RECOVERY Clinical Trial Pharmacy Briefing Document

(Based on Protocol V27.0 13-Sep-2023)

Contents

1 Introduction

The following medicines are listed as IMPs for this study. The supply arrangements for each arm is different (see table 1 below). This clinical trial is being run to make it as easy as possible, while ensuring that the outcome data from the patients is collected to inform future care of patients with COVID-19, influenza, and community-acquired pneumonia (CAP) caused by other pathogens.

Table 1: Medicines for RECOVERY Clinical Trial

Medicine	Formulation	Source	Accountability logs	Prescribed	IMP Annex 13 labelling
Randomisation Part E (high-dose dexamethasone for COVID-19)					
No additional treatment					
Dexamethasone	Oral tablet, oral suspension, intravenous ampoules	NHS stock. Licensed products – Standard Pharmaceutical Wholesalers	No	Yes	No
Randomisation Part G (influenza)					
No additional treatment					
Baloxavir marboxil	Oral tablet	Roche trial specific stock	No	Yes	No
Randomisation Part H (influenza)					
No additional treatment					
Oseltamivir	Oral capsule, Oral suspension	Roche trial specific stock	No	Yes	No
Randomisation Part I (low-dose dexamethasone for influenza)					
No additional treatment					
Dexamethasone	Oral tablet, oral suspension, intravenous ampoules	NHS stock. Licensed products – Standard Pharmaceutical Wholesalers	No	Yes	No
Randomisation Part J (COVID-19)					
No additional treatment					
Sotrovimab	Solution for Intravenous Infusion	GSK trial specific stock	No	Yes	No
Randomisation Part M (low-dose dexamethasone for community-acquired pneumonia)					
No additional treatment					
Dexamethasone	Oral tablet, oral suspension, intravenous ampoules	NHS stock. Licensed products – Standard Pharmaceutical Wholesalers	No	Yes	No

The MHRA is aware and have approved the study to allow any doctor working within the hospital to prescribe for this study (this can include FY1 doctors under supervision as per local practice). Similarly GCP trained research staff to take consent of the patient for this trial is not required. However, it is expected that all staff will complete online Recovery study training.

2 Dexamethasone

2.1 Initial supply and re-ordering

Dexamethasone will be sourced by local Pharmacy Procurement team via their normal routes.

2.2 Storage

As per SmPC

No temperature excursion reporting required. Follow Trust SOPs to manage temperature excursions.

2.3 Dispensing quantities

Different randomisation parts have different doses and duration – please check carefully.

Randomisation Part E (high-dose dexamethasone for COVID-19): Dexamethasone **20mg** (base) once daily by mouth, nasogastric tube or intravenous infusion for **5** days followed by dexamethasone **10mg** (base) once daily for **5** days. Treatment should be discontinued at 10 days or on discharge from hospital if sooner. See below for details of alternative corticosteroids for use in pregnant women.

Randomisation Part I (low-dose dexamethasone for influenza) and **Randomisation Part M** (low-dose dexamethasone for CAP): Dexamethasone **6mg** (base) once daily by mouth, nasogastric tube or intravenously for **10** days, discontinued on discharge from hospital if this happens sooner. See below for details of alternative corticosteroids for use in pregnant women.

Children aged under 18 years (Randomisation Part I only)

Greater than 36 weeks corrected gestational age: Dexamethasone 150 micrograms/kg (as base) once daily (max: 6 mg once daily) for 10 days (or until discharge if sooner). Enteral or intravenous route.

Less than 36 weeks corrected gestational age: Hydrocortisone (IV) 0.5 mg/kg every 12 hours for 7 days and then 0.5mg/kg once daily for 3 days. Enteral or intravenous route.

2.4 Returns and Destructions

If there is still stock at end of study, this can be returned to stock in the usual way or destroyed on site. No approval from Sponsor is required.

2.5 FAQs

Also see the intervention sheets here https://www.recoverytrial.net/for-site-staff/site-teams

Q. My patient is pregnant or breastfeeding can they be treated with dexamethasone?

A. No.

Randomisation Part E: Pregnant or breastfeeding women should be prescribed:
Prednisolone 130mg once daily orally or hydrocortisone (sodium succinate) 180mg three times a day or 135mg four times a day intravenously, or methylprednisolone (sodium succinate) 100mg once daily intravenously for 5 days. **Followed by** either prednisolone 65mg once daily orally or hydrocortisone (sodium succinate) 90mg three times a day or 70mg four times a day intravenously, or methylprednisolone (sodium succinate) 50mg once daily intravenously for 5 days.
Sites are free to choose between three times a day or four times a day dosing for the hydrocortisone (sodium succinate) treatment course.

