



A phase III, 2 arm, multi-centre, open label, parallel-group randomised designed clinical investigation of the use of a personalised early warning decision support system with novel saliva bio-profiling to predict and prevent acute exacerbations of Chronic Obstructive Pulmonary Disease - 'Predict & Prevent AECOPD'

ERDC Completion Guidelines

Version 1.0, 28th February 2020

Sponsor Number:	RG_19-050
IRAS Project ID Number:	261576

**UNIVERSITY OF
BIRMINGHAM**



Introduction

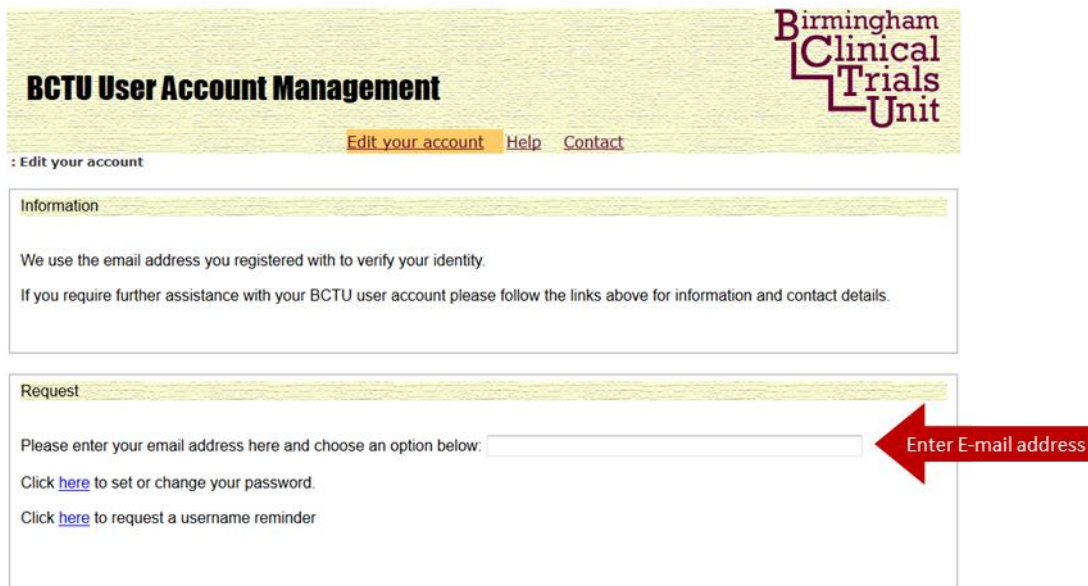
This document is intended to explain how to use the Predict and Prevent Online System. It does not go into the detail of either the protocol or the randomisation procedure itself, but provides essential information that will help you to use the Online System for randomisation and data entry.

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Accessing and Using the System

Username and Passwords

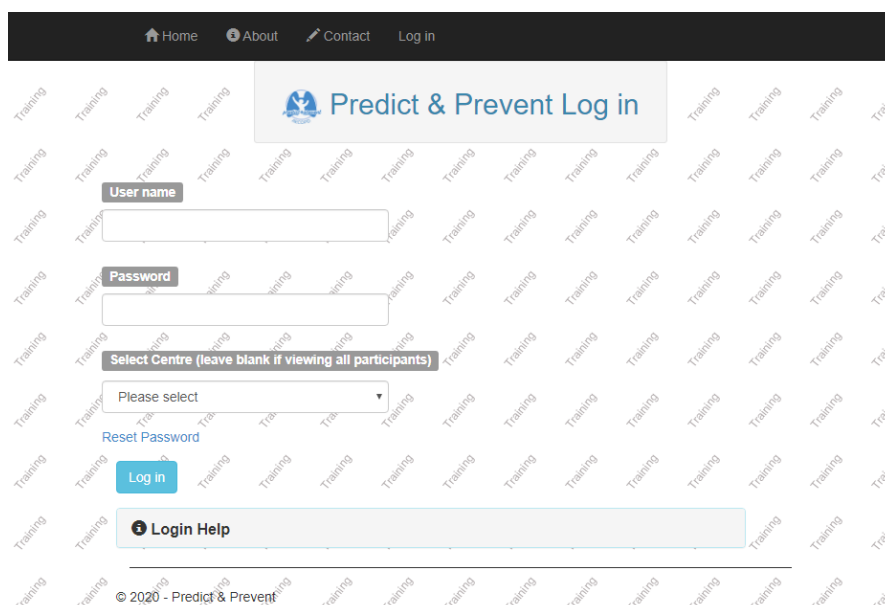
- You need a username and password to use the system.
- The Predict and Prevent Trial Office at BCTU will provide your User Name and grant access to the Predict and Prevent Online System based on the delegation log. If you don't have a User Name please contact predictandprevent@trials.bham.ac.uk
- You set your own password. Passwords are individual and should be known only to you.
- You will have one username and password for all BCTU-coordinated trials. If you use online systems for other BCTU trials, your username and password will also work for Predict and Prevent.
- To set or change your password:
 - Go to the BCTU User Account Management page: <https://www.trials.bham.ac.uk/Password/>.
 - Enter your e-mail address and click the link to set your password.
 - You must use the e-mail address held on our system. Please contact predictandprevent@trials.bham.ac.uk if your e-mail address is incorrect or changes.
- The user account management page will look like this:



- Follow the on-screen instructions to change/set your password.
- Password notes: Your password should be individual and known only to you. It should be composed of at least 8 characters including at least one number and mixed upper/lower case.
- After setting your password for the first time you will receive an email asking you to activate your password. Please follow the link as directed to activate your password.
- You may find that the activation email is directed into your 'Junk Email' folder. If this happens we suggest that you manually add bctu-webadmin@contacts.bham.ac.uk to your list of safe senders in your email clients.
- After activating your password you can Log-In using your Username and Password.

