# Project Study Information

## IRAS Information

| | | |
|---|---|---|
| IRAS Form | Reference: 99/AA/1234 | IRAS Version: 5.9.1 |
| **Short title for project:** | TEST | |

## Key people and organisations

**Chief investigator:**

**Project deputy:** No data available

**Project funder:** [redacted]

## Project scope

## CTIMP questions

| | |
|---|---|
| **Provide the project EudraCT ID. The required format is ####-######-##** | |
| **Will any research sites in this study be NHS organisations?** | Yes |
| **Does the study involve use of any ionising radiation?** | No |
| **Will you be taking new OR existing human tissue samples (or other human biological samples)?** | Yes |
| **Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?** | No |
| **Do you plan to include any participants who are children?** | No |
| **Do you plan to request research delivery network support? Selecting "yes", does not automatically submit an application for support from the research delivery network. For details on how to apply for support for your study, visit the NIHR website.** | No |
| **Do you plan to include any participants who are prisoners or young offenders?** | No |
| **Proposed Study End Date** | [redacted] |

## A. Administrative Details

1. In which countries of the UK will the research sites be located? (Tick all that apply)

☐ England
☐ Scotland
☐ Wales
☐ Northern Ireland

2. In which country of the UK will the lead NHS R&D office be located?

Select..

3. Will any research sites in this study be NHS organisations?
***Pleasenotedetailsenteredherewillbematchedtothesamequestion on Project details screen***

◉Yes ○No

4. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○Yes ○No

5. Is this a commercially sponsored Phase 1 or Phase 1/2a trial involving healthy volunteers?

○Yes ○No

6. Full title of the research
***Detailsenteredherewillbe entered into Medicines Information A3***

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7. Is this application linked to a previous study or another current application?

○Yes ○No

8. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○Yes ○No

9. Lay Summary of the study

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10. In which aspects of the research process have you actively involved or will you involve patients service users and/ or their carers or members of the public?

☐ Design of the research
☐ Management of the research
☐ Undertaking the research
☐ Analysis of results
☐ Dissemination of findings

☐ None of the above

11. Give details of involvement, or if none please justify the absence of involvement.

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12. Is the trial a Complex Innovative Design (CID) trial?

◯Yes ◯No

## B. Research Procedures, Risks and Benefits

1. Non-clinical interventions
***(Pleasecompleteforeachintervention/procedure as follows)***

1: Interventions/procedures to be received by each participant as part of the research protocol
2: Number of interventions/procedures which are part of standard care
3: Number of interventions/procedures which are additional to standard care
4: Total number of interventions/procedures
5: Average time taken per intervention/procedure (minutes, hours or days)
6: Details of who will conduct the intervention/procedure and where it will take place

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| No items | | | | | |

2. Clinical interventions
***(Pleasecompleteforeach intervention/procedure as follows)***

1: Interventions/procedures to be received by each participant as part of the research protocol
2: Number of interventions/procedures which are part of standard care
3: Number of interventions/procedures which are additional to standard care
4: Total number of interventions/procedures
5: Average time taken per intervention/procedure (minutes, hours or days)
6: Details of who will conduct the intervention/procedure and where it will take place

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| No items | | | | | |

3. Will you withhold an intervention, medicine or procedure, which would normally be considered a part of routine care?

◯Yes ◯No

4. What are the potential risks and burdens for research participants and how will you minimise them?

—

5. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◯Yes ◯No

6. What arrangements are being made for continued provision of the investigational medicinal product for participants, if appropriate, once the research has finished? If the intention is to not provide IMP to participants when the trial has completed, this must be clearly justified.

7. Will you inform the participants' General Practitioner that they are taking part in the trial? (and/or any other healthcare professional responsible for their care).

No
Yes

8. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

Select..

9. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?

10.Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- ☐ Access to medical records by those outside the direct care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
- ☐ Manual files (includes paper or film)
- ☐ NHS computers
- ☐ Social Care Service computers
- ☐ Home or other personal computers
- ☐ University computers
- ☐ Private company computers
- ☐ Laptop computers

11. Please describe the physical security arrangements for storage of personal data during the study

12. How will you ensure the confidentiality of personal data?

13. Who will have access to participants' personal data during the study?

14. Where will the data generated by the study be analysed and by whom?

15. How long will personal data be stored or accessed after the study has ended?

Select..

16. For how long will you store research data generated by the study?

—

17. Please give details of the long term arrangements for storage of research data after the study has ended.

—

18. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

—

19. Will individual researchers receive any personal payment over and above normal salary or any other benefits or incentives for taking part in this research?

◯Yes ◯No

20. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯Yes ◯No

21. Please confirm the arrangements for registration of this trial on a public database.

Select..

**C. Transparency**

1. How do you intend to report and disseminate the results of the study?

☐ Peer reviewed scientific journals
☐ Internal report
☐ Conference presentation
☐ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other

2. How will you enable sharing of study data with others?

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3. How will you enable sharing of tissue samples and associated data with others?

—

4. How and when will you inform participants of the study results?
If there will be no arrangements in place to inform partcipants please justify this.

—

5. Point of Contact for Publication

Select..

## D. Scientific and Statistical Review

1. How has the scientific quality of the trial been assessed?

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☐ Review within the Chief Investigator's institution or host organisation
- ☐ Other

2. Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

—

3. How have the statistical aspects of the research been reviewed?

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator’s institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise

4. In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Surname

Forename/Initials

Department

Institution

Street

City

Country

Post code

Email

Telephone

Mobile

5. How was the sample size decided upon?

## E. Management of the Research

1. Sponsor Organisation status

Select..

