



AD HOC Trial Database

REDCap User Guide **(Data Entry, Survey Management and Randomisation)**

Summary of Changes:

Version Number	Version Date	Affected Section(s)	Summary of Revisions Made:
1.0	24-Feb-2025		First version of ADHOC Trial database user guide
1.1	10.04.2025		Typos and minor mistakes corrected (mainly where procedures have changed from the feasibility study to the trial).

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1.0. General Data Entry Rules/Notes

Always be careful when entering data, check each screen before saving.

Always log out of database when not in use.

Always enter complete records and save, do not leave the form in the middle of data entry.

The system will timeout after ~10 minutes of inactivity.

Use the mouse or tab key (keyboard) to move between questions and mouse or arrow keys to select the answer. If an incorrect answer is selected, either click on the correct answer to change it or you can click on **reset** to clear the answer.

When you get to the end of a form, change the **Form Status** to COMPLETE (using the dropdown), then click on **Save & Go To Next Form** (use the dropdown to select, if not shown).

Please do ensure that at the end of each session you clearly log out and close the browser.



2.0. Help and Contacts

If you have any queries relating to the database, please contact the AD HOC study team by email on adhoc@qmul.ac.uk or by phone on 07916 136187.

Please include as much detail about the issue as possible, including screenshots, however do not screenshot live participant data. We may forward your query to our data management team if appropriate.

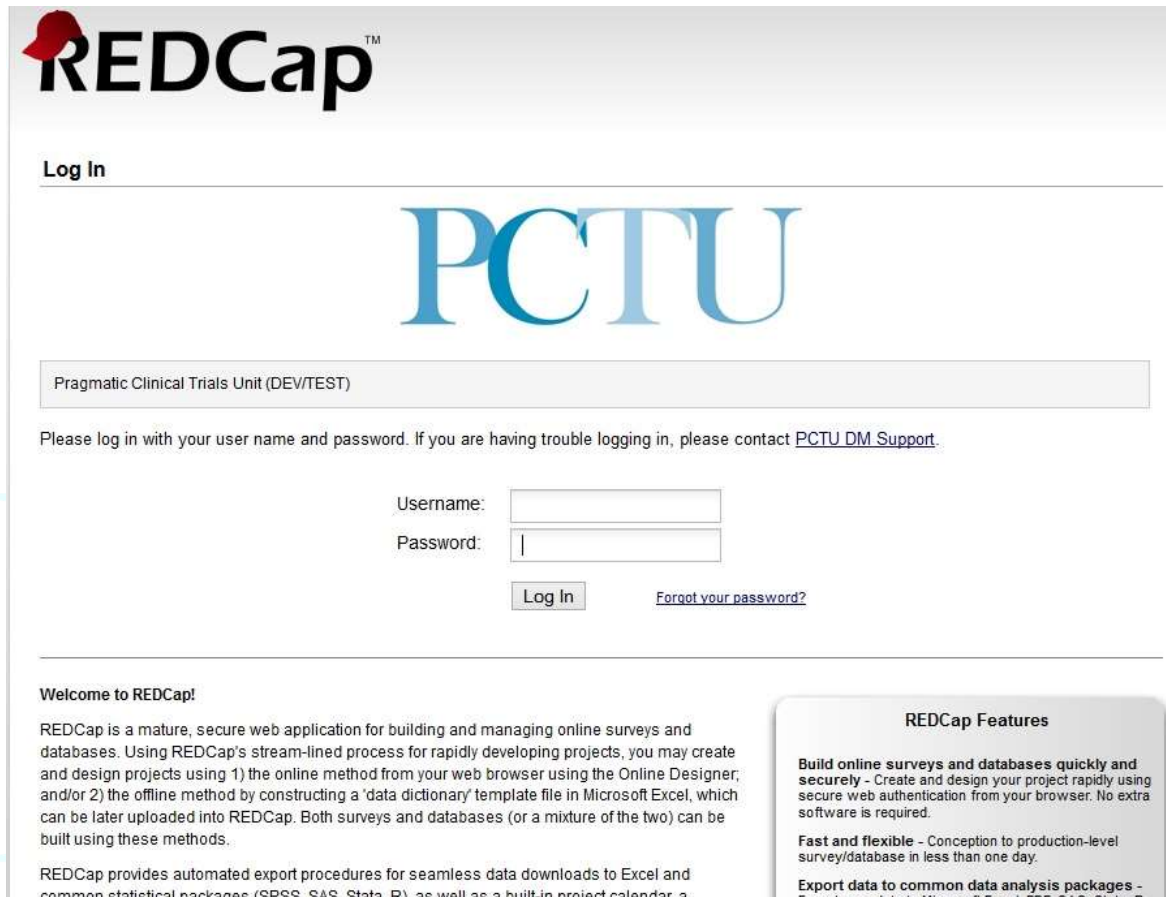
3.0. Logging on to the system

REDCap can be accessed through any of the latest internet browsers including Microsoft Internet Explorer or Microsoft Edge, Mozilla Firefox, Chrome and Apple Safari.

For training purposes, you will be asked to use the test database; please do not enter live data on the **test** system: <https://dm2.pctu.qmul.ac.uk>

Once you are fully trained, you will be given access to the **live** database, for participant data entry:
<https://trials2.pctu.qmul.ac.uk/>

You will be presented with the following login screen:



Your log in details will be sent to you by a member of the study team or the data management team (from an @qmul.ac.uk email address).

Open the link you have been sent and enter your username. The first time you access REDCap you will be prompted to create a password and a security question. If you forget your password you can reset it using the **Forgot your password?** Link on the login page. You will be prompted to enter your username to retrieve a temporary password to access your REDCap account.

The REDCap **live** system (section 3.3) is protected by **two-factor authentication** which would normally require you to verify your identity using another device (email, phone or any other security token device); every time you log in you will be presented with the screen below:

Two-step verification for REDCap login

Select an option below to complete the second half of REDCap's two-step verification login process. You will not be able to access REDCap until you have completed this verification step.

Email: Send an email containing your verification code to your email account.
Send to <account email address>

[Cancel](#)

Please click the button and enter the 6 digit REDCap **verification code** you will receive **via email** as shown in the screen below... Please note that the verification code **expires after two minutes**, so if you miss this time window you will need to re-click the button to send another verification code.

Enter your verification code

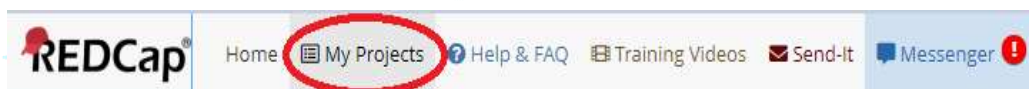
Enter the verification code that you obtained from

Email

[Submit](#) [Cancel](#)

4.0. Accessing Projects

When you first log in to the system you will be presented with the REDCap **home page** with the following tabs at the top of the page.



