

REQUEST FOR AUTHORISATION OF A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE COMMUNITY

For official use:

Date of receiving the request:	Date of request for additional information:	Grounds for non acceptance / negative opinion :
Date of request for information to make it valid:		Give date:
Date of valid application :	Date of receipt of additional / amended information :	Authorisation / positive opinion:
Date of start of procedure :		Give date:
Competent authority registration number :		Withdrawal of application :
Ethics Committee registration number :		Give date :

A: Trial identification

A1. National Competent Authority:

UK - MHRA

A2. European Clinical Trials Database (EudraCT) number:

2020-001113-21

A3. Full title of the trial:

Randomised Evaluation of COVID-19 Therapy (RECOVERY)

A3-1. Title of the trial for lay people, in easily understood, i.e. non-technical, language

RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

A3-2. Name or abbreviated title of the trial where available:

RECOVERY trial

A4. Sponsor's protocol:

Number: NDPHRECOVERY

Version: 28.0

Date: 30/06/2025

A5-1. ISRCTN number, if available :

ISRCTN50189673

A5-2. US NCT number:

NCT04381936

A5-3. Who Universal Trial Reference Number (UTRN)**A5-4. Other Identifiers:**

Name	Identifier

A6. Is this a resubmission?☐ Yes ☒ No**A7. Is the trial part of a Paediatric Investigation Plan?**☐ Yes ☒ No ☐ Not Answered**B: Identification of the sponsor responsible for the request****B1. Sponsor****SP1****Contact person**

Name of organisation	University of Oxford
Given name	NA
Family name	NA
Address	Research Governance, Ethics & Assurance, 1st Floor, Boundary Brook House, Old Road, Headington
Town/city	OXFORD
Post code	OX3 7GB
Country	United Kingdom
Telephone	00000
Fax	00000
E-mail	rgea.sponsor@admin.ox.ac.uk

B2. Legal Representative for the purpose of this CTIMP.

A legal representative must be appointed for a clinical trial of an investigational medicinal product (CTIMP) if the sponsor is not established in the UK or on the MHRA approved country list (please refer to question specific guidance).

Legal Representative 1**Contact person**

Name of organisation

Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

B3. Status of the sponsor: Non-Commercial

B.4 Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary):

B.5 Contact point designated by the sponsor for further information on the trial:

Name of organisation
Functional name of contact point
Street Address
Town/city
Post code
Country
Telephone
Fax
E-mail

C: Applicant identification

C1. Request for the competent authority

C1-1. Who is responsible for the Clinical Trial Authorisation Application?

Sponsor

C1-4. Complete the details of the applicant below even if they are provided elsewhere on the form:

Contact person

Person or organisation name: University of Oxford
Contact person Given name Ferdousi
Contact person Family name Chowdhury
Address Research Governance, Ethics & Assurance, First Floor, Boundary Brook House

Town/city	Headington, Oxford
Post code	OX3 7GB
Country	United Kingdom
Telephone	00000
Fax	00000
E-mail	rgea.sponsor@admin.ox.ac.uk

C1-5. Do you want a xml file copy of the CTA form data saved on EudraCT?

☐ Yes ☒ No ☐ Not Answered

C2.Request for ethics committee

C2-1. Who is responsible for the Clinical Trial Authorisation Application?

.....

C2-5. Complete the details of the applicant below even if they are provided elsewhere on the form

Person or organisation name:

Title:

Forename/Initials:

Surname:

Middlename:

Address:

Town/city:

Post code:

Country:

Telephone:

Fax:

E-mail:

Part D: Investigational Medicinal Products

D: Information on the IMPs

Information on each "bulk product" before trial-specific operations (blinding, trial specific packaging and labelling) should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator, if applicable. If the trial is performed with several products please create a separate set of the following questions for each product. If the product is a combination product please give separate information for each active substance.

Click on the first row and enter details of the product in the following screens. When you have completed the details, click on the navigate button or the "See All" link and return to this section to enter details of the next product. When you have completed details of all products please move to question D7 using the navigation screen.

D. Investigational medicinal products

PR7 [Hydrocortisone](#)

PR17 [Dexamethasone](#)

PR19 [Prednisolone](#)

PR22 [Oseltamivir](#)

PR23 [Baloxavir](#)

D1. Indicate which of the following is described below then repeat as necessary for each:

This refers to the IMP number: **PR7**

Investigational medicinal product category:

Test IMP

D2. Status of the IMP *If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2*

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

☐ Yes ☒ No ☐ Not Answered

D2-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

The products to be administered as IMPs are defined as belonging to an ATC group

☒ Yes ☐ No ☐ Not Answered

If yes, give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be

defined) in D.3.1

Other :

☐ Yes
 ☐ No
 ☒ Not Answered
D2-3. IMPD submitted:

Full IMPD

☐ Yes
 ☒ No
 ☐ Not Answered

Simplified IMPD

☐ Yes
 ☒ No
 ☐ Not Answered
Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

☒ Yes
 ☐ No
 ☐ Not Answered
D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?
☐ Yes
 ☒ No
 ☐ Not Answered
D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?
☐ Yes
 ☒ No
 ☐ Not Answered
D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?
☐ Yes
 ☒ No
 ☐ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

☐ Yes
 ☒ No
 ☐ Not Answered
CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

☐ Yes
 ☒ No
 ☐ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3. Description of IMP**D3-1.**

D.3.1 Product name where applicable Hydrocortisone

D.3.2 Product code where applicable

D.3.3 ATC codes, if officially H02AB09

registered

D.3.4 Pharmaceutical form (use standard terms)

D.3.4.1 Is this a specific paediatric formulation? ☐ Yes ☒ No ☐ Not Answered

D.3.5 Maximum duration of treatment of a subject according to the protocol 10 days

D.3.6 Dose allowed

D.3.6.1 First dose for first-in-human clinical trial

D.3.6.1 Specify per day or total: ☐ per day ☐ total ☐ Not Answered

D.3.6.1 Specify total dose (number and unit)

D.3.6.1 Route of administration (relevant to the first dose):

D.3.6.2 Maximum dose allowed 1600 mg

D.3.6.2 Specify per day or total ☐ per day ☒ total ☐ Not AnsweredD.3.6.2 Specify total dose (number and unit) 1600 mg
milligram(s)

D.3.6.2 Route of administration (relevant to the maximum dose): Intravenous use

D.3.7 Routes of administration for this IMP

Intravenous use

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3-8. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available): Hydrocortisone

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description of the Active Substance

Strength

Concentration unit:

Concentration type:

Concentration number (only use both fields for range):

D3-11. Type of IMP

Does the IMP contain an active substance:

Of chemical origin? ☒ Yes ☐ No ☐ Not Answered

Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP)) ☐ Yes ☒ No ☐ Not Answered

Is this a:

Advanced Therapy IMP (ATIMP) ⁽¹⁾ ☐ Yes ☒ No ☐ Not Answered

Combination product that includes a device, but does not involve an Advanced Therapy ☐ Yes ☒ No ☐ Not Answered

Radiopharmaceutical medicinal product? ☐ Yes ☒ No ☐ Not Answered

Immunological medicinal product (e.g. vaccine, allergen, immune serum)? ☐ Yes ☒ No ☐ Not Answered

Plasma derived medicinal product? ☐ Yes ☒ No ☐ Not Answered

Extractive medicinal product? ☐ Yes ☒ No ☐ Not Answered

Recombinant medicinal product? ☐ Yes ☒ No ☐ Not Answered

Medicinal product containing genetically modified organisms? ☐ Yes ☒ No ☐ Not Answered

Herbal medicinal product? ☐ Yes ☒ No ☐ Not Answered

Homeopathic medicinal product? ☐ Yes ☒ No ☐ Not Answered

Another type of medicinal product? ☐ Yes ☒ No ☐ Not Answered

Specify the mode of action for the active substance in this medicinal product

The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action.

