

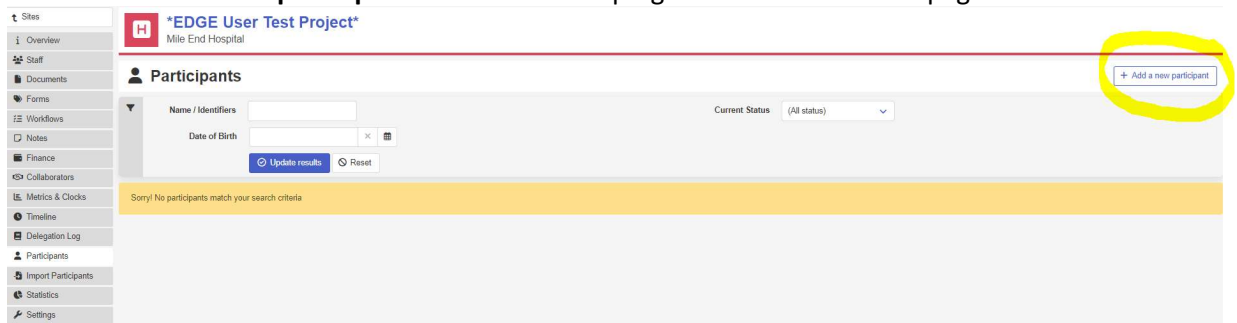
EDGE recruitment upload guide

Adding Individual Participants

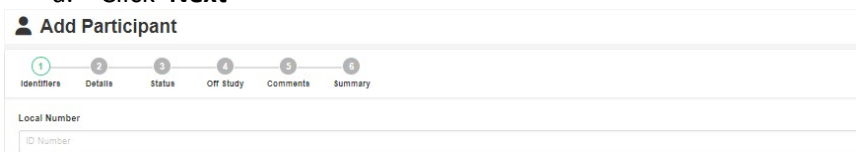
Note: To add a new participant, the user must be on the study delegation log and have clinical user permission on the EDGE project site record

No Patient Identifiable Information other than MRN should be recorded on EDGE

1. Log into EDGE at <https://www.edge.nhs.uk/>
2. To navigate to the Participants section of your project site record:
 - a. Click on **'Projects'** in the top ribbon.
 - b. Select the appropriate project.
 - c. Click **'Sites'** from the lefthand menu.
 - d. Select the appropriate site.
 - e. Click the **'Participants'** tab from the lefthand menu.
 - i. This tab will only appear if the staff member has "Clinical access" granted in the 'Staff' tab of the project site record.
3. Click the **'+ Add a new participant'** button in the top right-hand corner of the page.



4. For the 'Identifiers' step of the wizard, add a local number
 - a. This should be an anonymised ID.
5. Leave all other fields in the 'Identifiers' step blank.
 - a. Click **'Next'**



6. For the 'Details' steps of the wizard, you should record MRN in the "Hospital Number" field.
7. You may add (though it is not mandatory):
 - a. Screening Number (where applicable)
 - b. Registration Number (where applicable)
 - c. Randomisation number (where applicable)
8. Complete the "Participant Type"
9. Click **'Next'**

Add Participant

1 Identifiers 2 Details 3 Status 4 Off Study 5 Comments 6 Summary

Randomisation Number
Randomisation Number

Hospital Number
Hospital Number

Screening Number
Screening Number

Registration Number
Registration Number

Participant Type
Please select

Project Arms
Search for project arms Search

Consultant
Search for Consultant Search

Referring Site
Search for Sites Search

Date Referred
x

GP Name
GP Name

GP Address

10. For the 'Status' step of the wizard, complete all applicable status dates.

- Date fields must be in chronological order and must have an entry for each field up to and including the most recent action. E.g. if the latest date you want to enter is the 'Recruited/Randomised' date, all dates prior to this such as the "Pre-screened" must be completed
- All dates should be in the DD/MM/YYYY format
- A user with clinical access must be included in the 'Actioned By' column for all steps in the workflow with a completed date.

11. Click 'Next'

Add Participant

1 Identifiers 2 Details 3 Status 4 Off Study 5 Comments 6 Summary

Exit Wizard Previous Next

Participant transfer is not enabled on this project

	Status Date	Actioned By
Pre-Screened	16/05/2023	ZABED AHMED
Approached	16/05/2023	ZABED AHMED
Consented	16/05/2023	ZABED AHMED
Screened	16/05/2023	ZABED AHMED
Recruited / Randomised	16/05/2023	ZABED AHMED
On treatment		ZABED AHMED
On follow-up		ZABED AHMED
Completed		ZABED AHMED

Exit Wizard Previous Next

Note: Please refer to 'How to Update a Participant as Withdrawn/Rejected' section to take participant off study, this can be found in the next section below.