Select the **My Projects** tab to see a list of projects which you are authorised to access (please refer to screenshot below), and select **ADHOC Trial** (in the test database this will show as ADHOC Trial (TEST)):

REDCap Home **My Projects** Help & FAQ Training Videos Send-It Messenger

This is PCTU's DEV/UAT instance of REDCap, and no real study data can be entered on to any of the databases - ONLY TEST DATA IS ALLOWED. Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects		Organize		Collapse All		Filter projects by title	
Project Title	Records	Fields	Instruments	Type	Status		
ADHOC Trial (TEST)	116	82	270	7 forms 16 surveys			

This will take you to the Project home page of the study database where you can navigate to enter participant data (see section 5.0).

5.0. Home Page and Navigation

The **Project Home** Page looks like this, and shows an overview of the study:



The screenshot shows the REDCap interface for the ADHOC Trial (TEST). On the left is a navigation panel with sections: 'Project Home and Design' (containing Project Home, Codebook, and Project status: Development), 'Data Collection' (containing Record Status Dashboard and Add / Edit Records), and 'Applications' (containing Calendar, Data Exports, Reports, and Stats, and Field Comment Log). The main content area features the PCTU logo, project name 'ADHOC Trial (TEST)', and a 'Project Home' button. Below this, there is a summary table for 'Current Users' (6) and 'Project Statistics' (6 records in project).

On the left of the page you will always have your **navigation panel**, with links to all functionalities and applications you have access to according to your user role (see section 12). You can always click on **Project Home** to get back to this page, or on **My Projects** to get back to the list of projects which you have access to.

You are only likely to need to use two options under the **Data Collection** section of the navigation panel:

Record Status Dashboard: Lists all participants against all events in the study (section 5.13)

Add/Edit Records: Click to select a participant and add data to their record (sections 6.0 and 7.0)

6.0. Adding a participant

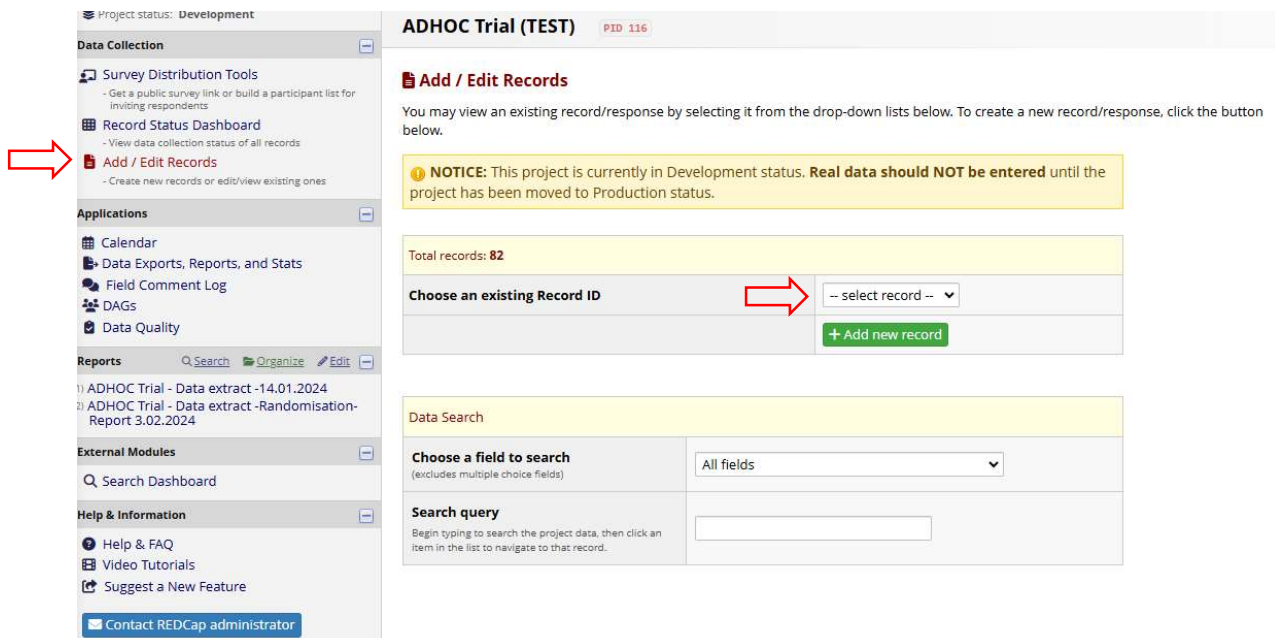
Please note that it is not possible to add new participants to the ADHOC Trial database. Participants are added when they complete an online survey sent to all eligible asthma patients by their GP practice manager via text message. A unique **Record ID** is generated when each online survey is submitted.

The AD HOC study team will have sent you a list of names and corresponding Record IDs for the patients you will be seeing to deliver the study intervention. Go to **section 8.0** for how to select a participant and add data to their record.

7.0. Data Entry

Accessing a Participant's record

To select a participant's record, click on **Add/Edit Records** in the navigation panel on the left of the screen:



The screenshot displays the REDCap interface for the 'ADHOC Trial (TEST)'. On the left, the navigation panel is visible, with 'Add / Edit Records' highlighted by a red arrow. The main content area shows a 'Total records: 82' summary, a 'Choose an existing Record ID' dropdown menu with a red arrow pointing to it, and a '+ Add new record' button. Below this is a 'Data Search' section with a 'Choose a field to search' dropdown and a 'Search query' input field.

Click on the dropdown arrow next to **select record** and scroll to select the correct **Record ID** for your patient (they are in numerical order). This will open the **Record Home Page** for this participant:

ADHOC Trial (TEST)

PID 116

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Choose action for record

Legend for status icons:

- Incomplete ● Incomplete (no data saved) ?
- Unverified ● Partial Survey Response
- Complete ● Completed Survey Response

Record ID **77** [10077]

Data Collection Instrument	Pre-screening Survey	Consent	Baseline PID	Baseline	Randomisation	Interim Follow-up 3 Months	Interim Follow-up 6 Months	Interim Follow-up 9 Months	Final Follow-Up	Supplementary
Screening (survey)	✔									
Asthma Symptoms (ACT) (survey)	✔									
Asthma Management (survey)	✔									
Eligibility (survey)	✔									
Contact Information (PID) (survey)	✔									
Consent		⓪								
Withdrawal										⓪

You will see a series of green ticks under **Pre-screening Survey**, indicating that the participant has completed the online survey, and a grey button under **Consent**. This indicates that the participant is eligible for the Trial (if not eligible, this grey button will not show).

