Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

14th & 15th September 2020

Agenda

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1. Introductions
2. Update on progress
3. Protocol V9.0
4. Future plans
5. Q&A
6. Pregnancy update
7. 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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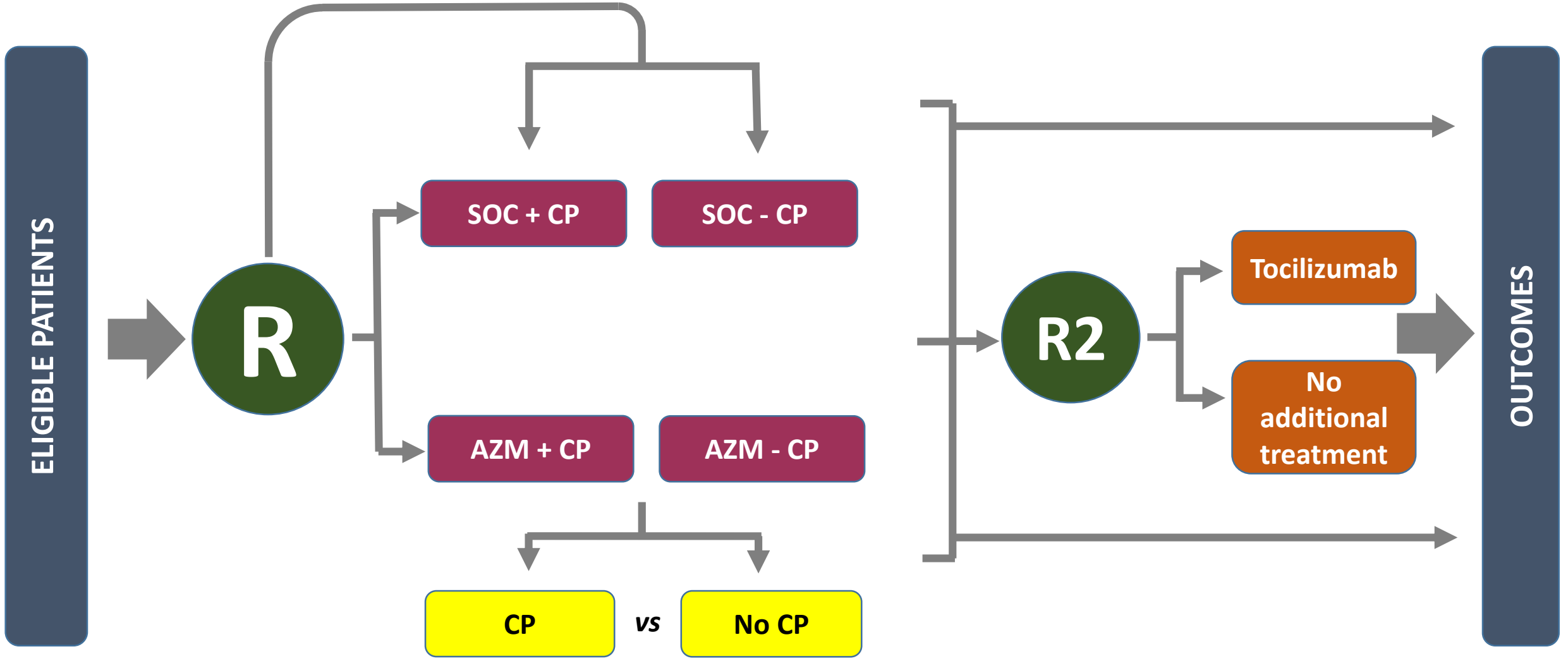

Recruitment by site and by time

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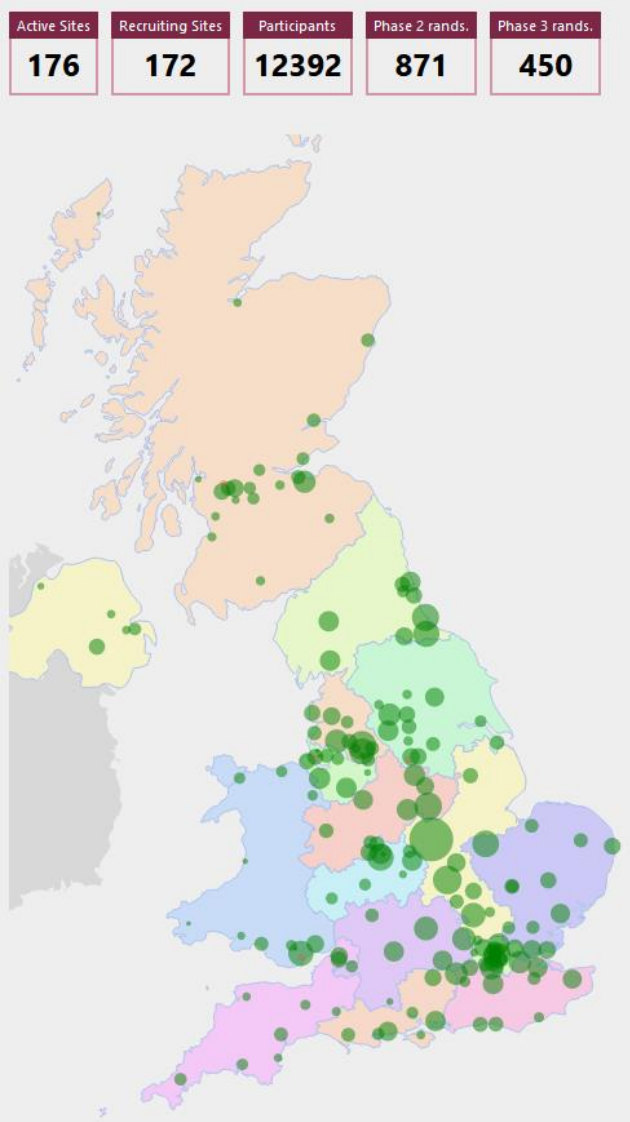

