CONTROLLED TRIAL OF HIGH-RISK CORONARY INTERVENTION WITH PERCUTANEOUS LEFT VENTRICULAR UNLOADING

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1. Purpose of this document

The purpose of this document is to give an overview of the electronic Case Report Form (eCRF) online database system for the CHIP-BCIS3 trial.

2. Accessing the system

Access to the CHIP-BCIS3 eCRF system is via https://www.sealedenvelope.com/access/ and users must log in with their email address and password before access is granted (see figure 1).

***Note**: the screenshots shown below are taken from the test site which uses dummy data.*

Figure 1:

There are two types of user accounts relevant to this WPD:

- **Investigator accounts** – these users can view patient records, complete data entry and edit data for patients at their own centre. Although they are labelled 'Investigator' accounts, this can be any site staff personnel delegated to use the eCRF system (e.g. research nurses, data entry staff, or clinicians).
- **Administrator accounts** (CHIP-BCIS3 staff at LSHTM CTU only) – an administrator has full access to all areas of the eCRF, including:
    - All patient records
    - Queries
    - Reports
    - Downloading eCRF data
    - User accounts
    - Audit trail

If a user does not have an account, or provides an incorrect password they will not be allowed access. Investigator accounts will be set up by a member of the LSHTM (London School of Hygiene and Tropical Medicine) CTU (Clinical Trials Unit) team. This will only occur once the appropriate training has taken place and the training and delegation logs have been signed. The training consists of reading the eCRF WPD.

After logging in the user will see Figure 2 (the "Access" page) and this will show a message that reads 'You have an invitation'. The user should click on this link and subsequently accept the invitation, this will add the trial to their access page.

Figure 2:

The user should then click on the "Access with role" link to enter the study, as shown in Figure 3.

Figure 3:

Clicking on "Access with role" will transfer the user to the home page (see figure 4), their name and unique user ID is always shown at the top of every page in the navigation bar.

Figure 4:

Once a user has finished using the database application, it is good practice to log out. This is particularly important if the user is using a shared computer or a computer that is not their own. To log out, click on the "Logout" link in the navigation bar at the top left of the page.

Note: To comply with good clinical practice (GCP), it is very important that users do not share accounts or allow others to access their accounts, even temporarily. If a user has forgotten their details or is unable to log in, please refer to section 3 for information.

3. Passwords

Forgotten passwords

Forgotten passwords can be reset by users by clicking the "Forgot your password?" link on the login page. This can only be done if they have set up a recovery email address (different to the account email address) or mobile phone number. If a user forgets their password but has not set up recovery contact details, they should contact the CHIP-BCIS3 CTU and the user's password will be reset by an administrator. This sends out a new password by email to the account holder.

It is highly recommended that users provide recovery details on their user account.

Note: There is no way to see a user's current password – they are stored in an encrypted format that not even Sealed Envelope* staff can decrypt. Requests for password resets made by site staff to Sealed Envelope will be referred to the CHIP-BCIS3 CTU to ensure the validity of the request.

*Sealed Envelope is the organisation responsible for developing and maintaining the CHIP-BCIS3 data management systems (https://www.sealedenvelope.com/).

Changing a password

If a user would like to change their password, go to the "Access" page and click on the "My account" link on the navigation bar. This link directs the user to the screen shown in figure 5 below. To change a password it is necessary for the user to enter their existing password. New passwords must be at least 8 characters long and it is recommended that they include at least one space in order to strengthen their security. It is advisable to avoid using passwords that are obvious or easily guessed.

Figure 5:

Passwords expire after 180 days, after which point a user is forced to change their password. Users with expired passwords have no access to the system except for the change password screen.

4. Auto time-out

After a set period of inactivity (15-20 minutes), the user is automatically logged out of the system.

5. Entering data

All data will be entered onto the system by delegated site staff. After logging into the system, from the home page, select the “Subjects” option from the navigation bar on the left hand side at the top of the page. You will then see a list of all patients that have been randomised at your site. Select the relevant patient and their details will appear on the right hand side of the screen (see figure 6). Select the data form you wish to enter from the list by clicking “Add”.

Figure 6:

5.1 Saving forms

After entering the data click “Save form” and a message will appear at the top of the form to confirm the data has been saved (see figure 7). A form can only be saved once all the data have been entered.