Administration: Hydrocortisone 70-180mg IV – give slowly over 5-10 minutes.
Methylprednisolone 50mg or 100mg IV – give slowly over 5 minutes.

Randomisation Part I and Randomisation Part M: Pregnant or breastfeeding women should be prescribed oral prednisolone 40mg once a day or intravenous hydrocortisone (sodium succinate) 80mg twice daily.

Q. How is dexamethasone to be prescribed as there are different salts available?

A. To be prescribed as dexamethasone base

Q. Is the dose the same for oral and IV for dexamethasone despite differences in bioavailability?

A. Yes, the dose will be as the base for both IV and oral.

Q. How should the oral dose be taken?
Dexamethasone should be taken with or after food to minimise irritation to the gastrointestinal tract. Drinks containing alcohol or caffeine should be avoided.

Q. The IV 6mg and 20mg dose of dexamethasone base of the 3.3mg/mL comes to 1.82mL or 6.06mL which cannot be measured accurately in a 2mL or 10mL syringe. What do we do?

A. Volume to be rounded to 6mg/1.8mL and 20mg/6mL, which is measurable.

Q. Our normal hospital practice is to dissolve dexamethasone 2mg tablets instead of using soluble tablets or oral liquid, is this permitted?

A. Yes. If sites cannot source the soluble tablets or liquid, then the 2mg tablets can be dissolved in 10mL of water. There are no issues with this going down a fine bore nasogastric tubes (Reference: Handbook of Drug Administration via Enteral Feeding Tubes).

Q. Is IV dexamethasone to be given as an IV bolus or infusion?

A. Either is acceptable, treating clinician to decide.

3 Baloxavir marboxil

3.1 Initial supply and re-ordering

Baloxavir marboxil will be sourced by local Pharmacy Procurement team free of charge from Roche Products Ltd. Baloxavir is available as packs of 2 x 40mg tablets.

Initial Order:
Please order 10 packs of baloxavir tablets (2 x 40mg) by emailing the electronic drug delivery request form to welwyn.cpg_general@roche.com. A copy of the form can be downloaded from www.recoverytrial.net/for-site-staff/pharmacy. Please complete this form electronically & save as a Word document, rather than doing it by hand. For the first order at your site, copy in recoverytrial@ndph.ox.ac.uk, so the trial team can confirm that your site can be supplied.

Reordering:

When stock falls to 4 packs of baloxavir tablets (2 x 40mg), please re-order by sending a new electronic drug delivery request form to welwyn.cpg_general@roche.com. The maximum stock holding should not exceed the initial supply (if this creates logistical problems because of high recruitment please discuss with the trial team).

Orders placed before 12:00 will aim to be delivered to site the following working day, however, some sites in the Highlands and islands will be in line with the delivery schedule followed for all other orders placed with Roche. If you have any questions/concerns about the medicine delivery, please contact welwyn.cpg_general@roche.com.

All sites will need to ensure clear storage separation between stock for this study and general hospital stock for flu patients (or stock used for other clinical trials), as well as having some way of identifying the difference between stock when dispensing and checking. This could be done via a number of ways such as adding an additional label on receipting of stock stating 'to be used in the RECOVERY trial only' and storing in different areas of pharmacy.

3.2 Storage

As per SmPC

No temperature excursion reporting required. Follow Trust SOPs to manage temperature excursions.

3.3 Dispensing quantities

Adults and adolescents (≥ 12 years of age)

<40kg	Not eligible for baloxavir comparison
40kg to <80kg	Baloxavir 40mg once daily by mouth on day 1 and day 4 ie 1 x 2 x 40mg pack
≥80kg	Baloxavir 80mg once daily by mouth on day 1 and day 4 ie 2 x 2 x 40mg packs

If the participant is discharged before the course is complete, the participant should be provided with medication to complete the course at home.

3.4 Returns and Destructions

During the study any patient returns should be destroyed on site. If there is still stock at end of study, please seek guidance from the sponsor.

3.5 FAQs

Also see the baloxavir intervention sheet https://www.recoverytrial.net/for-site-staff/site-teams

Q. Can baloxavir tablets be cut or crushed for patients who have swallowing difficulties or who have a feeding tube?

A. The tablet must **not** be crushed or split. It can be dissolved if needed: Place tablet in 100ml medicine bottle, add 50ml of water for irrigation at ambient temperature and shake for 10 minutes. Add 50ml ORA-Blend to mask the taste, shake again to mix well. The mixture has not been tested for enteral administration. ORA-Blend is the only option: do NOT mix with food or juice.