Immunomodulatory

Is it an IMP to be used in a first-in-human clinical trial? ☐ Yes ☒ No ☐ Not Answered

^(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable

^(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended

⁽⁴⁾ As defined in Article 2(1)(b) of Regulation 1394/2007/EC

⁽⁶⁾ Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

D1. Indicate which of the following is described below then repeat as necessary for each:This refers to the IMP number: **PR17**

Investigational medicinal product category:

Test IMP

D2. Status of the IMP *If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2*

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

☐ Yes ☒ No ☐ Not Answered

D2-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

The products to be administered as IMPs are defined as belonging to an ATC group

☐ Yes ☒ No ☐ Not Answered

Other :

☐ Yes ☒ No ☐ Not Answered

D2-3. IMPD submitted:

Full IMPD

☐ Yes ☒ No ☐ Not Answered

Simplified IMPD

☐ Yes ☒ No ☐ Not Answered

Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

☒ Yes ☐ No ☐ Not Answered

D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

☒ Yes ☐ No ☐ Not Answered

Specify which Member States:

AUSTRIA	<input type="checkbox"/>	BELGIUM	<input type="checkbox"/>	BULGARIA	<input type="checkbox"/>
CROATIA	<input type="checkbox"/>	CYPRUS	<input type="checkbox"/>	CZECH REPUBLIC	<input type="checkbox"/>
DENMARK	<input type="checkbox"/>	ESTONIA	<input type="checkbox"/>	FINLAND	<input type="checkbox"/>

FRANCE	<input type="checkbox"/>	GERMANY	<input type="checkbox"/>	GREECE	<input type="checkbox"/>
HUNGARY	<input type="checkbox"/>	ICELAND	<input type="checkbox"/>	IRELAND	<input type="checkbox"/>
ITALY	<input type="checkbox"/>	LATVIA	<input type="checkbox"/>	LIECHTENSTEIN	<input type="checkbox"/>
LITHUANIA	<input type="checkbox"/>	LUXEMBOURG	<input type="checkbox"/>	MALTA	<input type="checkbox"/>
NETHERLANDS	<input type="checkbox"/>	NORWAY	<input type="checkbox"/>	POLAND	<input type="checkbox"/>
PORTUGAL	<input type="checkbox"/>	ROMANIA	<input type="checkbox"/>	SLOVAKIA	<input type="checkbox"/>
SLOVENIA	<input type="checkbox"/>	SPAIN	<input type="checkbox"/>	SWEDEN	<input type="checkbox"/>
UNITED KINGDOM	<input checked="" type="checkbox"/>				

D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?

☐ Yes ☒ No ☐ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

☐ Yes ☒ No ☐ Not Answered

CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

☐ Yes ☒ No ☐ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3. Description of IMP**D3-1.**

D.3.1 Product name where applicable Dexamethasone

D.3.2 Product code where applicable

D.3.3 ATC codes, if officially registered H02AB02

D.3.4 Pharmaceutical form (use standard terms) Concentrate for solution for infusion

D.3.4.1 Is this a specific paediatric formulation? ☐ Yes ☒ No ☐ Not Answered

D.3.5 Maximum duration of treatment of a subject according to the protocol 10 days

D.3.6 Dose allowed

D.3.6.1 First dose for first-in-human clinical trial

D.3.6.1 Specify per day or total:

☐ per day ☐ total ☐ Not Answered

D.3.6.1 Specify total dose (number and unit)

D.3.6.1 Route of administration (relevant to the first dose):

D.3.6.2 Maximum dose allowed

60 mg

D.3.6.2 Specify per day or total

☐ per day ☒ total ☐ Not Answered

D.3.6.2 Specify total dose (number and unit)

60 mg
milligram(s)

D.3.6.2 Route of administration (relevant to the maximum dose): Intravenous use

D.3.7 Routes of administration for this IMP

Intravenous use

Oral use

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3-8. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available): Dexamethasone

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description
of the Active Substance*Strength*

Concentration unit: mg milligram(s)

Concentration type: equal

Concentration number (only use both fields for range): 5

D3-11. Type of IMP

Does the IMP contain an active substance:

Of chemical origin?

☒ Yes ☐ No ☐ Not Answered

Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP))

☐ Yes ☒ No ☐ Not Answered

Is this a:

Advanced Therapy IMP (ATIMP) ⁽¹⁾

☐ Yes ☒ No ☐ Not Answered

Combination product that includes a device, but does not involve an Advanced Therapy

☐ Yes ☒ No ☐ Not Answered

Radiopharmaceutical medicinal product?

☐ Yes ☒ No ☐ Not Answered

Immunological medicinal product (e.g. vaccine, allergen, immune serum)?

☐ Yes ☒ No ☐ Not Answered

Plasma derived medicinal product?

☐ Yes ☒ No ☐ Not Answered

Extractive medicinal product?

☐ Yes ☒ No ☐ Not Answered

Recombinant medicinal product?

☐ Yes ☒ No ☐ Not Answered

Medicinal product containing genetically modified organisms?

☐ Yes ☒ No ☐ Not Answered

Herbal medicinal product?

☐ Yes ☒ No ☐ Not Answered

Homeopathic medicinal product?

☐ Yes ☒ No ☐ Not Answered

Another type of medicinal product?

☐ Yes ☒ No ☐ Not Answered

Specify the mode of action for the active substance in this medicinal product

The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action. Immune response modulation

Is it an IMP to be used in a first-in-human clinical trial?

☐ Yes ☒ No ☐ Not Answered

^(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable

^(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended

⁽⁴⁾ As defined in Article 2(1)(b) of Regulation 1394/2007/EC

⁽⁶⁾ Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

D1. Indicate which of the following is described below then repeat as necessary for each:

This refers to the IMP number: **PR19**

Investigational medicinal product category:

Test IMP

D2. Status of the IMP *If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2*

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

☐ Yes ☒ No ☐ Not Answered

D2-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

The products to be administered as IMPs are defined as belonging to an ATC group

☒ Yes ☐ No ☐ Not Answered

If yes, give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.1

Other :

☐ Yes ☒ No ☐ Not Answered

D2-3. IMPD submitted:

Full IMPD

☐ Yes ☒ No ☐ Not Answered

Simplified IMPD

☐ Yes ☒ No ☐ Not Answered

Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

☒ Yes ☐ No ☐ Not Answered

D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

☒ Yes ☐ No ☐ Not Answered

Specify which Member States:

AUSTRIA

☐

BELGIUM

☐

BULGARIA

☐

CROATIA	<input type="checkbox"/>	CYPRUS	<input type="checkbox"/>	CZECH REPUBLIC	<input type="checkbox"/>
DENMARK	<input type="checkbox"/>	ESTONIA	<input type="checkbox"/>	FINLAND	<input type="checkbox"/>
FRANCE	<input type="checkbox"/>	GERMANY	<input type="checkbox"/>	GREECE	<input type="checkbox"/>
HUNGARY	<input type="checkbox"/>	ICELAND	<input type="checkbox"/>	IRELAND	<input type="checkbox"/>
ITALY	<input type="checkbox"/>	LATVIA	<input type="checkbox"/>	LIECHTENSTEIN	<input type="checkbox"/>
LITHUANIA	<input type="checkbox"/>	LUXEMBOURG	<input type="checkbox"/>	MALTA	<input type="checkbox"/>
NETHERLANDS	<input type="checkbox"/>	NORWAY	<input type="checkbox"/>	POLAND	<input type="checkbox"/>
PORTUGAL	<input type="checkbox"/>	ROMANIA	<input type="checkbox"/>	SLOVAKIA	<input type="checkbox"/>
SLOVENIA	<input type="checkbox"/>	SPAIN	<input type="checkbox"/>	SWEDEN	<input type="checkbox"/>
UNITED KINGDOM	<input checked="" type="checkbox"/>				

D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?

☐ Yes ☒ No ☐ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

☐ Yes ☒ No ☐ Not Answered

CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

☐ Yes ☒ No ☐ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3. Description of IMP**D3-1.**

D.3.1 Product name where applicable	Prednisolone
D.3.2 Product code where applicable	
D.3.3 ATC codes, if officially registered	H02AB06
D.3.4 Pharmaceutical form (use standard terms)	Tablet
D.3.4.1 Is this a specific paediatric formulation?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Answered
D.3.5 Maximum duration of treatment of a subject according to the protocol	10 days

D.3.6 Dose allowed

D.3.6.1 First dose for first-in-human clinical trial

D.3.6.1 Specify per day or total:

☐ per day ☐ total ☐ Not Answered

D.3.6.1 Specify total dose (number and unit)

D.3.6.1 Route of administration (relevant to the first dose):

D.3.6.2 Maximum dose allowed

400mg

D.3.6.2 Specify per day or total

☐ per day ☒ total ☐ Not Answered

D.3.6.2 Specify total dose (number and unit)

400

mg
milligram(s)

D.3.6.2 Route of administration (relevant to the maximum dose): Oral use

D.3.7 Routes of administration for this IMP

Oral use

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3-8. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available): Prednisolone

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description
of the Active Substance*Strength*

Concentration unit:

Concentration type:

Concentration number (only
use both fields for range):**D3-11. Type of IMP**

Does the IMP contain an active substance:

Of chemical origin?