Accessing the Predict and Prevent system

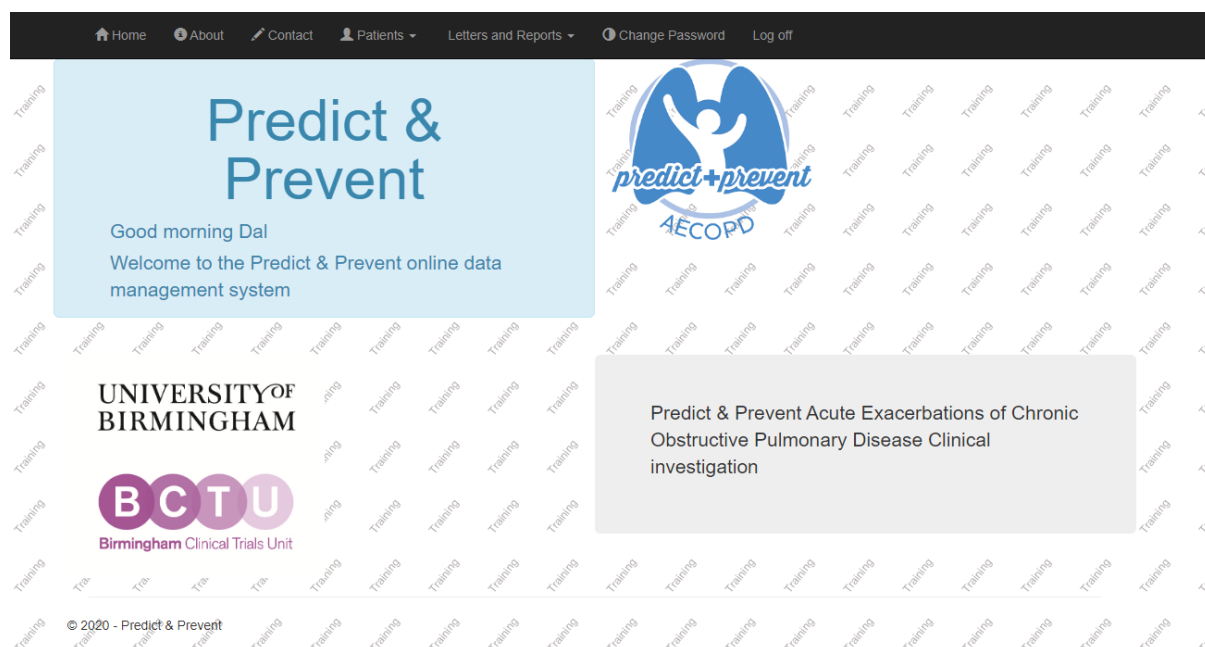
- Direct your web browser to <https://www.trials.bham.ac.uk/PredictPrevent>
- Log in using your username and password.
- The log-in page will look like this:
- Ensure you select the centre/site you work at



The screenshot shows the login interface for the Predict & Prevent system. At the top, there is a navigation bar with links for Home, About, Contact, and Log in. The main heading is "Predict & Prevent Log in". Below this, there are input fields for "User name" and "Password". A dropdown menu for "Select Centre (leave blank if viewing all participants)" is set to "Please select". There is a "Reset Password" link and a "Log in" button. A "Login Help" link is also present. The footer includes the copyright notice "© 2020 - Predict & Prevent".

Greeting

- Once you have logged in, the greeting page will look like this:



The screenshot shows the greeting page after logging in. The navigation bar includes links for Home, About, Contact, Patients, Letters and Reports, Change Password, and Log off. The main content area features a large blue box with the text "Predict & Prevent" and "Good morning Dal Welcome to the Predict & Prevent online data management system". To the right is the "predict+prevent AECOPD" logo. Below the blue box are the logos for the "UNIVERSITY OF BIRMINGHAM" and "BCTU Birmingham Clinical Trials Unit". A grey box on the right contains the text "Predict & Prevent Acute Exacerbations of Chronic Obstructive Pulmonary Disease Clinical investigation". The footer includes the copyright notice "© 2020 - Predict & Prevent".

- The welcome message should show your username or your preferred name. If there is any problem with this, please choose the logout option, and then log back in again.

Live or Training Data Connection

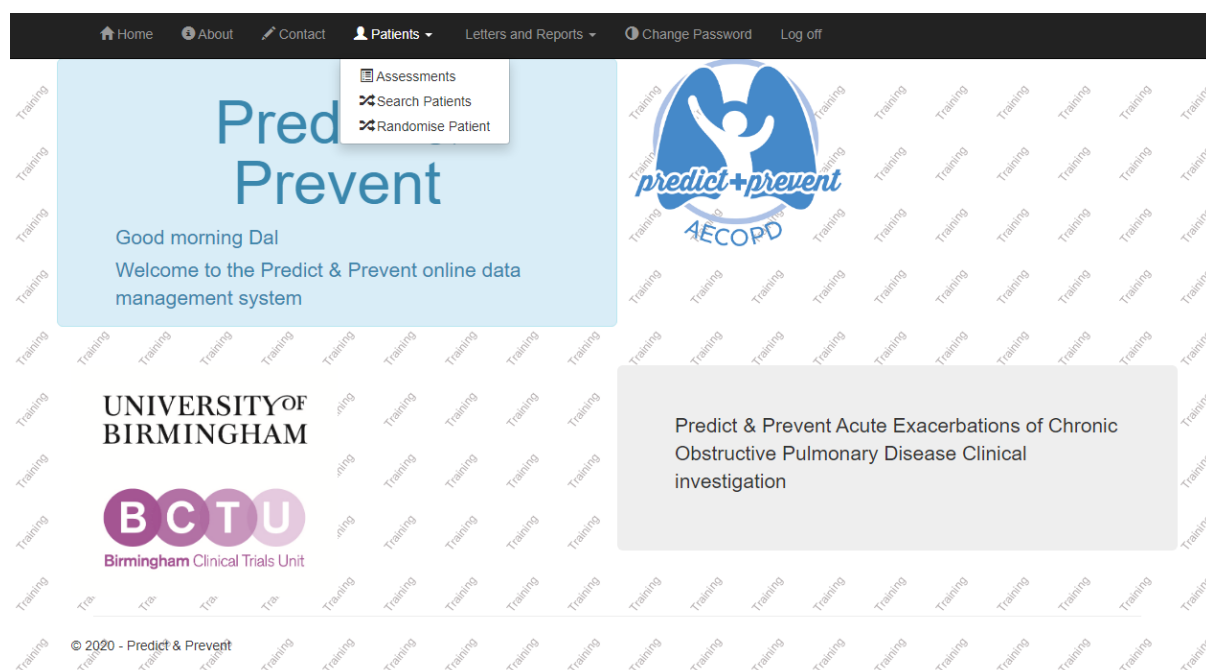
- You can use a 'Live' or 'Training' data connection. You should be connected to 'Live' data by default. If you want to train on the Predict and Prevent system without affecting real trial data, click on 'Change' to change the data connection to 'Training'. The pages will all display a 'Training' watermark making it clear if the connection is not live (as in the example above).

