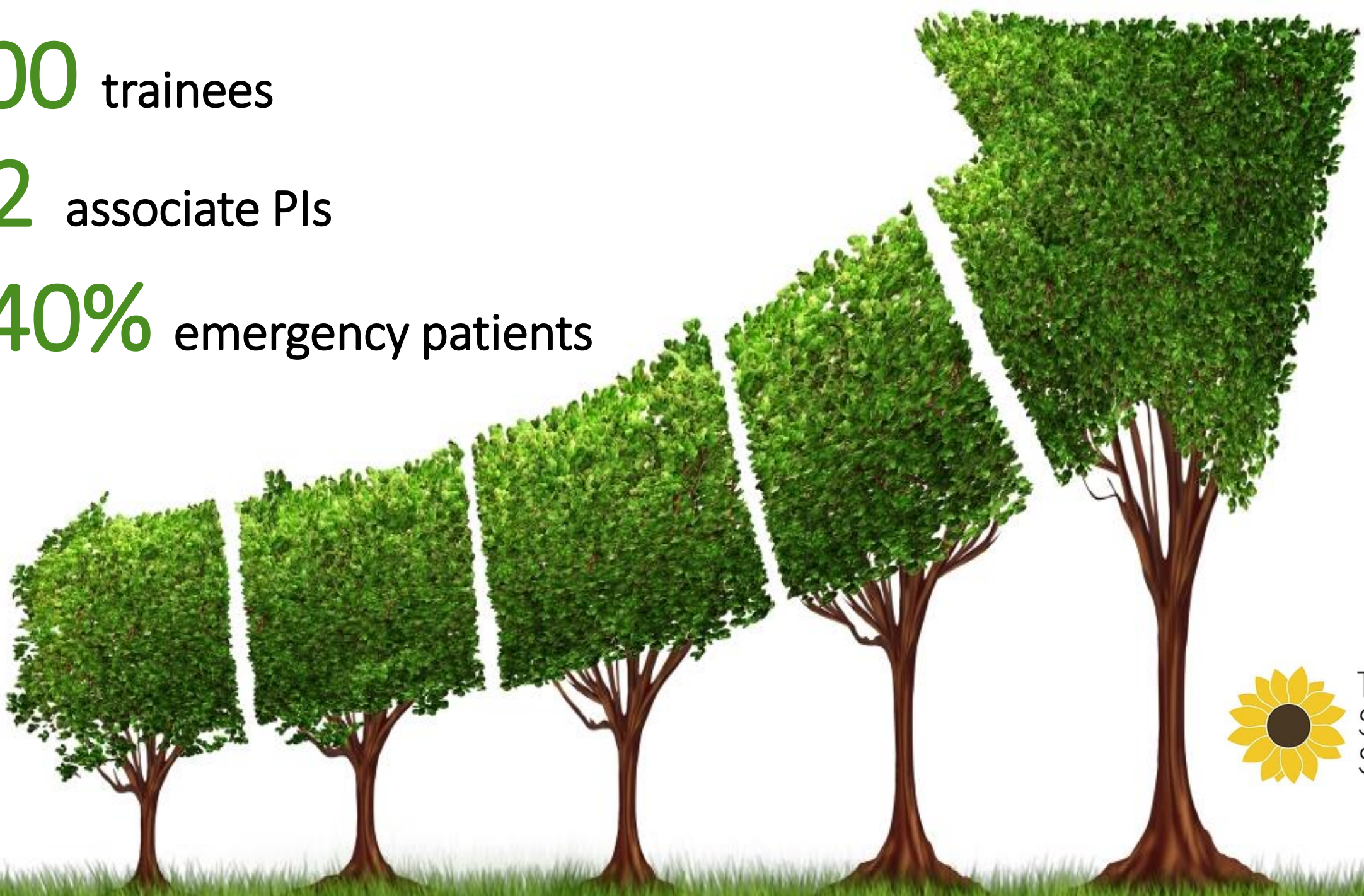
RECOVER

Randomised Evaluation of COVID-19 Therapy

100 trainees

52 associate PIs

>40% emergency patients



The
Sunflower
Study

Benefits

- Acquisition of research skills in short time
- Apprenticeship in research
- Develop leaders of the future
- Leadership/research role for CV





