



Site User Online Database Guidelines

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Randomising a patient

- If you don't already have access, to arrange access to the online randomisation database email TOPIC2@trials.bham.ac.uk and the trial office will set-up your account. You must be on the delegation log and the task delegated to you by PI sign off.
- The web address is: <https://www.trials.bham.ac.uk/TOPIC2>

Please note the screenshots have 'training' marked on them, this will not be the case when using the live system. If when randomising a patient you see the 'training' markings, you are not on the live system.

If you want to access the training system to practice or train another staff member you can connect to the training system by clicking "change" in the top right corner of the screen and then selecting "training" from the drop down list.

You are connected to: Live [Change](#) [Logout](#)

The screenshot shows the TOPIC2 website interface. At the top right, there is a navigation bar with 'HOME' and 'TRIAL WEBSITE'. Below this is a purple banner that says 'Please Log In'. In the center, there are two input fields: 'User Name:' and 'Password:'. Below the password field is a 'Log In' button and a link for 'Forgotten password?'. At the bottom of the login area is a 'cybertrust secured site' logo. In the top right corner, there is a 'Login' link and the Birmingham Clinical Trials Unit (BC TU) logo. A dropdown menu is open, showing options: 'Choose a connection....', 'Live', and 'Training' (which is highlighted in blue). The text 'You are connected to: Live' is visible to the left of the dropdown menu.

1. Enter your user name and password and click 'log in'. If you have forgotten your password you can use the forgotten password facility by clicking 'forgotten password?'

If you are entering the correct user name and password and are encountering log in issues please call the randomisation line on 0800 953 0274 to complete the randomisation and then inform the trial office.

Welcome to the TOPIC2 Online Randomisation Service

This site provides a secure entry form for baseline patient information. On completion the patient will be randomly allocated treatment. A patient trial number is also allocated which we will use in our correspondence to you. Confirmation of the allocation is automatically sent to the responsible clinician via email.

Click [here](#) to enter a patient into the trial.

If you have any questions about the TOPIC2 Trial please contact: topic2@trials.bham.ac.uk. If you experience any problems or have questions about this online service please contact: bctu-webadmin@contacts.bham.ac.uk

2. The main home page to the randomisation service should appear, to start a randomisation click on the 'here' link highlighted in yellow above.

Patients : Enter new patient

Patient Details

Site
Birmingham Heartlands Hospital

Initials
BW

Date of birth (dd-mmm-yyyy)
01-Jan-1951

Patient Gender
Female

[EXIT](#) [NEXT](#) [PREVIOUS](#)

3. This will load the 'enter new patient' screen. Click the site, which should be your hospital. Enter initials, date of birth (month is in three letter format e.g. JAN) and patient gender. Please note if you don't provide any of these data items you will not be able to proceed with the randomisation until they are available.

4. Click on 'next' as highlighted in yellow above.

If you have clicked to randomise a patient in error you can leave at any time prior to clicking randomise by clicking the 'exit' button, shown in the red square above.

If you need to go back to a previous screen at any time click the 'previous' button, as shown in the blue square above.

Patients : Enter new patient

Eligibility Checklist

Inclusion

Aged 18 or over?

Having an elective open thoracotomy?

Able to understand the study information and provide written informed consent?

State version of informed consent form signed by patient:

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

Exclusion

Contraindication to TEB or PVB e.g. known allergy to local anaesthetics; infection near the proposed puncture site; coagulation disorders, thoracic spine disorders

Will be having a rib/chest wall resection or planned pleurectomy?

Undergoing emergency thoracic surgery?

Has had a previous thoracotomy on the same side?

Has had a median sternotomy in the last 90 days?

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

5. Complete the inclusion and exclusion data items.

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

If Yes, specify:

6. If you answer 'yes' to the above data item then you need to specify the names of the trials that the patient is co-enrolling into. This information must be available in order for the randomisation to proceed.

7. Click 'next'

Patients : Enter new patient

Randomisation

Please note: if patient is having thoracotomy for suspected lung cancer they should be randomised to lung cancer resection

Reason for lung thoracotomy?

