

Medicines Information

A. Trial Identification

A1. National Competent Authority

UK - MHRA

A2. European Clinical Trials Database (EudraCT) number

A3. Full title of the trial

Please note details entered here will be inserted into Study Information A6

Sepsis Trials in Critical Care

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

SepTIC: Sepsis Trials in Critical Care

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

Please return to [Update project details](#) if you need to amend the short project title entered here.

SepTIC

A4-1. Sponsor's protocol code number:

A4-1- 22SM8039

A4-2. Sponsor's protocol version:

1.0

A4-3. Sponsor's protocol date:

21 February, 2023

A5-1. ISRCTN number

A5-2. ClinicalTrials.gov number

A5-3. WHO Universal Trial Reference Number (UTRN)

A5-4. Other Identifiers:

Name	Identifier
No items	

A6. Is this a resubmission?

☐ Yes ☒ No

A6-1. Indicate the resubmission letter or else select 'First submission'

A7. Is the trial part of a Paediatric Investigation Plan?

☐ Yes
 ☒ No
 ☐ Not Answered

B. Identification of the sponsor responsible for the request

B. Sponsor Identification

B1. Sponsor

B1-1 Name of organisation

Imperial College London

B1-2 Name of person to contact:

B1-2-1 Given Name

Rinat

B1-2-2 Middle Name

B1-2-3 Family Name

Ezra

Address

Street Address

Room 221, Level 2, Medical School Building, Norfolk Place

Town/City

London

Post Code

W2 1PG

Country

United Kingdom

Telephone Number

Country Dialing Prefix

+44

Local Area Code

020

Phone Number

7594 8081

Extension

n/a

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

r.ezra@imperial.ac.uk

B3. Status of the Sponsor

B3. Status of the Sponsor:

Non-Commercial

B4. Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary)

B4-1. Name of organisation	B4-2. Country
National Institute for Health and Care Research - Health Technology Assessment	United Kingdom

B5. Contact point designated by the sponsor for further information on the trial

B5-1 Name of organisation

Imperial College London

B5-2 Functional name of contact point

Janis Best-Lane

Address

Street Address

5.03 Medical School Building, Norfolk Place

Town/City

London

Post Code

W2 1PG

Country

United Kingdom

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

septic@imperial.ac.uk

C. Applicant Identification

C1. Request for Authorization to Competent Authority

C1-1, C1-2, C1-3 Who is responsible for the Clinical Authorization Application?

The sponsor

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

C1-4-1 Name of organisation

Imperial College London

C1-4-2 Name of person to contact:

C1-4-2-1 Given Name

Rinat

C1-4-2-2 Middle Name

C1-4-2-3 Family Name

Ezra

Address

Street Address

Room 221 | Level 2 | Medical School Building | Norfolk Place

Town/City

London

Post Code

W2 1PG

Country

United Kingdom

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

rgit.ctimp.team@imperial.ac.uk

C1-5 Request to receive a copy of the CTA data XML

C1-5-1 Do you want a xml file copy of the CTA form data saved on EudraCT?

☒Yes ☐No ☐Not Answered

C1-5-1-1 E-mail

E-mail

septic@imperial.ac.uk

C1-5-1-2 Secure E-mail (EudraLink account)?

☐Yes ☒No ☐Not Answered

C2. Request for Opinion of the Ethics Committee

C2-1, C2-2, C2-3, C2-4 Applicant Identification

The sponsor

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

C2-5-1 Organisation

Imperial College London

C2-5-2 Name of contact person

C2-5-2-1 Given Name

Rinat

C2-5-2-2 Middle Name

C2-5-2-3 Family Name

Ezra

Address

Street Address

Room 221 | Level 2 | Medical School Building | Norfolk Place

Town/City

london

Post Code

W2 1PG

Country

United Kingdom

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

rgit.ctimp.team@imperial.ac.uk

D. Investigational Medicinal Products

D. Investigational Medicinal Products

IMP Name:

PR1

D1/D2. IMP Identification and Status Details

D1-2/D1-3. Investigational medicinal product category:

Test 

D2. Status of the IMP

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

☐ Yes ☒ No ☐ Not Answered

D2-3. IMPD submitted / D2-4. IMP previously authorised / D2-5. IMP designated as an Orphan drug / D2-6. Subject of Scientific Advice

D2-3-1, D2-3-2 and D2-3-3: only one may be answered 'Yes' and the others must be answered 'No'

D2-3-1. Full IMPD

☒ Yes ☐ No ☐ Not Answered

D2-3-2. Simplified IMPD

☐ Yes ☒ No ☐ Not Answered

D2-3-3. 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

D3. Description of IMP

D3-1. Product name where applicable

Sargramostim (Leukine)


D3-2. Product code where applicable

GM-CSF

D3-3. ATC codes, if officially registered

L03AA09

D3-4. Pharmaceutical Form

Concentrate for solution for injection/infusion 

D3-4-1. Is this a specific paediatric formulation?