☒ Yes ☐ No ☐ Not Answered

- Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP)) ☐ Yes ☒ No ☐ Not Answered
- Is this a:*
- Advanced Therapy IMP (ATIMP) ⁽¹⁾ ☐ Yes ☒ No ☐ Not Answered
- Combination product that includes a device, but does not involve an Advanced Therapy ☐ Yes ☒ No ☐ Not Answered
- Radiopharmaceutical medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Immunological medicinal product (e.g. vaccine, allergen, immune serum)? ☐ Yes ☒ No ☐ Not Answered
- Plasma derived medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Extractive medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Recombinant medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Medicinal product containing genetically modified organisms? ☐ Yes ☒ No ☐ Not Answered
- Herbal medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Homeopathic medicinal product? ☐ Yes ☒ No ☐ Not Answered
- Another type of medicinal product? ☐ Yes ☒ No ☐ Not Answered

Specify the mode of action for the active substance in this medicinal product

The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action.

Immunomodulatory

Is it an IMP to be used in a first-in-human clinical trial? ☐ Yes ☒ No ☐ Not Answered

^(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable

^(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended

⁽⁴⁾ As defined in Article 2(1)(b) of Regulation 1394/2007/EC

⁽⁶⁾ Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

D1. Indicate which of the following is described below then repeat as necessary for each:

This refers to the IMP number: **PR22**

Investigational medicinal product category:

Test IMP

D2. Status of the IMP *If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2*

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

☐ Yes ☒ No ☐ Not Answered

D2-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

The products to be administered as IMPs are defined as belonging to an ATC group

☐ Yes ☒ No ☐ Not Answered

Other :

☐ Yes ☒ No ☐ Not Answered

D2-3. IMPD submitted:

Full IMPD

☐ Yes ☒ No ☐ Not Answered

Simplified IMPD

☐ Yes ☒ No ☐ Not Answered

Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

☒ Yes ☐ No ☐ Not Answered

D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?

☐ Yes ☒ No ☐ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

☐ Yes ☒ No ☐ Not Answered

CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

☐ Yes ☒ No ☐ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3. Description of IMP**D3-1.**

D.3.1 Product name where applicable Oseltamivir

D.3.2 Product code where applicable

D.3.3 ATC codes, if officially registered J05AH02

D.3.4 Pharmaceutical form (use standard terms) Capsule, hard

D.3.4.1 Is this a specific paediatric formulation? ☐ Yes ☒ No ☐ Not Answered

D.3.5 Maximum duration of treatment of a subject according to the protocol 10 days

D.3.6 Dose allowed

D.3.6.1 First dose for first-in-human clinical trial

D.3.6.1 Specify per day or total: ☐ per day ☒ total ☐ Not Answered

D.3.6.1 Specify total dose (number and unit)

D.3.6.1 Route of administration (relevant to the first dose):

D.3.6.2 Maximum dose allowed 1500 mg

D.3.6.2 Specify per day or total ☐ per day ☒ total ☐ Not Answered

D.3.6.2 Specify total dose (number and unit) 1500 mg
milligram(s)

D.3.6.2 Route of administration (relevant to the maximum dose): Oral use

D.3.7 Routes of administration for this IMP

Oral use

Nasogastric use (Noncurrent)

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3-8. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available): Oseltamivir

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description of the Active Substance

Strength

Concentration unit:

Concentration type:

Concentration number (only use both fields for range):

D3-11. Type of IMP

Does the IMP contain an active substance:

Of chemical origin?

☒ Yes ☐ No ☐ Not Answered

Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP))

☐ Yes ☒ No ☐ Not Answered*Is this a:*Advanced Therapy IMP (ATIMP) ⁽¹⁾☐ Yes ☒ No ☐ Not Answered

Combination product that includes a device, but does not involve an Advanced Therapy

☐ Yes ☒ No ☐ Not Answered

Radiopharmaceutical medicinal product?

☐ Yes ☒ No ☐ Not Answered

Immunological medicinal product (e.g. vaccine, allergen, immune serum)?

☐ Yes ☒ No ☐ Not Answered

Plasma derived medicinal product?

☐ Yes ☒ No ☐ Not Answered

Extractive medicinal product?

☐ Yes ☒ No ☐ Not Answered

Recombinant medicinal product?

☐ Yes ☒ No ☐ Not Answered

Medicinal product containing genetically modified organisms?

☐ Yes ☒ No ☐ Not Answered

Herbal medicinal product?

☐ Yes ☒ No ☐ Not Answered

Homeopathic medicinal product?

☐ Yes ☒ No ☐ Not Answered

Another type of medicinal product?

☐ Yes ☒ No ☐ Not Answered

Specify the mode of action for the active substance in this medicinal product

The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action. Antiviral therapy

Is it an IMP to be used in a first-in-human clinical trial?

☐ Yes ☒ No ☐ Not Answered

^(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable

^(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended

⁽⁴⁾ As defined in Article 2(1)(b) of Regulation 1394/2007/EC

⁽⁶⁾ Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

D1. Indicate which of the following is described below then repeat as necessary for each:

This refers to the IMP number: **PR23**

Investigational medicinal product category:

Test IMP

D2. Status of the IMP *If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2*

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

☐ Yes ☒ No ☐ Not Answered

D2-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?

☒ Yes ☐ No ☐ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

☐ Yes ☒ No ☐ Not Answered

The products to be administered as IMPs are defined as belonging to an ATC group

☐ Yes ☒ No ☐ Not Answered

Other :

☐ Yes ☐ No ☒ Not Answered

D2-3. IMPD submitted:

Full IMPD

☐ Yes ☒ No ☐ Not Answered

Simplified IMPD

☐ Yes ☒ No ☐ Not Answered

Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

☒ Yes ☐ No ☐ Not Answered

D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?

☐ Yes ☒ No ☐ Not Answered

D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?

☐ Yes ☒ No ☐ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

☐ Yes ☒ No ☐ Not Answered

CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

☐ Yes ☒ No ☐ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3. Description of IMP**D3-1.**

D.3.1 Product name where applicable	Baloxavir
D.3.2 Product code where applicable	
D.3.3 ATC codes, if officially registered	J05AX25
D.3.4 Pharmaceutical form (use standard terms)	Film-coated tablet
D.3.4.1 Is this a specific paediatric formulation?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Answered
D.3.5 Maximum duration of treatment of a subject according to the protocol	Two doses: day 1 and day 4

D.3.6 Dose allowed

D.3.6.1 First dose for first-in-human clinical trial	
D.3.6.1 Specify per day or total:	<input type="radio"/> per day <input type="radio"/> total <input type="radio"/> Not Answered
D.3.6.1 Specify total dose (number and unit)	
D.3.6.1 Route of administration (relevant to the first dose):	
D.3.6.2 Maximum dose allowed	160 mg
D.3.6.2 Specify per day or total	<input type="radio"/> per day <input checked="" type="radio"/> total <input type="radio"/> Not Answered
D.3.6.2 Specify total dose (number and unit)	160 mg milligram(s)
D.3.6.2 Route of administration (relevant to the maximum dose): Oral use	

D.3.7 Routes of administration for this IMP

Oral use

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

D3-8. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available): Baloxavir

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description of the Active Substance

Strength

Concentration unit:

Concentration type:

Concentration number (only use both fields for range):

D3-11. Type of IMP

Does the IMP contain an active substance:

Of chemical origin? ☒ Yes ☐ No ☐ Not Answered

Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP)) ☐ Yes ☒ No ☐ Not Answered

Is this a:

Advanced Therapy IMP (ATIMP) ⁽¹⁾ ☐ Yes ☒ No ☐ Not Answered

Combination product that includes a device, but does not involve an Advanced Therapy ☐ Yes ☒ No ☐ Not Answered

Radiopharmaceutical medicinal product? ☐ Yes ☒ No ☐ Not Answered

Immunological medicinal product (e.g. vaccine, allergen, immune serum)? ☐ Yes ☒ No ☐ Not Answered

Plasma derived medicinal product? ☐ Yes ☒ No ☐ Not Answered

Extractive medicinal product? ☐ Yes ☒ No ☐ Not Answered

Recombinant medicinal product? ☐ Yes ☒ No ☐ Not Answered

Medicinal product containing genetically modified organisms? ☐ Yes ☒ No ☐ Not Answered

Herbal medicinal product? ☐ Yes ☒ No ☐ Not Answered

Homeopathic medicinal product?