If administering via a feeding tube (where taste is not an issue), the tablets can be dissolved in 100ml water. (While the company's in house data on dispersing tablet has not been tested for enteral administration, baloxavir suspension is licensed in the US for administration via enteral feeding tube, suggesting drug interaction with tubing is unlikely to be an issue. Given the licensed baloxavir 2mg/mL suspension is bioequivalent to baloxavir tablet, and the suspension is a simple suspension formulation (excipients: non-colloidal silicon dioxide, hypromellose, maltitol, mannitol, povidone K25, sodium chloride, strawberry flavour, sucralose and talc), the administration of dispersed tablet suspension is likely to have minimal impact on bioavailability.)

Q. How should the tablets be taken?
A. The tablets must be swallowed whole with or without food.
Baloxavir should not be taken with products that contain polyvalent cations such as laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium

Q. Do tablets contain lactose?
The tablets contain lactose as an excipient, so patients who are lactose intolerant should not be randomised to receive this medicine.

Q. My patient is pregnant or breastfeeding can they be treated with baloxavir?

A. Yes; pregnant or breastfeeding women can be randomised to receive baloxavir in this trial, but see the advice in the intervention sheet.

4 Oseltamivir

4.1 Initial supply and re-ordering

Oseltamivir will be sourced by local Pharmacy Procurement team free of charge from Roche Products Ltd. Oseltamivir is available as 75mg capsules in packs of 10 capsules and as 6mg/mL powder for oral suspension (65mL = 390mg oseltamivir) in packs of 1 bottle per carton.

Initial Order:
Please order the following by emailing the electronic drug delivery request form to welwyn.cpg_general@roche.com:
- 5 packs of oseltamivir capsules (10 x 75mg).
- 5 bottles of powder for reconstitution containing 390 mg of oseltamivir.
A copy of the form can be downloaded from www.recoverytrial.net/for-site-staff/pharmacy. Please complete this form electronically & save as a word document, rather than doing it by hand. For the first order at your site, copy in recoverytrial@ndph.ox.ac.uk, so the trial team can confirm that your site can be supplied.

Reordering:
When stock falls to 2 packs of oseltamivir capsules (10 x 75mg) or 2 bottles of powder for suspension containing 390 mg of oseltamivir, please re-order by sending a new electronic drug delivery request form to welwyn.cpg_general@roche.com. The maximum stock holding should not exceed the initial supply (if this creates logistical problems because of high recruitment please discuss with the trial team).

Orders placed before 12:00 will aim to be delivered to site the following working day, however, some sites in the highlands and islands will be in line with the delivery schedule followed for all other orders placed with Roche. If you have any questions/concerns about the drug delivery, please contact welwyn.cpg_general@roche.com.

All sites will need to ensure clear storage separation between stock for this study and general hospital stock for flu patients (or stock used for other clinical trials), as well as having some way of identifying the difference between stock when dispensing and checking. This could be done via a number of ways such as adding an additional label on receipting of stock stating 'to be used in the RECOVERY trial only' and storing in different areas of pharmacy.

4.2 Storage

As per SmPC. No temperature excursion reporting required. Follow Trust SOPs to manage temperature excursions.

4.3 Dispensing quantities

Adults or children weighing >40 kg:

Oseltamivir 75mg capsules twice daily by mouth for 5* days.

Adults and children aged ≥ 1 year - dose for those weighing ≤40kg:

Body Weight	Recommended dose for 5* days
<10 kg	3 mg/kg twice daily
≥10 kg to 15 kg	30mg (5ml of 6mg/ml liquid) twice daily, 1 x 65ml bottle
>15 kg to 23 kg	45mg (7.5ml of 6mg/ml liquid) twice daily, 2 x 65ml bottle
>23 kg to 40 kg	60mg (10ml of 6mg/ml liquid) twice daily, 2 x 65ml bottles

Children aged 0-12 months (≥36 weeks corrected gestational age):

Body Weight	Recommended dose for 5* days
<10 kg	3 mg/kg twice daily
≥10kg	30mg (5ml of 6mg/ml liquid) twice daily, 1 x 65ml bottle

Neonates less than 36 weeks corrected gestational age:

1 mg/kg twice daily for 5* days.