You can also select a participant's record by clicking on **Record Status Dashboard** in the navigation panel on the left of the screen. This will take you to a grid showing all participants in the database, with each form under each event in the study:

ADHOC Trial (TEST) PID 116

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] v Create custom dashboard

Displaying record Page 1 of 1: "9" through "14" v of 4 records ALL (4) v records per page

+ Add new record

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Record ID	Pre-screening Survey					Consent	Baseline PID		Baseline					
	Ad Hoc Welcome Sheet	Asthma Symptoms	Asthma Management	Eligibility	Contact Information	Consent	Personal Details Part 1	Personal Details Part 2	Asthma Symptoms	Asthma Exacerbations	Quality Of Life (EQ-5D-5L)	Using the Internet for Health Information	Asthma Medications (MARS)	Ability to Perform Tasks (General Self Efficacy Scale)
9 [10009]	●	●	●	●	●	●	●	●	●	●	●	●	●	●
12 [10012]	●	●	●	●	●	●	●	●	●	●	●	●	●	●
13 [10013]	●	●	●	●	●	●	●	●	●	●	●	●	●	●
14 [10014]	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Note the **Record ID** is on the left. Scroll down to find your patient's ID. Please note, you may need to select a different page to find the correct ID number – select the dropdown next to **Displaying record** for a list of pages. Again, you will see a series of green ticks under **Pre-screening Survey**, indicating that the participant has completed the online survey, and a grey button under **Consent**.

Whichever way you have accessed the participant record, you will next need to click on the grey button under **Consent** in order to start the consultation with the patient and to start entering data.

Completing Forms

General Points

All fields marked **must provide value* are required and must be completed. Fields not marked with an asterisk are not required and can be left blank. Leaving a required field blank will prompt the following message upon saving:

NOTE: Some fields are required!

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- Date of visit

Okay Ignore and leave record Ignore and go to next form

Click **Okay** to go back to the form to complete the missing required fields. Please do not click **Ignore and leave record** or **Ignore and go to next form – go back and enter the required data**.

You will need to complete **Consent** (1 form), **Baseline PID** (2 forms) and **Baseline** (9 forms) before you can randomise the patient to Intervention or Care as usual. Once you have completed Consent, you will see a grey button next to each of the forms to be completed. The button for each form will change to green once it has been completed and saved.

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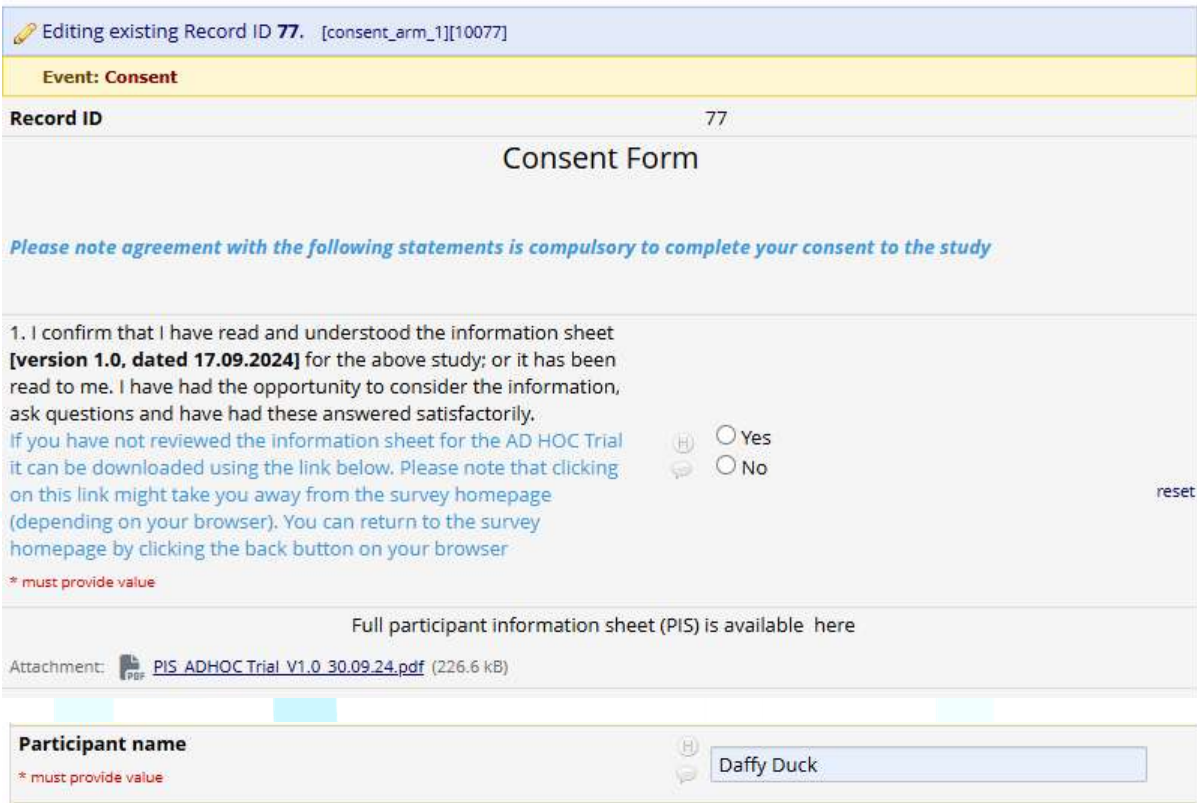
Record ID **77** [10077]

Data Collection Instrument	Pre-screening Survey	Consent	Baseline PID	Baseline
Screening <small>(survey)</small>	<input checked="" type="checkbox"/>			
Asthma Symptoms (ACT) <small>(survey)</small>	<input checked="" type="checkbox"/>			<input type="checkbox"/>
Asthma Management <small>(survey)</small>	<input checked="" type="checkbox"/>			
Asthma Exacerbations <small>(survey)</small>				<input type="checkbox"/>
Eligibility <small>(survey)</small>	<input checked="" type="checkbox"/>			
Contact Information (PID) <small>(survey)</small>	<input checked="" type="checkbox"/>			
Consent		<input checked="" type="checkbox"/>		
Quality Of Life (EQ-5D-5L) <small>(survey)</small>				<input type="checkbox"/>
Using the Internet for Health Information <small>(survey)</small>				<input type="checkbox"/>
Asthma Medications (MARS) <small>(survey)</small>				<input type="checkbox"/>
Ability to Perform Tasks (General Self Efficacy Scale) <small>(survey)</small>				<input type="checkbox"/>
Smoking Status <small>(survey)</small>				<input type="checkbox"/>
Symptoms Of Depression (PHQ-8) <small>(survey)</small>				<input type="checkbox"/>
Symptoms of Anxiety (GAD-7) <small>(survey)</small>				<input type="checkbox"/>
Personal Details Part 1 (Directly Identifiable Data)			<input type="checkbox"/>	
Personal Details Part 2 (Demographic)			<input type="checkbox"/>	
Randomisation Allocation				
Withdrawal				

You will need to complete each form in turn, showing the screen to the patient and either reading the text to them or asking them to read it themselves, and answer the questions as indicated by the patient. The majority of questions use buttons to select one answer from a choice of 4 or 5. If an incorrect answer is selected or the patient wants to change their answer, click the **reset** button, at the right of the screen, and then select the correct answer.