Logging off

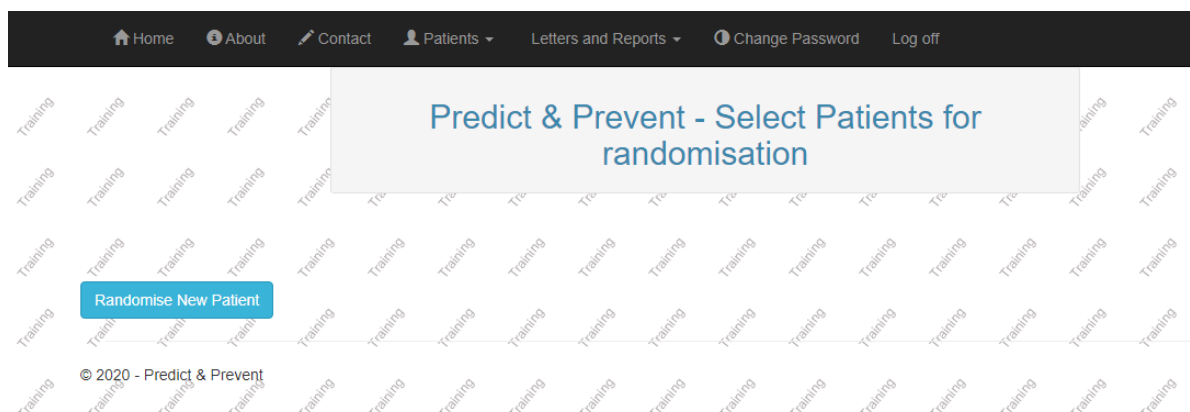
- To log off the system simply click the 'Logout' link at the top right hand side of the page. Remember to save any progress with form completion before you log out.

Randomisation

To randomise a patient, you will select the patient tab at the top of the page and select randomise patient from the drop-down menu.



You will be redirected to the randomisation page where you will select randomise new patient.

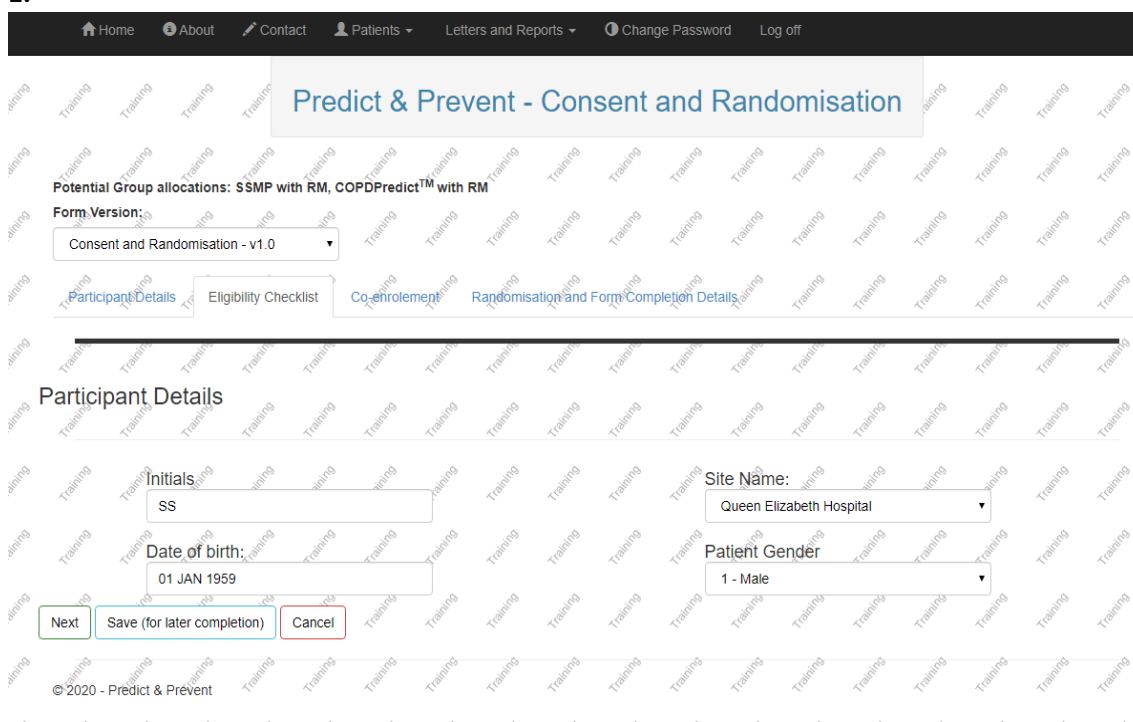


You will then follow through the randomisation wizard, see example below...