12. Ticking the 'Off Study' checkbox in the 'Off Study' step of the wizard allows a participant to be recorded as withdrawn or rejected.

- Add the date the participant was taken off the study
- Add the clinical user who took the participant off of the study.
- The reason field will be automatically completed with "Rejected" or "Withdrawn" dependent on where the participant is in the status workflow. i.e. participants are "rejected" until they have been recruited and withdrawn after being recruited.
- Select the appropriate source of the "Decision", either 'Clinical', 'Participant' or 'Service'
- Different reasons will appear in the 'Description' dropdown menu based on the selection in 'Decision'

- f. **To record a 'Screen failure for Portfolio NIHR Portfolio studies:** The 'Off-study date', combined with the reasons; 'Rejected, Clinical Decision, Ineligible - screening tests failure', will be used to identify screen failures. If a participant is recorded with any other off study reason (for example, the participant does not want additional tests), this will not be classed as a screen failure and will not be sent to CPMS.
 - g. Click **'Next'**.
13. Add any relevant participant comments in the 'Comments' step of the wizard.
 - a. No identifiable information should be recorded.
 - b. click **'Next'**
 14. Review the full participant summary and click **'Finish'** or, if applicable, click **Previous** to go back and correct the data.

Add Participant

1 Identifiers
2 Details
3 Status
4 Off Study
5 Comments
6 Summary

<p>Local Number</p> <p>Name</p> <p>Date Of Birth</p> <p>Gender</p> <p>Address</p> <p>Postcode</p> <p>Email</p> <p>Phone</p> <p>Mobile</p> <p>Language</p> <p>Ethnicity</p>	<p>Randomisation Number</p> <p>Hospital Number</p> <p>Screening Number</p> <p>Registration Number</p> <p>Participant Type Participant with the relevant condition</p> <p>Consultant</p> <p>Referring Site</p> <p>Date Referred</p> <p>GP Name</p> <p>GP Address</p> <p>GP Postcode</p> <p>GP Phone</p> <p>Emergency Contact First Name</p> <p>Emergency Contact Last Name</p> <p>Emergency Contact Phone</p> <p>Emergency Contact Relationship</p> <p>Project Arm</p>
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Status	Date	Actioned by
Pre-Screened	16/05/2023	ZABED AHMED
Approached	16/05/2023	ZABED AHMED
Consented	16/05/2023	ZABED AHMED
Screened	16/05/2023	ZABED AHMED
Recruited / Randomised	16/05/2023	ZABED AHMED

Patient is NOT off study

Comments

15. Once reviewed and you have clicked on **Finish** the data will be imported and will be viewed as below.

(anonymous)

i Overview

Audit Mode
Delete Participant

Participant Details Edit

Title

First name

Last name

Date of Birth

Gender

Address

Postcode

Email

Phone

Mobile

Language

Ethnicity

Hospital Number

Randomisation Number

Screening Number

Registration Number

Project Arm

Referring Site

Date Referred

Comments

Participant Type Participant with the relevant condition

Consultant

Deceased ×

Participant Status Edit Status Take Off Study

Status	Date	Actioned by
Pre-Screened	16/05/2023	AHMED, ZABED
Approached	16/05/2023	AHMED, ZABED
Consented	16/05/2023	AHMED, ZABED
Screened	16/05/2023	AHMED, ZABED
Recruited / Randomised	16/05/2023	AHMED, ZABED

Identifiers + Add

No identifiers have been recorded for this participant.

GP Data Edit

GP Name

GP Address

GP Postcode

GP Phone

Note: Fields and content may differ based on the organisation-defined Participant Data Collection Plan. All mandatory fields are marked with a red asterisk.

Updating Participants

Note: To add a amend participant details, the user must be on the study delegation log and have clinical user permission on the EDGE project site record

1. Log into EDGE at <https://www.edge.nhs.uk/>
2. To navigate to the Participants section of your project site record:
 - a. Click on **'Projects'** in the top ribbon.
 - b. Select the appropriate project.
 - c. Click **'Sites'** from the lefthand menu.
 - d. Select the appropriate site.
 - e. Click the **'Participants'** tab from the lefthand menu.
 - i. This tab will only appear if the staff member has "Clinical access" granted in the 'Staff' tab of the project site record.
3. Select the participant whose details you want to update.
 - a. You can also search for the participant using the 'Name/Identifiers' field. (See ["Searching for Participants"](#) section of this guide)