☐ Yes ☒ No ☐ Not Answered

Another type of medicinal product?

☐ Yes ☒ No ☐ Not Answered

Specify the mode of action for the active substance in this medicinal product

The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action. Anti-viral.

Is it an IMP to be used in a first-in-human clinical trial?

☐ Yes ☒ No ☐ Not Answered

(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable

(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended

(4) As defined in Article 2(1)(b) of Regulation 1394/2007/EC

(6) Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

D8. Information on placebo (if relevant; repeat as necessary)**D8. Is there a placebo:**

☐ Yes ☒ No ☐ Not Answered

D9. Sites responsible for final QP release for distribution to investigators.**D9-1. IMPs and placebos for which no responsible site needs to be identified.**

This section is used to identify IMPs and placebos which:

- Have an MA in the EU **and**
- Are sourced from the EU market **and**
- Are used in the trial without modification (eg not overencapsulated) **and**
- The packaging and labeling is carried out for local use only as per article 9.2 of the Directive 2005/28/EC (GCP Directive).

If all the conditions above are met, then select below the IMPs and placebos to which this applies.

Finished IMP
PR7

Finished IMP
PR17

Finished IMP
PR19

Finished IMP
PR22

Index of Sites where the qualified person certifies batch release

In accordance with paragraph 38 of Annex 13 of Volume 4 of the Rules Governing Medicinal Products in the European Union

D9-2. Who is responsible in the Community for the certification of the finished IMP or placebo?

This section is dedicated to finished IMPs, i.e. medicinal products randomised, packaged, labelled and certified for use in the clinical trial. If there is more than one site or more than one IMP is certified, use extra pages and give each IMP its number from section D1 or D7. In the case of multiple sites indicate the product certified by each site.

RS8

Importer

Name of the organisation: Roche Pharma AG
Address: Emil Barell-Strasse 1
Town/city: Grenzach-Whylen
Post code: 79639
Country: Germany

Give the manufacturing authorisation number

DE_BW_01_MIA_2020_0096

If no authorisation, give the reasons:

Select the relevant IMP(s) and Placebo(s) from the drop down lists.

IMP

PR23

RS9

Importer

Name of the organisation: Roche Product Limited

Address 6 Falcon Way, Shire Park

Town/city Welwyn Garden City

Post code AL7 1TW

Country United Kingdom

Give the manufacturing authorisation number

MIA(IMP)31

If no authorisation, give the reasons:

Select the relevant IMP(s) and Placebo(s) from the drop down lists.

IMP

PR23

E: Design of the Trial.

E.1 Medical Condition or Disease under Investigation

E1-1. Medical condition or disease under investigation ⁽¹⁾

Specify the medical condition(s) to be investigated (free text) :

Viral or bacterial pneumonia

Medical condition in easily understood language

Pneumonia

Identify the therapeutic area

Diseases [C] - Respiratory Tract Diseases [C08]

⁽¹⁾ In the case of healthy volunteer trials, the intended indication for the product under development should be provided.

E1-2. MedDRA information ⁽²⁾

MR3

Version	23
Level	PT
Classification Code	10035664
Term	Pneumonia
SOC	10021881 - Infections and infestations

(2) Applicants are encouraged to provide the MedDRA lower level term (LLT) if applicable and classification code.

E1-3. Is any of the conditions being studied a rare disease? ⁽³⁾

☐ Yes ☒ No ☐ Not Answered

(3) Refer to "Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation": COM/436/01
(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/09/WC500003773.pdf)

E2. Objective of the trial

E2-1. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

The primary objective is to provide reliable estimates of the effect of study treatments on death within 28 days of randomisation (with subsidiary analyses of cause of death).

E2-2. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

The secondary objectives are to assess the effects of study treatments on duration of hospital stay and on need for (and duration of) ventilation or renal replacement therapy.

E2-3. Is there a sub-study?

☐ Yes ☒ No ☐ Not Answered

E3. Please list the principal inclusion criteria (list the most important, max 5000 characters).

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

(i) Hospitalised

(ii) Pneumonia syndrome

(iii) Confirmed influenza infection or diagnosis of community-acquired pneumonia

(iv) 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

In addition, if the attending clinician believes that there is a specific contra-indication (see Appendix 2; section 8.2) to one of the active drug treatment arms, then the patient will not be excluded from randomisation to that arm.

E4. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Participants may be excluded from receiving one or more of the possible randomised options if their medical history suggests that a treatment may be contraindicated.

Corticosteroid

Contraindications:

- Known contra-indication to short-term corticosteroid.

Endemic infections may be screened for as required by local practice. Patients in the UK with SARS-CoV-2 infection are not eligible for the low-dose dexamethasone comparison for influenza infection because of the proven benefits of dexamethasone in COVID-19.

Baloxavir Marboxil

Contraindications:

- Weight <40kg
- Known hypersensitivity to baloxavir marboxil or the drug product excipients
- Participants who have received baloxavir marboxil for the current influenza infection

Oseltamivir

Contraindications:

- Known hypersensitivity to oseltamivir or the drug product excipients
- Participants who have received oseltamivir for the current influenza infection

Cautions:

- Dose should be reduced in presence of renal impairment
 - o eGFR ≥ 30 mL/min/1.73m²: dose as in normal renal function (75 mg twice daily)
 - o eGFR ≥ 10 <30 mL/min/1.73m²: 75 mg once daily
 - o eGFR <10 mL/min/1.73m²: 75 mg as a single dose on day 1

E5-1. What is the primary outcome measure for the study?(max 5000 characters)

All-cause mortality within 28 days of randomisation.

Duration of hospitalisation (co-primary for influenza comparisons).

Timepoint(s) of evaluation of this end point (max 800 characters)

28 days after randomisation.

The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points.

E5-2. Secondary end point(s) (max 5000 characters)

Duration of hospitalisation (co-primary for influenza comparisons).

Use of ventilation.

Timepoint(s) of evaluation of this end point (max 800 characters)

28 days

E6. What is the scope of the trial?

- | | | | |
|-----------------|--------------------------------------|-------------------------------------|------------------------------------|
| Diagnosis | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Prophylaxis | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Therapy | <input checked="" type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Answered |
| Safety | <input checked="" type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Answered |
| Efficacy | <input checked="" type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Answered |
| Pharmacokinetic | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Pharmacodynamic | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Bioequivalence | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Dose Response | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |
| Pharmacogenetic | <input type="radio"/> Yes | <input checked="" type="radio"/> No | <input type="radio"/> Not Answered |

Pharmacogenomic ☐ Yes ☒ No ☐ Not Answered

Pharmacoeconomic ☐ Yes ☒ No ☐ Not Answered

Others ☐ Yes ☒ No ☐ Not Answered

Specify:

E7-1. Trial type and phase ⁽¹⁾

Human pharmacology (Phase I) ☐ Yes ☒ No ☐ Not Answered

Therapeutic exploratory (Phase II) ☒ Yes ☐ No ☐ Not Answered

Therapeutic confirmatory (Phase III) ☒ Yes ☐ No ☐ Not Answered

Therapeutic use (Phase IV) ☒ Yes ☐ No ☐ Not Answered

(1) The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.

E8. Design of the Trial.

E8-1. Is the trial design controlled?

☒ Yes ☐ No ☐ Not Answered

Specify:

Randomised ☒ Yes ☐ No ☐ Not Answered

Open ☒ Yes ☐ No ☐ Not Answered

Single blind ☐ Yes ☒ No ☐ Not Answered

Double blind ☐ Yes ☒ No ☐ Not Answered

Parallel group ☒ Yes ☐ No ☐ Not Answered

Cross over ☐ Yes ☒ No ☐ Not Answered

Other ☐ Yes ☒ No ☐ Not Answered

E8-2. If controlled, specify the comparator:

Other medicinal product(s) ☒ Yes ☐ No ☐ Not Answered

Placebo ☐ Yes ☒ No ☐ Not Answered

Other ☒ Yes ☐ No ☐ Not Answered

Specify the comparator

Standard care

Number of treatment arms in the trial

4

E8-3. Single site in the Member State concerned (see also section G):

☐ Yes ☒ No ☐ Not Answered

E8-4. Multiple sites in the Member State concerned (see also section G):

☒ Yes ☐ No ☐ Not Answered

Number of sites anticipated in Member State concerned
68

E8-5. Multiple Member States

☐ Yes ☒ No ☐ Not Answered

Number of sites anticipated in the Community.