☐Yes ☒No ☐Not Answered

D3-5. Maximum duration of treatment of a subject according to the protocol

Up to eight days

Note: Content will be enabled for D3-6-1 and D3-6-2 only E7-1-1 is selected

D3-6. Dose allowed

D3-6-1. For first trial only

D3-6-1. First dose for first-in-human clinical trial

D3-6-1. Specify per day or total

☐Per day ☐Total ☐Not Answered

D3-6-1. Specify total dose number

D3-6-1. Specify total dose units

Select.. 

D3-6-1. Route of administration (relevant to the first dose)

Select.. 

D3-6-2. For all trials

D3-6-2. Maximum dose allowed

D3-6-2. Specify per day or total

☒ Per day ☐ Total ☐ Not Answered

D3-6-2. Specify total dose number

500µg for patients ≥50kg, and 250µg for patients <50kg

D3-6-2. Specify total dose units

µg/kg microgram(s)/kilogram

D3-6-2. Route of administration (relevant to the maximum dose)

Subcutaneous use

D3-7. Routes of administration for this IMP

Selected Routes of administration
Cutaneous use

D3-8. Active substances

D3-8. Name of Active Substance (INN or proposed INN if available)

Sargramostim

D3-9-1. CAS Number:

123774-72-1

D3-9-2. Current Sponsor Code:

GM-CSF

D3-9-3. Other Descriptive Name:

Leukine

D3-9-4. EudraVigilance Substance Code (if known):

D3-9-5. Full Molecular Formula

C639H1006N168O196S8

D3-9-6. Chemical/Biological Description of the Active Substance

Sargramostim is a recombinant version of GM-CSF, which is a glycoprotein made of 127 amino acids; sargramostim is mixture of three versions of GM-CSF that have molecular weights of 19,500, 16,800 and 15,500 Daltons. It is manufactured in yeast. Sargramostim is a version of GM-CSF, which has a normal role in human biology, causing progenitor cells to differentiate into neutrophils, monocytes, macrophages, and, myeloid-derived dendritic cells; it can also activate mature granulocytes and macrophages, and can contribute to the differentiation of megakaryocytic progenitors and erythroid progenitor cells.

D3-10. *Strength*

D3-10-1. Concentration Unit:

µg/ml microgram(s)/millilitre

D3-10-2. Concentration Type:

Equal

D3-10-3. Concentration Number (only use both fields for range):

250/ug/1mL

D3-10-3. Concentration Number (only use both fields for range):

D3-11. Type of IMP

Does the IMP contain an active substance:

D3-11-1. Of chemical origin?

☐Yes ☒No ☐Not Answered

D3-11-2. Of biological/biotechnological origin? (other than Advanced Therapy IMP (ATIMP))

☒Yes ☐No ☐Not Answered

Is this IMP a:

D3-11-3. Advanced Therapy IMP (ATIMP)?

☐Yes ☒No ☐Not Answered

D3-11-4. Combination product that includes a device, but does not involve an Advanced Therapy

☐Yes ☒No ☐Not Answered

D3-11-5. Radiopharmaceutical medicinal product?

☐Yes ☒No ☐Not Answered

D3-11-6. Immunological medical product (eg vaccine, allergen, immune serum)?

☒Yes ☐No ☐Not Answered

D3-11-7. Plasma derived medicinal product?

☐Yes ☒No ☐Not Answered

D3-11-8. Extractive medicinal product?

☐Yes ☒No ☐Not Answered

D3-11-9. Recombinant medicinal product?

☒Yes ☐No ☐Not Answered

D3-11-10. Medicinal product containing genetically modified organisms?

☐Yes ☒No ☐Not Answered

D3-11-11. Herbal medicinal product?

☐Yes ☒No ☐Not Answered

D3-11-12. Homeopathic medicinal product?

☐Yes ☒No ☐Not Answered

D3-11-13. Another type of medicinal product?

☐Yes ☒No ☐Not Answered

D3-12. Specify the mode of action for the active substance in this medicinal product

Sargramostim is a growth factor that stimulates the production, maturation and activation of three types of white blood cells (WBC): neutrophils, macrophages and dendritic cells. Each of these three cells has a distinct purpose and function within the immune system. Neutrophils are the most abundant WBC and are the first to respond. Macrophages are longer acting and recognize more invaders than neutrophils. Dendritic cells are important during infection detection.

D3-13. Is it an IMP to be used in a first-in-human clinical trial

☐Yes ☒No ☐Not Answered

D8. Placebo Information

D8-1. Is there a placebo

Yes

D8-2. Placebo

PL1

D8-3. Pharmaceutical form

Concentrate for solution for injection

D8-4. Route of administration

Subcutaneous use

D8-5. Which IMP(s) is it a placebo for?