Reconstitution of oseltamivir powder (390mg) to provide oral suspension 6mg/ml or 30mg/5ml and 65ml total volume:

1. Tap the closed bottle gently several times to loosen the powder.

2. Measure 55 ml of water by filling the measuring cup to the indicated level (measuring cup included in the box).

3. Add all 55 ml of water into the bottle, recap the bottle and shake the closed bottle well for 15 seconds.

4. Remove the cap and push the bottle adapter into the neck of the bottle.

5. Close the bottle tightly with the cap (on the top of the bottle adapter). This will make sure that the bottle adapter fits in the bottle in the right position.

Suspension will appear as an opaque and white to light yellow suspension after reconstitution.

*Course can be extended to 10 days for immunosuppressed patients at the managing clinician's discretion. If the participant is discharged before the course is complete, the participant should be provided with medication to complete the course at home.

4.4 Returns and Destructions

During the study any patient returns or if there is still stock at end of study, please contact the sponsor.

4.5 FAQs

Also see the oseltamivir intervention sheet https://www.recoverytrial.net/for-site-staff/site-teams

Q. My patient has renal impairment, can they receive oseltamivir?

A. Yes; the twice a day dose should be reduced if renal function is impaired (this dose is 75mg in adults and children weighing >40kg, but a lower dose should be used in children weighing <40kg, as above):

- eGFR ≥10 to <30mL/min/1.73m^2 dose to be given once daily
- eGFR <10mL/min/1.73m^2 single dose to be given on day 1.

Q. My patient is pregnant or breastfeeding can they be treated with oseltamivir?

A. Yes; pregnant or breastfeeding women can be randomised to receive oseltamivir.

5 Sotrovimab

5.1 Initial supply and re-ordering

Sotrovimab is available as 500mg in 8mL vials, 1 vial per carton. The initial supply of sotrovimab will be sent by Fisher to each site for this arm (under instruction from the sponsor). The Principal Investigator will need to have completed the necessary training for this arm and the site activated before IMP is shipped.

Sites are to re-order supplies of sotrovimab when stock levels are running low by emailing the RECOVERY trial team: recoverytrial@ndph.ox.ac.uk

5.2 Receipt and Storage

As per SmPC.
Pharmacy department should receive all shipments.

All shipments will come with a temperature monitoring device. Follow the temperature monitoring device instructions included in the shipment. Please email the shipment temperature data to the RECOVERY trial team (see below) to confirm receipt. Discard the temperature monitoring device, in

an appropriate waste bin for electrical components, after the temperature readout report has been downloaded and emailed.

During storage only temperature excursions (i.e. temperatures outside of 2 – 8°C) for more than 1 hour are considered reportable to the RECOVERY trial team only.

If there has been a temperature excursion during shipping or during storage at site, then affected stock must be physically quarantined until further guidance is given. Sites will need to complete the 'Clinical Investigational Medicinal Product (IMP) Temperature Excursion or Damage Form'. Send the completed form to the RECOVERY trial team only: recoverytrial@ndph.ox.ac.uk

All sites will need to ensure clear storage separation between stock for this study and general stock, as well as having some way of identifying the difference between stock when dispensing and checking. This could be done via a number of ways such as adding an additional label on receipting of stock stating 'To be used in the RECOVERY trial only' and storing in different areas of pharmacy.

Please note that the expiry date of sotrovimab batches used in RECOVERY has been extended and so the date on the carton may not be accurate. Batch specific variations for lots **2T8F** and **UK3F** have been approved by the MHRA, the most recent of which extends their expiry date to 36 months from the date of manufacture (lot 2T8F now expires February 2024 and lot UK3F March 2024). All stock held will need to have the expiry date extended. Please see Appendix 2 for a worksheet to support this. Note a further expiry extension is being requested and we will inform sites when this is approved, please contact the trial team in the meantime with any questions.

5.3 Dispensing quantities

Sotrovimab dispense 2 x 500mg vials for a single **1000mg dose** to be administered as an intravenous infusion over **60 minutes** using a 0.2micron low protein binding in-line filter.

Note: *The dose and duration are different to SmPC license.*

5.4 Preparation Guidance

Doses of Sotrovimab may be made on the ward as per individual Trust guidance and risk assessment for monoclonal antibodies. Trust must have an IV monograph available on the wards where doses will be prepared (see Appendix 1 for an example).