E8-6. Trial being conducted both within and outside the EEA

☒ Yes ☐ No ☐ Not Answered

Trial conducted completely outside EEA

☐ Yes ☒ No ☐ Not Answered

Specify the countries in which trial sites are planned

Vietnam

Indonesia

Nepal

Ghana

South Africa

Belgium

Estonia

France

Italy

Netherlands

Portugal

Romania

Spain

Sweden

Specify the number of sites anticipated outside of the EEA

20

E8-7. Will a data monitoring committee (DMC) be convened?☒ Yes ☐ No ☐ Not Answered**E8-8.****Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial.**

If it is the last visit of the last subject, please enter "LVLS". If it is not LVLS provide the definition.

All randomised participants are to be followed up until death, discharge from hospital or 28 days post-randomisation (whichever is sooner). Longer term follow-up will be sought through linkage to electronic healthcare records and medical databases including those held by NHS Digital, Public Health England and equivalent bodies. The end of the study is the date of the final data extraction from NHS Digital (anticipated to be 10 years after the last patient is enrolled).

E8-9. How long do you expect the study to last? ⁽¹⁾

In all countries concerned by the trial

Years: 17 Months: 2 Days: 13

In the MS concerned

Years: 11 Months: 6 Days: 11

⁽¹⁾ From the first inclusion until the last visit of the last subject.

E8-10. Recruitment start date

Recruitment start date in MS

19/03/2020

In any country

19/03/2020

⁽¹⁾ If not provided in the protocol.

F: Population of Trial Subjects**F1. What is the age span of the trial subjects?**

Less than 18 years ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 500

Please specify the estimated number of participants planned in each age range for the whole trial:

In Utero ☐ Yes ☒ No ☐ Not Answered Approx no of participants: 0

Preterm newborn infants (up to gestational age less than 37 weeks) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 10

Newborn (0-27 days) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 10

Infant and toddler (28 days - 23 months) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 10

Children (2-11 years) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 240

Adolescent (12-17 years) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 240

Adult (18-64 years) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 30000

Elderly (greater than 65 years) ☒ Yes ☐ No ☐ Not Answered Approx no of participants: 30000

The number of participants will be initial estimates. Applicants will not be required to update this information nor do they constitute an authorisation or restriction on the inclusion of these numbers of patients in the trial.

F2. What is the gender of the trial subjects?

Female ☒ Yes ☐ No ☐ Not Answered

Male ☒ Yes ☐ No ☐ Not Answered

F3. Please select the categories of the trial subjects:

Healthy volunteers ☐ Yes ☒ No ☐ Not Answered

Patients ☒ Yes ☐ No ☐ Not Answered

Specific vulnerable populations ☐ Yes ☒ No ☐ Not Answered

F4. Planned number of subjects to be included:

In the member state 60000

For a multinational trial:

In the European community: 58000

In the whole clinical trial: 60000

F5. Plans for treatment or care after a subject has ended his/her participation in the trial. If it is different from the expected normal treatment, please specify:

It would not be appropriate for participants to continue to receive their study treatment after the end of the trial as it is an acute treatment for an acute condition.

G1. and G2. Investigator Details**G1. National coordinating investigator** (for a multicentre trial) **or principal investigator** (for a single centre trial)☒ National coordinating investigator☐ Principal investigator

Given name Peter
 Family name Horby
 Qualification (MD...) MBBS PhD FRCP
 Institution name University of Oxford
 Institution department name Nuffield Department of Medicine
 Street address New Richards Building, Old Road Campus, Headington
 Town/city Oxford
 Post Code OX3 7LG
 Country United Kingdom
 Telephone 01865 612940
 Fax
 E-mail peter.horby@ndm.ox.ac.uk

G2. Other principal Investigators (for a multicentre trial)**IN2**

Given name Heinke
 Family name Kunst
 Qualification (MD...) Doctor (GMC 4232632)
 Institution name Barts Health NHS Trust
 Institution department name
 Street address The Royal London Hospital, Newark Street
 Town/city LONDON
 Post Code E1 2ES
 Country United Kingdom
 Telephone
 Fax
 E-mail h.kunst@nhs.net

IN3

Given name Gareth
 Family name Hardy
 Qualification (MD...) Doctor (GMC 6140603)
 Institution name Blackpool Teaching Hospitals NHS Foundation Trust
 Institution department name
 Street address Victoria Hospital, Whinney Heys Road
 Town/city BLACKPOOL
 Post Code FY3 8NR
 Country United Kingdom
 Telephone

Fax
E-mail gareth.hardy@nhs.net

IN4

Given name Madhu
Family name Balasubramaniam
Qualification (MD...) Doctor (GMC 6050397)
Institution name Bolton NHS Foundation Trust
Institution department name
Street address The Royal Bolton Hospital, Minerva Road, Farnworth
Town/city BOLTON
Post Code BL4 0JR
Country United Kingdom
Telephone
Fax
E-mail Madhu.Balasubramaniam@boltonft.nhs.uk

IN5

Given name Muhammad Sheharyar
Family name Khan
Qualification (MD...) Doctor (GMC 7865031)
Institution name Buckinghamshire Healthcare NHS Trust
Institution department name
Street address Amersham Hospital, Whielden Street
Town/city AMERSHAM
Post Code HP7 0JD
Country United Kingdom
Telephone
Fax
E-mail sheharyar.khan2@nhs.net

IN6

Given name Purav
Family name Desai
Qualification (MD...) Doctor (GMC 6128273)
Institution name Calderdale and Huddersfield NHS Foundation Trust
Institution department name
Street address Trust Headquarters, Acre Street, Lindley
Town/city HUDDERSFIELD
Post Code HD3 3EA
Country
Telephone
Fax
E-mail Purav.desai@cht.nhs.uk

IN7

Given name Martin
Family name Knolle
Qualification (MD...) Doctor (GMC 6091345)

Institution name	Cambridge University Hospitals NHS Foundation Trust
Institution department name	
Street address	Cambridge Biomedical Campus, Hills Road
Town/city	CAMBRIDGE
Post Code	CB2 0QQ
Country	United Kingdom
Telephone	
Fax	
E-mail	martinknolle@nhs.net

IN8

Given name	Jonathan
Family name	Underwood
Qualification (MD...)	Doctor (GMC 6129917)
Institution name	Cardiff & Vale University LHB
Institution department name	
Street address	Woodland House, Maes-Y-Coed Road
Town/city	CARDIFF
Post Code	CF14 4HH
Country	United Kingdom
Telephone	
Fax	
E-mail	Jonathan.Underwood@wales.nhs.uk

IN9

Given name	Ceri-Ann
Family name	Lynch
Qualification (MD...)	Doctor (GMC 6074961)
Institution name	Cwm Taf Morgannwg University LHB
Institution department name	
Street address	Dewi Sant Hospital, Albert Road
Town/city	PONTYPRIDD
Post Code	CF37 1LB
Country	United Kingdom
Telephone	
Fax	
E-mail	Ceri.Lynch5@wales.nhs.uk

IN10

Given name	Jonathan
Family name	Douse
Qualification (MD...)	Doctor (GMC 4476128)
Institution name	East Suffolk and North Essex NHS Foundation Trust (Ipswich hospital)
Institution department name	
Street address	Colchester Dist General Hospital, Turner Road
Town/city	COLCHESTER
Post Code	CO4 5JL
Country	United Kingdom

Telephone
 Fax
 E-mail jonathan.douse@esneft.nhs.uk

IN11

Given name Simon
 Family name Winn
 Qualification (MD...) Doctor (GMC 6105236)
 Institution name Epsom and St Helier University Hospitals NHS Trust
 Institution department name
 Street address St Helier Hospital, Wrythe Lane
 Town/city CARSHALTON
 Post Code SM5 1AA
 Country United Kingdom
 Telephone
 Fax
 E-mail simon.winn@nhs.net