Consent

Click on the grey button under or next to **Consent** to open the **Consent Form**:



Editing existing Record ID 77. [consent_arm_1][10077]

Event: Consent

Record ID 77

Consent Form


Please note agreement with the following statements is compulsory to complete your consent to the study

1. I confirm that I have read and understood the information sheet [version 1.0, dated 17.09.2024] for the above study; or it has been read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. If you have not reviewed the information sheet for the AD HOC Trial it can be downloaded using the link below. Please note that clicking on this link might take you away from the survey homepage (depending on your browser). You can return to the survey homepage by clicking the back button on your browser

Yes No

* must provide value

Full participant information sheet (PIS) is available here

Attachment:  [PIS ADHOC Trial V1.0 30.09.24.pdf](#) (226.6 kB)

Participant name

* must provide value

At the top of the page, you will see the **Record ID** and at the bottom of the page, the **Participant name** – check that these are correct. Show the screen to the patient and either read the text to the patient or ask the patient to read it themselves. The first question confirms that the patient has **read the PIS** and had the opportunity to ask questions. They will have been sent the PIS to read beforehand, but if they want to look at it you can open the PDF using the link. Click the button next to Yes to continue to the next question.

Read through and answer the questions with the patient (13 questions in total). Note that questions 8 to 12 are optional – the patient can answer No to these although it is preferable if they answer Yes. If they are unsure about any of the questions, please answer any queries they have. The final question will appear once 1-12 have been answered.

Ask the patient to add their electronic **signature and date**, then add your **name, electronic signature and date**.

To add your name, click in the box and type using the keyboard. To sign, click on **Add signature** to bring up the signature box and sign (as best you can) using the mouse. Click on **Save signature**. Click on **Today** to add today's date.

Participant name <small>* must provide value</small>	<input type="text" value="Daffy Duck"/>
Participant Electronic signature <small>* must provide value</small>	Add signature
Participant signature Date <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> <input type="button" value="D-M-Y"/>
Name of healthcare professional taking consent: <small>* must provide value</small>	<input type="text"/>
Healthcare professional electronic signature: <small>* must provide value</small>	Add signature
Healthcare professional signature date: <small>* must provide value</small>	<input type="text"/> <input type="button" value="Today"/> <input type="button" value="D-M-Y"/>

Add signature ✕

Participant Electronic signature* must provide value

SIGN HERE

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Exit Form**.

Form Status	
Complete?	<input type="button" value="Complete"/> ▾
	<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Go To Next Form"/> ▾
	<input type="button" value="- Cancel -"/>

Baseline-PID Forms

Click on the first grey button under **Baseline PID (Personal details Part 1)**. Confirm the **area/region** and **GP surgery** are correct (these will have been auto-filled using data from the online survey completed by the patient). If not, correct by selecting from the dropdown.

Add the **date** (click on **Today**).

Add the patient's **NHS number**, confirm their **name**, enter their **date of birth** and check that their **home postcode**, **email address** and **mobile phone number** are correct. If not, please edit by typing directly into the relevant box. Check that the email is the address they want to use to sign up to the Asthma Forum. If not, please edit it accordingly.

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Personal Details Part 1 (Directly Identifiable Data)

Data Access Group: [No Assignment] ?

Editing existing Record ID 77. [baseline_pid_arm_1][10077]

Event: Baseline PID

Record ID 77

You may wish to show the screen to the patient, if you are entering the data online, but please ask them the questions and enter the answers as given.

Your area/region * must provide value

GP surgery * must provide value

Please confirm that the area/region and GP surgery name are correct, if not please correct.

Date of intervention delivery: Today * must provide value

NHS number: * must provide value
10 characters remaining
10 Digits

Please enter the patient's NHS number from their electronic record.

Participant name * must provide value

Please confirm that the participant's name is spelled correctly and is written in 'First Name Last Name' (e.g., John Smith) format, if not please correct it.

Patient date of birth: Today * must provide value

Participant home postcode: * must provide value
CAPITAL LETTERS

Participant email: (Please read/spell it back to the patient to check it is correct.) * must provide value

Please confirm that the participant's email address is spelled correctly and is the address they want to use to sign up to the asthma online health community, if not please correct it.

Mobile phone number: * must provide value
0 characters remaining
UK mobile phone number 11 digits, starting 07

Please read it back to the participant to check that it is recorded correctly.

To add the date manually, for **date of birth**, click in the box and type using the keyboard, e.g. 1.1.23 or 1/1/23. Patients must be aged over 18 to be eligible. This will have been verified when they completed the survey. If you enter a date outside the age range set (i.e. under 18 or over 99) you will see a warning message and a warning box will pop up:



Click on **Close**, correct the date entered and the warning will disappear.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

The second form, **Personal Details Part 2**, contains the demographics. Please work through the questions with the patient. They may chose not to answer (Prefer not to say) or select Other and specify their own answer by typing in the box. If possible, let the patient complete this form themselves, but check all questions have been answered before changing the **Form Status** to COMPLETE and clicking **Save & Exit Form**.

Baseline Forms

There are 9 forms to complete. From the patient record, click on the first grey button under Baseline (**Asthma Symptoms (ACT)**).

Asthma Symptoms (ACT)



This section includes the 5 questions of the **Asthma Control Test (ACT)** which most patients will be familiar with. **Select ONE answer for each question**, as indicated by the patient. The **ACT score** is automatically calculated and shown at the end.


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Asthma Symptoms (ACT)

Data Access Group: [No Assignment] ?

Invitation status: 

 Survey options 

 Editing existing Record ID **77**. [baseline_arm_1][10077]

Event: Baseline

Record ID 77

Part 1: About your asthma symptoms

This section is about your asthma symptoms. For each question, select the ONE answer from the list that best applies to you.

You may wish to show the screen to the patient, if you are entering the data online, but please ask them the questions and enter the answers as given.

During the *past 4 weeks*, how often have you had shortness of breath?
* must provide value

- More than once a day
- Once a day
- 3 to 6 time a week
- Once or twice a week
- Not at all

reset

In the *past 4 weeks*, how much of the time did your *asthma* keep you from getting as much done at work, school or home?
* must provide value

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

reset

During the *past 4 weeks*, how often did your *asthma* symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
* must provide value

- 4 or more nights a week
- 2 or 3 nights a week
- Once a week
- Once or twice in the past 4 weeks
- Not at all

reset

During the *past 4 weeks*, how often did you have to use your rescue (blue) inhaler or nebuliser medication?
* must provide value


- 3 or more times a day
- 1 or 2 times a day
- 2 or 3 times a week
- Once a week or less
- Not at all

reset

How would you rate your *asthma* control over the *past 4 weeks*?
* must provide value

- Not controlled at all
- Poorly controlled
- Somewhat controlled
- Well controlled
- Completely controlled