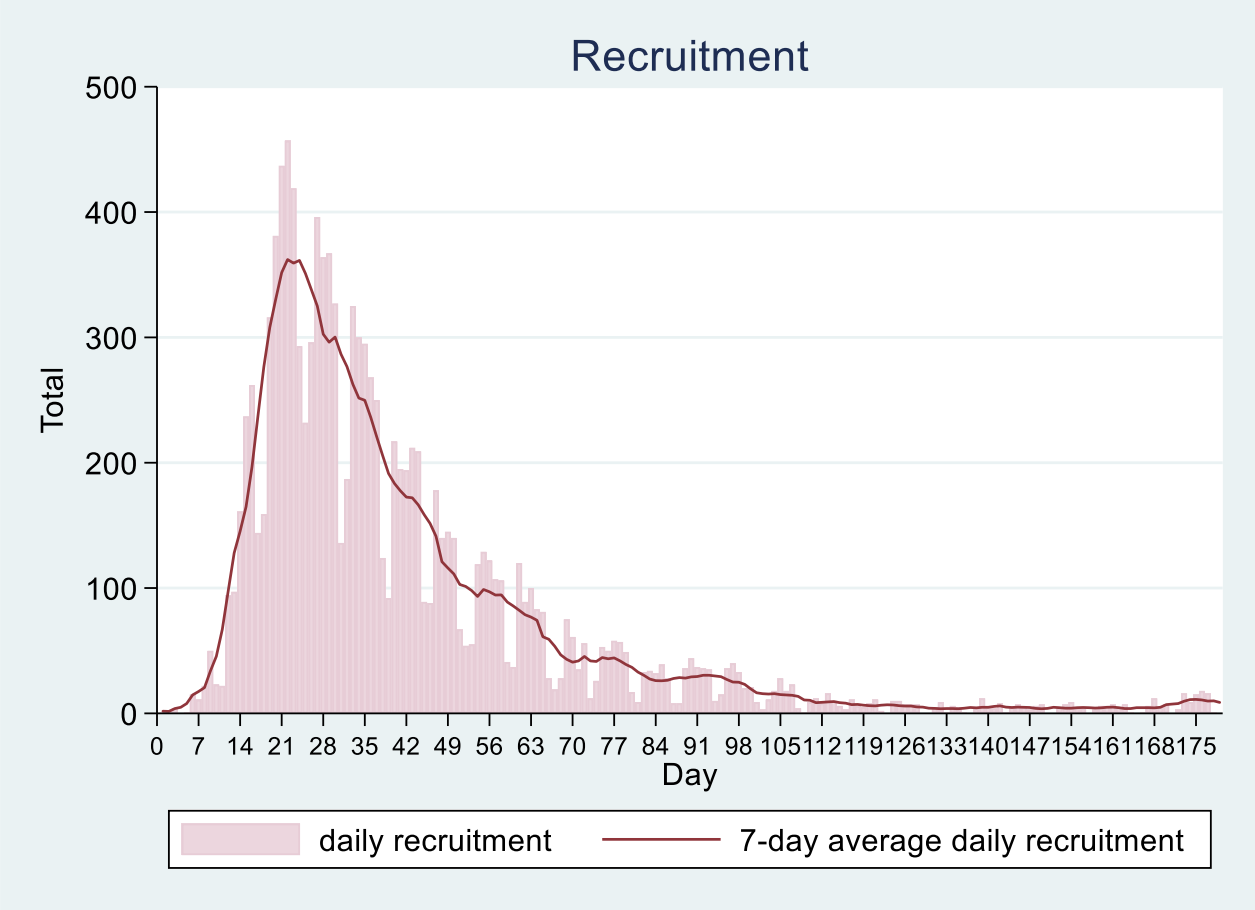

Recruitment compared to pandemic

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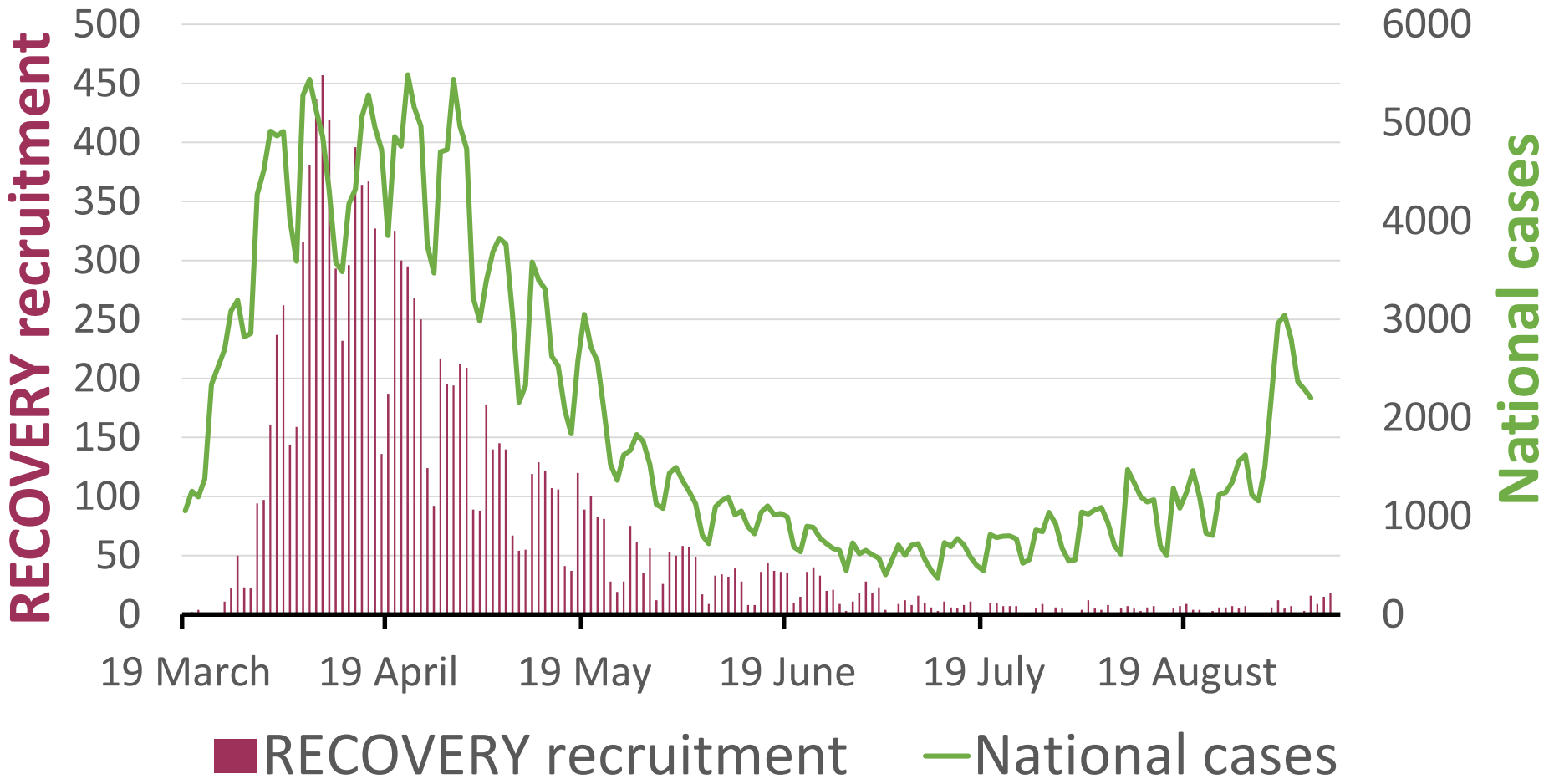

Recruitment

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- Continued recruitment is essential

- As local outbreaks occur, please consider discussing with your teams how to ensure that all available admissions with Covid-19 are identified and enrolled if possible
  - Daily catch-up with admitting teams
  - Links with laboratory for all positive swabs among patients to be reported
  - Plan for weekend recruitment

- Please consider “re-launching” the trial at your site to refresh people and inform any new team members of how they can contribute

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PROTOCOL V9.0

Protocol V9.0

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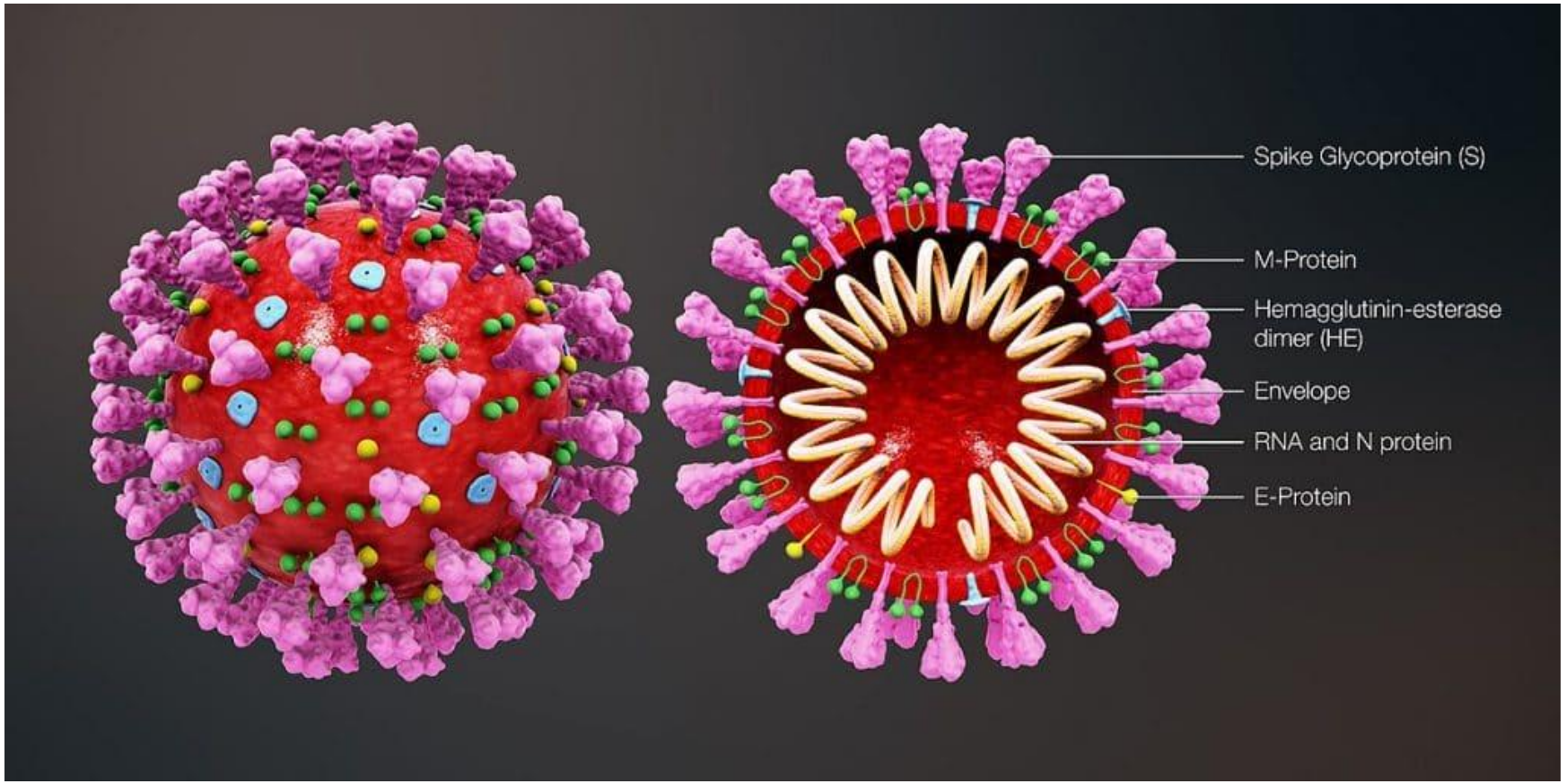
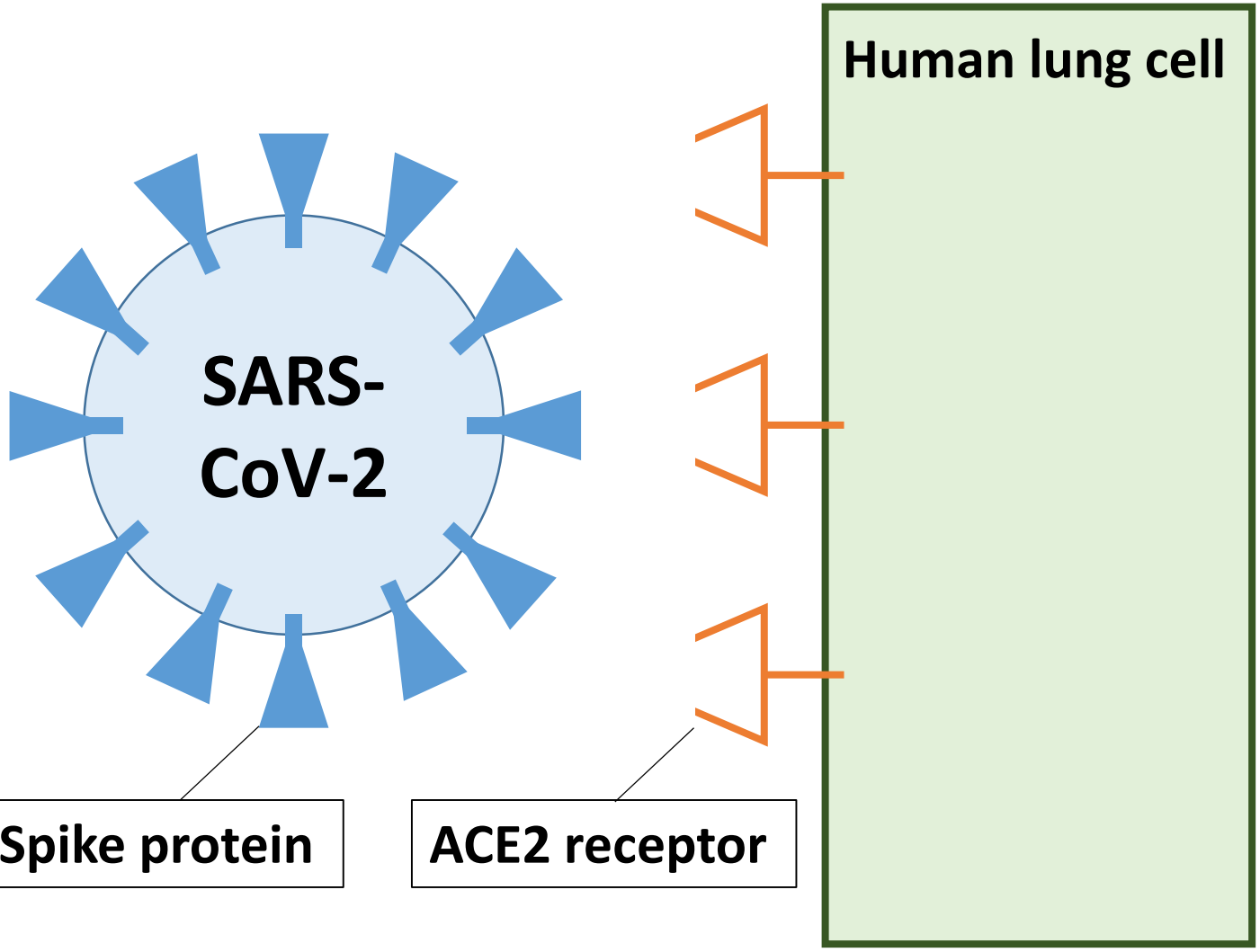
- Several companies are now producing monoclonal antibodies (mAbs) against SARS-CoV-2 “spike” protein