NIHR ASSOCIATE PI SCHEME



Associate PI Scheme



Jon Wadsley
National Speciality Lead (cancer, surgery
and oral and dental)

Associate PI Scheme- Background

- Developed by the West Midlands Research Collaborative, Birmingham Surgical Trials Consortium, Birmingham Clinical Trials Unit and the West Midlands NIHR Clinical Research Network.
- Being actively rolled out to other specialties
- Endorsed by the NIHR Clinical Research Network and the following Royal Colleges - RCS(England), RCP , RCR, RCEM, RCoA

Associate PI Scheme – Mission Statement

- To develop junior doctors, nurses and allied health professionals to be PIs of the future.
- To increase opportunities for patients to be involved in high quality research to improve care.
- To engage, recognise and promote junior doctor, nurse and allied health professional engagement in NIHR portfolio research.

Associate PI Scheme - Aims

- To integrate clinical research as part of routine clinical training.
- To develop a structure for junior doctors, nurses and allied health professionals to gain experience in local leadership of clinical trials, supported by mentors.
- To recognise junior doctor, nurse and allied health professional engagement in a standardised and consistent manner across all NIHR portfolio trials.

Associate PI Scheme - Structure

- Open to any junior doctor (FY1-St8 or equivalent) willing to make a significant contribution to the conduct and delivery at a local level.
- For the RECOVERY study there may be more than one Associate PI per site at any given time, but no more than one per specialty and only on agreement with the PI.
- Participation in the Associate PI Scheme does not absolve local PIs of their responsibilities at site.
- Commitment of at least 6 months will be required for gaining Associate PI status.
- **Must register prospectively- retrospective recognition is not possible**

Associate PI Scheme - Process

- Applicants complete a registration form, checked with the PI and Study Coordinator.
- Checklist completed during their (6 month) rotation.
- Signed off by Local PI and Study Coordinator.
- NIHR CRN issue a certificate confirming Associate PI status.
- In the RECOVERY study everyone who randomises a participants gets an acknowledgment in publication.

The Associate PI Scheme - Checklist

- Signature on study-specific delegation log?
Dissemination to the department.
- Engagement with staff, research team meetings (Diary of research team meetings)
- Site log, protocol amends, data returns and quality
- Train staff (GCP, protocol)
- Screening logs, recruitment/consent of patients
- Deputising for PI
- PPI activities

How to register

- Go to website - https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040#Step_2 - Register yourself - Register yourself (the RECOVERY study already registered)
- Complete registration form



Associate PI Scheme - Applicant Registration Form

This form should be completed by applicants wishing to register for the Associate PI scheme. The scheme has been endorsed by the NIHR Clinical Research Network and the following Royal Colleges:

- Royal College of Surgeons (England)
- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Emergency Medicine
- Royal College of Anaesthetists

For further details about the scheme please visit the Associate PI Scheme website (<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>)

Associate Principal Investigator (PI) Scheme

The NIHR Associate Principal Investigator (PI) scheme aims to develop junior doctors, nurses and allied health professionals to become the PIs of the future at the same time as helping to deliver studies to time and target. Registration is quick and easy, just follow the steps below.

Register study

● Check if the study you want to register to be Associate PI for is on the [list of registered studies](#). If not then complete the [Associate PI Scheme Study Registration Form](#).

Register yourself

● Register to the scheme by completing the [API Scheme Applicant Registration Form](#) once you have approval from the Site PI and CTU Study / Trial Manager

Complete Checklist

● Once you are registered to the scheme you will be sent a welcome email with a link to the [Associate PI Scheme Checklist](#) which you need to complete and get signed off by your PI and the CTU Study / Trial Manager within six months of registering to the scheme.

Receive certificate

● Once you have submitted your fully signed off Checklist the NIHR Associate PI Scheme Team will issue you with a certificate. You are then free to register to another study at the same or another site.

For further information about the scheme, please visit the [NIHR Associate PI Scheme](#) website.

If you have any questions about the scheme please email the NIHR Associate PI Scheme Team on associatepischeme@nihr.ac.uk.

Website -

<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>

Email:

associatepischeme@nihr.ac.uk

Frequently Asked Questions:

<https://www.nihr.ac.uk/documents/associate-pi-scheme-faqs/11698>

Many thanks for your attention.

**Please enter any questions into the
Q&A box.**

We look forward to working with you!