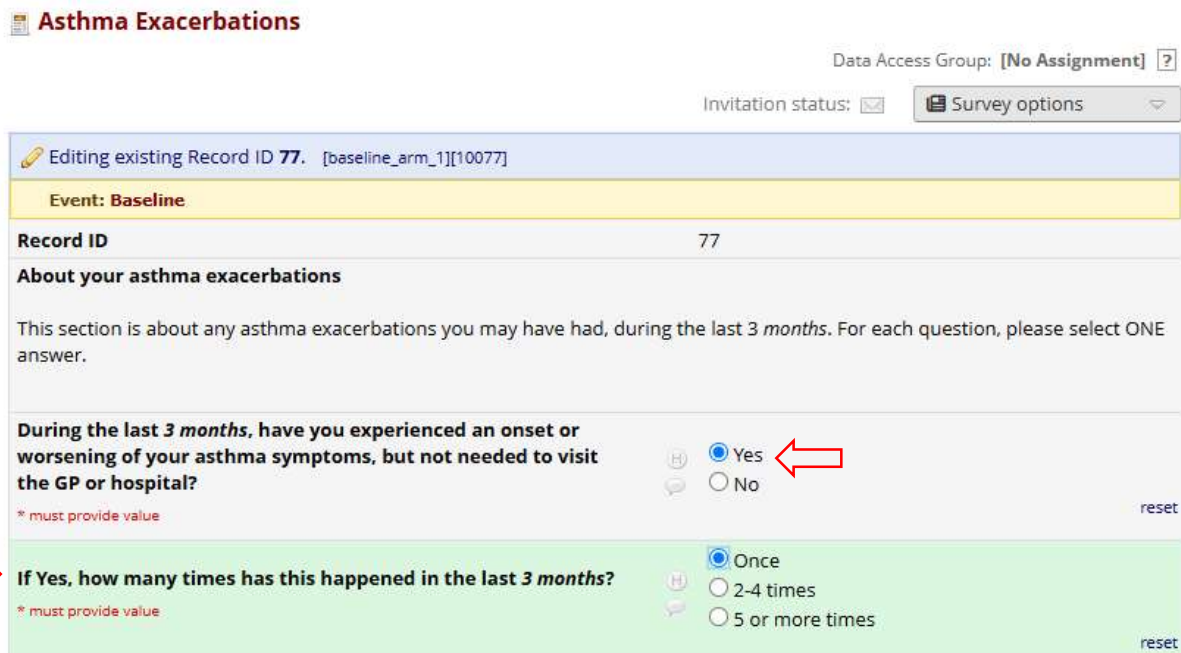
reset

ACT score  [View equation](#)

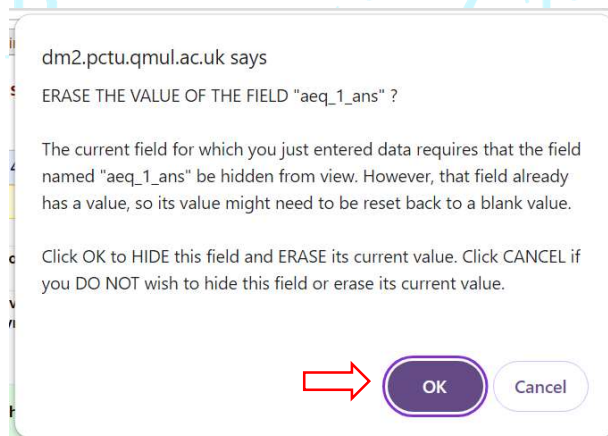
Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next**.

Asthma Exacerbations

This section is about any **asthma exacerbations** the patient may have had, **during the last 3 months**. There are 5 questions, asking about asthma symptoms with increasing severity and about time off work. For each question, if they answer Yes, this leads to a second question requiring further detail (branching questions). If they answer No, the branching question remains hidden.



If, having answered Yes and answered the branching question, you try to change the answer of the first question to No, a warning will pop up because the answer to the branching question will no longer be valid. Click **OK** and the answer to the branching question will be deleted.



Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

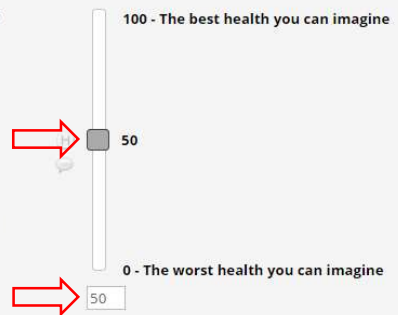
EQ-5D-5L

The next section is a standardised questionnaire about **quality of life**, with 5 questions and a sliding numerical scale. **Select ONE answer for each question.** For the **sliding scale**, click on the slider and drag it up or down to the correct number, as indicated by the patient. The number is shown in the box below.

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

- 100 means the best health you can imagine. 0 means the worst health you can imagine.
- Please click on the scale to indicate how your health is TODAY.



100 - The best health you can imagine

50

0 - The worst health you can imagine

50

* must provide value reset

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

Using the Internet for Health Information

This first part of this section is about **how/whether the patient uses the Internet for health information**. There are 8 statements with a scale ranging Strongly disagree to Strongly agree – click on **one answer for each statement**.

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About using the Internet for support with your health (Part 1)


This section is about using the Internet for health information. For each statement, select the answer from the dropdown list that best applies to you.

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
I know what health resources are available on the Internet <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know where to find helpful health resources on the Internet <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know how to find helpful health resources on the Internet <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know how to use the Internet to answer my questions about health <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know how to use the health information I find on the Internet to help me <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have the skills I need to evaluate the health resources I find on the Internet <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I can tell high quality health resources from low quality health resources on the Internet <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel confident in using information from the Internet to make health decisions <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>


In the second section, there are three Yes/No questions about **looking for advice about asthma online**. For each question, there is the option of entering a free-text explanation of their answer. The explanations are optional.

About using the Internet for support with your health (Part 2)


Would you consider looking for advice about your asthma online? Please tick one box.
* must provide value Yes No reset

Please explain your answer 

Would you consider looking for advice online from other people with asthma in a safe and well-moderated online health forum (a community for asthma patients who are interested in supporting each other online)?
* must provide value Yes No reset

Please explain your answer 

Would you consider it appropriate for your GP or practice nurse to encourage you to engage in a safe and well-moderated online health forum for patients with asthma?
* must provide value Yes No reset

Please explain your answer 

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

MARS

The next section is a standardised questionnaire about **taking medication**, with 10 statements and a scale of answers ranging from Always to Never. If the patient queries which medication this is referring to, say that it refers to their asthma medications. Select **ONE answer for each statement**.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

Ability to Perform Tasks (General Self Efficacy Scale)

This is a standardised questionnaire about how the person views their **ability to perform tasks**, with 10 statements and a scale of answers ranging from Not at all true to Exactly true. Select **ONE answer for each statement**.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

Smoking Status

This section is about **whether the patient smokes or vapes**. Choose the appropriate answers from the dropdowns.

Smoking Status



Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

PHQ-8

This is a standardised questionnaire about **symptoms of depression**, with 8 questions. **This section is not required – the patient can skip the whole section or any of the questions**. If they are happy to continue, select **ONE answer for each question**.