Age?

8. Provide the reason for lung thoracotomy and patient's age (under 65 or older than 65).

9. Click 'next'

Form Completion

Form completed by:

Signature?

Date:

Principal Investigator Name

Enter text to reduce the selection and then click on Search

Principal Investigator Signature:

Date:

10. Complete the form completion details. Select the principal investigator name by clicking on the name.

September, 2019

Su	Mo	Tu	We	Th	Fr	Sa
25	26	27	28	29	30	31
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	1	2	3	4	5

Today: September 2, 2019

The dates can be selected using the calendar function as per above. Months can be moved forwards or backwards using the left and right arrows. To select a date click on the required number.

Principal Investigator Signature:

Please note if the above data item is set as 'no' the randomisation can still proceed as the form does not need to be signed by the PI in order for a patient to be randomised.

11. Click 'next'

Patients : Enter new patient

Complete

Site: Birmingham Heartlands Hospital

Principal Investigator: Mr Babu Naidu

DOB: 24-jun-1975

Gender: Female

Reason for lung thoracotomy?: Lung cancer resection

Age: <65

You will be randomising between:

Paravertebral Blockade (PVB)

Thoracic Epidural Blockade (TEB)

Only click on Randomise if you are happy to allocate any one of these intervention arms.

RANDOMISE

PREVIOUS

12. The above provides a summary of the randomisation details that have been recorded, please double check they are correct. If any details have been entered incorrectly then click previous to go to the required page to correct the details.

13. Click 'randomise', as highlighted in yellow above.

Results

Site: Birmingham Heartlands Hospital

Principal Investigator: Mr Babu Naidu

DOB: 24-jun-1975

Trial Number: 1222

Intervention: Thoracic Epidural Blockade (TEB)

EXIT

14. This will allocate the patient to an intervention, see yellow highlighting above.

15. Click 'exit' to return to the home screen.

You should have received a confirmation email for the randomisation. If you do not receive this please contact the trial office immediately.

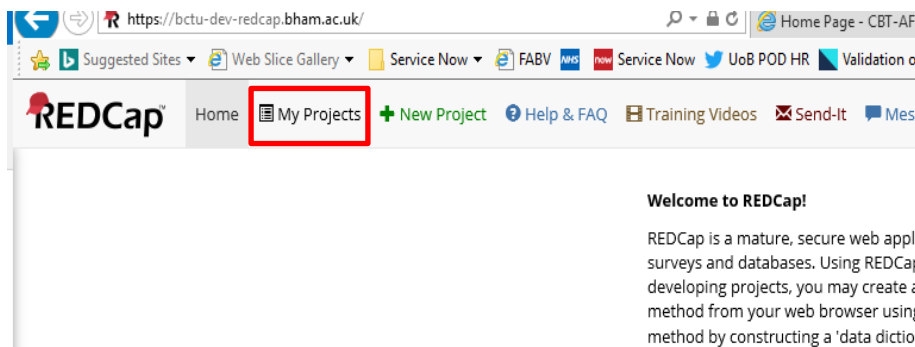
Accessing the TOPIC2 online database

- To arrange access to the online database email TOPIC2@trials.bham.ac.uk and the trial office will set-up your account. You must be on the delegation log and the task delegated to you by PI sign off.
- The web address is: <https://bctu-redcap.bham.ac.uk>
- Enter **User Name** and **Password** where indicated and click 'log In'

Accessing a patient's CRF

Once logged in:

1. Click on 'My Projects'

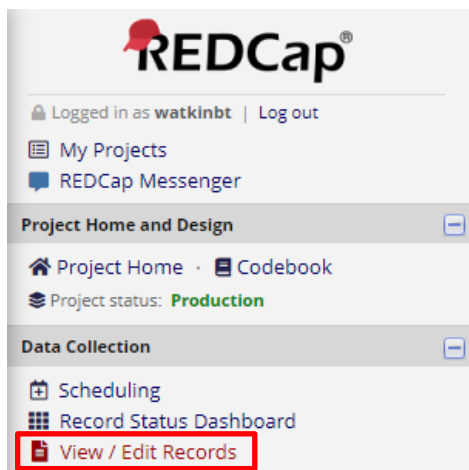


2. Click on 'TOPIC2'

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](#).