A few points to remember when randomising a patient

- All fields must be completed or you will not be allowed to proceed
- All inclusion criteria must be 'yes' or you will not be allowed to proceed
- All exclusion criteria must be 'no' or you will not be allowed to proceed
- At the end of each page select next to move forward or save to complete later and cancel to quit the randomisation process
- Patient can co-enrol but this must be previously discussed with the trial team at BCTU

1.



2.

Home About Contact Patients Letters and Reports Change Password Log off

Potential Group allocations: SSMP with RM, COPDPredict™ with RM

Form Version:
Consent and Randomisation - v1.0

Participant Details Eligibility Checklist Co-enrolment Randomisation and Form Completion Details

Aged 18 or over?
1 - Yes

Clinically diagnosed COPD, confirmed by post-bronchodilator spirometry and defined as FEV1/FVC<0.7 and lower limit of normal for age post bronchodilator use?
1 - Yes

Has the patient had ≥2 AECOPD in the previous 12 months according to the patient or =1 hospital admission for AECOPD?
1 - Yes

Willing and able to comply with completion of questionnaires out to 12 months post-randomisation ?
1 - Yes

Ability to use intervention as judged by the investigator at screening, upon demonstration of the system to the patient?
1 - Yes

State Version of informed consent form signed by patient: e.g. 1.0, 2.0 etc.
1 - Version 1

Is the patient unable to consent to research?
0 - No

Life expectancy <12 months from a condition other than COPD?
0 - No

Previous Next Save (for later completion) Cancel

3.

Home About Contact Patients Letters and Reports Change Password Log off

Predict & Prevent - Consent and Randomisation

Potential Group allocations: SSMP with RM, COPDPredict™ with RM

Form Version:
Consent and Randomisation - v1.0

Participant Details Eligibility Checklist Co-enrolment Randomisation and Form Completion Details

Has the patient, or is the patient intending to co-enrol into another trial/study?
1 - Yes

If Yes, specify (details of other trial)
Co-enrolment to X study, agreed with BCTU

Previous Next Save (for later completion) Cancel

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4.

Home About Contact Patients Letters and Reports Change Password Log off

Form Version:
Consent and Randomisation - v1.0

Participant Details Eligibility Checks Co-enrolment Randomisation and Form Completion Details

Randomisation

Recruitment setting?
1 - At discharge from hospital

Age
1 - <60 years

Severity of disease
1 - FEV1 <50% Predicted

Form Completion Details

Form completed by
Mr Paul Riley (Research Nurse - Queen)

Signature?
1 - Yes

Date signed (dd mmm yyyy)
27 Feb 2020

Principal Investigator Name
Dr Dalbir Kaur (Principal Investigator - Qi)

Principal Investigator Signature?
1 - Yes

Date PI Signed (dd mmm yyyy)
27 Feb 2020

Previous Randomise Save (for later completion) Cancel

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5.

Home About Contact Patients Letters and Reports Change Password Log off

Predict & Prevent - Consent and Randomisation

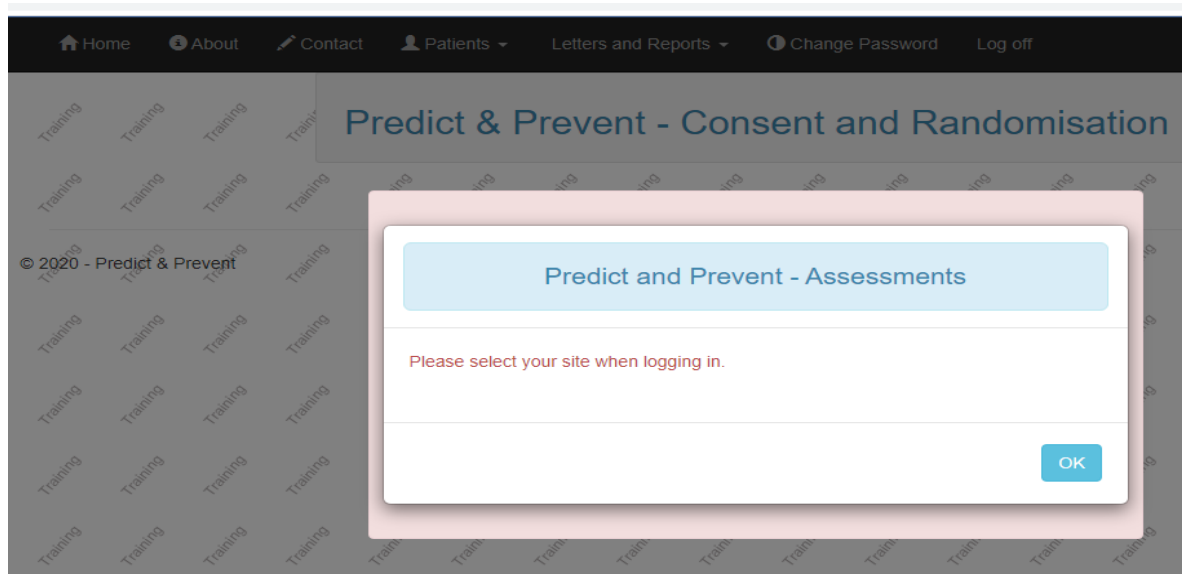
Predict & Prevent - Randomisation

Patient 1008 successfully randomised to SSMP with RM.