Spike protein



Spike protein

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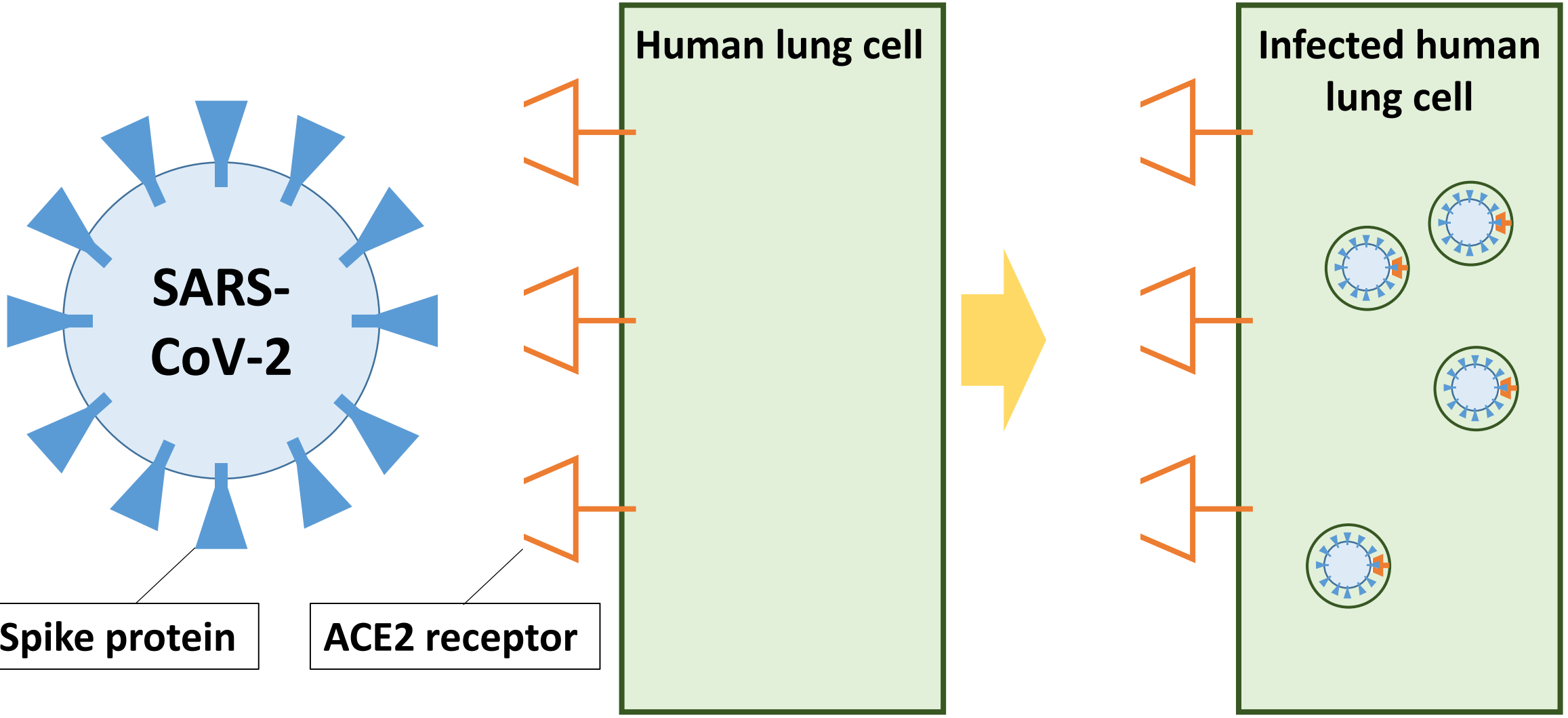
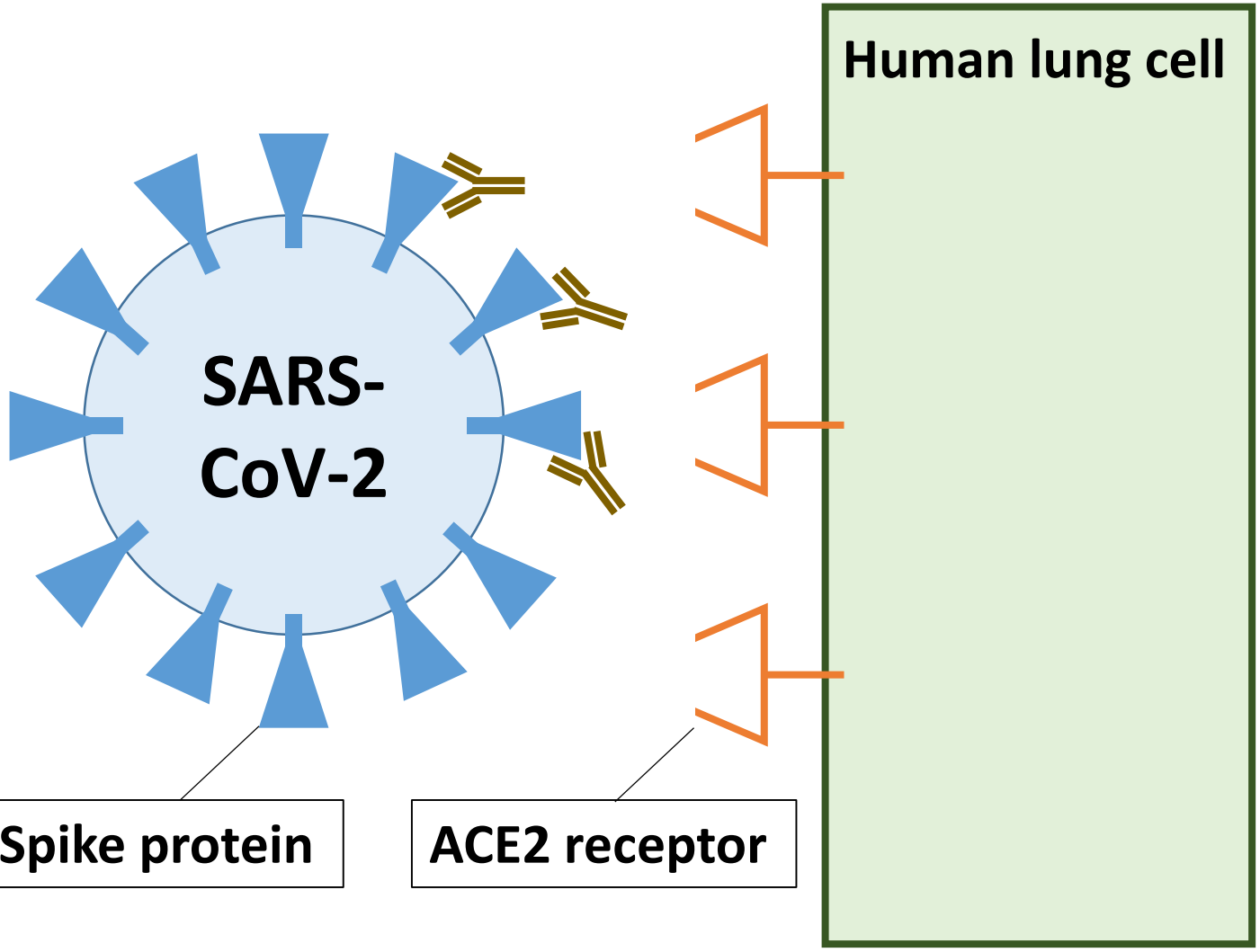