Project Title	Records	Fields	Instrument	Type	Status
TOPIC 2 Dev	38	862	18 forms		
TOPIC 2	30	861	18 forms		

3. Click on 'View/Edit Records' in the left hand tool bar



4. Click drop down next to 'Choose an existing Study ID' to view the list of trial numbers



5. Select a trial number from drop down list

Total records: 30

Choose an existing Study ID

-- select record --

-- select record --

1 (1001)

2 (1002)

3 (1003)

Accessing a specific data form

Once you have clicked on a specific patient trial number the below 'data collection instrument' table will display. To open a specific data form please click on the circle in the corresponding row e.g. to open 'baseline medical data form' click highlighted circle as shown in the red box below.

Data Collection Instrument	Randomisation	Before Surgery	During Surgery	After surgery days 1-3	After surgery days 4-discharge	3 month follow-up	6 month follow-up	12 month follow-up	Trial Exit/Change of Status	SAE
Consent and Randomisation - Part 1	<input type="radio"/>									
Consent and Randomisation - Part 2	<input type="radio"/>									
Consent and Randomisation - Part 3	<input type="radio"/>									
Baseline Medical Data	<input type="radio"/>									
Intervention			<input type="radio"/>							
Operation Details			<input type="radio"/>							
Acute Phase Days 1 To 3				<input type="radio"/>						
Acute Phase Day 4 To Discharge					<input type="radio"/>					
Trial Exit Change Of Status Form									<input type="radio"/>	
Serious Adverse Event Reporting Form										<input type="radio"/>
Baseline Patient Completed Booklet		<input type="radio"/>								
Acute Day 1 Patient Completed Booklet				<input type="radio"/>						
Acute Day 2 Patient Completed Booklet				<input type="radio"/>						
Acute Day 3 Patient Completed Booklet				<input type="radio"/>						
Hospital Discharge Patient Completed Booklet					<input type="radio"/>					
Three Month Follow Up Patient Completed Booklet						<input type="radio"/>				
Six Month Follow Up Patient Completed Booklet							<input type="radio"/>			
Twelve Month Follow Up Patient Completed Booklet								<input type="radio"/>		

This will open up the desired form as shown in the example below:

Logged in as xx001 | Log out

My Projects

Project Home

REDCap Messenger

Project status: Development

Data Collection

Scheduling

Record Status Dashboard

Add / Edit Records

Study ID 96-2

Event: Randomisation

Data Collection Instruments:

- Consent and Randomisation - Part 1
- Consent and Randomisation - Part 2
- Consent and Randomisation - Part 3
- Baseline Medical Data**

TOPIC 2 Dev

Actions: Download PDF of instrument(s) VIDEO: Basic data entry

Baseline Medical Data

Adding new Study ID 96-2

Event Name: Randomisation

Study ID: 96-2

Participant Details

Initials:

Baseline Demographics

Date of assessments: Today D-M-Y

Was height measured?

Was weight measured?

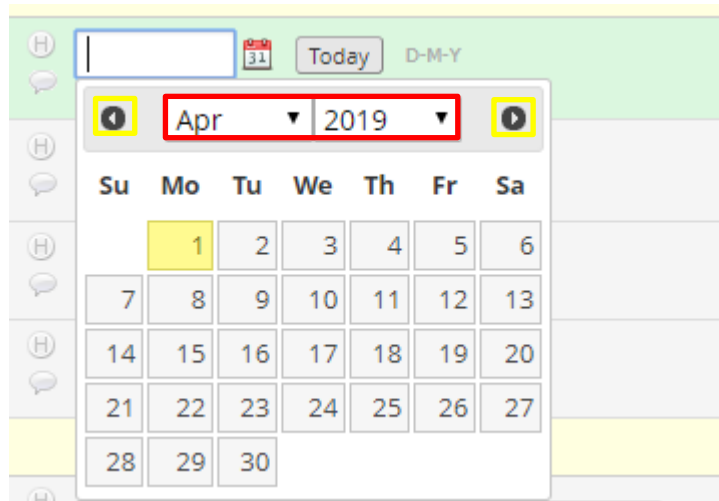
Date and time functions

Data items that require date or time can have a date or time entered manually in the desired format or the calendar or clock symbols can be clicked, highlighted in the red boxes below.