OK

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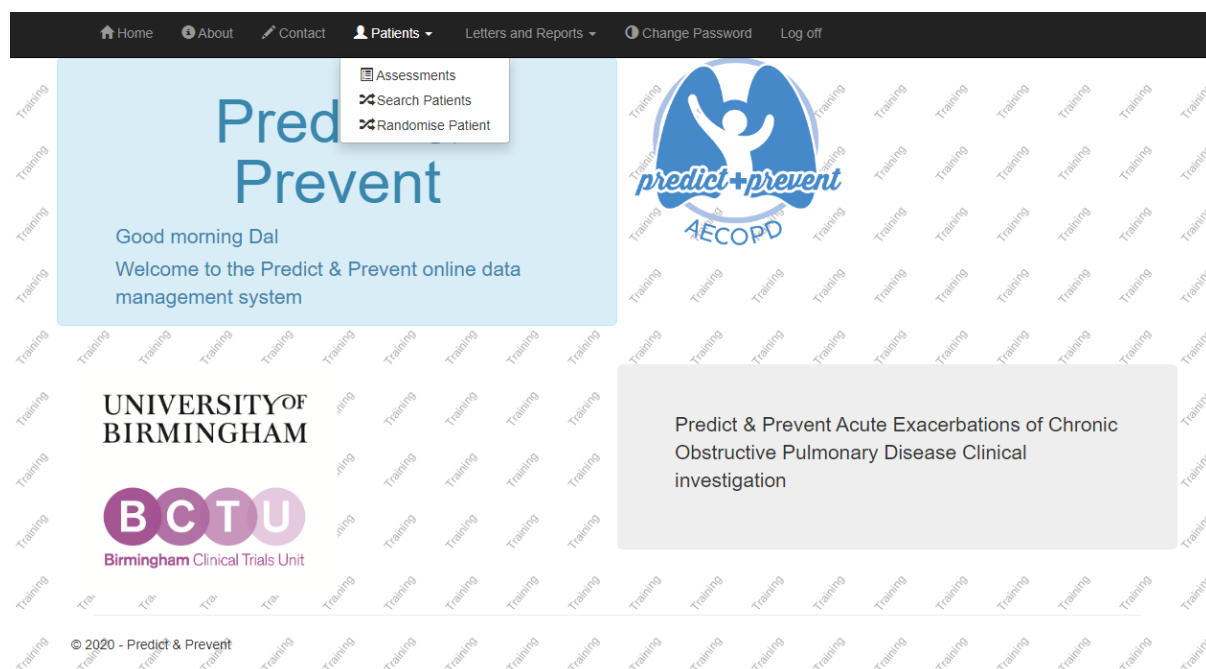
If you select randomise new patient and the following pop-up appears, then you need to log back in selecting the site you work at.



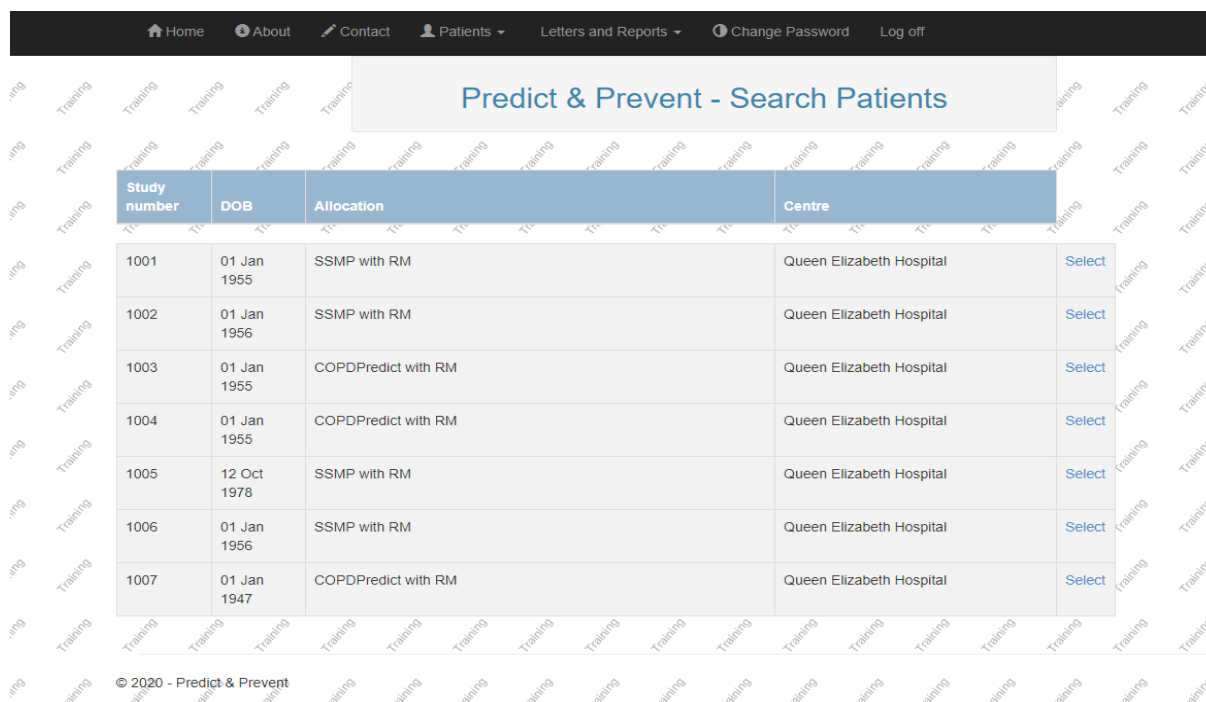
Entering data

To view a patient's record:

1. From the Home page, select 'Patients' and then 'Search Patient', as shown below:

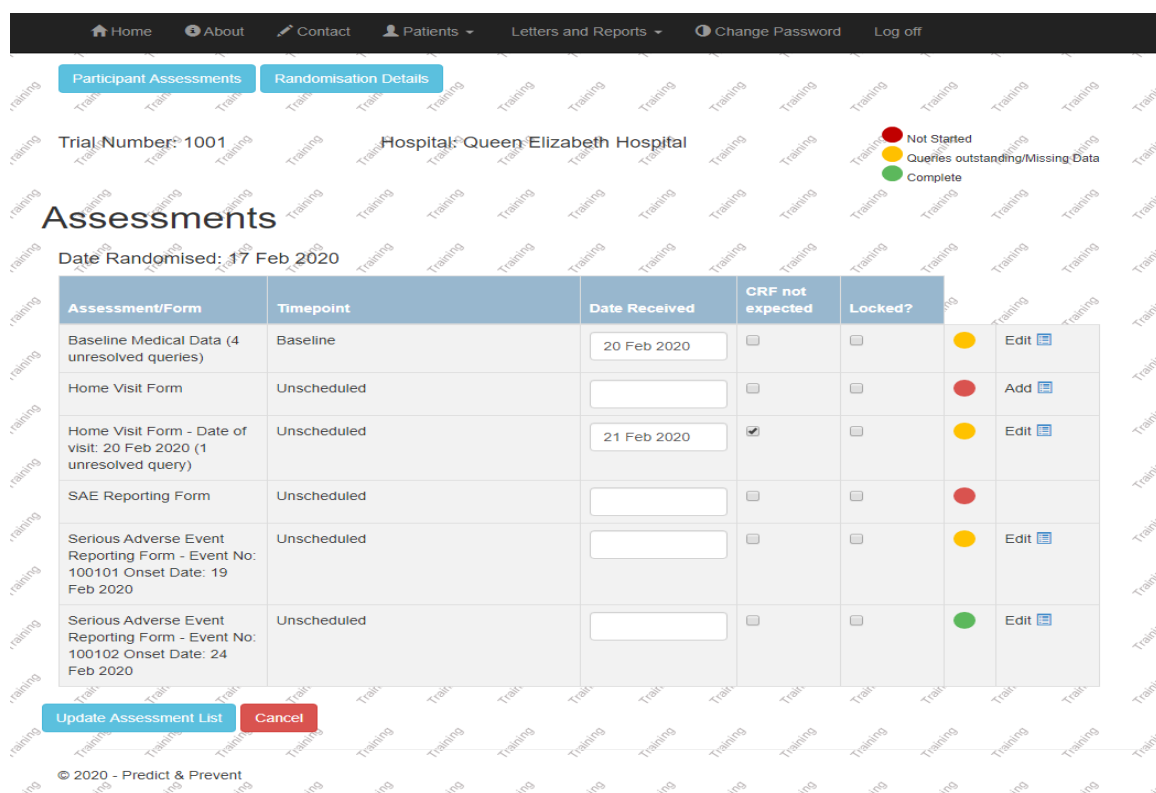


2. This will show a list of patients, identified by their Predict and Prevent trial ID number, date of birth in mmm/yyyy format, treatment allocation as below. You will only be able to see patients from your centre.



Study number	DOB	Allocation	Centre	
1001	01 Jan 1955	SSMP with RM	Queen Elizabeth Hospital	Select
1002	01 Jan 1956	SSMP with RM	Queen Elizabeth Hospital	Select
1003	01 Jan 1955	COPDPredict with RM	Queen Elizabeth Hospital	Select
1004	01 Jan 1955	COPDPredict with RM	Queen Elizabeth Hospital	Select
1005	12 Oct 1978	SSMP with RM	Queen Elizabeth Hospital	Select
1006	01 Jan 1956	SSMP with RM	Queen Elizabeth Hospital	Select
1007	01 Jan 1947	COPDPredict with RM	Queen Elizabeth Hospital	Select

- Once you select the patient you can see and enter assessments forms. **Please note that only the Baseline Form, Home Visit Form and the SAE Form programmed into version 1.0 of the database.** The healthcare contacts form, concomitant medications form, trial exit/change of status form, 3month to 12months follow-up forms and 3month to 12month booklet will be programmed in version 2.0 shortly.
- From the list of assessments you can add or edit forms by selecting the blue form icon next to edit/add.



Trial Number: 1001 Hospital: Queen Elizabeth Hospital

Assessments

Date Randomised: 17 Feb 2020

Assessment/Form	Timepoint	Date Received	CRF not expected	Locked?	Status	Action
Baseline Medical Data (4 unresolved queries)	Baseline	20 Feb 2020	<input type="checkbox"/>	<input type="checkbox"/>	Yellow	Edit
Home Visit Form	Unscheduled		<input type="checkbox"/>	<input type="checkbox"/>	Red	Add
Home Visit Form - Date of visit: 20 Feb 2020 (1 unresolved query)	Unscheduled	21 Feb 2020	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Yellow	Edit
SAE Reporting Form	Unscheduled		<input type="checkbox"/>	<input type="checkbox"/>	Red	
Serious Adverse Event Reporting Form - Event No: 100101 Onset Date: 19 Feb 2020	Unscheduled		<input type="checkbox"/>	<input type="checkbox"/>	Yellow	Edit
Serious Adverse Event Reporting Form - Event No: 100102 Onset Date: 24 Feb 2020	Unscheduled		<input type="checkbox"/>	<input type="checkbox"/>	Green	Edit

Update Assessment List Cancel

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- The traffic light system is employed, red and yellow flags are for site-staff attention, green is for completed forms. For unscheduled forms like the Home Visit Form, they will only need to be entered if applicable.
- The only form that you will not be able to edit is the SAE form. SAE forms need to be sent directly to the trial's office via fax/email. A notification will be sent once the trial team has received the SAE form, if you do not receive it then please contact the trials office immediately.
- The trial exit/change of status form should be sent to the trials office as soon as completed.

To add a form, enter data and submit a form

1. CRF data must be submitted electronically for Predict and Prevent. From the list of assessments, click 'Add' for the desired form. Please contact the trial office if you need to enter an assessment that is not available. Please note do not enter date received or select CRF not expected and locked, these are trial team controls only.