Preparation steps

1. Remove **TWO** vials of sotrovimab from the refrigerator to allow the vials to equilibrate to room temperature, protected from light, for approximately 15 minutes
2. Obtain one **100mL** sodium chloride 0.9% or glucose 5% infusion bag
3. Visually inspect each vial to ensure it is a clear, colourless or yellow to brown solution, free from visible particles and that there is no visible damage to the vial
4. Gently swirl each vial several times before use without creating air bubbles. Do not shake or vigorously agitate the vials
5. Withdraw **16mL** of sotrovimab from the two vials
6. Add **16mL** of sotrovimab to a 100mL sodium chloride 0.9% or glucose 5% infusion bag

7. Gently rock the infusion bag back and forth 3 to 5 times. Do NOT invert the infusion bag. Avoid forming air bubbles

The stability concentration range is 1 – 10mg/mL. Sites must ensure that the brand of IV bag being used can hold this additional volume safely and that there is no additional risk of spillage/inadvertent loss when the ward nurse spikes the bag. The diluted solution should be administered immediately. If not possible then it may be stored at room temperature (up to 25°C) for up to 6 hours or refrigerated (2 – 8°C) for up to 24 hours from the time of dilution.

Please ensure the time of infusion is recorded in the medical records (if not done routinely).

5.5 Returns and Destructions

During the study if there is any damaged or expired stock, or if there is still stock at end of study, this can be destroyed on site. No approval from Sponsor is required.

5.6 FAQs

Also see the sotrovimab intervention sheet https://www.recoverytrial.net/for-site-staff/site-teams

Q. My patient has renal impairment and/or hepatic impairment, can they be treated with sotrovimab?

A. Yes, no dose adjustment is required.

Q. My patient weighs less than 40kg, can they be treated with Sotrovimab?

A. Yes, unless they are ≥12 <18 years old in which case they must weight >40 kg.

Q. Can adolescents under 12 years receive sotrovimab?

No, and see protocol for other arms.

Q. My patient is pregnant or breastfeeding can they be treated with sotrovimab?

A. Yes; pregnant or breastfeeding women can be randomised to receive sotrovimab, but the consent process must explain the risks and benefits.

6 General FAQs

Q. What happens if our site does not have one of the medications used in the study in stock?

A. The co-ordinating centre should be informed (e-mail to recoverytrial@ndph.ox.ac.uk). It is possible to indicate on the randomisation form if a treatment is unavailable (and this can be set at a site level), so participants would not be assigned it.

Q. How will the cost of IMPs be covered?

A. Baloxavir and oseltamivir will be free of charge from Roche. Sotrovimab will be free of charge from GSK. Dexamethasone, hydrocortisone, methylprednisolone and prednisolone could be covered by assigning to the government's COVID-19 cost centre as part of their overall treatment costs. Please liaise with your finance department to identify the mechanism set-up on how to claim for these extra COVID-19 costs. Corticosteroids for non-COVID-19 patients are provided by the site and

are not directly reimbursed, but are treated as research costs in the SoECAT (with a treatment course of dexamethasone typically costing a few pounds).

Q. Can patients treated according to local pathway/protocol guidance still be considered for the RECOVERY trial further down the line?

A. All patients should receive standard care according to their local protocol. Randomisation is in addition to that.

Q. Are you allowing co-enrolment into other clinical trials of COVID-19?

A. Yes, as long as the clinical trial does not directly conflict with RECOVERY. Please see the trial website for further information.

Q. To ensure consistency for all patients, can the sponsor provide some guidance on how urgent (hours) the trial patient needs to receive the first dose of treatment?

A. We have no specific guidance on this, but within 6 hours would be ideal.

Q. Is Sponsor happy for sites to 'pre-pack' tablets into patient courses?

A. Yes for use within one trust, with appropriate documentation and checks.
It is not legal to pre-pack for another Trust, unless the trust holds the relevant MHRA licenses.

Q. If patients are discharged early are pharmacy expected to use the left over medication to maximise stock (if sites SOPs allow)?

A. Yes if local site SOPs allow

Q. Are sites able to add their own dispensing/additional labels to manage the study as they feel is most appropriate?

A. Yes

Q. Can non-medical prescribers be utilised to prescribe trial medications?

A. Yes if local SOPs allow

7 Appendix 1: Worksheet for sotrovimab preparation

See next page.

RECOVERY
Randomised Evaluation of COVID-19 Therapy

Clinical Area Preparation Record – Sotrovimab 1000mg in 100mL Sodium Chloride 0.9% Infusion Bag (Total volume = 116 mL)

Set up

Step 1
Remove from the refrigerator:
- 2 x Sotrovimab 500mg (62.5mg/mL) Concentrate for Solution for Infusion vial.