The data item can also be automatically populated with the current date or time, if appropriate, by clicking the buttons highlighted in the yellow boxes below.

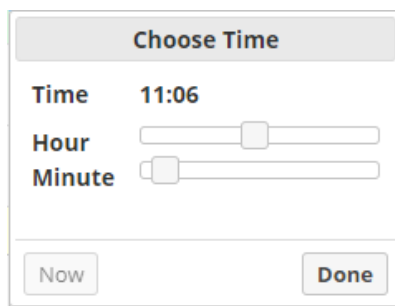
Date of thoracotomy: <small>* must provide value</small>	<input type="text"/>   D-M-Y dd-mm-yyyy
Arrival at theatre <small>* must provide value</small>	<input type="text"/> HH:MM   H:M 24 hour format
Knife to skin	<input type="text"/> HH:MM   H:M 24 hour format
Time left theatre	<input type="text"/> HH:MM   H:M 24 hour format

If the calendar symbol is clicked a calendar will pop up. Individual months and/or years can be selected using the drop down boxes, highlighted in the red box below, or earlier/later months can be moved through using the arrows, highlighted in the yellow boxes below. Select a date by clicking on the relevant date square.



The image shows a date picker interface. At the top, there is a text input field, a calendar icon, and a 'Today' button. Below this, a calendar is displayed with the month 'Apr' and year '2019' selected in red boxes. Navigation arrows are highlighted in yellow boxes. The calendar grid shows days of the week (Su, Mo, Tu, We, Th, Fr, Sa) and dates from 1 to 30.

If the clock symbol is clicked the choose time window opens which allows the specific hour and minute to be selected by moving the bars on the scales. Once the relevant time has been selected click 'done'.



The image shows a 'Choose Time' dialog box. The title is 'Choose Time'. The current time is '11:06'. There are sliders for 'Hour' and 'Minute'. At the bottom, there are 'Now' and 'Done' buttons.

Saving and exiting forms

Save buttons are at the top and bottom of each record:

The screenshot shows the top section of a form record. At the top left, it says 'TOPIC 2'. Below that, there are 'Actions:' with a 'Download PDF of instrument(s)' button and a 'VIDEO: Basic data entry' link. On the right side, there is a red box highlighting three buttons: 'Save & Exit Form', 'Save & Stay' (with a dropdown arrow), and '-- Cancel --'. Below the actions, there is a section for 'Baseline Medical Data' with an 'Assign record to a Data Access Group?' dropdown menu set to '-- select a group --'. A green bar indicates 'Adding new Study ID 33'. Below that, a yellow bar shows 'Event Name: Randomisation'. A table below shows 'Study ID' as 33.

The screenshot shows the bottom section of a form record, titled 'Form Status'. It includes a 'Complete?' dropdown menu set to 'Incomplete'. Below that, there is a 'Lock this record for this form?' section with a 'Lock' button and a warning: 'If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.' At the bottom, there is a red box highlighting three buttons: 'Save & Exit Form', 'Save & Stay' (with a dropdown arrow), and '-- Cancel --'.

- Save and stay will save the form and stay on the same form
- Save and exit record will take you back to the data collection instrument table.

NOTE: a window may open stating some fields are required and it will list all of the fields that are blank and require data. Please check you have not missed entering any data in error, however if the data is currently unavailable you can still leave the form by clicking 'ignore and leave record' as highlighted in the red box below.