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Go To Next Form**.

GAD-7

This is a standardised questionnaire about **symptoms of anxiety**, with 8 questions. **This section is not required – the patient can skip the whole section or any of the questions**. If they are happy to continue, select ONE answer for each question. If an answer is given to any of the first 7 questions, the 8th question will appear. Select ONE answer.

This is the last section of the Baseline data collection. Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Exit Form**. This will take you back to the **Record Home Page** and you will see 9 green dots under **Baseline** – indicating that all forms have been completed. At this point, the next step is **Randomisation**.

✔ Record ID 141 successfully edited.

Record ID 141 [1141]

Data Collection Instrument	Pre-screening Survey	Baseline	Follow-Up	Supplementary
Ad Hoc Welcome Sheet (survey)	✔			
Consent		●		
Baseline-PID Form		●		
Asthma Health (survey)	✔	●	○	
Ehealth Literacy Scale (survey)	✔			
Eq5d5l (survey)	✔	●	○	
Phq8 (survey)	✔	●	○	
GAD-7 (survey)	✔	●	○	
About You Form (survey)	✔			
MARS (survey)		●	○	
General Self Efficacy Scale (survey)		●	○	
Asthma Exacerbations Questions (survey)		●	○	
Asthma OHC Engagement (survey)		●	○	
Withdrawal				○

8.0. Randomisation

Randomisation determines whether the patient will receive the AD HOC Intervention or Care as Usual. Before completing the Randomisation Allocation form, all other forms must have been completed, i.e., eligibility has been verified, and the Consent, Personal Details Part 1, and Part 2 forms have been completed. The randomisation is based on **age** and **ACT** score, both of which are automatically calculated based on answers in previous forms (DOB in Personal Details part 1 form and ACT score from the screening survey Asthma Symptoms form). If any of this information is missing, randomisation cannot proceed. Please ensure to double check before you proceed with randomising, as the record will be permanently assigned with an allocation even if you do not save the form.

Once the randomisation has taken place, the Age group and ACT score group cannot be altered.


Click on the grey button under Randomisation to open the Randomisation Allocation Form.

ADHOC Trial (TEST)

PID 116


Actions:

 Modify instrument

 Download PDF of instrument(s)

 Video: [Basic data entry](#)

 **Randomisation Allocation**

 Editing existing Record ID **16**. [randomisation_arm_1][10016]

Event: **Randomisation**

Record ID	16
Age (Read Only):	<input type="text" value="24"/>
Act Score (Read Only):	<input type="text" value="11"/>
Age Group (Read Only):	<input checked="" type="radio"/> 18-49 <input type="radio"/> 50-120
ACT Score Group (Read Only):	<input type="radio"/> 1-9 <input checked="" type="radio"/> 10-20
Which group has the patient been randomised to?	<input type="button" value="Randomize"/>
Form Status	
Complete?	<input type="text" value="Incomplete"/>

You will see age and ACT score fed through automatically from the other forms, and the age and ACT score groups into which the patients have been assigned. Click the Randomize button.

Pragmatic Clinical Trials Unit

✕ Randomizing Record ID "16" ✕

Below you may perform randomization for Record ID "16" on the field **Which group has the patient been randomised to?** (*treatment_arm*). Please note that the fields below will become permanently locked and uneditable on the data entry form once this record has been randomized.

Provide any missing values below for Record ID **16**, then click the Randomize button below.


Age Group (Read Only):	<input checked="" type="radio"/> 18-49 <input type="radio"/> 50-120
ACT Score Group (Read Only):	<input type="radio"/> 1-9 <input checked="" type="radio"/> 10-20

REMINDER: This project is still in development status, so you should NOT be randomizing real subjects yet. You should only be randomizing real subjects after moving the project into in production status.

Randomize Cancel

This will open another window. Click Randomize and the pop-up will inform you which group they have been randomised to – ‘Intervention’ or ‘Care as usual’. Click close to close the pop-up.

✕ Randomizing Record ID "16" ✕



Record ID "16" was randomized for the field "**Which group has the patient been randomised to?**" and assigned the value "**Intervention**" (1).

Close

Returning to the Randomisation Allocation Form, you will see the group is now displayed.

Event: Randomisation	
Record ID	16
Age (Read Only):	<input type="text" value="24"/>
Act Score (Read Only):	<input type="text" value="11"/>
Age Group (Read Only):	<input checked="" type="radio"/> 18-49 <input type="radio"/> 50-120
ACT Score Group (Read Only):	<input type="radio"/> 1-9 <input checked="" type="radio"/> 10-20
Which group has the patient been randomised to?	<input type="text" value="Already randomized"/> <input type="text" value="Intervention"/>
Form Status	
Complete?	<input type="text" value="Complete"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Stay"/>	
<input type="button" value="- Cancel -"/>	

Change the **Form Status** to COMPLETE using the dropdown and click on **Save & Exit Form**. This is the **end of the data entry**, so you can **logout of REDCap** and close it at this point.

If the patient has been assigned to **Intervention**, you can now go on to deliver the intervention.

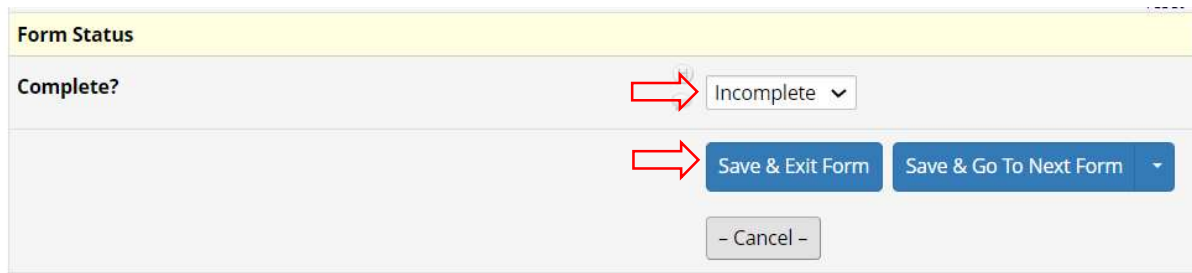
If the patient has been assigned to **Care as Usual**, you should now follow the checklist for Care as Usual patients.

9.0. Participant withdrawal

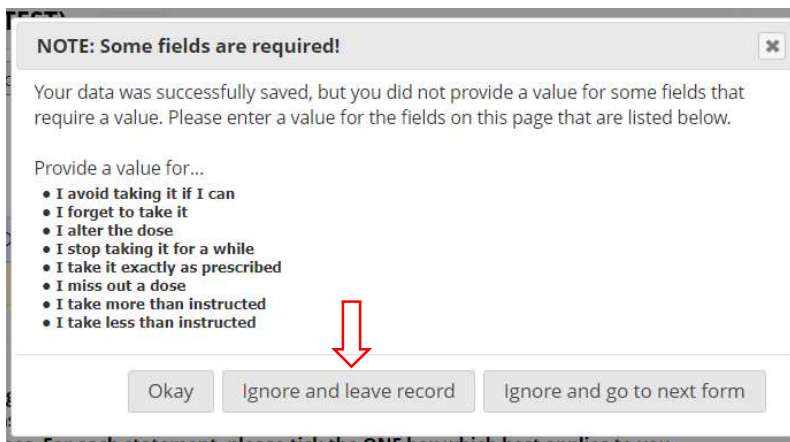
If a patient decides to withdraw

Participants are free to withdraw from the study at any point without needing to give an explanation. If a patient decides during the baseline consultation that they don't want to take part in the study, then that is absolutely within their rights to do so. Please reassure the patient that their withdrawal will have no impact on their future care and thank them for their time.