IMP:

PR1-Concentrate for solution for injection/infusion ☒

D8-5-1. Composition, apart from the active substance(s):

D8-5-2. Is it otherwise identical to the IMP?

☒Yes ☐No ☐Not Answered

D9. Site(s) where the qualified person certifies batch release

D9-1. IMPs and placebos for which no responsible site needs to be identified

If all the conditions below are met, then tick this box and select below the IMPs and placebos to which this applies ☐

This section is used to identify IMPs and placebos which:

- has a MA in the EU and
- is sourced from the EU market and
- is used in the trial without modification (eg. Not over-encapsulated) and
- the packaging and labelling is carried out for local use only as per article 9.2 of the Directive 2005/28/EC (GCP Directive)

D9-2. Add Responsible Site

D9-2. Who is responsible in the Community for the certification of the finished IMPs?

D9-2-1/D9-2-2. As a manufacturer, importer or both?

Manufacturer

D9-2-3. Site Organisation Name

Victoria Pharmaceuticals

D9-2-4. Address

Street Address

Plenum Building, Royal Hospitals

Town/City

Belfast

Post Code

BT12 6BA

Country

United Kingdom

D9-2-5. Manufacturer authorisation number

MIA(IMP) 32485

D9-2-5-1. If no authorisation, give the reasons

D9-2. Site where the qualified person certifies batch release

Finished IMP

Description	Associate
PR1-Concentrate for solution for injection/infusion	<input type="checkbox"/>

Placebo

Pharmaceutical Form	Route of Administration	Associate
No items		

E. General Information on the Trial

E. Design of the Trial

Medical condition or disease under investigation

E1-1. Specify the medical condition(s) to be investigated:

Sepsis

E1-1-1. Medical condition in easily understood language

Sepsis - multiple organ failure

E1-1-2. Identify The Therapeutic Area

Diseases [C] - Bacterial Infections and Mycoses [C01]

E1-2. MedDRA information

MedDRA Search

Version	Term	Level	Classification Code	SOC	
22.1	Sepsis, bacteraemia, viraemia and fungaemia NEC	HLT	10040054	Blood and lymphatic system disorders	
22.1	Sepsis, bacteraemia, viraemia and fungaemia NEC	HLT	10040054	Blood and lymphatic system disorders	
22.1	Escherichia sepsis	PT	10015296	Infections and infestations	
22.1	Meningococcal sepsis	PT	10027280	Infections and infestations	
22.1	Postpartum sepsis	PT	10036422	Infections and infestations	
22.1	Sepsis	PT	10040047	Infections and infestations	
22.1	Sepsis neonatal	PT	10040049	Infections and infestations	
22.1	Sepsis pasteurella	PT	10040051	Infections and infestations	
22.1	Umbilical sepsis	PT	10045470	Infections and infestations	
22.1	Urosepsis	PT	10048709	Infections and infestations	
22.1	Streptococcal sepsis	PT	10048960	Infections and infestations	

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

☐ Yes ☒ No ☐ Not Answered

E2. Objective of the trial

E2-1. Main objective of the trial

To assess the clinical effectiveness and cost-effectiveness of:

- 1) rapid PCR-based microbiological diagnostics combined with procalcitonin (in the Diagnostic trial)
- 2) conservative fluid therapy with an active fluid de-resuscitation strategy (in the Fluids trial)
- 3) GM-CSF, using an enrichment strategy to both identify patients at higher risk of mortality (prognostic enrichment) and who are more likely to respond to treatment (predictive enrichment) (in the GM-CSF trial).

E2-2. Secondary objectives of the trial

To collect blood samples from recruited patients to be stored in the Imperial Tissue Bank for use in later ethically approved studies

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)

1. Adults (≥16 years of age) admitted to ICU due to suspected sepsis and expected to stay for at least two calendar days (i.e. expected to still be in ICU the day after tomorrow).

2. Receiving intravenous antibiotics for suspected sepsis

3. According to local clinical judgement, patient has received adequate initial early fluid resuscitation

The following inclusion are for intervention 3 only (can be after initial trial entry):-

1. Intubated and mechanically ventilated and expected to continue for another 24 hours

2. Or requiring two organ support (i.e. vasopressors or renal replacement therapy)
3. An absolute lymphocyte count $< 1.2 \times 10^9 / L$ on two consecutive calendar days at least 12 hours apart, with no values $> 1.2 \times 10^9 / L$ in between.