4. To update a participant's status e.g. from consented to recruited, click **'Edit Status'**
5. Update, add and edit all applicable status dates and click **'save'**
 - a. Date fields must be in chronological order and must have an entry for each field up to and including the most recent action. E.g. if the latest date you want to enter is the 'Recruited/Randomised' date, all dates prior to this such as the "Pre-screened" must be completed
 - b. All dates should be in the DD/MM/YYYY format
 - c. A user with clinical access must be included in the 'Actioned By' column for all steps in the workflow with a completed date

6. Saved fields can be seen below.

Audit Mode Delete Participant

Participant Status Edit Status Take Off Study

Status	Date	Actioned by
Pre-Screened	05/02/2024	AHMED, ZABED
Approached	05/02/2024	AHMED, ZABED
Consented	05/02/2024	AHMED, ZABED
Screened	05/02/2024	AHMED, ZABED
Recruited / Randomised	07/02/2024	AHMED, ZABED

Identifiers + Add

Local Number patient1234 ✎

7. To take a participant Off Study, click **'Take Off Study'**.

a. Tick **'Participant is Off Study'**.

b. Complete the fields as per step 12 of the ["Adding Individual Participants"](#) section of the guide.

c. Click **'Save'**.

Participant Status Edit Status Take Off Study

Status	Date	Actioned by
Pre-Screened	30/10/2023	AHMED, ZABED
Approached	30/10/2023	AHMED, ZABED
Consented	30/10/2023	AHMED, ZABED
Screened	30/10/2023	AHMED, ZABED
Recruited / Randomised	30/10/2023	AHMED, ZABED

Edit Participant Off Study

Participant is Off Study

Save Cancel

Participant Status Edit Off Study Details

Status	Date	Actioned by
Pre-Screened	30/10/2023	AHMED, ZABED
Approached	30/10/2023	AHMED, ZABED
Consented	30/10/2023	AHMED, ZABED
Screened	30/10/2023	AHMED, ZABED
Recruited / Randomised	30/10/2023	AHMED, ZABED
Off Study	05/02/2024	AHMED, ZABED

Reason Withdrawn

Decision Clinical

Description Adverse Event

Comments

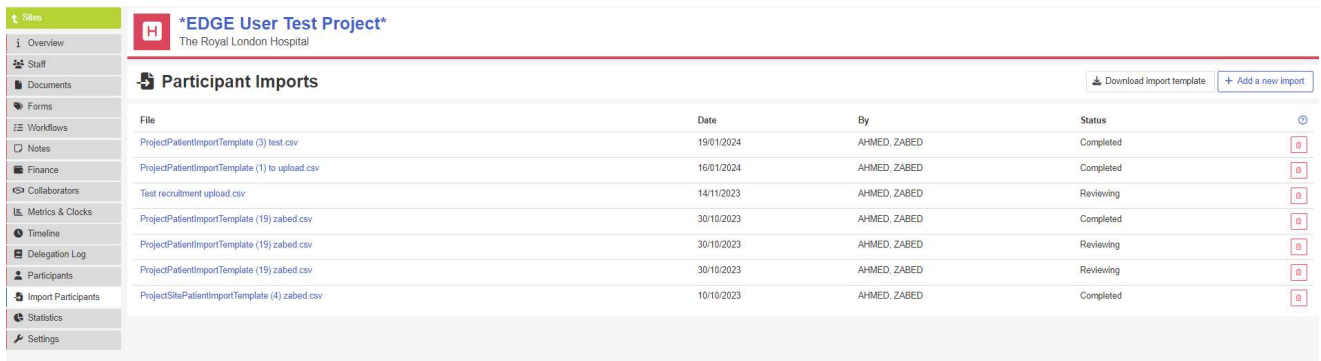
Bulk adding multiple participants to a single Project Site

Note: To add a new participant, the user must be on the study delegation log and have clinical user permission on the EDGE project site record

No Patient Identifiable Information other than MRN should be recorded on EDGE

1. Log into EDGE at <https://www.edge.nhs.uk/>

2. To navigate to the Participants section of your project site record:
 - a. Click on **'Projects'** in the top ribbon.
 - b. Select the appropriate project.
 - c. Click **'Sites'** from the lefthand menu.
 - d. Select the appropriate site.
 - e. Click the **'Import Participants'** tab from the lefthand menu.
 - i. This tab will only appear if the staff member has "Clinical access" granted in the 'Staff' tab of the project site record.
3. Click **'Download import template'**
 - a. Save in an appropriate location.