You will need to terminate the data entry and consultation at this point. If you are part way through one of the forms on REDCap, leave the **Form Status** as INCOMPLETE and click on **Save & Exit Form**.



If you are on any form other than the PHQ-8 or GAD-7, a warning box will pop up to prompt you to complete the missed questions. You should click on **Ignore and leave record**.



Complete the withdrawal procedure as per the patient consultation checklist.

Recording a withdrawal

Please record the patient withdrawal in the **Site File** and **email the AD HOC Study team** adhoc@qmul.ac.uk to inform us of the withdrawal and reason (if given). Please include the patient's **Record ID and the GP surgery name and date of consultation**, but do not send any identifiable patient details.

The study team will complete the withdrawal form in REDCap. If a **Read Code** has been added to the patient's record indicating their participation in the AD HOC study, this will need to be removed (see consultation checklist for how to do this).

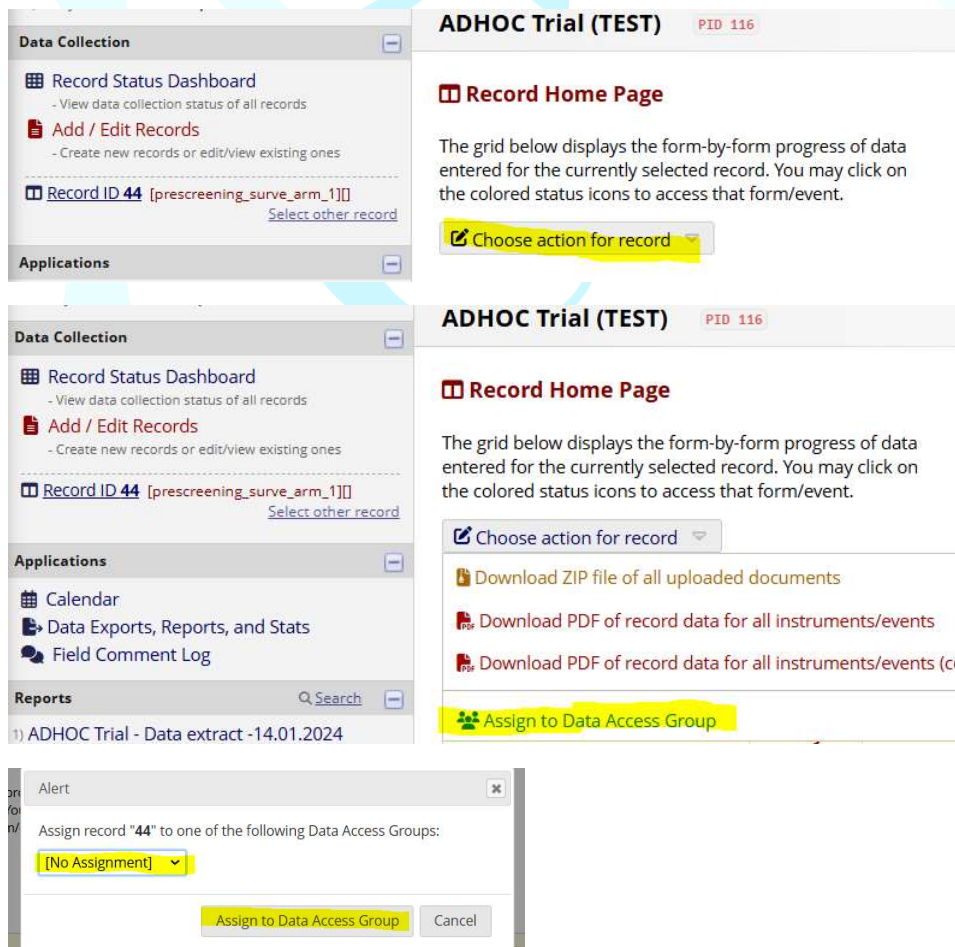
10.0. For the AD HOC Study team only

Please note this section is for the attention and use of the AD HOC Study team (Central Research Team) only, not for clinicians (HCP).

Assigning the participants Data Access Group (GP Practice)

When the participant has completed their survey and the grey button appears within the consent form column on the record status dashboard (indicating they are eligible for the study and want to participate) you will need to add them to their correct Data Access Group so that the HCP can access the participant.

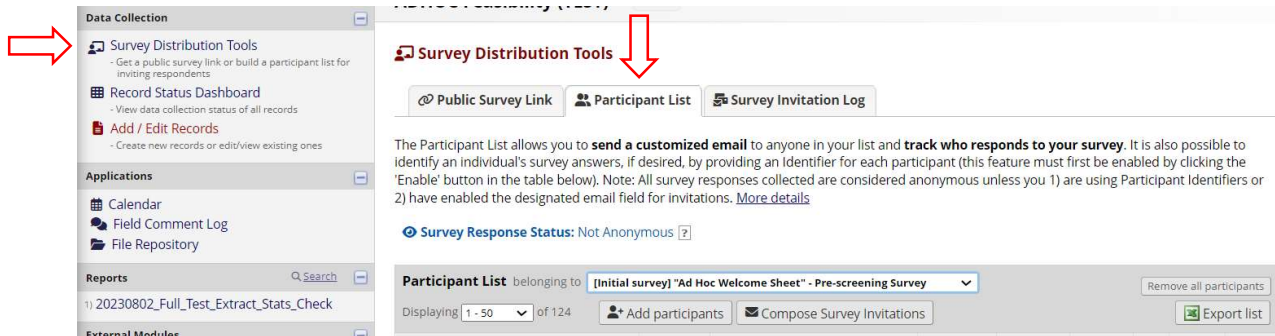
1. Click on the record ID
2. Select 'Choose action for record'
3. Click 'Assign to Data Access Group'
4. Select the correct GP practice from the dropdown list
5. Click 'Assign to Data Access Group'



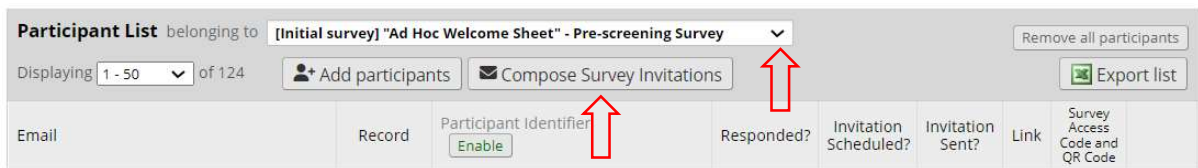
The screenshot shows the ADHOC Trial database interface. The left sidebar contains navigation options like 'Record Status Dashboard', 'Add / Edit Records', and 'Record ID 44'. The main content area shows the 'Record Home Page' for 'ADHOC Trial (TEST) PID 116'. A dropdown menu 'Choose action for record' is highlighted in yellow. Below it, there are options to 'Download ZIP file of all uploaded documents' and 'Download PDF of record data for all instruments/events'. The 'Assign to Data Access Group' button is also highlighted in yellow. At the bottom, an 'Alert' dialog box is shown, asking to 'Assign record "44" to one of the following Data Access Groups:' with a dropdown menu showing '[No Assignment]' and buttons for 'Assign to Data Access Group' and 'Cancel'.