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

1. More than 24 hours since ICU admission (this does NOT apply for trial 3, GM-CSF). Note: As early intervention in sepsis is important, the aim should be to enrol eligible patients as soon after ICU admission as is practically possible.
2. Previously admitted to ICU due to sepsis on this hospital admission
3. Not expected to survive 90 days, due to pre-existing chronic (end-stage) disease
4. Not expected to survive initial resuscitation (24 hours)
5. Neutropaenia (< 0.5 neutrophils $\times 10^9 / L$) due to chemotherapy/malignancy (but not due to sepsis)
6. A source of infection that will require a prolonged course of antibiotics, for greater than 21 days (e.g. infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis)
7. Diabetic ketoacidosis (DKA) or hyperglycaemic hyperosmolar state (HHS)
8. Within 21 days of a spontaneous subarachnoid haemorrhage
9. Diabetes Insipidus
10. Weight < 40 Kg

The following additional criteria relate to intervention 3 only:-

1. More than 120 hours since ICU admission
2. Already receiving G-CSF or GM-CSF
3. A total white blood cell count $> 50 \times 10^9 / L$
4. Allergy or previous adverse reaction to GM-CSF
5. Known to be pregnant or breastfeeding
6. Known recent (required treatment within the last 5 years) haematological malignancy
7. Solid organ or bone marrow transplantation
8. Patient weight > 125 kg
9. Known anaphylaxis to GM-CSF or yeast-derived products

E5-1. Primary end point(s) (max 5000 characters)

90-day mortality combined with clinical state (in-hospital with organ support, in-hospital without organ support, discharged from hospital) over time

E5-1-1. Timepoint(s) of evaluation of this end point (max 800 characters)

90 days

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

1. Duration of mechanical ventilation, shock, renal replacement therapy up to 90 days
2. Length of stay in ICU and hospital up to 90 days
3. Antibiotic use (defined daily doses per 1000 occupied bed days) up to 90 days
4. Infection relapse / recurrence or secondary infection requiring further antibiotic treatment up to 90 days
5. Adverse events and adverse drug reactions (including antibiotic related adverse events) up to 90 days
6. Health-related Quality of Life (EQ-5D-5L) and cognitive function (MoCA-Blind) at 6 months
7. 1-year mortality

E5-2-1. Timepoint(s) of evaluation of this end point (max 800 characters)

1 year from randomisation is the final end point

E6. Scope of the trial

E6-1. Diagnosis

☐ Yes ☒ No ☐ Not Answered

E6-2. Prophylaxis

☐Yes ☒No ☐Not Answered

E6-3. Therapy

☒Yes ☐No ☐Not Answered

E6-4. Safety

☐Yes ☒No ☐Not Answered

E6-5. Efficacy

☒Yes ☐No ☐Not Answered

E6-6. Pharmacokinetic

☐Yes ☒No ☐Not Answered

E6-7. Pharmacodynamic

☐Yes ☒No ☐Not Answered

E6-8. Bioequivalence

☐Yes ☒No ☐Not Answered

E6-9. Dose Response

☐Yes ☒No ☐Not Answered

E6-10. Pharmacogenetic

☐Yes ☒No ☐Not Answered

E6-11. Pharmacogenomic

☐Yes ☒No ☐Not Answered

E6-12. Pharmacoeconomic

☒Yes ☐No ☐Not Answered

E6-13. Others

☐Yes ☒No ☐Not Answered

E7. Trial type and phase

E7-1. Human pharmacology (Phase I)

☐Yes ☒No ☐Not Answered

E7-2. Therapeutic exploratory (Phase II)

☐Yes ☒No ☐Not Answered

E7-3. Therapeutic confirmatory (Phase III)

☐Yes ☒No ☐Not Answered

E7-4. Therapeutic use (Phase IV)

☒Yes ☐No ☐Not Answered

E8. Design of the Trial

E8-1. Controlled?

☒Yes ☐No ☐Not Answered

Specify:

E8-1-1. Randomised

☒Yes ☐No ☐Not Answered

E8-1-2. Open

☒Yes ☐No ☐Not Answered

E8-1-3. Single blind

☐Yes ☒No ☐Not Answered

E8-1-4. Double blind

☒Yes ☐No ☐Not Answered

E8-1-5. Parallel group

☒Yes ☐No ☐Not Answered

E8-1-6. Cross over

☐Yes ☒No ☐Not Answered

E8-1-7. Other

☒Yes ☐No ☐Not Answered

E8-1-7-1. Specify the design of the trial

Multi-factorial

E8-2. If controlled, specify the comparator:

E8-2-1. Other medicinal product(s)

☐Yes ☒No ☐Not Answered

E8-2-2. Placebo

☒Yes ☐No ☐Not Answered

E8-2-3. Other

☐Yes ☒No ☐Not Answered

E8-2-4. Number of treatment arms in the trial

6

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

E8-4-1. Number of sites anticipated in Member State concerned

60

E8-5. Multiple Member States

☐Yes ☒No ☐Not Answered

E8-6. Trial involving sites outside the EEA

E8-6-1. Trial being conducted both within and outside the EEA

☐Yes ☒No ☐Not Answered

E8-6-2. Trial conducted completely outside of the EEA

☐Yes ☒No ☐Not Answered

E8-7. Trial having an independent data monitoring committee?

☒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.

The study will be considered terminated upon completion of all patient treatments and evaluations and after the end of the 12 month post trial observation period and the database is locked.