4. Open the downloaded file.
5. Populate the import excel template with your data, one row per participant
 - a. Field list is below - those with an asterisk are compulsory
 - b. The **headers** must not be changed, as this will cause the import to fail. No columns can be deleted
 - c. Date fields must be in chronological order and must have an entry for each field up to and including the most recent action. E.g. if the latest date you want to enter is the 'Recruited/Randomised' date, all dates prior to this such as the "Pre-screened" must be completed
 - d. All dates should be in the DD/MM/YYYY format
 - e. The 'actioned by' fields (e.g. 'Pre-screened by' and 'Pre-screened date' etc.) must match the format used by EDGE i.e. [Surname] comma [First name] and must reference someone with clinical access on the Project Site record.
 - f. For each stage where a date has been entered e.g. "Recruited By", the user who completed that action must also be entered. For example, the Recruited Date must have a Recruited By user in the column next to it.
6. Save the spreadsheet as a CSV (Comma delimited) file.

Field name:

Identifier*
Title
Forename
Surname
Date of Birth
Gender
Date of Death
Hospital Number* - MRN
Randomisation Number
Participant Type* - Must match one of: <ul style="list-style-type: none"> • Carers • Diagnostic, screening or prevention participants • Genetically predisposed

<ul style="list-style-type: none"> • Other • Participant with the relevant condition • Participant without condition • Pre-condition • Professionals • Relations
Project Arm
Referring Site
Consultant
Pre-Screened By* - this is your name as it appears on Edge e.g. Surname, First name
Pre-Screened Date* - date format xx/xx/xxxx
Pre-Screened By* - this is your name as it appears on Edge e.g. Surname, First name
Approached Date* - date format xx/xx/xxxx
Approached By* - this is your name as it appears on Edge e.g. Surname, First name
Consented Date* - date format xx/xx/xxxx
Consented By* - this is your name as it appears on Edge e.g. Surname, First name
Screened Date* - date format xx/xx/xxxx
Screened By* - this is your name as it appears on Edge e.g. Surname, First name
Recruited / Randomised Date* - date format xx/xx/xxxx
Recruited / Randomised By* - this is your name as it appears on Edge e.g. Surname, First name
On Treatment Date
On Treatment By
On Follow-up Date
On Follow-up By
Off Study Date
Off Study By
Off Study Reason
Off Study Detail

- To upload the spreadsheet to EDGE, click the + **Add a new import** icon in **Participant Imports** tab at the project site level.
- Drag your complete file to the upload box or click in the box to select your file when prompted.

File	Date	By	Status
ProjectPatientImportTemplate (3) test.csv	19/01/2024	AHMED, ZABED	Completed
ProjectPatientImportTemplate (1) to upload.csv	16/01/2024	AHMED, ZABED	Completed
Test recruitment upload.csv	14/11/2023	AHMED, ZABED	Reviewing
ProjectPatientImportTemplate (19) zabed.csv	30/10/2023	AHMED, ZABED	Completed
ProjectPatientImportTemplate (19) zabed.csv	30/10/2023	AHMED, ZABED	Reviewing
ProjectPatientImportTemplate (19) zabed.csv	30/10/2023	AHMED, ZABED	Reviewing
ProjectSitePatientImportTemplate (4) zabed.csv	10/10/2023	AHMED, ZABED	Completed

9. Review your imported data.
 - a. Any data where EDGE has not been able to recognise will be highlighted. Within the 'Errors' column of the review table, EDGE will highlight where the error has occurred.
10. Errors can be edited within EDGE or can be fixed in the sourced spreadsheet and then reupload.
 - a. To edit errors with participant details (e.g. duplicate identifier number or incorrect participant type) click the '**Edit Participant Details**' pencil icon on the righthand side of the table.
 - i. Edit the information on the 'Edit Participant Import Record' page.
 - ii. Click '**Save**'.
 - b. To edit errors with status dates (e.g. incorrect dates or unmatched user) click the '**Edit status dates**' pencil and square icon on the righthand side of the table.
 - i. Edit the information on the 'Edit Participant Import Record' page.
 - ii. Click '**Save**'.
 - c. After amending any errors click '**+ Validate this import**' to revalidate the data and identify any new errors.