Role of antibody



Role of antibody

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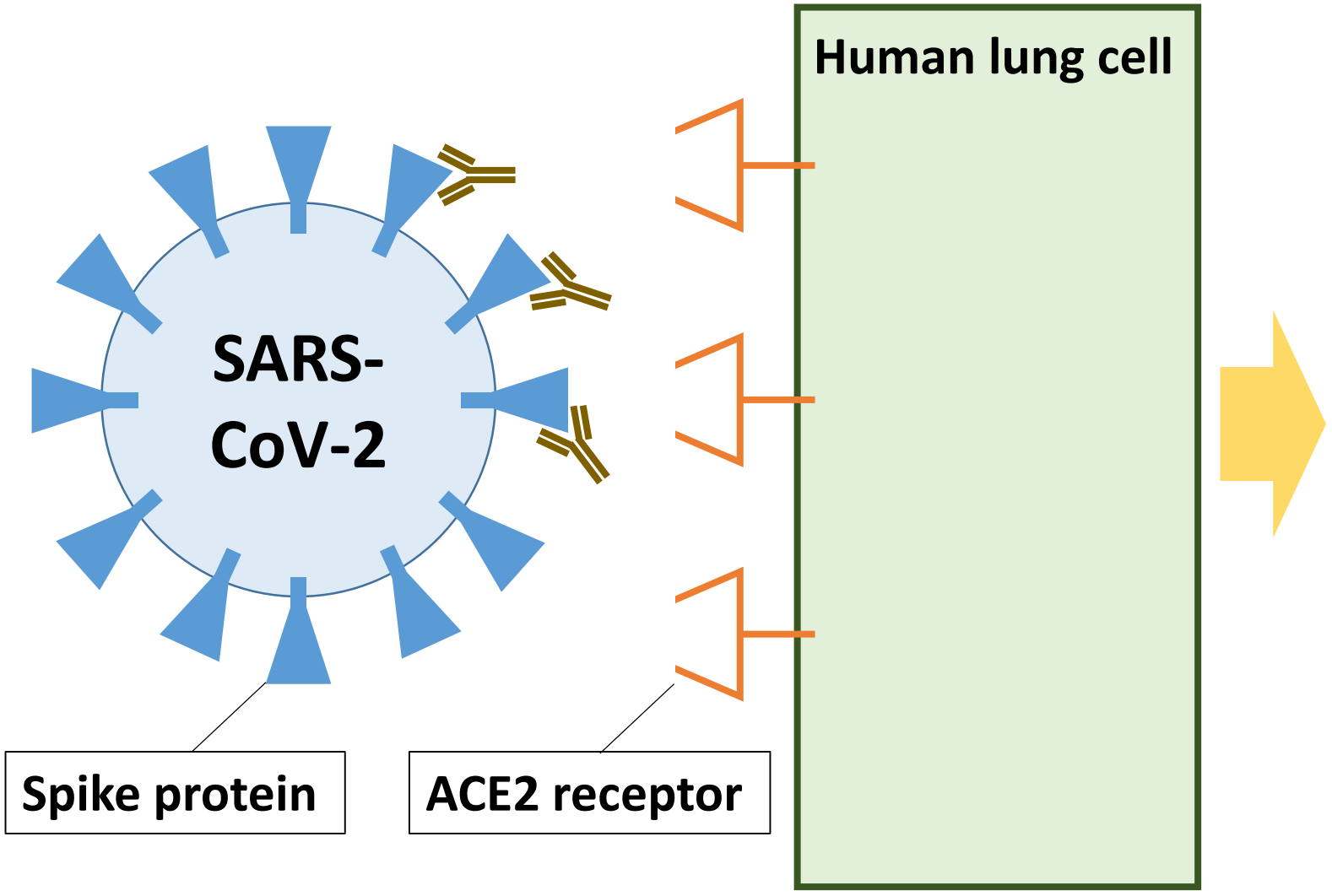

1. Virus binding to its receptor is inhibited, so cells infected less readily

2. Antibody can activate other parts of immune system to kill infected cells and capture free virus

Source of antibody

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- Most patients with Covid-19 will develop antibodies by day 14
- Convalescent plasma contains mixture of many different anti-coronavirus antibodies
- Monoclonal antibodies are now in production

REGN-COV2

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- RECOVERY is collaborating with Regeneron who have developed a mixture of two monoclonal antibodies (mAbs: REGN10933 and REGN10987)

- These are fully human antibodies directed against spike protein

- Two different antibodies mean that if virus mutates its spike protein such that one antibody doesn't bind so well, the other antibody probably still will

Safety of REGN-COV2

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- ~500 patients have entered trials of REGN-COV2 mAb in early phase trials
  - No serious adverse reactions
  - 4 patients have had minor infusion reactions which could be controlled symptomatically and infusion completed in 3/4 cases

- Other trials ongoing in other clinical scenarios e.g. outpatient, prophylaxis

New trial design

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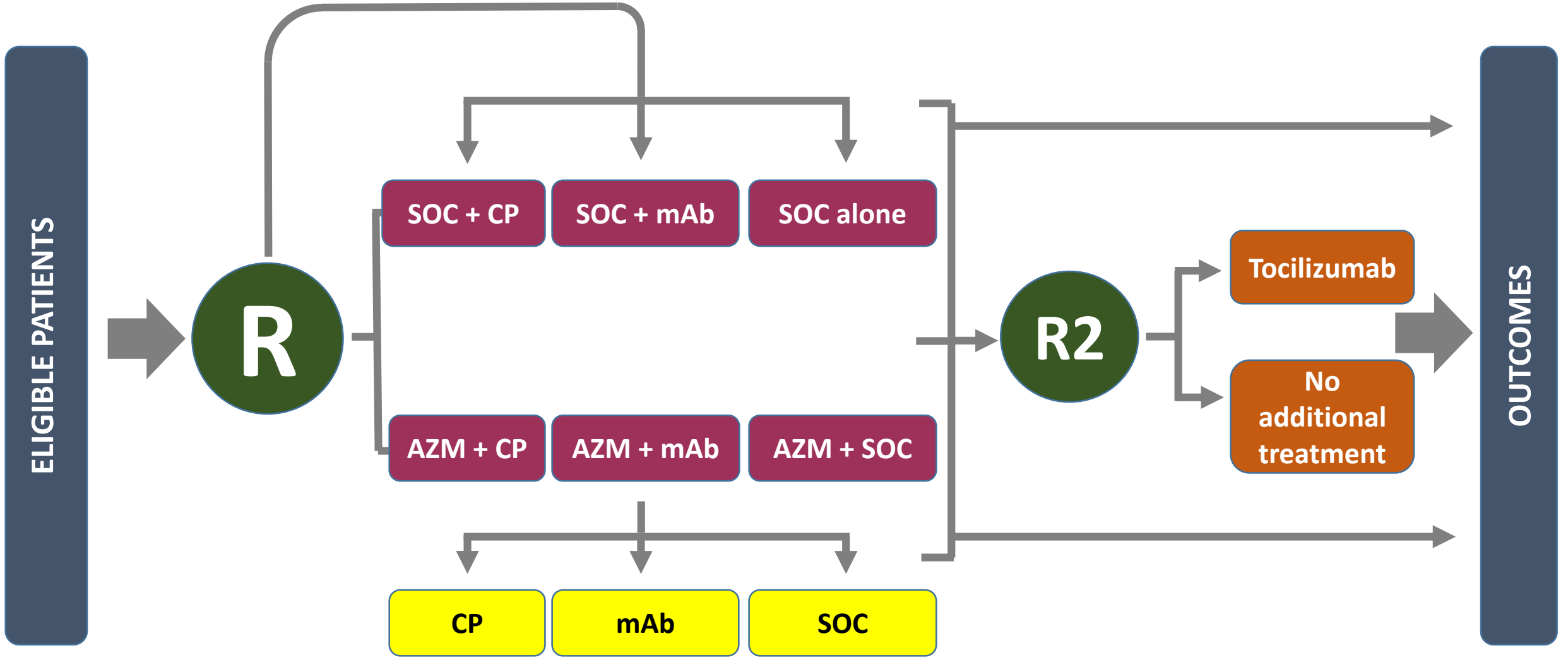