E8-9. Initial estimate of the duration of the trial (years, months, days)

E8-9-1. In the MS concerned

Years	Months	Days
4	0	0

E8-10. Proposed date of start of recruitment

E8-10-1. In the Member State concerned

02 January, 2023

E8-10-2. In any country

02 January, 2023

F. Population Of Trial Subjects

F1. Age Range

F1-1. Are the trial subjects under 18?

☐Yes ☒No ☐Not Answered

F1-2. Adult (18-64 years)

☒Yes ☐No ☐Not Answered

F1-2-1. Number of subjects for this age range:

1879

F1-3. Elderly (greater than 65 years)

☒Yes ☐No ☐Not Answered

F1-3-1. Number of subjects for this age range:

1879

F2. Gender

F2-1. Female

☒Yes ☐No ☐Not Answered

F2-2. Male

☒Yes ☐No ☐Not Answered

F3. Group of trial subjects

F3-1. Healthy volunteers

☐Yes ☒No ☐Not Answered

F3-2. Patients

☒Yes ☐No ☐Not Answered

F3-3. Specific vulnerable populations

☒Yes ☐No ☐Not Answered

F3-3-1. Women of childbearing potential not using contraception

☒Yes ☐No ☐Not Answered

F3-3-2. Women of childbearing potential using contraception

☒Yes ☐No ☐Not Answered

F3-3-3. Pregnant women

☒Yes ☐No ☐Not Answered

F3-3-4. Nursing women

☒Yes ☐No ☐Not Answered

F3-3-5. Emergency situations

☒Yes ☐No ☐Not Answered

F3-3-6. Subjects incapable of giving consent personally

☒Yes ☐No ☐Not Answered

F3-3-6-1. If yes, please specify:

Critical care patients with sepsis in an emergency situation will often not have capacity to consent .

F3-3-7. Others

☐Yes ☒No ☐Not Answered

F4. Planned number of subjects to be included

F4-1. In the member state

3758

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:

Study treatment will not be provided after participant have left the study.

G. Investigator Details

G1. National coordinating investigator (for a multicentre trial) or principal investigator (for a single centre trial)

National Coordinating Investigator

G1-1. Given Name

Anthony

G1-2. Middle Name

G1-3. Family Name

Gordon

G1-4. Qualification (MD...)

MBBS, MD, FFICM, FMedSci

G1-5. Institution Name

Imperial College

G1-5. Institution Department Name

Surgery & Cancer

Address

Street Address

Town/City

St Mary's Hospital, Praed Street

London

Post Code

W2 1NY

Country

United Kingdom

G1-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

44

Local Area Code

20

Phone Number

33126328

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

anthony.gordon@imperial.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Mark

G2-2. Middle Name

G2-3. Family Name

Blunt

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Queen Elizabeth Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

King's Lynn

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix Local Area Code Phone Number
Extension

E-mail

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Gavin

G2-2. Middle Name

G2-3. Family Name

Perkins

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Birmingham Heartlands Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Birmingham

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix Local Area Code Phone Number
Extension

Fax Number

Country Dialing Prefix Local Area Code Phone Number
Extension

E-mail

g.perkins@warwick.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Phil

G2-2. Middle Name

G2-3. Family Name

Hopkins

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

King's College London

G2-5. Institution Department Name

Address

Street Address

Town/City

London

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

p.hopkins@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Matt

G2-2. Middle Name

G2-3. Family Name

Wise

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

University of Hospital, Wales

G2-5. Institution Department Name

Address

Street Address

Town/City

Cardiff

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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Extension

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Phone Number

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E-mail

mattwise@doctors.org.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Anton

G2-2. Middle Name

G2-3. Family Name

Krige

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Blackburn Teaching Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Blackburn

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

anton.krige@elht.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Richard

G2-2. Middle Name

G2-3. Family Name

Pugh

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Glan Clwyd Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Rhyll

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

richard.pugh@wales.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Elankumaran

G2-2. Middle Name

G2-3. Family Name

Paramasivam

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Leeds General Infirmary

G2-5. Institution Department Name

Address

Street Address

Town/City

Leeds

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Fax Number

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Phone Number

Extension

E-mail

eparamasivam@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Elankumaran

G2-2. Middle Name

G2-3. Family Name

Paramasivam

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

St James' University Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Leeds

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

eparamasivam@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Neil

G2-2. Middle Name

G2-3. Family Name

Richardson

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

William Harvey Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Kent

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Extension

E-mail

neil.richardson3@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Paul

G2-2. Middle Name

G2-3. Family Name

Johnston

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Antrim Area Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Antrim

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

paul.johnston@northerntrust.hscni.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Barbara

G2-2. Middle Name

G2-3. Family Name

Philips

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Sussex County Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Brighton

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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E-mail

b.philips@bsms.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Liza

G2-2. Middle Name

G2-3. Family Name

Keathing

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Berkshire Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Berkshire

