sealed envelope™

Red Pill
Version 9

Contents

Chapter 1

Overview

Red Pill is an online application for collecting and managing data on patients recruited to a clinical trial or other study. It also includes a contact section for managing data on trial sites and related personnel.

Note that all data shown in this help is fictional and for illustrative purposes only.

This documentation applies to version 9, released on 28th October 2014. The version number is shown in the footer of every page when logged into Red Pill.

Chapter 2

Accessing the system

The Access application is the gateway for Red Pill systems. Systems set up before 2015 have Access URLs that are specific to a client - e.g. *www.sealedenvelope.com/abc_trialsunit*. Systems set-up after 2015 generally have the same common URL: *www.sealedenvelope.com/access*. In either case the URL will be contained in automated emails sent out when a new user account is created.

Users are requested to authenticate themselves by providing their log-in credentials. See the Access help for more information.

Chapter 3

Getting started

Investigator accounts

If you will be entering CRF data on patients, an administrator for your trial will create your user account. Administrators are usually staff at the trial coordinating centre. The login details will be sent to your email address. This user account will normally be associated with your site and you will only be able to view and add data for patients at this site.

When you login, you will normally first arrive at a summary page showing the trials you have access to. You can also manage your account details and change your password here. You can get to the summary page at any time using the **Home** link.

Once you access a trial you will be able to see enrolled patients at your site and enter data yourself.

Administrator accounts

When a Red Pill system is set up, the first administrator account is created by Sealed Envelope and the login details are sent to that person's email address. The administrator should log in and create the trial sites, unless the sites have been pre-coded by Sealed Envelope.

You do not need to add all your sites at once - you can come back later and add more sites as needed.

Next you should add some investigator accounts for each site so that data entry can be performed by staff at the sites. You do this through the Access application.

Finally check the specification page and case record forms and report any discrepancies or errors to Sealed Envelope.

Chapter 4

Patients

Patient records can be viewed by clicking on the **Patients** link in the the left-hand sidebar. This shows a list of all patients entered into the study to date. An amber question mark in the status column of the patient listing indicates that there is an open query for that patient.

Figure 4.1: Viewing an individual patient record

Adding patients

New patients may be added to the list at any time by clicking on the **Add a patient** link in the left-hand sidebar. This opens the study entry form which requests a patient identifier and date of study entry. Note that at least one site contact must be created before any patients can be added.

Some trials may be configured such that patients are randomised into the trial. If this is the case case you can add a patient by clicking the **Randomise** link in the left-hand sidebar. Check the specification page to see if this is the case.

Deleting patients

Patients may be deleted by administrative users providing the delete patient setting is enabled. A delete patient option is shown in the 'Patient details' section. The user will be asked to confirm they wish to go ahead. Deleting the patient will also delete all associated forms and queries. This cannot be undone so administrators should think carefully before deleting.

Searching

The search box filters the patient list to match the entered terms. Note that form data is not searched.

Patient details

Clicking on a patient in the list shows patient details from the study entry form, any queries and provides links to add, view and edit the forms for that patient grouped by visit.

Schedule

For visits at specific timepoints (for instance 30 days after study entry) the due date is shown. Overdue forms are highlighted in red. If the Withdrawal form has been completed and the patient marked as withdrawn from follow-up, then any visits due after the date of withdrawal will not be shown as overdue. All uncompleted forms in these visits will become inaccessible. Forms that were completed before the patient was marked as withdrawn will remain accessible and may be viewed and edited in the normal way.

Figure 4.2: A follow-up visit due after patient withdrew

Missing forms

Sometimes forms within a visit are not available because, for instance, the patient did not attend a follow-up appointment, the data was not collected or was lost. Forms within visits can be marked as missing using the **Mark as data missing** links. Marking the data as missing in this way causes all uncompleted forms in the visit to become inaccessible and they will not be shown as overdue. Forms that were completed before a visit was marked as missing will remain accessible and may be viewed and edited in the normal way.

Figure 4.3: A follow-up visit marked as missing

Patient-entered forms

A link may be displayed to invite the patient to self-complete the forms in a visit if patient entered forms are enabled.

Form status

A green tick next to a form name indicates that it has been marked as validated. An amber question mark symbol next to a form name indicates that the form has an open query.

Chapter 5

Data entry of forms

Forms can be completed by clicking on the **Add** link shown on the patient details screen next to the name of the form. At the top of every form is a banner reminding the user of which patient they are entering data on. Date fields can be completed manually or by using the date-picker that appears when a user clicks on the calendar icon.