Progress

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- Collaboration agreed with Regeneron
- MHRA, HRA and REC submission imminent
  - Will initially include pregnant women and children ≥12 years old and >40 kg weight
  - Age range may extend lower when further data available
- Further information for sites will be available soon

Other developments: Phase 2

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- RECOVERY has been asked by CMOs to become the principal vehicle for publicly funded phase 2 trials

- National committee meets regularly to assess candidates and make recommendations to RECOVERY Chief Investigators

As well as increasing recruitment now we must also ensure that our research and trial systems are strengthened and ready to increase recruitment if the number of COVID-19 cases increases. The national coverage and recruitment success of RECOVERY means it is uniquely well placed to take forward the clinical evaluation of COVID-19 therapeutics.

RECOVERY will therefore continue to be supported as the national clinical trial platform for COVID-19 phase III therapeutics trials and will also be extended to include phase II trials. The expanded RECOVERY platform will form the principal vehicle for all publicly funded phase II studies.

Dr Frank Atherton
Chief Medical Officer for Wales

Dr Gregor Smith
Chief Medical Officer for Scotland

Dr Michael McBride
Chief Medical Officer for Northern Ireland

Professor Chris Whitty
Chief Medical Officer for England

Professor Stephen Powis
National Medical Director
NHS England and NHS Improvement

Other developments: RECOVERY international

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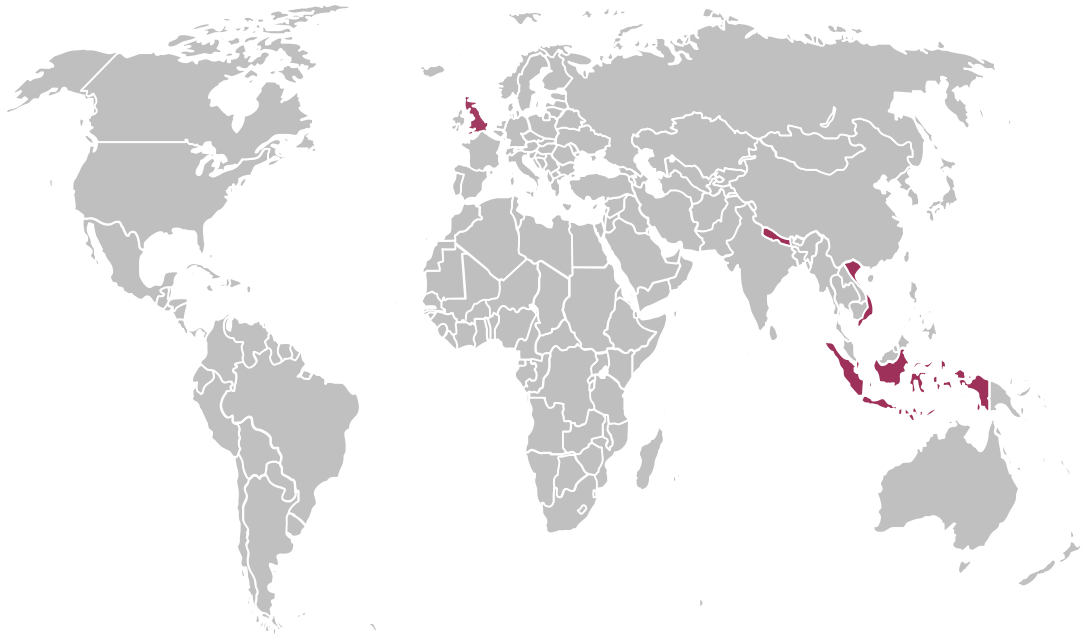
- RECOVERY has been approached by other countries asking to participate

- Discussions are ongoing with Vietnam, Indonesia and Nepal



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TRIAL PROCEDURES

Serum samples

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- Participants entering convalescent plasma comparison (in future the "antibody comparison" as it will also include the mAb) need to have serum sample collected prior to randomisation

- Can be taken with G&S sample after consent prior to randomisation to limit venepunctures

- Must be taken for all participants in that comparison (regardless of allocation)

Completeness of follow-up

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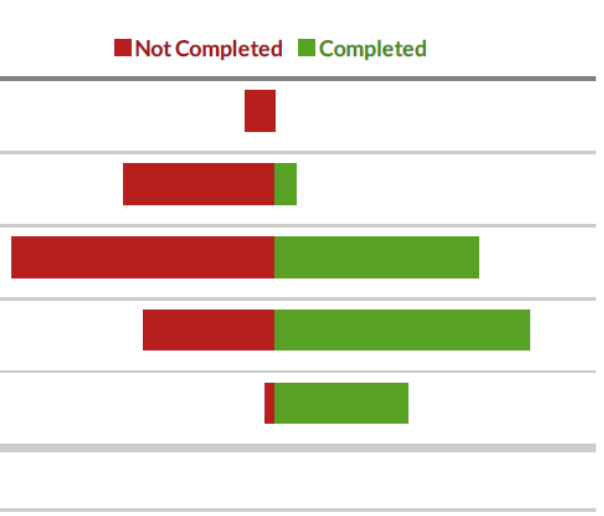
- Weekly reminders highlighting participants randomised >28 days ago without complete form **and also** those needing an Antibody Comparison 72h safety form

- 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**



Carry on recruiting!

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- RECOVERY is expanding both in terms of therapies being tested and geography covered, so it is an exciting time for the trial.
- As admission rates may be rising, please ensure team are aware and prepared to recruit
- Need to continue recruitment and collection of follow-up information to provide DMC with information about efficacy and safety of study treatments
- Thank you for your support.

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

14 September 2020

RECOVERY for pregnant women

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1. Update on covid-19 and pregnancy
2. Update on adaptions
3. Update on UKOSS
4. Future plans
5. Q&A

Covid-19 and pregnancy

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RESEARCH

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,[1] Kathryn Bunch,[1] Nicola Vousden,[2] Edward Morris,[3] Nigel Simpson,[4] Chris Gale,[5] Patrick O'Brien,[6] Maria Quigley,[1] Peter Brocklehurst,[7] Jennifer J Kurinczuk,[1] On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

For numbered affiliations see end of the article.

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Additional material is published online only. To view please visit the journal online.

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Accepted: 27 May 2020

ABSTRACT

OBJECTIVES

To describe a national cohort of pregnant women admitted to hospital with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the UK, identify factors associated with infection, and describe outcomes, including transmission of infection, for mothers and infants.

DESIGN

Prospective national population based cohort study using the UK Obstetric Surveillance System (UKOSS).

SETTING

All 194 obstetric units in the UK.

over, and 145 (34%) had pre-existing comorbidities. 266 (62%) women gave birth or had a pregnancy loss; 196 (73%) gave birth at term. Forty one (10%) women admitted to hospital needed respiratory support, and five (1%) women died. Twelve (5%) of 265 infants tested positive for SARS-CoV-2 RNA, six of them within the first 12 hours after birth.

CONCLUSIONS

Most pregnant women admitted to hospital with SARS-CoV-2 infection were in the late second or third trimester, supporting guidance for continued social distancing measures in later pregnancy. Most had good outcomes, and transmission of SARS-CoV-2 to

BMJ: first published as 10.1136/bmj.m2107 on 8 June 2020.

