

## OpenClinica at Imperial College London User Activation Form (UAF)

Please complete the form to gain access to OpenClinica clinical studies at Imperial College London.

### User Information for Access

1. Does the user have an OpenClinica account at Imperial College:  Yes  No  
(If yes, answer question 2 then skip to 'Invitation to the Study' section, if the answer is no then complete all sections)
2. Username preference (cannot be email id): Click or tap here to enter text.
3. First and Last Name: Click or tap here to enter text.
4. Email (email address must be unique to all accounts): Click or tap here to enter text.  
(Each role per study must be assigned to a different email address e.g., j.bloggs@server.com and joe.bloggs@server.com)
5. Phone number: Click or tap here to enter text.
6. Organisation (e.g., Imperial College, NHS): Click or tap here to enter text.

### How did you complete your training?

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> In person at Imperial College London | <input type="checkbox"/> E-learning course via Imperial College London | <input type="checkbox"/> Externally via another organisation |
|---|--|--|

### Invitation to the Study

Study Name: Click or tap here to enter text.

Only one form must be provided for each role

#### Role required (access to all sites)

- Data Entry - Study     Monitor - Study     Chief Investigator (CI) - Only one CI access per study and should match user on the protocol     Read Only - Study

#### Role required (access to specific sites) – Site name must be provided

- Data Entry - Site     Monitor - Site     Principal Investigator or Co-Investigator (PI)     Read Only - Site
- Other - Some studies may have additional roles – Please enter any other role if applicable
- Randomisation User

Name of site requiring access: Click or tap here to enter text.

### User Instructions

1. The completed UAF and training certificate must be sent to [cds\\_support@imperial.ac.uk](mailto:cds_support@imperial.ac.uk) after the Study Manager has countersigned the form.
2. The user will be invited to the study once the CDS Team have filed the training certificate and UAF.
3. An email from OpenClinica with a link to the study will be automatically generated and sent to the user. Users should check their spam emails and add OpenClinica to the safe-senders list.

### User Acknowledgement

#### ALL USERS

I acknowledge that:

1. I will create my own private password unknown to anyone else.
2. I understand that I am not allowed to share passwords. Any suspected fraudulent use of the EDC system should be reported to Imperial College at the address below.
3. I accept giving my personal data (i.e. my name, email address, phone number etc.)

4. I accept that my electronic signature is equivalent to my hand-written signature in legal terms. **Please note: a typed signature or an image of the signature is not acceptable.**

**FOR NON-COLLEGE USERS**

5. I will have access to information which is of a confidential nature (including potentially participant data and other personal data) (“Confidential Information”).

I understand that where I come across such Confidential Information, I will:

- keep the Confidential Information secret and confidential; and
- not copy, use or exploit the Confidential Information in any way, except for or in connection with my work for my PI.

If I need to use any Confidential Information for any other purpose, I will discuss this first with the Sponsor and obtain their written consent. I will continue to abide by these confidentiality obligations after the end of my role, with no limit in time.

6. I confirm that I have read, understood and will comply with the policies, codes of practice, guidelines, and the PI’s instructions.

**Name:**

**Signature:**

**Date:**

Signature must be electronic or in wet ink, images of signatures cannot be accepted.

X

EDC User Signature

**Study Manager/CI/Study Team Member**

I acknowledge that:

1. If the user requesting access is the Study Manager, then I am the CI, or if the user requesting access is the CI, then I am the Study Manager.
2. I am not countersigning my own form.
3. If a study team member is signing, make sure it is documented.
4. The details entered are correct, specifically the Role and the Site access requested.
5. The user requires access to Insight for reporting functions, if stated.
6. I accept giving my personal data (i.e. my name and signature)
7. I accept that my electronic signature is equivalent to my hand-written signature in legal terms. **Please note: a typed signature or an image of the signature is not acceptable**

**Name:**

**Signature:**

**Date:**

Signature must be electronic or in wet ink, images of signatures cannot be accepted.

Please send or email a signed copy of this form to: Imperial Clinical Trials Unit, Imperial College London, Stadium House, 68 Wood Lane, London, W12 7RH. Email: [cds\\_support@imperial.ac.uk](mailto:cds_support@imperial.ac.uk)