The screenshot shows a dialog box titled 'NOTE: Some fields are required!'. The text inside says: '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.' Below this, it says 'Provide a value for...' and lists several items with bullet points: 'Please indicate analgesic given:', 'Please indicate opioid added:', 'Infusion start time after initial bolus:', 'Local Anaesthetic Agent', 'Please indicate opioid added:', and 'Please confirm all the analgesia have been considered and only those ticked were used?'. At the bottom, there are three buttons: 'Okay', 'Ignore and leave record' (highlighted with a red box), and 'Ignore and go to next form'.

- If you want to exit the record without saving your data entry/edit click 'cancel'

NOTE: when entering data if any data items are not applicable or not done/known please record this in the 'notes' field at the end of the form to avoid unnecessary data queries. Example shown below:

The screenshot shows the 'Notes' field at the end of a form. The text 'Alcohol consumption not done' is entered in the field.

Adding Principal Investigator (or delegate) signature

This function is only enabled for principal investigators (or delegates). **You should only sign a form when you have been informed to do so by the trial office.**

To add a signature scroll down to the 'form completion' at the bottom of the form.

1. Enter your signature as text in the 'PI (or delegate) confirmation signature' field as indicated in the red box below.

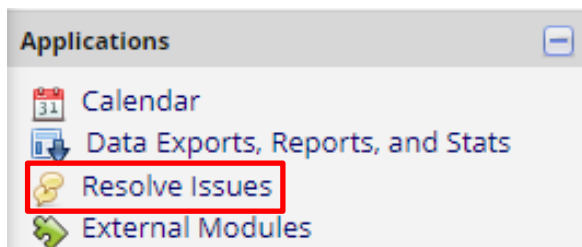
Form Completion Details	
Completed by:	<input type="text"/>
Signature:	<input type="text"/>
Date:	<input type="text"/> Today D-M-Y dd-mm-yyyy
PI (or delegate) confirmation signature:	<input type="text" value="J Smith"/>

2. Click 'save' button as indicated in the red box below.

Complete?	<input type="text" value="Incomplete"/>
<input type="button" value="Save & Exit Form"/> <input type="button" value="Save & Exit Record"/>	

Resolving data queries

1. Click on **resolve issues** in the left hand bar



2. This will open the 'data resolution dashboard' that lists all outstanding queries allocated to each patient on a data item basis.

To go to a specific data item query within a form click on the **record number** as shown below in the red box.

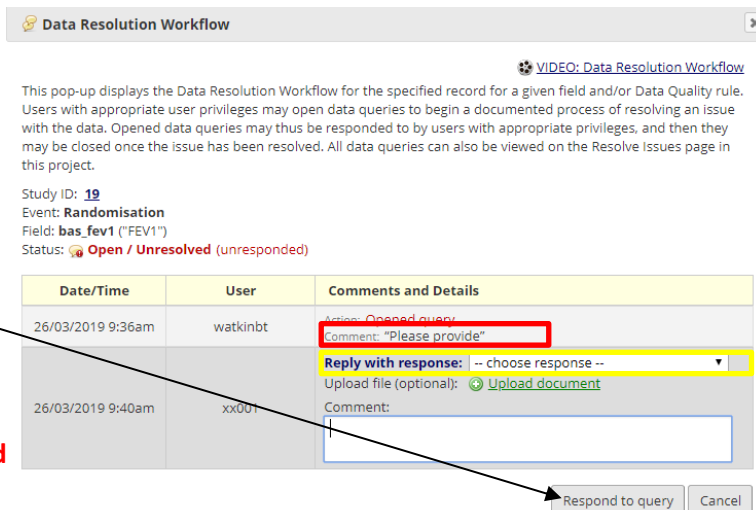
1 comment	19 (1019) Randomisation	Field: bas_fev1 (FEV1)	-	0	watkinbt (26/03/2019 9:36am): "Please provide"	[same as first update]
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3. The data item with a query will have the symbol shown in the red box below visible, to open the query click the **symbol**.