Covid-19 and pregnancy (UKOSS 2020)

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Characteristic	Estimated No of maternities	No of pregnant women admitted with SARS-CoV-2	Incidence per 1000 maternities	Rate ratio (95% CI)
Age*, years:				
<20	2532	4	1.6	0.4 (0.1 to 1.1)
20-34	63 768	248	3.9	1 (reference)
≥35	19 992	175	8.8	2.3 (1.8 to 2.7)
Body mass index†:				
Normal (<25)	36 377	126	3.5	1 (reference)
Overweight (25 to <30)	20 836	141	6.8	2.0 (1.5 to 2.5)
Obese (≥30)	16 154	140	8.7	2.5 (2.0 to 3.2)
Ethnic group (England only)‡:				
White	49 282	173	3.5	1 (reference)
Asian	7400	103	13.9	4.0 (3.1 to 5.1)
Black	3135	89	28.4	8.1 (6.2 to 10.5)
Chinese/other	2960	28	9.5	2.7 (1.7 to 4.0)
Mixed	1304	9	6.9	2.0 (0.9 to 3.8)

Covid-19 and pregnancy

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Check for updates

FAST TRACK

Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis

John Allotey,[1,2] Elena Stallings,[3,4] Mercedes Bonet,[5] Magnus Yap,[6] Shaunak Chatterjee,[6] Tania Kew,[6] Luke Debenham,[6] Anna Clavé Llavall,[6] Anushka Dixit,[6] Dengyi Zhou,[6] Rishab Balaji,[6] Siang Ing Lee,[1] Xiu Qiu,[7,8,9] Mingyang Yuan,[1,7] Dyuti Coomar,[1] Madelon van Wely,[10] Elizabeth van Leeuwen,[11] Elena Kostova,[10] Heinke Kunst,[12,13] Asma Khalil,[14] Simon Tiberi,[12,13] Vanessa Brizuela,[5] Nathalie Broutet,[5] Edna Kara,[3] Caron Rahn Kim,[5] Anna Thorson,[5] Olufemi T Oladapo,[5] Lynne Mofenson,[15] Javier Zamora,[3,4,16] Shakila Thangaratinam,[2,17] for PregCOV-19 Living Systematic Review Consortium

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Additional material is published online only. To view please visit the journal online.

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http://dx.doi.org/10.1136/bmj.m3320

Accepted: 23 August 2020

ABSTRACT

OBJECTIVE

To determine the clinical manifestations, risk factors, and maternal and perinatal outcomes in pregnant and recently pregnant women with suspected or confirmed coronavirus disease 2019 (covid-19).

DESIGN

Living systematic review and meta-analysis.

DATA SOURCES

Medline, Embase, Cochrane database, WHO COVID-19 database, China National Knowledge Infrastructure (CNKI), and Wanfang databases from 1 December 2019 to 26 June 2020, along with preprint servers, social media, and reference lists.

meta-analysis was performed, with estimates pooled as odds ratios and proportions with 95% confidence intervals. All analyses will be updated regularly.

RESULTS

77 studies were included. Overall, 10% (95% confidence interval 7% to14%; 28 studies, 11 432 women) of pregnant and recently pregnant women attending or admitted to hospital for any reason were diagnosed as having suspected or confirmed covid-19. The most common clinical manifestations of covid-19 in pregnancy were fever (40%) and cough (39%). Compared with non-pregnant women of reproductive age, pregnant and recently pregnant women with covid-19 were less likely to report symptoms of fever (odds ratio 0.43, 95% confidence

Covid-19 and pregnancy (SR and MA)

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Pregnant women are considered to be a high risk group for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and the potential adverse effects of the virus on maternal and perinatal outcomes are of concern

In non-pregnant populations admitted to hospital with coronavirus disease 2019 (covid-19) the most common symptoms are fever, cough, and dyspnoea, reported in more than two thirds of individuals

Advancing age, high body mass index, non-white ethnicity, and pre-existing comorbidities are risk factors for severe covid-19 in the general population

WHAT THIS STUDY ADDS

Pregnant and recently pregnant women with covid-19 diagnosed in hospital are less likely to manifest symptoms of fever and myalgia than non-pregnant women of reproductive age and might be at increased risk of admission to an intensive care unit

Risk factors for severe covid-19 in pregnancy include increasing maternal age, high body mass index, and pre-existing comorbidities

Pregnant women with covid-19 are more likely to experience preterm birth and their neonates are more likely to be admitted to a neonatal unit

Covid-19 and pregnancy

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Maternal, Newborn and Infant Clinical Outcome Review Programme

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

Saving Lives, Improving Mothers' Care

Rapid report: Learning from SARS-CoV-2-related and associated maternal deaths in the UK

Covid-19 and pregnancy

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1. Key messages

New recommendations

1. Ensure all pregnant or post-partum women with COVID-19 receive multidisciplinary team care and obstetric leadership with daily review. This is essential in order to ensure timely recognition of deterioration, early assessment of the need for iatrogenic birth to help respiratory function and identification of postnatal complications. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
2. Ensure that pregnant and postpartum women are considered for antiviral or other specific therapies for COVID-19 as part of routine care, early access or compassionate use programmes. Pregnant and postpartum women should not be excluded from clinical trials unless there is a clear contraindication. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
3. Provide specific advice to pregnant and post-partum women with COVID-19 infection about the risk of deterioration and when to seek urgent medical attention or go to the hospital.This should be communicated via an interpreter if necessary. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association COVID-19 Guideline Development Group]**
4. Ensure that communication with partners and families, including via an interpreting service if necessary, and facilitating visits between women and their partners is a priority when women are critically ill. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
5. Establish triage processes to ensure that women with mental health concerns can be appropriately assessed, including face-to-face if necessary, and access specialist perinatal mental health services in the context of changes to the normal processes of care due to COVID-19. Perinatal mental health services are essential and face to face contact will be necessary in some circumstances. There is a clear role for involvement of the lead mental health obstetrician or midwife in triage and clinical review. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/Royal College of Psychiatrists COVID-19 Guideline Development Groups; Local Maternity Systems; Mental Health Service Providers; Health Boards]**
6. Ensure that referral with mental health concerns on more than one occasion is considered a 'red flag' which should prompt clinical review, irrespective of usual access thresholds or practice. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal College of Psychiatrists COVID-19 Guideline Development Groups; Local Maternity Systems; Mental Health Service Providers; Health Boards]**
7. Update guidance to reflect that safeguarding actions, including removal to a place of safety if necessary, should be followed in the context of public health measures such as lockdown. **[ACTION: Local Authorities, Adult Protection Committees, Northern Ireland Adult Safeguarding Partnership, Hospitals and Health Boards, Primary Care]**

Covid-19 and pregnancy

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1. Ensure all pregnant or post-partum women with COVID-19 receive multidisciplinary team care and obstetric leadership with daily review. This is essential in order to ensure timely recognition of deterioration, early assessment of the need for iatrogenic birth to help respiratory function and identification of postnatal complications. **[ACTION:**

2. Ensure that pregnant and postpartum women are considered for antiviral or other specific therapies for COVID-19 as part of routine care, early access or compassionate use programmes. Pregnant and postpartum women should not be excluded from clinical trials unless there is a clear contraindication. **[ACTION: Royal College**

3. Provide specific advice to pregnant and post-partum women with COVID-19 infection about the risk of deterioration and when to seek urgent medical attention or go to the hospital.This should be communicated via an interpreter if necessary. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of**

4. Ensure that communication with partners and families, including via an interpreting service if necessary, and facilitating visits between women and their partners is a priority when women are critically ill. **[ACTION: Royal**

Covid-19 and pregnancy

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Published: 25 August 2020

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight, [1] R Katie Morris, [2] Jenny Furniss, [3] Lucy C Chappell[4]

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting that women are denied investigations and life preserving treatments simply because they are pregnant or breastfeeding.[1 2] These inquiries emphasise that the default position should be to investigate and treat pregnant and breastfeeding women in the same way as non-pregnant women, unless there are clear reasons not to.[1]

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women, meaning data are unavailable or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals.

Even if regulatory barriers have been overcome, gatekeeping or inertia may occur if local ethics committees take an overwhelming precautionary approach, overriding recognition of the potential benefits of including pregnant and breastfeeding women. This problem can be mitigated by a strong network of maternity researchers, familiar with delivering drug trials in pregnancy, who can be rapidly mobilised to help implement studies.

Covid-19 and pregnancy

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Headline messages:

- Covid-19 affects pregnant women
- Additional risk factors identified
- Pregnant and postnatal women need evidence-based treatments
- Actively include pregnant and postnatal women in research

- RECOVERY trial has changed clinical practice, including for pregnant women

Covid-19 and pregnancy: RCOG

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- Be aware of the interim government guidance based on the results of the RECOVERY trial, which states that steroid therapy should be considered for 10 days or to hospital discharge, whichever is sooner, for adults unwell with COVID-19 and requiring oxygen (in pregnant adults, use oral prednisolone 40 mg once a day or intravenous hydrocortisone 80 mg twice a day).

RECOVERY for pregnant women

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HOME FOR PATIENTS FOR SITE STAFF NEWS Search

For Site Staff / site teams

Site teams

This page contains additional information for RECOVERY site team members. Follow these links for guidance on randomisation and how to collect follow-up data.