Sending the follow-up questionnaire

From the navigation panel, under **Data Collection**, click on **Survey Distribution Tools**, and select the **Participant List** tab.



Change the **Participant List** belonging to to **'Follow-up Information Sheet – Final Follow-Up'** using the dropdown, and click on **Compose Survey Invitations**.



Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
		Enable					

This will open a pop up. On the right of the pop up there is a list (in alphabetical order) of the email addresses for all survey participants who are eligible for the Trial but HAVE NOT completed the follow-up questionnaire. **Blue ticked boxes** will show next to those addresses where the follow-up questionnaire hasn't yet been sent; **unticked boxes** will show next to those addresses which have been sent the questionnaire, but not yet completed it. For the latter, there will also be a blue envelope with green tick under **Sent?** The **Record ID** is shown in brackets under or next to the email address.

Participant List		Actions: -- check/uncheck participants --			
(those who have not responded completely)					
<input type="checkbox"/>	Email (9 selected)	Participant Identifier	Scheduled?	Sent?	Responded?
<input checked="" type="checkbox"/>	6) [redacted] (ID 117)		-		
<input checked="" type="checkbox"/>	[redacted] (ID 42)		-		
<input type="checkbox"/>	3) [redacted] (ID 66)		-		
<input checked="" type="checkbox"/>	15) [redacted] (ID 136)		-		
<input checked="" type="checkbox"/>	4) helen.wood@qmul.ac.uk (ID 131)		-		
<input type="checkbox"/>	5) helen.wood@qmul.ac.uk (ID 141)		-		
<input checked="" type="checkbox"/>	2) [redacted] (ID 26)		-		
<input type="checkbox"/>	[redacted] (ID 116)		-		
<input checked="" type="checkbox"/>	[redacted] (ID 62)		-		
<input checked="" type="checkbox"/>	[redacted] (ID 34)		-		
<input checked="" type="checkbox"/>	[redacted] (ID 120)		-		
<input checked="" type="checkbox"/>	1) [redacted] (ID 30)		-		

You can either send the email with the follow-up questionnaire to all those addresses with blue ticked boxes (i.e. those that haven't received it) or select specific address(es) by **unchecking all** using the box next to **Email** then checking the one(s) you want to send it to.

Once you have selected the address(es) you want to email, move to the panel on the right of the pop-up screen. Select **At specified time** to schedule the questionnaire in advance. Choose the time and date at which it should be sent (i.e. 10am on the nearest weekday to the 12-month anniversary of the consultation). Select **Enable reminders** and specify when you want reminders to be sent (1 week and 2 weeks after the initial email: select the weekday and time at which you are sending the first email and for recurrence, select send up to two times). Try not to send the initial email or reminders on a public holiday.

Under **Compose message**, change the **From address** to ADHOC@qmul.ac.uk and **Display name** to AD HOC Study Team, and add the **Subject** (AD HOC Study follow-up survey).

Send a Survey Invitation to Participants

Info
Survey title: Follow-up Information Sheet
Event: Final Follow-Up

When should the emails be sent?

Immediately

At specified time: D-M-Y H:M

The time must be for the time zone Europe/London, in which the current time is 14-02-2025 13:54.

Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time? (Times below refer to AFTER original invitation time.)

Send every -- select day -- at time H:M

Send every days hours minutes

Send at exact date/time: D-M-Y H:M

- AND -

Recurrence:

Compose message

From:

(select any project user to be the 'Sender')

To:

Subject:

[Send test email](#)

The first time the follow-up survey is sent, the text of the email will need to be composed, but subsequently, you can re-use the same email by using the dropdown next to **Select a previously sent email...**, below the body of the email.

Check the text of the email and double check all the details entered/selected before clicking **Send Invitations** at the bottom right of the screen.

Survey link

Please note, the **URL** for the **AD HOC pre-screening survey** can be found under the **Public Survey Link** tab on **Survey Distribution Tools**, should you need it (note that the URL shown in the screenshot below is that for the TEST database survey).

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: 

Note that opening the survey link will create a record and a record ID in the LIVE database, so **MUST NOT** be done, other than in the TEST database using the TEST survey link.

Completing the withdrawal form

If a participant requests to withdraw from either the survey or the Trial, the **Withdrawal form** will need to be completed on REDCap by a member of the AD HOC Study team. The Withdrawal form is located under the **Supplementary** event in the patient record.

To begin, click **Yes** next to **Participant withdrawn...** and this will open the rest of the form.

Withdrawal

Data Access Group: [No Assignment] ?

Editing existing Record ID 57. [supplementary_arm_1][10057]

Event: Supplementary

Record ID 57

This form is for participants who wish to withdraw from the AD HOC TRIAL and therefore no further contact should be made. Only complete this form if the participant has requested to withdraw from the AD HOC TRIAL or if another party (e.g. healthcare professional) has decided that the participant should be withdrawn.

If a participant could not be contacted for follow-up they are not automatically withdrawn.

Participant withdrawn from AD-HOC study? Yes No reset

* must provide value

Form Status

Complete? Incomplete

Save & Exit Form Save & Stay - Cancel -

Complete the questions, including the additional branching questions, as relevant.

Participant withdrawn from AD-HOC study? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Date the participant was withdrawn <small>* must provide value</small>	<input type="text"/>  Today D-M-Y	
Who requested withdrawal?: <small>* must provide value</small>	<input type="text"/>	
Primary reason for withdrawal <small>* must provide value</small>	<input type="text"/>	
Point at which participant was withdrawn <small>* must provide value</small>	<input type="text"/>	

Once the form is complete, change the **Form Status** to COMPLETE and click **Save & Exit**.

The AD HOC Team may be informed of a participant withdrawal by the participant themselves or by their GP practice. The PI may also decide that a participant should be withdrawn. If notification comes to the team from the participant or from the PI, the **GP practice should be informed** at the earliest opportunity, as per the relevant SOP (**ADHOC Trial SOP_03 Participant withdrawal**) and be requested to follow the procedures therein.