IN12

Given name Dina
 Family name Mansour
 Qualification (MD...) Doctor (GMC 6149246)
 Institution name Gateshead Health NHS Foundation Trust
 Institution department name
 Street address Queen Elizabeth Hospital, Sheriff Hill
 Town/city GATESHEAD
 Post Code NE9 6SX
 Country United Kingdom
 Telephone
 Fax
 E-mail dina.mansour@nhs.net

IN13

Given name Simon
 Family name Message
 Qualification (MD...) Doctor (GMC 3558609)
 Institution name Gloucestershire Hospitals NHS Foundation Trust
 Institution department name
 Street address Cheltenham General Hospital, Sandford Road
 Town/city CHELTENHAM
 Post Code GL53 7AN
 Country United Kingdom
 Telephone
 Fax
 E-mail simon.message@nhs.net

IN14

Given name Mark
 Family name Peters

Qualification (MD...)	Doctor (GMC 3289743)
Institution name	Great Ormond Street Hospital For Children NHS Foundation Trust
Institution department name	
Street address	Great Ormond Street
Town/city	LONDON
Post Code	WC1N 3JH
Country	United Kingdom
Telephone	
Fax	
E-mail	Mark.Peters@gosh.nhs.uk

IN15

Given name	Anthony
Family name	Kerry
Qualification (MD...)	Doctor (GMC 4326144)
Institution name	Great Western Hospitals NHS Foundation Trust
Institution department name	
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Town/city	SWINDON
Post Code	SN3 6BB
Country	United Kingdom
Telephone	
Fax	
E-mail	anthony.kerry1@nhs.net

IN16

Given name	Paul
Family name	Dargan
Qualification (MD...)	Doctor (GMC 4028439)
Institution name	Guy's and St Thomas' NHS Foundation Trust
Institution department name	
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Town/city	LONDON
Post Code	SE1 7EH
Country	United Kingdom
Telephone	
Fax	
E-mail	paul.dargan1@nhs.net

IN17

Given name	Graham
Family name	Cooke
Qualification (MD...)	Doctor (GMC 4156084)
Institution name	Imperial College Healthcare NHS Trust
Institution department name	
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Town/city	LONDON
Post Code	W2 1BL
Country	United Kingdom

Telephone
 Fax
 E-mail graham.cooke@nhs.net

IN18

Given name Nasir
 Family name Siddique
 Qualification (MD...) Doctor (GMC 4489427)
 Institution name Kettering General Hospital NHS Foundation Trust
 Institution department name
 Street address Rothwell Road
 Town/city KETTERING
 Post Code NN16 8UZ
 Country United Kingdom
 Telephone
 Fax
 E-mail nasirsiddique@nhs.net

IN19

Given name Paul
 Family name Hine
 Qualification (MD...) Doctor (GMC 7037655)
 Institution name Liverpool University Hospitals NHS Foundation Trust
 Institution department name
 Street address Royal Liverpool University Hospital, Prescot Street
 Town/city LIVERPOOL
 Post Code L7 8XP
 Country United Kingdom
 Telephone
 Fax
 E-mail paul.hine@liverpoolft.nhs.uk

IN20

Given name Ashley
 Family name Whittington
 Qualification (MD...) Doctor (GMC 6149034)
 Institution name London North West University Healthcare NHS Trust
 Institution department name
 Street address Northwick Park Hospital, Watford Road
 Town/city HARROW
 Post Code HA1 3UJ
 Country United Kingdom
 Telephone
 Fax
 E-mail a.whittington@nhs.net

IN21

Given name Andrew

Family name	Ross-Parker
Qualification (MD...)	Doctor (GMC 7284184)
Institution name	Maidstone and Tunbridge Wells NHS Trust
Institution department name	
Street address	The Maidstone Hospital, Hermitage Lane
Town/city	MAIDSTONE
Post Code	ME16 9QQ
Country	United Kingdom
Telephone	
Fax	
E-mail	a.ross-parker@nhs.net

IN22

Given name	Jaydip
Family name	Majumdar
Qualification (MD...)	Doctor (GMC 5201665)
Institution name	Mid Cheshire Hospitals NHS Foundation Trust
Institution department name	
Street address	Leighton Hospital, Leighton
Town/city	CREWE
Post Code	CW1 4QJ
Country	United Kingdom
Telephone	
Fax	
E-mail	Jaydip.majumdar@mcht.nhs.uk

IN23

Given name	Brendan
Family name	Sloan
Qualification (MD...)	Doctor (GMC 6118893)
Institution name	Mid Yorkshire Hospitals NHS Trust
Institution department name	
Street address	Pinderfields Hospital, Aberford Road
Town/city	WAKEFIELD
Post Code	WF1 4DG
Country	United Kingdom
Telephone	
Fax	
E-mail	brendan.sloan1@nhs.net

IN24

Given name	Richard
Family name	Stewart
Qualification (MD...)	Doctor (GMC 6025185)
Institution name	Milton Keynes University Hospital NHS Foundation Trust
Institution department name	
Street address	Standing Way, Eaglestone
Town/city	MILTON KEYNES
Post Code	MK6 5LD

Country	United Kingdom
Telephone	
Fax	
E-mail	richard.stewart1@mkuh.nhs.uk

IN25

Given name	Samuel
Family name	Allen
Qualification (MD...)	Doctor (GMC 3563120)
Institution name	NHS Ayrshire and Arran/University Hospital Crosshouse
Institution department name	
Street address	Kilmarnock Road
Town/city	KILMARNOCK
Post Code	KA2 0BE
Country	United Kingdom
Telephone	
Fax	
E-mail	sam.allen@aapct.scot.nhs.uk

IN26

Given name	Devesh
Family name	Dhasmana
Qualification (MD...)	Doctor (GMC 4741499)
Institution name	NHS Fife
Institution department name	
Street address	Hayfield Road
Town/city	KIRKCALDY
Post Code	KY2 5AH
Country	United Kingdom
Telephone	
Fax	
E-mail	devesh.dhasmana@nhs.scot

IN27

Given name	Jeyakumar
Family name	Selwyn
Qualification (MD...)	Doctor (GMC 4734550)
Institution name	NHS Forth Valley/Forth Valley Royal Hospital
Institution department name	
Street address	Stirling Road
Town/city	LARBERT
Post Code	FK5 4WR
Country	United Kingdom
Telephone	
Fax	
E-mail	jeyakumar.selwyn@nhs.scot

IN28

Given name	Manish
Family name	Patel
Qualification (MD...)	Doctor (GMC 4441744)
Institution name	NHS Lanarkshire/University Hospital Hairmyres
Institution department name	
Street address	Eaglesham Road, East Kilbride
Town/city	GLASGOW
Post Code	G75 8RG
Country	United Kingdom
Telephone	
Fax	
E-mail	Manish.Patel@lanarkshire.scot.nhs.uk

IN29

Given name	Manish
Family name	Patel
Qualification (MD...)	Doctor (GMC 4441744)
Institution name	NHS Lanarkshire/University Hospital Monklands
Institution department name	
Street address	Monkscourt Avenue
Town/city	AIRDRIE
Post Code	ML6 0JS
Country	United Kingdom
Telephone	
Fax	
E-mail	Manish.Patel@lanarkshire.scot.nhs.uk

IN30

Given name	Manish
Family name	Patel
Qualification (MD...)	Doctor (GMC 4441744)
Institution name	NHS Lanarkshire/University Hospital Wishaw
Institution department name	
Street address	50 Netherton Street
Town/city	WISHAW
Post Code	ML2 0DP
Country	United Kingdom
Telephone	
Fax	
E-mail	Manish.Patel@lanarkshire.scot.nhs.uk

IN31

Given name	Alasdair
Family name	Gray
Qualification (MD...)	Doctor (GMC 3328712)
Institution name	NHS Lothian/Royal Infirmary of Edinburgh
Institution department name	
Street address	51 Little France Crescent, Old Dalkeith Road
Town/city	EDINBURGH

Post Code	EH16 4SA
Country	United Kingdom
Telephone	
Fax	
E-mail	alasdair.gray@nhslothian.scot.nhs.uk

IN32

Given name	Oliver
Family name	Koch
Qualification (MD...)	Doctor (GMC 6043322)
Institution name	NHS Lothian/Western General Hospital
Institution department name	
Street address	Crewe Road South
Town/city	EDINBURGH
Post Code	EH4 2XU
Country	United Kingdom
Telephone	
Fax	
E-mail	oliver.koch@nhs.scot