INTERVENTION INFORMATION

RECOVERY intervention sheet - lopinavir-ritonavir

RECOVERY intervention sheet - hydroxychloroquine

RECOVERY intervention sheet - dexamethasone

RECOVERY intervention sheet - azithromycin

RECOVERY intervention sheet - tocilizumab

GUIDES FOR SPECIFIC PATIENT GROUPS

RECOVERY for pregnant and postpartum women

RECOVERY for patients with chronic kidney disease

RECOVERY Privacy Notice for Trial Staff

COLLABORATORS' MEETING

Slides presented at the collaborators' meeting on 20 & 21 April 2020

Slides presented at the collaborators' meetings on 6 & 7 April 2020

Eligibility = same

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2.1 Eligibility

Patients are eligible for the study if all of the following are true:

(i) Hospitalised
(ii) SARS-CoV-2 infection (clinically suspected[1] or laboratory confirmed)
(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

- No criterion for ‘requiring oxygen’

Notes on eligibility

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- What about women with a positive covid-19 swab result but initially admitted for another reason…?
- Are you uncertain about the benefits of treatment or not for this woman, and whether it might 'treat' or prevent deterioration?
- If you are uncertain, then reasonable to provide the information to the woman, offer the trial and make a shared decision.

- **For any woman reportable to UKOSS, ask yourself whether you can offer her participation in RECOVERY**

Interventions = the same

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Current trial design

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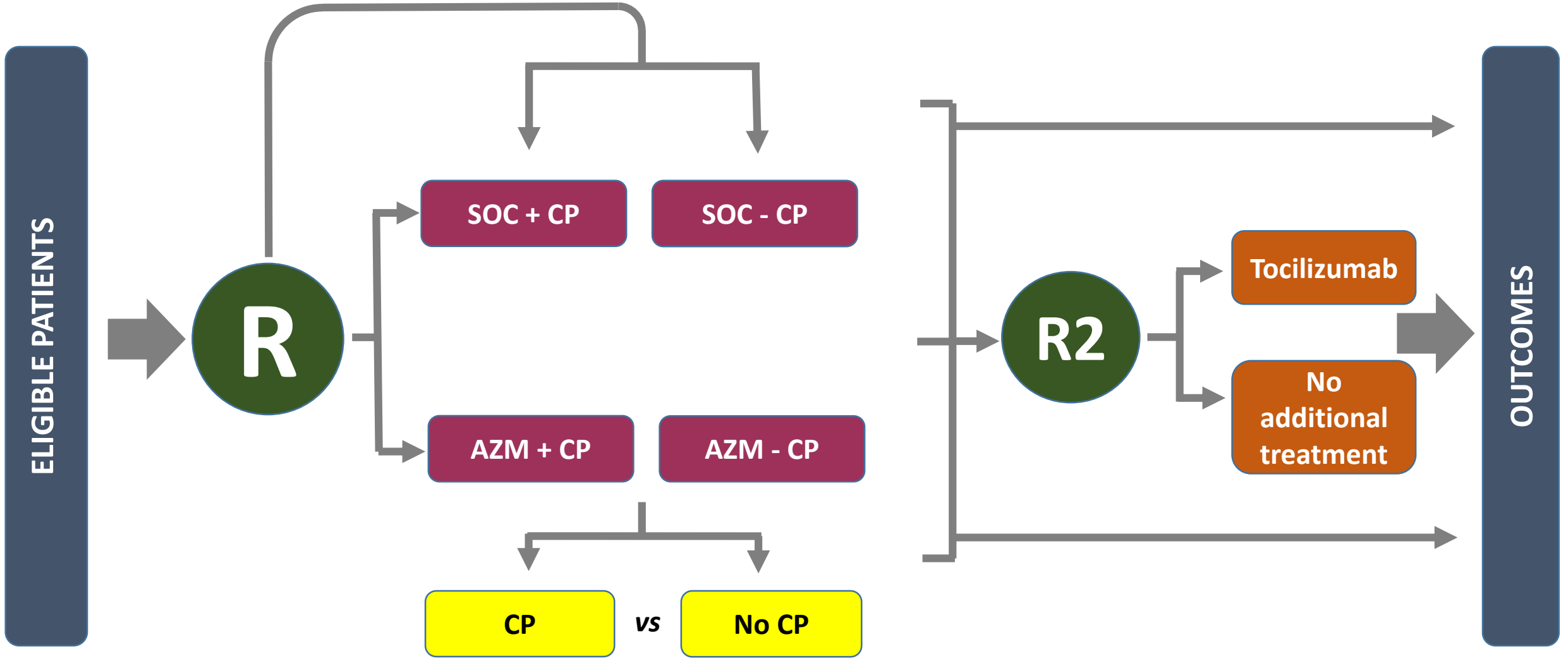

Use of drugs in pregnancy

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Annex A: Trial drugs in pregnancy and during lactation

All trial drugs have been used in pregnant women with pre-existing medical disorders where benefits outweigh the risks to fetus or woman, including in the first trimester. The existing data related to each drug is summarized below.

Annex A: Trial drugs in pregnancy and during lactation
All trial drugs have been used in pregnant women with pre-existing medical disorders where benefits outweigh the risks to fetus or woman, including in the first trimester. The existing data related to each drug is summarized below.

Azithromycin
Azithromycin is used in pregnancy to treat genital Chlamydia trachomatis infection, with a Cochrane systematic review and meta-analysis reporting fewer gastrointestinal side-effects compared to erythromycin, and inconsistent results on risk of preterm birth, preterm rupture of membranes, perinatal mortality and low birthweight, confounded by the indication for treatment.[1] A recent systematic review and meta-analysis of all macrolide antibiotics acknowledges potential bias in child outcome reports due to treatment indication.[2] The UK Teratology Information Service monograph concludes that there is no definitive evidence linking azithromycin with increased risk of miscarriage or congenital malformations (https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MACROLIDES-IN-PREGNANCY/). Azithromycin is detected in only low levels in breastmilk and is not expected to cause adverse events in breastfed infants (reviewed in Lactmed database: www.ncbi.nlm.nih.gov/books/NBK501200/) Azithromycin has also been used in several trials in preterm infants as a prophylactic treatment to prevent bronchopulmonary dysplasia.[3]

Additional randomisation intervention: Convalescent plasma (prepared with Dr Sue Pavord, Consultant Haematologist)
Convalescent plasma is plasma from people who had confirmed COVID-19 (SARS-Cov-2) infection, and have now recovered and been free of the infection for 28 days. The plasma contains antibodies that their immune systems have produced in fighting the virus. It is hoped that giving this plasma will help speed up recovery of a patient with active infection and improve their chances of survival. Plasma is already used as a treatment in pregnant patients who are bleeding,[4] or have particular blood conditions.[5, 6] The plasma being used in this trial is from a selected donor and hopefully contains anti-SARS-Cov-2 antibodies, but is otherwise no different. Plasma infusions can occasionally cause side effects. Mostly this is a rise in temperature, itching or a rash, and in very extreme cases, anaphylaxis. Other potential complications include breathlessness and changes in blood pressure. Monitoring of pulse and blood pressure takes place before and after the infusion. There is no risk of miscarriage or fetal loss, preterm birth, preterm rupture of membranes, perinatal mortality or low birthweight, from plasma transfusions and there are no concerns with breast feeding.

Second randomisation intervention: Tocilizumab
Two pharmaceutical global safety registry database studies have reported on tocilizumab use in pregnancy, including outcomes from 288 pregnancies [7] and 61 pregnancies,[8] typically for rheumatoid or other arthritides, and with the majority having received the drug in the first trimester. These data suggest that the rates of congenital abnormality, spontaneous pregnancy loss and other adverse outcomes were not higher than in the general population.[8] Small studies have shown that tocilizumab is transferred to the fetus with serum concentrations approximately 7-fold lower than those observed in maternal serum at the time of birth.[9] Very low concentrations of tocilizumab are identified in breast milk and no drug is transferred into the serum of breast fed infants.[9, 10] Women should be advised that if treated after 20 weeks' gestation, their infant should not be immunised with live vaccines (rotavirus and BCG) for the first 6 months of life. All non-live vaccinations are safe and should be undertaken.[11]