Select:
- 1 x Sodium Chloride 0.9% 100mL Infusion Bag
- 1 x 20mL luer lock syringe
- 1 x drawing up needle
- 1 x 0.2 micron administration filter

Step 2
Visually inspect the Sotrovimab vials
- The solution should be clear, colourless or yellow to brown and free from visible particles

Should particulate matter or discoloration be observed, the vial must be discarded and replaced with a new vial.

Step 3
Place to the left side of the preparation area:
- 2 x Sotrovimab 500mg vial
- 1 x Sodium Chloride 0.9% 100ml Infusion Bag

Step 4
Prepare an infusion additive label with the following details:
- Sotrovimab 1000mg in Sodium Chloride 0.9% (Total volume = 116 mL)
- Date and time prepared
- [Additional details as required by local label format]

Preparation of Infusion Bag

Step 1
Bring the Sodium Chloride 0.9% 100mL Infusion Bag from the left side of the preparation area into the middle, swab the bung with a sterile 70% alcohol wipe and allow to dry.

Step 2
Bring the Sotrovimab 500mg vials from the left side of the preparation area into the middle, swab the bungs with sterile 70% alcohol wipe and allow to dry.

Step 3
Gently swirl the vials several times before use without creating air bubbles. **Do not shake or vigorously agitate the vial.**

Step 4
Attach a drawing up needle to a 20mL luer lock syringe and draw up **1 x 16mL** of Sotrovimab 500mg (62.5mg/mL) from the 2 vials

Step 5
Add **16mL** of Sotrovimab (62.5mg/mL) to the Sodium Chloride 0.9% 100mL Infusion Bag. Discard the syringe and needle into a yellow lidded sharps bin

Step 6
Gently rock the infusion bag back and forth 3 to 5 times.
NB: Do not invert the infusion bag. Avoid forming air bubbles. Do not shake

Step 7
Attach the pre-prepared label to the bag

Step 8
Ensure the product is administered using an [Insert local in-line or add-on 0.2µm filter used] as a single IV infusion for 60 minutes

Step 9
Record details of the patient who will receive the bag below, and file the completed *Clinical Area Preparation Record* in accordance with local guidance

Patient Name		Hospital No		Date of Birth	

8 Appendix 2: Worksheet for sotrovimab expiry extension

See next page.

RECOVERY Trial Pharmacy Expiry Extension Labelling Worksheet
SOTROVIMAB 500mg in 8mL Concentrate solution for infusion

Site:	
Date of over-labelling operation:	
Storage conditions whilst over-labelling:	Sotrovimab vials may be out of the fridge (2 – 8°C) for no more than 60 minutes
GSK/Vir confirmation of shelf-life expiry extension	Attach a copy to this work sheet

Product	Qty	Batch Number	Current Expiry Date	New Expiry Date	Assembled By:	Checked By:
Sotrovimab 500mg in 8mL Solution for Infusion (1 vial per carton)		UK3F				
		2T8F				

Label Production	
Master Label:	Sample Label:
	Affix the last label printed here

Method		
	Performed By:	Checked By:
1. Ensure the work area is clean and free from all materials not required in this process		
2. Calculate number of labels need A = (no. of vials x 2) +1, print the labels		
3. Remove sotrovimab vials from the fridge Record time removed: ……		
4. Apply label to the carton and vial		
5. Replace sotrovimab vials back in the carton and into the fridge Record time replaced: ……		
6. Calculate total time removed from fridge ……. minutes		
7. Check that this is less than 60 minutes		

Label Reconciliation			
	No. of Labels	Performed By:	Checked By:
No. of labels printed (A)			
No. of sample labels attached to worksheet (B)			
No. of labels attached to vials (C)			
No. of labels attached to carton (D)			
No. of excess labels destroyed (E)			
Total number of labels accounted for A = B + C + D + E	Y / N		

Approvals:
The above product has been over-labelled with new expiry extension labels according to the instructions above. Any remaining labels have been destroyed.

Actions completed by:

_____ (Print Name) _____ (Sign) _____ (Initials) _____ (Date)

Actions Pharmacist checked by:

_____ (Print Name) _____ (Sign) _____ (Initials) _____ (Date)

Comments / Deviations

Storage of document:
Completed worksheet must be retained in the RECOVERY pharmacy site file, along with evidence of expiry date extension.