Trial Number: 1008 Hospital: Queen Elizabeth Hospital

Date Randomised: 27 Feb 2020

Legend:
● Not Started
● Queries outstanding/Missing Data
● Complete

Assessments

Assessment/Form	Timepoint	Date Received	CRF not expected	Locked?	Status	Action
Baseline Medical Data	Baseline	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not Started	Add
Home Visit Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not Started	Add
SAE Reporting Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not Started	

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2. The next page you will see is the form you've added. Enter data using the drop-down lists and data fields. Save the data entered for the whole form by clicking 'Save'. Clicking 'Undo' will remove all data entered since the last save (see below)
3. There is also an option to delete the form if you have added it by mistake (see below)

Form Completion Details

Completed By:
 Signed?:

Principal Investigator Name:
 Principal Investigator Signature?:
 Date signed by PI:

Notes






CRF complete - no more data expected ☐

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- If the information isn't complete then click save and you can edit it from the assessment list, see below (the flag on the form will be yellow) The flag will also be yellow if a DCF/query has been raised on the form by the trial team.

Assessments

Date Randomised: 17 Feb 2020



Assessment/Form	Timepoint	Date Received	CRF not expected	Locked?	
Baseline Medical Data (4 unresolved queries)	Baseline	20 Feb 2020	<input type="checkbox"/>	<input type="checkbox"/>	● Edit 
Home Visit Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	● Add 
Home Visit Form - Date of visit: 20 Feb 2020 (1 unresolved query)	Unscheduled	21 Feb 2020	<input checked="" type="checkbox"/>	<input type="checkbox"/>	● Edit 
SAE Reporting Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	●
Serious Adverse Event Reporting Form - Event No: 100101 Onset Date: 19 Feb 2020	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	● Edit 
Serious Adverse Event Reporting Form - Event No: 100102 Onset Date: 24 Feb 2020	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	● Edit 

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- You can also edit the form if it is complete but you need to change the information supplied as it was incorrectly entered (the flag will be green).

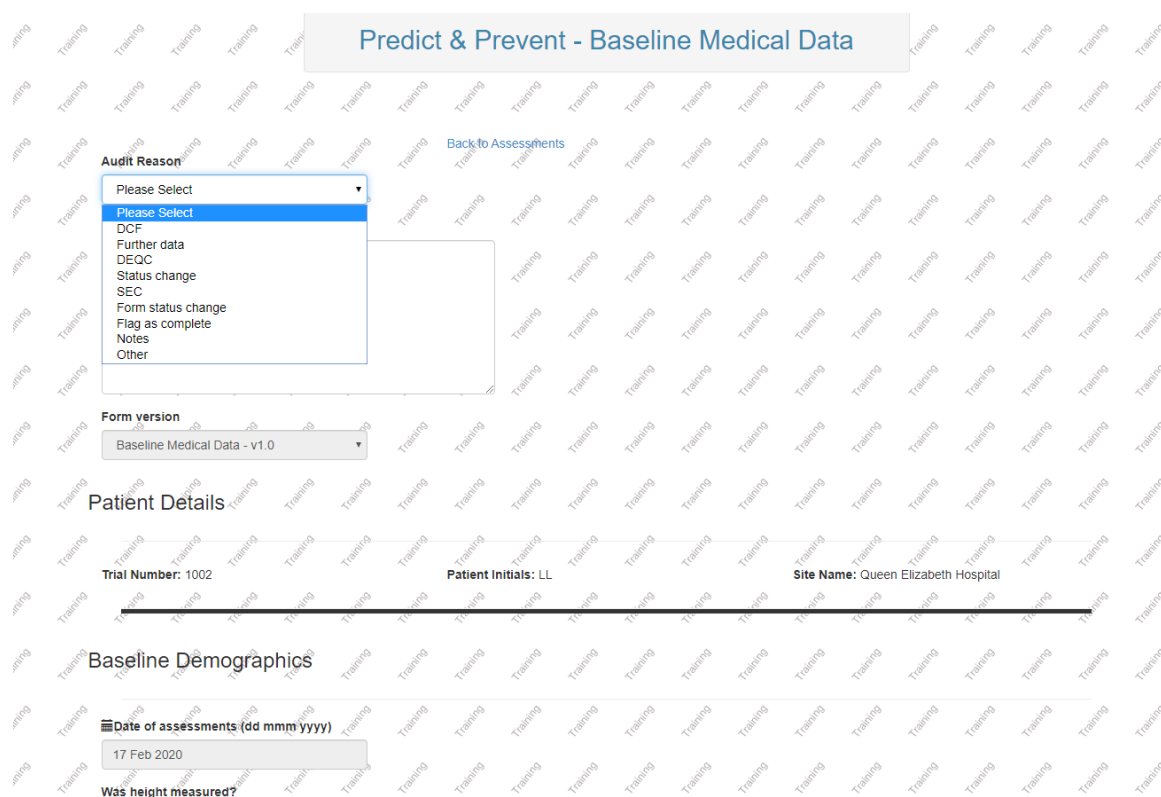
Assessments

Date Randomised: 17 Feb 2020

Assessment/Form	Timepoint	Date Received	CRF not expected	Locked?	
Baseline Medical Data	Baseline	17 Feb 2020	<input type="checkbox"/>	<input type="checkbox"/>	● Edit 
Home Visit Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	● Add 
SAE Reporting Form	Unscheduled	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	●

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6. In order to edit any form regardless of flag you must select the form from the blue icon next to edit button and select the audit reason why this form is to be edited as below. This section is at the top of any form and will appear on the form page once you click to edit.