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Phone Number

Extension

E-mail

liza.keathing@royalberkshire.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Mark

G2-2. Middle Name

G2-3. Family Name

Wilkinson

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Lancaster Infirmary

G2-5. Institution Department Name

Address

Street Address

Town/City

Lancaster

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Phone Number

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E-mail

mark.wilkinson1@mbht.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Dan

G2-2. Middle Name

G2-3. Family Name

Harvey

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Queens Medical Centre

G2-5. Institution Department Name

Address

Street Address

Town/City

Nottingham

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

daniel.harvey@nun.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Simon

G2-2. Middle Name

G2-3. Family Name

Fletcher

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Norfolk and Norwich Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Norwich

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

simon.fletcher@nnuh.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Julian

G2-2. Middle Name

G2-3. Family Name

Sonksen

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Russells Hall

G2-5. Institution Department Name

Address

Street Address

Town/City

Dudley

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Extension

E-mail

julian.sonksen@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Catherine

G2-2. Middle Name

G2-3. Family Name

Snelson

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Queen Elizabeth Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Birmingham

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

catherine.snelson@uhb.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Peter

G2-2. Middle Name

G2-3. Family Name

Alexander

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Wythenshawe Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Manchester

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

peter.alexander1@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Jeremy

G2-2. Middle Name

G2-3. Family Name

Henning

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

James Cook University Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Middlesbrough

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

jeremy.henning@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Lawrence

G2-2. Middle Name

G2-3. Family Name

Wilson

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Countess of Chester

G2-5. Institution Department Name

Address

Street Address

Town/City

Chester

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

lawrence.wilson@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Ben

G2-2. Middle Name

G2-3. Family Name

Attwood

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Warwick Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Warwick

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Extension

E-mail

ben.attwood@swft.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Ben

G2-2. Middle Name

G2-3. Family Name

Creagh-Brown

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Surrey Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Guildford

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

benchb@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

David

G2-2. Middle Name

G2-3. Family Name

Pogson

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Queen Alexandra Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Portsmouth

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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Phone Number

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Extension

E-mail

david.pogson@porthosp.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Ingeborg

G2-2. Middle Name

G2-3. Family Name

Welters

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Liverpool University Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Liverpool

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Extension

E-mail

i.welters@liverpool.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

John

G2-2. Middle Name

G2-3. Family Name

Berridge

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

York Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

York

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

John.Berridge@york.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

David

G2-2. Middle Name

G2-3. Family Name

Antcliffe

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Charing Cross Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

London

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

Local Area Code

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Extension

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Country Dialing Prefix

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Extension

E-mail

d.antcliffe@imperial.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Stephen

G2-2. Middle Name

G2-3. Family Name

Brett

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Hammersmith Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

London

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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E-mail

stephen.brett@imperial.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Irina

G2-2. Middle Name

G2-3. Family Name	G2-4. Qualification (MD...)	G2-5. Institution Name
Grecu	MD	Royal Hampshire County Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Winchester

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

irina.grecu@hhft.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Rebecca

G2-2. Middle Name

G2-3. Family Name

Cusack

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

University Hospital of Southampton

G2-5. Institution Department Name

Address

Street Address

Town/City

Southampton

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

r.cusack@uhs.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Matt

G2-2. Middle Name

G2-3. Family Name

Thomas

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Southmead Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Bristol

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

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Extension

E-mail

matt.thomas@nbt.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Jon

G2-2. Middle Name

G2-3. Family Name

Silversides

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Royal Victoria Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Belfast

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

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Extension

E-mail

jon.silversides@belfasttrust.hscni.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Jon

G2-2. Middle Name

G2-3. Family Name

Silversides

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Mater Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Belfast

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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jon.silversides@belfasttrust.hscni.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Jon

G2-2. Middle Name

G2-3. Family Name

Silversides

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Belfast City Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Belfast

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

jon.silversides@belfasttrust.hscni.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Jonathan

G2-2. Middle Name

G2-3. Family Name

Barnard-Smith

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Manchester Royal Infirmary

G2-5. Institution Department Name

Address

Street Address

Town/City

Manchester

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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E-mail

Jonathan.Bannardsmith@mft.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Henrik

G2-2. Middle Name

G2-3. Family Name

Reschreiter

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Poole Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Poole

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

henrik.reschreiter@uhd.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Nikitas

G2-2. Middle Name

G2-3. Family Name

Nikitas

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Derriford Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Plymouth

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Local Area Code

Phone Number

Extension

E-mail

nikitas.nikitas@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Richard

G2-2. Middle Name

G2-3. Family Name

Innes

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Musgrove Park Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Taunton

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Extension

E-mail

richard.innes@somersetft.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Matt

G2-2. Middle Name

G2-3. Family Name

Charlton

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Leicester Royal Infirmary

G2-5. Institution Department Name

Address

Street Address

Town/City

Leicester

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

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Phone Number

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Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

matthew.charlton@uhl-tr.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Richard

G2-2. Middle Name

G2-3. Family Name

Stewart

G2-4. Qualification (MD...)