Figure 7:

5.1.1 Saving drafts

Ideally all the data in each form should be entered at one time and then saved. If you wish to save a draft version, where you still have some remaining questions to answer, you can do so. Any forms saved as draft will continue to appear on the overdue list until all data have been entered and the form is saved.

- In order to save a draft version you should first enter all the data you have into the form. The form automatically saves a draft of the data entered every 10 seconds, and a message appears on the top righthand side of the form to indicate every time this happens (see figure 8). Once you have entered all the data you then wait for this message to update and then click on the “return to subject” button at the top of the screen.
- When you are ready to enter the remaining data you need to click on the “add” form button and a message will pop up informing you that a draft exists, at this point you should click on “load draft” and it will bring up the draft form you saved previously.

Figure 8:

5.2 Due dates

Due dates for all of the data forms will be displayed in the "Subject details" page below each visit (see figure 6). Overdue forms are shown in red and forms not yet due are shown in black, you can view all overdue data forms by clicking the "Overdue forms" option from the navigation bar on the left hand side. Overdue forms are calculated from the date of randomisation.

5.3 General guidance

- The system is pre-programmed with a series of logic, range and value checks which help reduce the possibility of accidentally entering incorrect data. Warning screens will pop up in cases where incorrect or unsuitable data are suspected, however these can be overridden if values are outside the range checks within the system.
- Help: some questions have additional help text beneath them, this guidance will appear in green font.

5.4 Form specific guidance

<u>NHS Number</u>

- Once an NHS number or CHI number has been added by a site the data are encrypted so that administrators at CHIP-BCIS3 CTU cannot see the data.

EQ-5D-5L and KCCQ forms (baseline, 90 day and 1 year follow ups)

- If for any reason the patient did not complete any of these, please still enter the relevant EQ-5D-5L or KCCQ form, and answer the first question with "no, not completed". You will then just need to answer "reason why not completed", and save the form.

PCI forms

- To access the PCI forms, from the subject details page please click on "View PCI" (see figure 9).

Figure 9:

- This will then take you to the main PCI screen (see figure 10), then click on "Add Pre-PCI" to add the Pre-PCI form for the first PCI procedure.

Figure 10:

- At the top of each PCI form you need to enter the PCI procedure number. If a patient has only had one PCI this number will always be 1. If a patient has had more than one PCI then you should enter the PCI procedure number as 1 for the first PCI, 2 for the second and so on.
- For each PCI there 10 forms to enter. If a patient has more than one PCI procedure it is best to enter all 10 forms for the first PCI (PCI number 1) before starting to enter any forms for the second PCI.
- It is best to add a new form from the main PCI screen (see figure 11) rather than using the "Jump to form…" function to add a new form.

Figure 11:

- If a patient is admitted but the PCI doesn't go ahead, then enter the Pre-PCI and the first Peri-procedural form, and on the Peri-procedural form you answer "Did the patient undergo PCI?" with "no". Then the only other form you will need to enter is the first "Discharge" form (the rest of the forms will not be available for data entry).

<u>Death forms</u>

- If a patient has died you still need to complete the next follow-up after their death (e.g. they died on Day 60, you still complete the Day 90 follow-up, but not the 1 year follow-up). This is because there is still some data we need to collect on the follow-up forms (e.g. did patient have an MI etc).
- Once you have entered that the patient has died on the follow-up form, the EQ-5D-5L, KCCQ and Medication forms will automatically be hidden, as you won't have this data for patients who have died.
- Note that once you have entered the Cause of Death form the due date of the next follow-up will change and will show as the date of death.

<u>Attachments</u>

- For deaths, strokes, MIs and cardiovascular hospitalisations we require supporting documentation from sites. Some of this documentation is used so events can be validated by the Clinical Events Committee (CEC). Any other relevant documents can also be uploaded in this way. Supporting documentation needs to be uploaded to the patient's record as an attachment (see figure 12).

Figure 12:

- Once you click on 'upload an attachment', the following page (see figure 13) will load. It is vital that all attachments uploaded to the database **do not contain any patient identifiable information**. You must tick the agreement confirming this before you upload the attachment.