Predict & Prevent - Baseline Medical Data

[Back to Assessments](#)

Audit Reason

- Please Select
- DCF
- Further data
- DEQC
- Status change
- SEC
- Form status change
- Flag as complete
- Notes
- Other

Form version

Baseline Medical Data - v1.0

Patient Details

Trial Number: 1002 **Patient Initials:** LL **Site Name:** Queen Elizabeth Hospital

Baseline Demographics

Date of assessments (dd mmm yyyy)

17 Feb 2020

Was height measured?

Once an audit reason has been selected the form fields will allow edits. Until a reason is selected the form will remain locked.

Data Queries

- The Online System automatically flags some issues, mostly missing or out of range data. These are listed as queries in red on the electronic form (see Entering data section above). Try to resolve these issues before you submit a form.
- If the data is not available, e.g. because a test was not performed, you can minimise queries by providing an explanation in the 'notes' field of the form. This will not remove the automatic query, but will prevent BCTU raising a query about it.
- In addition to the automatic queries, BCTU check all incoming data. Any inconsistencies are queried according to the process below.
- In order to see any DCFs raised on any given form, select the manage queries button at the bottom of the form

Form Completion Details

Completed By Dr Dalbir Kaur (Principal Investigator - Qi)	Signed? 0 - No	
Principal Investigator Name Mrs ALison Durie (Principal Investigator - Qi)	Principal Investigator Signature? 1 - Yes	Date signed by PI. 25 Feb 2020

Notes

CRF complete - no more data expected ☒

[Manage Queries](#)
[Save](#)
[Cancel](#)
[Delete](#)

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The following page will then appear

[Home](#)
[About](#)
[Contact](#)
[Patients](#)
[Letters and Reports](#)
[Change Password](#)
[Log off](#)

Predict & Prevent - Data Queries

[Back to Assessments](#)

Assessment: Baseline Medical Data Study number: 1001
Site: Queen Elizabeth Hospital

Question	Query	Old Value	Query Status	
Date of assessments (dd mmm yyyy)	Baseline date has not been completed, please complete.	17 Feb 2020	Active	Select
Was shortness of breath assessed?		1 - Yes	Opened	Select
Was smoking status assessed?		0 - No	Opened	Select
Was height measured?	Height measure question has been left blank, please complete.	0 - No	Pending Resolution	Select

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How to resolve queries

Only **active queries** are for site-staff attention. Once you select an active query, you can see more detail on the query. The only field you will complete on this page is the comments section and click save, then edit the form directly as discussed above by selecting DCF as audit reason (if applicable).

[Home](#)
[About](#)
[Contact](#)
[Patients](#)
[Letters and Reports](#)
[Change Password](#)
[Log off](#)

Question	Query	Old Value	Query Status	
Date of assessments (dd mmm yyyy)	Baseline date has not been completed, please complete.	17 Feb 2020	Active	Select
Was shortness of breath assessed?		1 - Yes	Opened	Select
Was smoking status assessed?		0 - No	Opened	Select
Was height measured?	Height measure question has been left blank, please complete.	0 - No	Pending Resolution	Select

CRF Question

Date of assessments (dd mmm yyyy)

Nature of the query

Baseline date has not been completed, please complete.

Old value

17 Feb 2020

Comments

Completed by (initials)

Query Status

Active

[Save](#) [Cancel](#)

Home About Contact Patients Letters and Reports Change Password Log off

Predict & Prevent - Baseline Medical Data

[Back to Assessments](#)

Audit Reason

- Please Select
- Please Select
- DCP**
- Further data
- DEQC
- Status change
- SEC
- Form status change
- Flag as complete
- Notes
- Other

Form version

Baseline Medical Data - v1.0

Patient Details

Trial Number: 1002 **Patient Initials:** LL **Site Name:** Queen Elizabeth Hospital

Baseline Demographics

Date of assessments (dd mmm yyyy)

17 Feb 2020

Was height measured?

Once an audit reason has been selected the form fields will allow edits. Until a reason is selected the form will remain locked.

Once complete the query will change to pending resolution (can take up to around 24hours to update). The trial team will then address these and if the information supplied is sufficient then the team will close the query.

Important General Notes

Dates

All dates entered into the system are in the “dd-mmm-yyyy” format. This means that the first 2 digits indicate the days of the month, then a hyphen (“-”), then the next 3 letters indicate the month, another hyphen, and then the four digits indicating the year. For example:

Date	Long Date	How to enter the date in the Predict and Prevent system
1/10/30	1 st October 1930	01-Oct-1930
12/11/98	12 th November 1998	12-Nov-1998
1/4/02	1 st April 2002	01-Apr-2002

This ensures that there is no possibility of mixing up days and months, and years such as 1912 and 2012.

Dates can be entered either by typing the date into the box in the following format: dd-mmm-yyyy (e.g. 05-sep-2012), or accessing the drop down calendar by clicking into the box.

The Next and Previous Buttons

It is advised that whilst using the system, the use of the browser back and forward browser buttons are *avoided*. Please use the navigation control buttons on the web forms: ‘Next’ and ‘Previous’. (Moving away from a page using the browser back & forward buttons would mean any data entered is not saved).

Security

When using the Predict and Prevent Online Randomisation, all data that is sent over the Internet is encrypted. There should be no danger of anyone being able to intercept the information and use it. However, if anyone has your user name and password then they can use the system as you do. Please do not reveal your user name and password to anyone. Each person using the Predict and Prevent Online Randomisation and Data Entry System will have their own User Name and Password.

Web Browsers

The system is usable by the most common browsers including Chrome, Firefox, Microsoft Edge and Internet Explorer. Please let us know about any compatibility issues you may have.

Questions or Problems

If you have any problems please contact the Renal Trials Team on 0121 415 9120 or e-mail us at predictandprevent@trials.bham.ac.uk.

Consent and SAE forms

* Consent forms and SAE forms cannot be submitted online. Please fax them to BCTU or email them to predictandprevent@trials.bham.ac.uk. The data will be entered onto the online system by staff at BCTU.