MD

G2-5. Institution Name

Milton Keynes University Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Milton Keynes

Post Code

Country

United Kingdom

G2-5-5. Please indicate if site is:

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Phone Number

Extension

E-mail

Richard.Stewart1@mkuh.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Mike

G2-2. Middle Name

G2-3. Family Name

Spivey

G2-4. Qualification (MD...)

Dr

G2-5. Institution Name

Royal Cornwall Hospital

G2-5. Institution Department Name

Address

Street Address

Town/City

Country

Post Code

United Kingdom

G2-5-5. Please indicate if site is:

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Telephone Number

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Country Dialing Prefix	Local Area Code	Phone Number
Extension		
E-mail		
MichaelSpivey@nhs.net		

G2. What is the role of this investigator?
G2 Other principal investigator for a multicentre trial

G2-1. Given Name	G2-2. Middle Name	G2-3. Family Name
Luigi		Camporota
G2-4. Qualification (MD...)	G2-5. Institution Name	G2-5. Institution Department Name
MD	Cleveland Clinic London	Critical Care

Address	
Street Address	Town/City
33 Grosvenor Place	London
Post Code	Country
SW1X 7HY	United Kingdom

G2-5-5. Please indicate if site is:
Non-NHS

Telephone Number

Country Dialing Prefix	Local Area Code	Phone Number
Extension		
Fax Number		

Country Dialing Prefix	Local Area Code	Phone Number	Extension
+44	020	34237000	
E-mail			
camporl@ccf.org			

G3. Central technical facilities

G3-1. Name of Organisation
Imperial College London

G3-2. Central Technical Facility Organisation Department

Central Laboratory

G3-3. Name of Contact Person

G3-3-1. Given Name

Graham

G3-3-2. Middle Name

G3-3-3. Family Name

Taylor

Address

Street Address

Medical School Building, St Mary's Campus

Town/City

London

Post Code

W2 1PG

Country

United Kingdom

Telephone Number

Country Dialing Prefix

+44

Local Area Code

0207

Phone Number

5943910

Extension

Fax Number

Country Dialing Prefix

Extension

Local Area Code

Phone Number

E-mail

g.p.taylor@imperial.ac.uk

G3-8. Enter the details of any duties subcontracted to this central technical facility in this trial:

G3-8-1. Routine Clinical Pathology Testing

☒Yes ☐No ☐Not Answered

G3-8-2. Clinical Chemistry

☐Yes ☒No ☐Not Answered

G3-8-3. Clinical Haematology

☐Yes ☒No ☐Not Answered

G3-8-4. Clinical Microbiology

☒Yes ☐No ☐Not Answered

G3-8-5. Histopathology

☐Yes ☒No ☐Not Answered

G3-8-6. Serology/Endocrinology

☐Yes ☒No ☐Not Answered

G3-8-7. Analytical Chemistry

☐Yes ☒No ☐Not Answered

G3-8-8. ECG Analysis/Review

☐Yes ☒No ☐Not Answered

G3-8-9. Medical Image Analysis/Review - x-ray, MRI, ultrasound, etc

☐Yes ☒No ☐Not Answered

G3-8-10. Primary/Surrogate Endpoint Test

☐Yes ☒No ☐Not Answered

G3-8-11. Other

☐Yes ☐No ☒Not Answered

G4. Trial Networks

G5. Sponsor's Subcontractor Facilities

G5. Enter the details if the sponsor has transferred any major or all the sponsor's trial related duties and functions to another organisation or third party

G5-1-1. Organisation Name

Molzym GmbH & Co. KG

G5-1-2. Organisation Department

G5-1-3. Name of Contact Person

G5-1-3-1. Given Name

Laureen

G5-1-3-2. Middle Name

G5-1-3-3. Family Name

Ferchaud

Address

Street Address

Mary-Astell-Str. 10

Town/City

Bremen

Post Code

28359

Country

Germany

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

Ferchaud@molzym.com

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

G5-1-8. All Tasks of the Sponsor

☐ Yes ☒ No ☐ Not Answered

G5-1-9. Monitoring

☐ Yes ☒ No ☐ Not Answered

G5-1-10. Regulatory (eg preparation of applications to CA and Ethics Committee)

☐ Yes ☒ No ☐ Not Answered

G5-1-11. Investigator Recruitment

☐ Yes ☒ No ☐ Not Answered

G5-1-12. IVRS - Treatment Randomisation

☐ Yes ☒ No ☐ Not Answered

G5-1-13. Data Management

☐ Yes ☒ No ☐ Not Answered

G5-1-14. E-data Capture

☐ Yes ☒ No ☐ Not Answered

G5-1-15. SUSAR Reporting

☐ Yes ☒ No ☐ Not Answered

G5-1-16. Quality Assurance Auditing

☐ Yes ☒ No ☐ Not Answered

G5-1-17. Statistical Analysis

☐ Yes ☒ No ☐ Not Answered

G5-1-18. Medical Writing

☐ Yes ☒ No ☐ Not Answered

G5-1-19. Other Duties Subcontracted?