EDGE User Test Project
Newham University Hospital

Participant Import + Validate this import + Import patients

Import Details

Filename: ProjectSitePatientImportTemplate (8).csv Status: Reviewing
Date File Uploaded: 21/11/2023 Rows: 11 in total, 0 ignored and 0 are valid.
Date Import Performed:

State: (All)

Page size: 100 Previous Next

Include	Valid	Errors	Name	Site	Date Of Birth	
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✗	• Patient status users are mandatory when a date has been entered	null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✗	• Patient status dates are mandatory when a user has been entered	null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✗	• Patient status users are mandatory when a date has been entered	null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		

11. Once reviewed click the '**+ Import patients**' button.

EDGE User Test Project
Newham University Hospital

Participant Import + Validate this import + Import patients

Import Details

Filename: ProjectSitePatientImportTemplate (8).csv Status: Reviewing
Date File Uploaded: 21/11/2023 Rows: 11 in total, 0 ignored and 11 are valid.
Date Import Performed:

State: (All)

Page size: 25 Previous Next

Include	Valid	Errors	Name	Site	Date Of Birth	
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		
<input checked="" type="checkbox"/>	✓		null, null	Newham University Hospital		

12. Previous imports can be seen in the 'Participant Imports' tab.
13. The imported participants can be viewed in the 'Participants' tab.

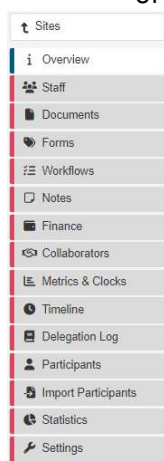
The screenshot shows the 'Participants' tab in the EDGE User Test Project interface. The top ribbon displays the project name and hospital. The search filters include 'Name / Identifiers', 'Date of Birth', and 'Current Status'. The table below lists 13 participants with columns for Name, Date of Birth, Identifiers, Hospital Number, Randomisation Number, Screening Number, Registration Number, Current Status, and Current Status Date.

Name	Date of Birth	Identifiers	Hospital Number	Randomisation Number	Screening Number	Registration Number	Current Status	Current Status Date
(anonymous)		Local Number: patient123		xxxx123	xxxx123	xxxx123	Recruited / Randomised	01/01/2023
(anonymous)		Local Number: patient124		xxxx124	xxxx124	xxxx124	Recruited / Randomised	02/01/2023
(anonymous)		Local Number: patient125		xxxx125	xxxx125	xxxx125	Recruited / Randomised	03/01/2023
(anonymous)		Local Number: patient126		xxxx126	xxxx126	xxxx126	Recruited / Randomised	04/01/2023
(anonymous)		Local Number: patient127		xxxx127	xxxx127	xxxx127	Recruited / Randomised	05/01/2023
(anonymous)		Local Number: patient128		xxxx128	xxxx128	xxxx128	Recruited / Randomised	06/01/2023
(anonymous)		Local Number: patient129		xxxx129	xxxx129	xxxx129	Recruited / Randomised	07/01/2023
(anonymous)		Local Number: patient130		xxxx130	xxxx130	xxxx130	Recruited / Randomised	08/01/2023
(anonymous)		Local Number: patient131		xxxx131	xxxx131	xxxx131	Recruited / Randomised	09/01/2023
(anonymous)		Local Number: patient132		xxxx132	xxxx132	xxxx132	Recruited / Randomised	10/01/2023
(anonymous)		Local Number: patient133		xxxx133	xxxx133	xxxx133	Recruited / Randomised	11/01/2023

Searching for Participants

Note: To add a view participants and amend details, the user must be on the study delegation log and have clinical user permission on the EDGE project site record

1. Log into EDGE at <https://www.edge.nhs.uk/>
2. To navigate to the Participants section of your project site record:
 - a. Click on 'Projects' in the top ribbon.
 - b. Select the appropriate project.
 - c. Click 'Sites' from the lefthand menu.
 - d. Select the appropriate site.
 - e. Click the 'Participants' tab from the lefthand menu.
 - i. This tab will only appear if the staff member has "Clinical access" granted in the 'Staff' tab of the project site record.



3. Enter the participant details in the 'Name/ Identifiers' search fields and click **Update Results**

The screenshot shows the 'Participants' search interface. The 'Name / Identifiers' search field contains the text 'pat12345'. An arrow points to this field from the text above. The 'Update results' button is highlighted in blue.

4. Click the participant's name to open the participant's record.

Participants

Name / Identifiers: patient124

Date of Birth: [] x []

[Update results] [Reset]

Page 1 of 1

Name	Date of Birth	Identifiers	Hospital Number
(anonymous)		Local Number: patient124	

Further Support

Contact the organisation Lead Admins with any questions or for further support. The Barts Health NHS Trust EDGE Lead Administrator details can be found in the 'Support' tab in the top ribbon of EDGE.

Additional guides for recruitment upload can be found in the EDGE Support KnowledgeBase:

<https://www.edge.nhs.uk/#/help/group/11/sections>