Figure 13:

5.5 Patient withdrawal

The withdrawal form in the eCRF can only be entered by the CHIP-BCIS3 CTU. Please complete a hard copy of the form and email it to CTU for data entry.

There are 3 types of patient withdrawal:

- Treatment – if the patient withdraws from the trial treatment
- Partial – if the patient no longer wants to be contacted about the trial, but is happy for data to be collected from their notes, GP, or NHS records
- Complete – if the patient withdraws their consent for any further data collection

If a patient withdraws completely, then once the withdrawal form has been entered by the CTU to show this, then this stops any forms being shown on the overdue list after the withdrawal date.

6. Viewing and editing data

6.1 Viewing data

To view any data that has been entered select the relevant patient, identify which of the data forms you want to view, and select the "View" option. When finished, click the "Return to subject" option.

6.2 Editing data

Site staff can edit the CHIP-BCIS3 database after data has been submitted, in the case of data entry error or if additional data has been obtained at a later date.

On the subject details page, select the "Edit" option to reopen the subject's relevant form (see figure 14), and enter the correct or updated data, following the same process as with normal data entry. You will be required to provide a reason for the edit (see figure 15) and then click on "save form" to save your changes. Suitable reasons for edit include "Data entry error" or "Updated information available".

Figure 14:

Figure 15:

Once edits have been saved on a form, the updated questions will be highlighted in yellow and an audit trail of the data originally entered and all changes will be saved in case of further error.

7. Queries

Administrators and investigators can create, view and add messages to queries but queries can only be closed by administrators.

7.1 Creating queries

A query can be opened either on the "subject details" panel or when viewing a form, by clicking on the "Create a query" link at the top of the page (see figure 16).

Figure 16:

The query must be given a title and an initial message (the title will appear in any email notifications, see section 7.3 below). To link the query to a specific question within a specific form, choose the appropriate question and form from the relevant drop-down options (see figure 17).

Figure 17:

Once it has been created, the query will be shown on the subject details panel and form specific queries will also be shown when viewing the form. In addition, if a form has an open query attached, a yellow warning symbol appears next to the form name in the subject details panel.

7.2 Responding to queries

Messages may be added to queries by site staff or administrators by clicking on the relevant open query from the subject details panel and then selecting “add message” (see figure 18), forming a conversation thread. Administrators can close a query when the issue has been resolved. Administrators may also re-open a closed query by setting the action to ‘Reopen’ when adding a new message to it.

Figure 18:

7.3 Email notifications

When a query is created or updated an email notification is sent out to:

- On creation: all administrators, and all site staff with an investigator account at the site the query relates to.
- On update and on closing: all site users who have participated in the query (e.g. created the query or added a message to the query) and all administrators.

The format of the notification email is:

Reply all | Delete | Junk | Block | ...

[CHIP-BCIS3 - TEST] Query created for subject CH11001

Label: Staff mailbox default delete after 7 years (7 years) Expires: Thu 12/10/2028 15:58

SE Sealed Envelope
Thu 14/10/2021 15:58
To: Laura Van Dyck; Steven Robertson; Laura Van Dyck; Faran Dhaliwal

*** This message originated outside LSHTM ***

A query "Baseline platelet count" has just been created by Laura Van Dyck (ID 608 - Administrator). You can view the query here:

https://www.sealedenvelope.com/redpill-staging/chipbcis3/query/view/2

** WARNING! This message was sent during testing and should not be acted upon **

Note, this message was auto-generated on 14 Oct 2021 14:57 (UTC) and was sent from an email address that does not accept replies.

_____
Sealed Envelope
www.sealedenvelope.com

Reply | Reply all | Forward

7.4 Listing queries

A list of queries for your site is displayed by clicking on the 'Queries' link in the navigation bar. The conversation thread for a query can be viewed by clicking on the query in the list. This view also displays links for editing the query or viewing the related patient or form.

8. Contacting the CHIP-BCIS3 CTU

If you require help with this instruction manual please contact the CHIP-BCIS3 CTU by emailing us at chip-bcis3@LSHTM.ac.uk.

The CHIP-BCIS3 CTU is based at the London School of Hygiene and Tropical Medicine (LSHTM) which is part of the University of London.