☒ Yes ☐ No ☐ Not Answered

G5-1-19-1. If 'Yes', specify the other duties

Provision of diagnostic test used for intervention in trial.

G5. Enter the details if the sponsor has transferred any major or all the sponsor's trial related duties and functions to another organisation or third party

G5-1-1. Organisation Name

Partner Therapeutics Inc

G5-1-2. Organisation Department

G5-1-3. Name of Contact Person

G5-1-3-1. Given Name

Mary

G5-1-3-2. Middle Name

Ruth

G5-1-3-3. Family Name

Sikes

Address

Street Address

5900 Martin Luther King Jr. Hwy,

Town/City

Greenville, NC

Post Code

27834

Country

United States

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

maryruth.sikes@thermofisher.com

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

G5-1-8. All Tasks of the Sponsor

☐ Yes ☒ No ☐ Not Answered

G5-1-9. Monitoring

☐ Yes ☐ No ☐ Not Answered

G5-1-10. Regulatory (eg preparation of applications to CA and Ethics Committee)

☐Yes ☒No ☐Not Answered

G5-1-11. Investigator Recruitment

☐Yes ☒No ☐Not Answered

G5-1-12. IVRS - Treatment Randomisation

☐Yes ☒No ☐Not Answered

G5-1-13. Data Management

☐Yes ☒No ☐Not Answered

G5-1-14. E-data Capture

☐Yes ☒No ☐Not Answered

G5-1-15. SUSAR Reporting

☐Yes ☒No ☐Not Answered

G5-1-16. Quality Assurance Auditing

☐Yes ☒No ☐Not Answered

G5-1-17. Statistical Analysis

☐Yes ☒No ☐Not Answered

G5-1-18. Medical Writing

☐Yes ☒No ☐Not Answered

G5-1-19. Other Duties Subcontracted?

☒Yes ☐No ☐Not Answered

G5-1-19-1. If 'Yes', specify the other duties

Provision of IMP for trial

G5. Enter the details if the sponsor has transferred any major or all the sponsor's trial related duties and functions to another organisation or third party

G5-1-1. Organisation Name

Victoria Pharmaceuticals

G5-1-2. Organisation Department

G5-1-3. Name of Contact Person

G5-1-3-1. Given Name

G5-1-3-2. Middle Name

G5-1-3-3. Family Name

Address

Street Address

Plenum Building, Royal Hospitals

Town/City

Belfast

Post Code

BT12 6BA

Country

United Kingdom

Telephone Number

Country Dialing Prefix

+44

Local Area Code

02896

Phone Number

151000

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

PlenumAdmin@belfasttrust.hscni.net

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

G5-1-8. All Tasks of the Sponsor

☐ Yes ☒ No ☐ Not Answered

G5-1-9. Monitoring

☐ Yes ☒ No ☐ Not Answered

G5-1-10. Regulatory (eg preparation of applications to CA and Ethics Committee)

☐ Yes ☒ No ☐ Not Answered

G5-1-11. Investigator Recruitment

☐ Yes ☒ No ☐ Not Answered

G5-1-12. IVRS - Treatment Randomisation

☐ Yes ☒ No ☐ Not Answered

G5-1-13. Data Management

☐ Yes ☐ No ☐ Not Answered

G5-1-14. E-data Capture

☐ Yes ☒ No ☐ Not Answered

G5-1-15. SUSAR Reporting

☐ Yes ☒ No ☐ Not Answered

G5-1-16. Quality Assurance Auditing

☐ Yes ☒ No ☐ Not Answered

G5-1-17. Statistical Analysis

☐ Yes ☒ No ☐ Not Answered

G5-1-18. Medical Writing

☐ Yes ☒ No ☐ Not Answered

G5-1-19. Other Duties Subcontracted?

☒ Yes ☐ No ☐ Not Answered

G5-1-19-1. If 'Yes', specify the other duties

Distribution of IMP to investigator sites for the trial

H. Ethics Committee/National Competent Authority

H. National Competent Authority

H2-1. National Competent Authority name

UK - MHRA

H2.2. Address

Street Address

Town/City


Post Code

Country

H2-3. Date of submission

H3. Authorisation/Opinion

H3-1/H3-2/H3-3. What is the status of the National Competent Authority's authorisation

To be requested 

H. Ethics Committee

H2-1. Ethics Committee name

Not yet known

H2.2. Address

Street Address

Town/City

Post Code

Country

H2-3. Date of submission

H3. Authorisation/Opinion

H3-1/H3-2/H3-3. What is the status of the Ethics Committee's opinion?

Select.. 