New information for women

RECOVERY
Randomised Evaluation of COVID-19 Therapy

RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

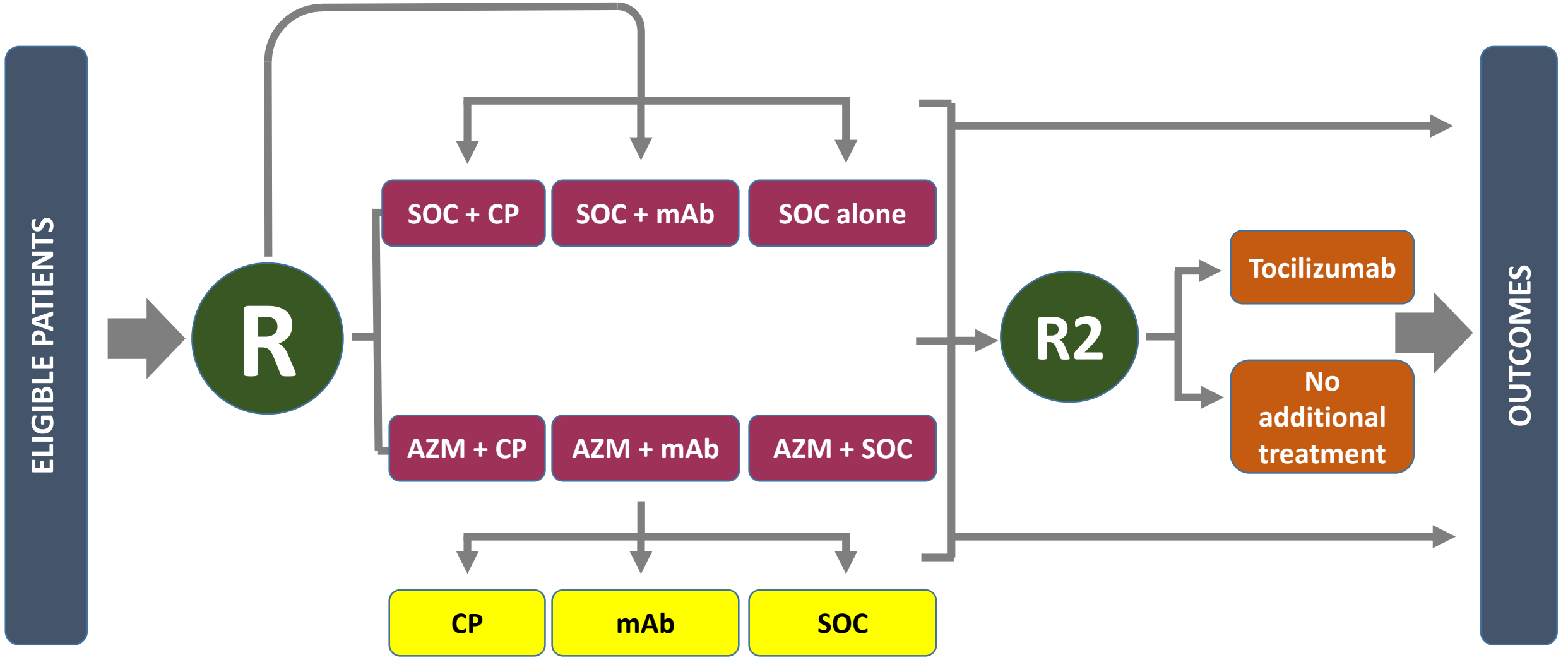
for pregnant and breastfeeding women

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

2. **Where can I find information specifically written for pregnant women about the drugs?**
   The links below are provided with permission from the bumps (best use of medicines in pregnancy) website, who have developed information leaflets for each of the drugs used in the RECOVERY trial. The bumps website and information are provided by the UK Teratology Information Service (UKTIS), a not-for-profit organisation funded by Public Health England on behalf of the UK Health Departments.
   - Azithromycin: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Azithromycin/
   - Tocilizumab: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Tocilizumab/

New trial design

RECOVERY
Randomised Evaluation of COVID-19 Therapy



Progress

RECOVERY
Randomised Evaluation of COVID-19 Therapy

- Collaboration agreed with Regeneron
- MHRA, HRA and REC submission imminent
  - Will initially include pregnant women and children ≥12 years old and >40 kg weight
  - Age range may extend lower when further data available
- Further information for sites will be available soon

Follow-up = the same, + linkage

RECOVERY
Randomised Evaluation of COVID-19 Therapy

NPEU

Nuffield Department of
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Search (e.g. Randomisation)

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COVID-19 in Pregnancy

UKOSS
UK Obstetric Surveillance System

Key points

- Covid-19 is an infectious disease caused by a new strain of coronavirus.
- Covid-19 had not been detected in humans before the outbreak in December 2019.
- As the virus is new, little is known about its effect on certain groups of people, including pregnant women.

Surveillance period

1st March 2020 – 31st March 2021

Background

On this page

Update on progress

RECOVERY
Randomised Evaluation of COVID-19 Therapy

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

- 18 antenatal women recruited

Update from UKOSS this week

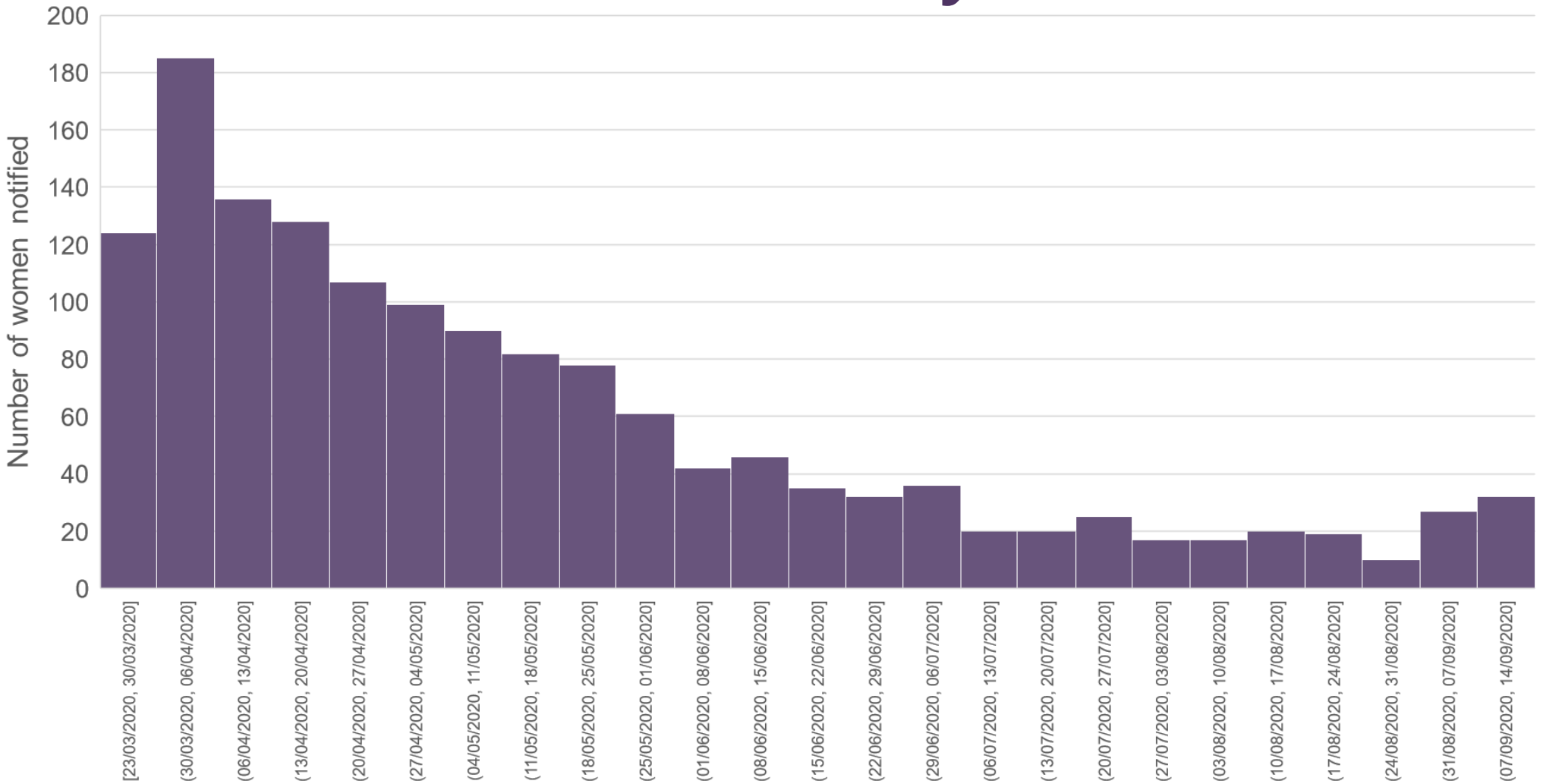
RECOVERY
Randomised Evaluation of COVID-19 Therapy

Update from UKOSS this week

Nuffield Department of POPULATION HEALTH
Medical Sciences Division
UNIVERSITY OF OXFORD

UKOSS
UK Obstetric Surveillance System

Notifications by week



Where are we now: positives

RECOVERY
Randomised Evaluation of COVID-19 Therapy

- Equity of access to the trial
- Readiness for future cases
- Link with UKOSS for outcomes
- Research working across disciplines within sites
- Strong ongoing support from RH&C teams

Moving forward

If reporting to UKOSS, check: can we offer the trial…?

Lessons learned from recruiting sites:

- Engaged PI, research midwives and nurses
- Good liaison with main site PI (e.g. sharing information)
- Avoidance of ‘gatekeeping’
- Understanding fetal safety data (see UKTIS)
- Embedding into usual clinical care (aim of RECOVERY trial)

Q&A

RECOVERY
Randomised Evaluation of COVID-19 Therapy