2. Is this study?

◯Single Centre
◯Multi Centre

3. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?

☐ NHS indemnity scheme will apply (NHS sponsors only)
☐ Other insurance or indemnity arrangements will apply (give details below)

4. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?

☐ NHS indemnity scheme will apply (NHS sponsors only)
☐ Other insurance or indemnity arrangements will apply (give details below)

5. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/ collaborators arising from harm to participants in the conduct of the research?

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

6. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

◯Yes ◯No

## F. Ionising Radiation

1. Does the study involve exposures to radioactive materials?

◯Yes ◯No

2. Does the study involve other diagnostic or therapeutic ionising radiation?

◯Yes ◯No

3. Has the trial been authorised by a Clinical Radiation Expert (CRE) and a Medical Physics Expert (MPE)?

◯Yes ◯No

4. What are the risks associated with ionising radiation exposures within the trial?

## G. Tissue

1. List the human biological material/tissue samples which will be removed and/or stored as part of the research

2. Please explain what licensing arrangements apply to the procurement, processing, distribution or import of the tissues and cells to be used in the research.

3. If you are using existing tissue samples where will the samples be obtained from?

☐ NHS pathology department(s)/diagnostic archive(s)
☐ Other research tissue bank(s) or sample collection(s)

4. Please give details of where the samples will be stored, who will have access and the custodial arrangements.

5. If you are obtaining existing tissue samples, will there be consent in place?

Select..

6. What will happen to the samples at the end of the research?

☐ Transfer to research tissue bank
☐ Storage by research team pending ethical approval for use in another project
☐ Storage by research team as part of a new research tissue bank
☐ Storage by research team of biological material which is not “relevant material” for the purposes of the Human Tissue Act
☐ Disposal in accordance with the Human Tissue Authority’s Code of Practice
☐ Other
☐ Not yet known

7. Please give further details of the proposed arrangements:

## H. Recruitment and Informed Consent Procedure

1. How will potential participants be identified?

2. What resources will be used for recruitment?

3. Will identification of potential participants involve access to identifiable information?

◯Yes ◯No

4. Who will be approaching potential participants and who will be obtaining informed consent?

—

5. How, when and where will informed consent be obtained?

—

6. How long will potential participants (or their legal representative) be given to decide whether to participate?

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7. How will it be assured that potential participants (or their legal representative) have understood the information and that consent is informed?

—

8. What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak English?

—

9. How will it be ensured that participants can withdraw their consent at any point?

—

10. Please provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere.

—

11. Provide a clear indication of what the first act of recruitment will be.

—

13. Clinical Trials in Emergency Situations

13a. Will the trial recruit participants in an emergency situation whereby consent from the participant cannot be sought or a legal representative cannot be consulted prior to the participant being recruited into the trial?

◯Yes ◯No

15. Impartial Witness

15a. Is the trial likely to include participants who are unable to sign the consent form and therefore an impartial witness would be required?

◯Yes ◯No

16. Cluster Trials

16a. Will the trial involve the recruitment and allocation of an IMP to groups of participants rather than individual participants (cluster trial)?

◯Yes ◯No

**I. Payment of Compensation**

1. Will payment or compensation be offered?

◯Yes ◯No

2. Describe arrangements for how any payment or compensation will be paid/provided

3. Are there any conditions attached to the payment or compensation?

◯Yes ◯No

## A. Trial Identification

A1. National Competent Authority

Select..

A2. European Clinical Trials Database (EudraCT) number

—

A3. Full title of the trial

***Pleasenotedetailsentered here will be inserted into Study Information A6***

—

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

—

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

***PleasereturntoUpdateprojectdetailsifyouneedtoamend the short project title entered here.***

TEST

A4-1. Sponsor's protocol code number:

—

A4-2. Sponsor's protocol version:

—

A4-3. Sponsor's protocol date:

—

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

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

## C. Applicant Identification

C1. Request for Authorization to Competent Authority

C2. Request for Opinion of the Ethics Committee

## D. Investigational Medicinal Products

**D. Investigational Medicinal Products**

**D8. Placebo Information**

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

**D9-2. Add Responsible Site**

## E. General Information on the Trial

E. Design of the Trial

Medical condition or disease under investigation

E1-2. MedDRA information

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

—

E2-2. Secondary objectives of the trial

—

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)

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

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

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

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

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

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

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

E8-5. 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.***

—

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

E8-9-1. In the MS concerned

| Years | Months | Days |
|---|---|---|

—

—

E8-10. Proposed date of start of recruitment

E8-10-1. In the Member State concerned

—

E8-10-2. In any country

—

**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

F1-3. Elderly (greater than 65 years)

◯Yes◯No◯Not Answered

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

F4. Planned number of subjects to be included

F4-1. In the member state

F5. Plans for treatment or care after a subject has ended his/her participation in the trial.
***Ifit is different from theexpected normal treatment,pleasespecify:***

—

**G. Investigator Details**

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

G3. Central technical facilities

G4. Trial Networks

G5. Sponsor's Subcontractor Facilities

**H. Ethics Committee/National Competent Authority**

H. National Competent Authority

H2-1. National Competent Authority name

H2.2. Address

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

Select..

H. Ethics Committee

H2-1. Ethics Committee name

—

H2.2. Address

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..