IN33

Given name	David
Family name	Arnold
Qualification (MD...)	Doctor (GMC 7265263)
Institution name	North Bristol NHS Trust
Institution department name	
Street address	Southmead Hospital, Southmead Road, Westbury-On-Trym
Town/city	BRISTOL
Post Code	BS10 5NB
Country	United Kingdom
Telephone	
Fax	
E-mail	david.arnold@nbt.nhs.uk

IN34

Given name	Clive
Family name	Graham
Qualification (MD...)	Doctor (GMC 3478253)
Institution name	North Cumbria Integrated Care NHS Foundation Trust
Institution department name	
Street address	Voreda House, Portland Place
Town/city	PENRITH
Post Code	CA11 7BF
Country	United Kingdom
Telephone	
Fax	
E-mail	clive.graham@ncic.nhs.uk

IN35

Given name Ben
 Family name Prudon
 Qualification (MD...) Doctor (GMC 6101440)
 Institution name North Tees and Hartlepool NHS Foundation Trust
 Institution department name
 Street address University Hospital Of Hartlepool, Holdforth Road
 Town/city HARTLEPOOL
 Post Code TS24 9AH
 Country United Kingdom
 Telephone
 Fax
 E-mail ben.prudon@nhs.net

IN36

Given name Paul
 Family name Minnis
 Qualification (MD...) Doctor (GMC 6120164)
 Institution name Northern HSC Trust
 Institution department name
 Street address Antrim Area Hospital, Bush Road
 Town/city ANTRIM
 Post Code BT41 2RL
 Country United Kingdom
 Telephone
 Fax
 E-mail Paul.Minnis@northerntrust.hscni.net

IN37

Given name Alastair
 Family name Green
 Qualification (MD...) Pharmacist (GPhC 2208641)
 Institution name Northumbria Healthcare NHS Foundation Trust
 Institution department name
 Street address North Tyneside General Hospital, Rake Lane
 Town/city NORTH SHIELDS
 Post Code NE29 8NH
 Country United Kingdom
 Telephone
 Fax
 E-mail Alastair.green@northumbria-healthcare.nhs.uk

IN38

Given name Wei Shen
 Family name Lim
 Qualification (MD...) Doctor (GMC 3275522)
 Institution name Nottingham University Hospitals NHS Trust
 Institution department name
 Street address Trust Headquarters, Queens Medical Centre, Derby Road

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 Post Code NG7 2UH
 Country United Kingdom
 Telephone
 Fax
 E-mail weishen.lim@nhs.net

IN39

Given name Brian
 Family name Angus
 Qualification (MD...) Doctor (GMC 3312984)
 Institution name Oxford University Hospitals NHS Foundation Trust
 Institution department name
 Street address John Radcliffe Hospital, Headley Way, Headington
 Town/city OXFORD
 Post Code OX3 9DU
 Country United Kingdom
 Telephone
 Fax
 E-mail brian.angus@ouh.nhs.uk

IN40

Given name Thomas
 Family name Brown
 Qualification (MD...) Doctor (GMC 6076300)
 Institution name Portsmouth Hospitals NHS Trust
 Institution department name
 Street address Queen Alexandra Hospital, Southwick Hill Road, Cosham
 Town/city PORTSMOUTH
 Post Code PO6 3LY
 Country United Kingdom
 Telephone
 Fax
 E-mail Thomas.Brown@porthosp.nhs.uk

IN41

Given name Matthew
 Family name Frise
 Qualification (MD...) Doctor (GMC 6102244)
 Institution name Royal Berkshire NHS Foundation Trust
 Institution department name
 Street address Royal Berkshire Hospital, London Road
 Town/city READING
 Post Code RG1 5AN
 Country United Kingdom
 Telephone
 Fax
 E-mail Matthew.Frise@royalberkshire.nhs.uk

IN42

Given name Sanjeev
 Family name Gupta
 Qualification (MD...) Doctor (GMC 5117986)
 Institution name Royal Cornwall Hospitals NHS Trust
 Institution department name
 Street address Royal Cornwall Hospital, Treliske
 Town/city TRURO
 Post Code TR1 3LJ
 Country United Kingdom
 Telephone
 Fax
 E-mail sanjeev.gupta3@nhs.net

IN43

Given name Ray
 Family name Sheridan
 Qualification (MD...) Doctor (GMC 4037057)
 Institution name Royal Devon and Exeter NHS Foundation Trust
 Institution department name
 Street address Royal Devon & Exeter Hospital, Barrack Road
 Town/city EXETER
 Post Code EX2 5DW
 Country United Kingdom
 Telephone
 Fax
 E-mail ray.sheridan@nhs.net

IN44

Given name Sanjay
 Family name Bhagani
 Qualification (MD...) Doctor (GMC 3539149)
 Institution name Royal Free London NHS Foundation Trust
 Institution department name
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 Town/city LONDON
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 Country United Kingdom
 Telephone
 Fax
 E-mail s.bhagani@nhs.net

IN45

Given name Alain
 Family name Vuylsteke
 Qualification (MD...) Doctor (GMC 4161251)
 Institution name Royal Papworth Hospital NHS Foundation Trust
 Institution department name

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Town/city	CAMBRIDGE
Post Code	CB2 0AY
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Fax	
E-mail	a.vuylsteke@nhs.net

IN46

Given name	Rohan
Family name	Mehta
Qualification (MD...)	Doctor (GMC 3690509)
Institution name	Salisbury NHS Foundation Trust
Institution department name	
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Town/city	SALISBURY
Post Code	SP2 8BJ
Country	United Kingdom
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Fax	
E-mail	rohan.mehta@nhs.net

IN47

Given name	Paul
Family name	Collini
Qualification (MD...)	Doctor (GMC 4546869)
Institution name	Sheffield Teaching Hospitals NHS Foundation Trust
Institution department name	
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Town/city	SHEFFIELD
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Country	United Kingdom
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Fax	
E-mail	paul.collini@nhs.net

IN48

Given name	Mark
Family name	Roberts
Qualification (MD...)	Doctor (GMC 4673884)
Institution name	Sherwood Forest Hospitals NHS Foundation Trust
Institution department name	
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Town/city	SUTTON-IN-ASHFIELD
Post Code	NG17 4JL
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Fax	
E-mail	mark.roberts@nhs.net

IN49

Given name David
 Family name Chadwick
 Qualification (MD...) Doctor (GMC 3479481)
 Institution name South Tees Hospitals NHS Foundation Trust
 Institution department name
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 Country United Kingdom
 Telephone
 Fax
 E-mail davidr.chadwick@nhs.net

IN50

Given name Stefania
 Family name Pintus
 Qualification (MD...) Doctor (GMC 6143765)
 Institution name Mersey and West Lancashire Teaching Hospitals NHS Trust
 Institution department name
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 Country United Kingdom
 Telephone
 Fax
 E-mail stefania.pintus@merseywestlancs.nhs.uk

IN51

Given name Claire
 Family name Mullender
 Qualification (MD...) Doctor (GMC 7043399)
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 Institution department name
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 Town/city LONDON
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 Country United Kingdom
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 Fax
 E-mail clairemarie.mullender@stgeorges.nhs.uk

IN52

Given name Greg
 Family name Barton
 Qualification (MD...) Pharmacist (GPhC 2049547)
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IN53

Given name Brendan
 Family name Healy
 Qualification (MD...) Doctor (GMC 4524784)
 Institution name Swansea Bay University Local Health Board
 Institution department name
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 Post Code SA12 7BR
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 Telephone
 Fax
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IN54

Given name Al-Tahoor
 Family name Butt
 Qualification (MD...) Doctor (GMC 7136325)
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 Institution department name
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 Post Code OL6 9RW
 Country United Kingdom
 Telephone
 Fax
 E-mail al-tahoor.butt@tgh.nhs.uk

IN55

Given name Ewan
 Family name Hunter
 Qualification (MD...) Doctor (GMC 6079082)
 Institution name The Newcastle Upon Tyne Hospitals NHS Foundation Trust
 Institution department name
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 Town/city NEWCASTLE UPON TYNE
 Post Code NE7 7DN
 Country United Kingdom
 Telephone
 Fax