> Tip: When entering dates or times manually, just type the numbers – the / or : will be filled in automatically.

Validation

Validation (e.g. range checking) is carried out on the form to reduce errors. There are two types of error messages - those in the form of popup messages and those displayed in red on the form. The popup message alerts may warn the user of a value that may be incorrect (such as a high blood pressure) or give some other message. The user must dismiss the alert before proceeding. Red error messages require either a change to the value entered or providing a justification for overriding the validation check before proceeding.

Some fields are always required - these are displayed in bold text - whilst others may become required or not applicable depending on the answers to previous questions. Other fields are optional and may be left blank if desired.

Review step

Once the form has been completed without errors the **Save form** button will usually present the user with a review page. Here the user can visually check that the data entered is correct

Figure 5.1: Overriding form validation

and, if satisfied, complete the declaration by entering their password to save the form.

> This review step may be disabled for some systems, in which case the data is saved
> immediately.

If there are errors the user may return to the previous page to make changes. Once the declaration has been successfully completed the form is saved to the database.

Auto-saved drafts

Once data entry is commenced, forms are auto-saved periodically. A message showing the time of last save is shown at the top of the form. This allows the user to navigate away from the form and return to it later without losing data. When returning to a form that has a saved draft, the user is shown a message and given the option to load the draft data or ignore it. If the draft is ignored and data-entry started again the original data will no longer be available.

> There is only one draft per form/patient and it is accessible to all users (not just
> the author of the draft).

Figure 5.2: Reviewing a form before saving

If the user navigates away from the page before saving the data, a pop-up message is shown to warn the user that the data has not been permanently saved yet. This is because, even though a draft may exist, it could be lost by the actions of another user.

Figure 5.3: Saved draft message

Form completion messages

After a form has been saved, the user may be prompted to complete other forms based on the answers they have given. For instance, an event form may be required if a stroke has been recorded. If the form contains any of these rules and they are triggered by the data recorded, the user will see a message asking them to complete the related forms. A query will also be automatically opened to remind the user to complete the required forms.
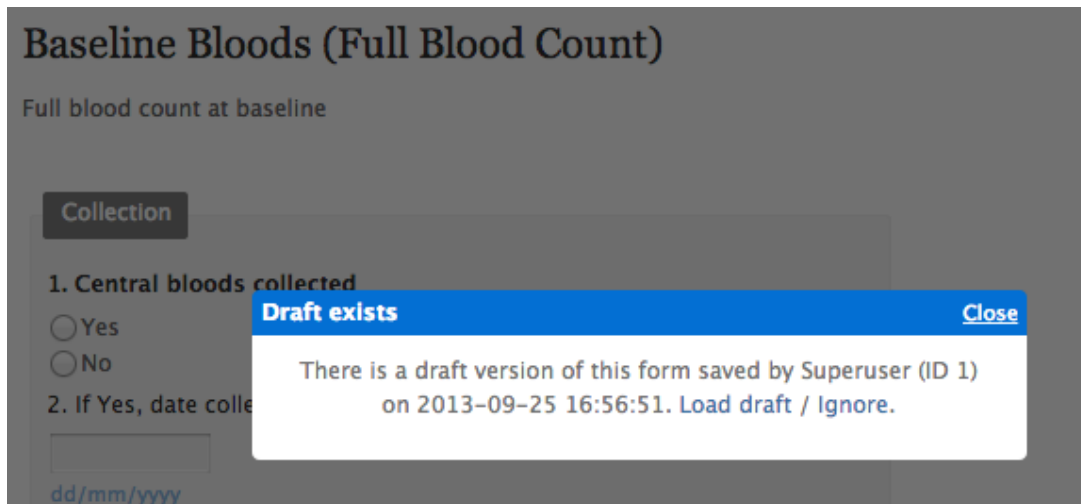
Figure 5.4: Load draft dialogue

Figure 5.5: Message to remind user to complete related forms

Chapter 6

Editing forms

Completed forms may only be edited by users with administrator accounts. Forms are edited by clicking on the **Edit** link next to the selected form shown on the patient details screen, or by clicking on the **Edit this form** link shown when viewing a form. The form is displayed in the same way as when adding the form but with some extra fields for recording validation status and reason for editing. The user may change any of the values in the form and they must complete the reason for editing field before reviewing and saving the form.