Lung Function	
Has Forced Expiratory Volume (FEV1) been documented in the last 6 months?	<input type="text" value="Yes"/>
FEV1	<input type="text" value="litres"/>

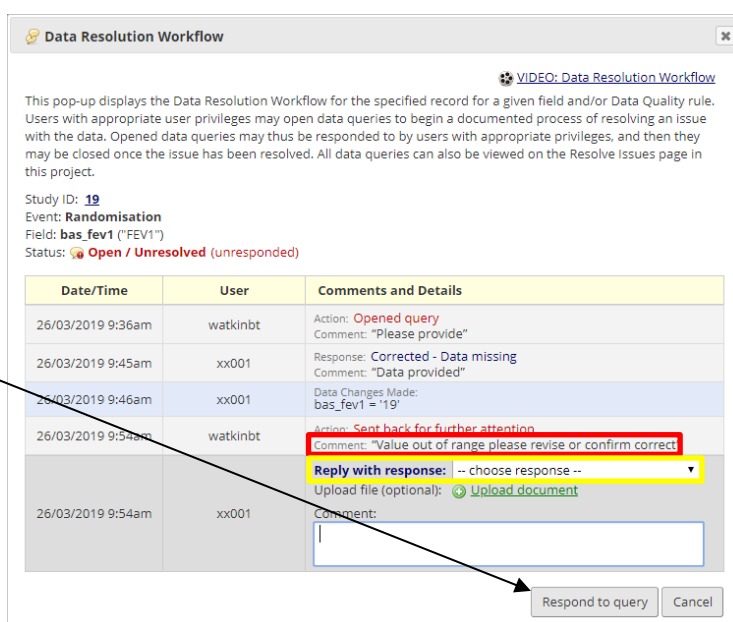
4. A new window will open called 'data resolution workflow'. This will provide details of the query as highlighted in the red box. In order to respond to the query click the drop down list called 'reply with response' highlighted in the yellow box and select the appropriate option. Also add an appropriate comment in the comments box and then click 'respond to query'

NOTE – if data needs to be entered/updated please ensure this is done after clicking 'respond to query' and the form is saved



5. The trial office will review the response and if it doesn't resolve the query a further comment will be generated. This will appear in the 'data resolution dashboard' as described in step 2. In order to respond to the further query, as highlighted in the red box select the appropriate action from 'reply with response' drop down list as highlighted in the yellow box and add an appropriate comment. Then click 'respond to query'

NOTE – if data needs to be entered/updated please ensure this is done after clicking 'respond to query' and the form is saved



The trial office will review the further response and if this resolves the query it will be closed and disappear from the 'data resolution dashboard'

Entering screening data

1. Click TOPIC2 screening log

Project Title	Records	Fields	Instruments	Type	Status
TOPIC 2 Dev	110	1,755	26 forms		
TOPIC 2	482	1,739	25 forms		✓
ProTask	198	141	2 forms		✓
STOP-APE	6	1,369	17 forms		✓
TOPIC2 Screening Log	413	15	1 form		✓
Data management tasks	61	37	1 form		✓
Stopape_Screening	90	20	1 form		✓

2. Click add/edit records

The screenshot shows the REDCap web interface. At the top, the REDCap logo is displayed. Below it, the user is logged in as 'watkinbt' with a 'Log out' link. The main navigation area includes 'My Projects' and 'REDCap Messenger' with a notification icon. The interface is divided into three main sections: 'Project Home and Design', 'Data Collection', and 'Applications'. The 'Data Collection' section is expanded, showing 'Record Status Dashboard' and 'Add / Edit Records', which is highlighted with a yellow background. Below this, there is a link to 'Show data collection instruments'. The 'Applications' section lists various tools like Alerts & Notifications, Calendar, Data Exports, Reports, and Stats, Data Import Tool, Data Comparison Tool, Logging, Field Comment Log, File Repository, User Rights and DAGs, Data Quality, REDCap Mobile App, and External Modules.

3. Click add new record

Total records: 413	
Choose an existing Screening ID	-- select record -- ▾
	+ Add new record

For queries relating to the online database please email topic2@trials.bham.ac.uk