E-mail ewan.hunter1@nhs.net

IN56

Given name Anil
 Family name Hormis
 Qualification (MD...) Doctor (GMC 4713263)
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 Institution department name
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 Fax
 E-mail anilhormis@nhs.net

IN57

Given name Mahdad
 Family name Noursadeghi
 Qualification (MD...) Doctor (GMC 4208606)
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 Institution department name
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 Town/city LONDON
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 Country
 Telephone
 Fax
 E-mail mahdadnoursadeghi@nhs.net

IN58

Given name Christopher
 Family name Green
 Qualification (MD...) Doctor (GMC 6103860)
 Institution name University Hospitals Birmingham NHS Foundation Trust
 Institution department name
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 Country United Kingdom
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 Fax
 E-mail cgreen16@nhs.net

IN59

Given name Thomas
 Family name Bewick
 Qualification (MD...) Doctor (GMC 6075805)

Institution name	University Hospitals Of Derby and Burton NHS Foundation Trust
Institution department name	
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Town/city	DERBY
Post Code	DE22 3NE
Country	United Kingdom
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Fax	
E-mail	tom.bewick1@nhs.net

IN60

Given name	Christopher
Family name	Brightling
Qualification (MD...)	Doctor (GMC 4021092)
Institution name	University Hospitals Of Leicester NHS Trust
Institution department name	
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Country	United Kingdom
Telephone	
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E-mail	ceb17@leicester.ac.uk

IN61

Given name	Shahedal
Family name	Bari
Qualification (MD...)	Doctor (GMC 4688037)
Institution name	University Hospitals Of Morecambe Bay NHS Foundation Trust
Institution department name	
Street address	Westmorland General Hospital, Burton Road
Town/city	KENDAL
Post Code	LA9 7RG
Country	United Kingdom
Telephone	
Fax	
E-mail	Shahedal.Bari@mbht.nhs.uk

IN62

Given name	Timothy
Family name	Kemp
Qualification (MD...)	Doctor (GMC 6101972)
Institution name	University Hospitals Of North Midlands NHS Trust
Institution department name	
Street address	Newcastle Road
Town/city	STOKE-ON-TRENT
Post Code	ST4 6QG
Country	United Kingdom
Telephone	

Fax
E-mail Timothy.Kemp@uhnm.nhs.uk

IN63

Given name Cyrus
Family name Daneshvar
Qualification (MD...) Doctor (GMC 4607463)
Institution name University Hospitals Plymouth NHS Trust
Institution department name
Street address Derriford Hospital, Derriford Road, Derriford
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Post Code PL6 8DH
Country United Kingdom
Telephone
Fax
E-mail cyrus.daneshvar@nhs.net

IN64

Given name Luke
Family name Hodgson
Qualification (MD...) Doctor (GMC 6102849)
Institution name Western Sussex Hospitals NHS Foundation Trust
Institution department name
Street address Worthing Hospital, Lyndhurst Road
Town/city WORTHING
Post Code BN11 2DH
Country United Kingdom
Telephone
Fax
E-mail Luke.Hodgson2@nhs.net

IN65

Given name Chetan
Family name Parmar
Qualification (MD...) Doctor (GMC 6083302)
Institution name Whittington Health NHS Trust
Institution department name
Street address The Whittington Hospital, Magdala Avenue
Town/city LONDON
Post Code N19 5NF
Country United Kingdom
Telephone
Fax
E-mail cparmar@nhs.net

IN66

Given name Ingrid
Family name DuRand

Qualification (MD...)	Doctor (GMC 4470593)
Institution name	Wye Valley NHS Trust
Institution department name	
Street address	County Hospital, 27 Union Walk
Town/city	HEREFORD
Post Code	HR1 2ER
Country	United Kingdom
Telephone	
Fax	
E-mail	Ingrid.DuRand@wvt.nhs.uk

IN67

Given name	Andrew
Family name	Broadley
Qualification (MD...)	Doctor (GMC 3678077)
Institution name	Yeovil District Hospital NHS Foundation Trust
Institution department name	
Street address	Yeovil District Hospital, Higher Kingston
Town/city	YEOVIL
Post Code	BA21 4AT
Country	United Kingdom
Telephone	
Fax	
E-mail	andrew.broadley@Somersetft.nhs.uk

IN68

Given name	Daniel
Family name	Trushell-Pottinger
Qualification (MD...)	Doctor (GMC 7014683)
Institution name	Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Institution department name	
Street address	Doncaster Royal Infirmary, Thorne Rd
Town/city	DONCASTER
Post Code	DN2 5LT
Country	United Kingdom
Telephone	
Fax	
E-mail	danieltrushell@nhs.net

For multi-centre trials where the CI is also a local PI, please list the CI as a PI at G2 (single-centre).

G3. Central Technical Facility Details

G3. Central technical facilities to be used in the conduct of the trial. *Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised.*

Organisation

Central technical facility organisation name
 Central technical facility organisation department
 Contact person Given name
 Contact person Family name
 Street address
 Town/city
 Post code
 Country
 Work Telephone
 Fax
 E-mail

Enter the details of any duties subcontracted to this central technical facility in this trial:

Routine clinical pathology testing	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Clinical chemistry	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Clinical haematology	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Clinical microbiology	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Histopathology	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Serology / endocrinology	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Analytical chemistry	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
ECG analysis / review	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Primary/ surrogate endpoint test	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered
Other	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<input type="radio"/> Not Answered

Network organisation details

G4. Network organisation details

Organisation
 Contact person Given name
 Contact person Middle name
 Contact person Family name
 Street address
 Town/city
 PostCode
 Country
 Telephone number
 Fax number
 E-mail

Activities carried out by the network

G5. Organisations to whom the sponsor has transferred trial related duties and functions

G5. Subcontractor organisations.

Enter details of central CRO facilities supplying services for at least this Member State.

Organisation

Department

Contact person Given name

Contact person Family name

Street address

Town/city

PostCode

Country

Telephone number

Fax

E-mail

Enter the details of any duties/ functions subcontracted to this sponsor's subcontractor facility in this trial

All tasks of the sponsor: ☐ Yes ☒ No ☐ Not Answered

Monitoring: ☐ Yes ☒ No ☐ Not Answered

Regulatory (e.g. preparation of applications to CA and Ethics Committee): ☐ Yes ☒ No ☐ Not Answered

Investigator recruitment: ☐ Yes ☒ No ☐ Not Answered

IVRS⁽¹⁾ - treatment randomisation: ☐ Yes ☒ No ☐ Not Answered

Data management: ☐ Yes ☒ No ☐ Not Answered

E-data capture: ☐ Yes ☒ No ☐ Not Answered

SUSAR reporting: ☐ Yes ☒ No ☐ Not Answered

Quality assurance auditing: ☐ Yes ☒ No ☐ Not Answered

Statistical analysis: ☐ Yes ☒ No ☐ Not Answered

Medical writing: ☐ Yes ☒ No ☐ Not Answered

Other duties subcontracted: ☐ Yes ☒ No ☐ Not Answered

H: Ethics Committee

H1-1. Type of application

Please tick the Ethics Committee box and give information of the Ethics committee concerned.

Ethics committee ☒

H2-1. Limited Name and address of ethics committee:

Organisation HRA REC Cambridge East

Work Address

PostCode

Country

Fax

H2-2. Date of submission:

12/03/2020

H2-3. Current status of Ethics Committee Opinion at the time of submission to the National Competent Authority:

☐ To be requested ☐ Pending ☒ Given

If "Given", please specify:

Date of opinion: 16/03/2020

State opinion: ☒ Accepted ☐ Not Accepted

I: Signature Of The Applicant In The Member State

I1. I hereby confirm that /confirm on behalf of the sponsor (tick which is applicable) that:

- ☒ The information provided is complete;
- ☒ The attached documents contain an accurate account of the information available;
- ☒ the clinical trial will be conducted in accordance with the protocol;
- ☒ The clinical trial will be conducted, and SUSARs and result-related information will be reported, in accordance with the applicable legislation.

I2. Applicant of the request for the competent authority (as stated in section C.1):

This section was signed electronically by Research Governance, Ethics & Assurance RGEA Sponsorship on 01/08/2025 09:12.

Job Title/Post: Magda Laskawiec-Szkonter, Research Support Manager

Organisation: University of Oxford

Email:

J: Checklist

J3. For details of the documents required for applications to the MHRA in the UK please see <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/Whattosend/index.htm>