Validation status

When editing a form, the validation status can be set to 'Validated' provided there are no open queries for the form. Once a form is marked as validated, a green tick appears next to the form name in the patient details. If a query is added to the form after the form has been marked as validated, the validation status will automatically be changed to 'Not validated'. It is up to the trial coordinating team to decide what constitutes a validated form. It may, for instance, be as a result of a formal monitoring visit, or alternatively visual check against the source data by someone who did not enter the data.

Completed forms may not be deleted. However, the validation status may be set to 'Data unusable' to indicate that the whole form should be disregarded.

Figure 6.1: Editing a form

Chapter 7

Patient entered forms

Patient entered forms are forms which can be self-completed by the patient. See the specification page to see if this feature is enabled and information on email templates and information shown to patients when logging in.

Inviting patients

Patients must be invited to complete their forms for a particular visit. To do this the patient must be selected from the patient list and the **Invite patient to complete forms for this visit** link used. The "Patient invitation summary" section shows if the patient has been invited previously. Links to invite patients will only be displayed when the visit is due. In some cases sending out invitations to complete forms for follow-up visits is automated - see the specification page for details.

The form to invite the patient requires the patient name and their personal email address. These fields will be pre-populated on second and subsequent invites. An invitation will be sent to the email address provided containing a unique URL that the patient must visit within 30 days to complete the forms. The patient will also require a password that you have agreed with them in advance.

What the patient sees

Once a patient goes to the URL in their email invitation and enters the correct password they will see a list of forms to complete. Clicking on the name of the form takes them to that form where they can complete their answers. Unlike data entry of forms by investigator and administrator accounts, patients cannot override the validation checks on fields. They also will not

Patient invitation summary

Invited to complete forms for Baseline visit on 12 Sep 2013 14:49 (1st invitation).

Forms

Baseline

Invite patient to complete forms for this visit

Study entry	Add	View	Edit
Nurse Completed – Patient History from their Notes	Add	View	Edit
Nurse Completed – Clinical measures taken at appointment	Add	View	Edit

Figure 7.1: Viewing a patient record with invitation to complete baseline forms

see the review step - once they press the save button the form is saved immediately and cannot be viewed or edited by the patient. Entered forms are shown as completed in the list of forms.

The patient can return to complete the forms at any time until the unique link in their email expires. Once all the forms are completed a thank you message is displayed.

Patient invitation

This will invite patient 03002 to complete the following form(s) for the Baseline visit:

- Questions about you
- Questions about living with diabetes
- Questions about your mood over the last week
- Questions about how confident you are at managing your diabetes
- Questions about your diabetes treatment
- Questions about your health
- Questions about your use of NHS services
- Blood tests

Name

Vanessa Edge

Email

v.edge@myisp.com

Send invitation

Invitation history

Patient 03002 has been invited to complete these forms once.

Invitation sent	Sent to	Number of logins by the patient
12 Sep 2013 14:49	v.edge@myisp.com	0

Figure 7.2: Sending an invitation to complete baseline forms to a patient

Thank you for agreeing to take part in this research study. We would like to
your ability. Once you have completed all of the questions you will be assig
information entered will be held in the strictest confidence. We will send yo
websites can help people with type 2 diabetes to manage their condition be

Please complete the following forms:

1. ✅ Questions about you (completed)
2. Questions about living with diabetes
3. Questions about your mood over the last week
4. Questions about how confident you are at managing your diabetes
5. Questions about your diabetes treatment
6. Questions about your health
7. Questions about your use of NHS services
8. Blood tests

Figure 7.3: List of forms as seen by the patient

Chapter 8

Overdue forms

An overview of overdue forms for all patients may be viewed by clicking the **Overdue forms** link in the left-hand side bar. Each patient is shown as a row in the table, with a cell for each form in a visit with a time-point.

> Note that visits without time-points are not shown

Completed forms are shown in green, overdue forms in red. Forms that will never be completed because the patient withdrew or did not attend a visit are shown in grey. Blue cells indicate that the form is not applicable to that patient - for instance because a form is only collected on patients with a baseline abnormality. Clicking on a cell displays the name of the associated form. The table may be filtered by entering terms in the search box.

The percentages of forms completed, overdue etc are shown in the summary by site and overall. Note that percentages are calculated excluding forms that are not yet due in the denominator. So although 100% of forms may be shown as done today, this may change in the future as forms become due.

Overdue forms

View a summary

Detail by patient

Key ▮ Form completed ▮ Form overdue ▯ Not due yet ▮

Visits
A: Registration
B: Baseline
C: 6 Week Follow–up
D: 12 Week Follow–up

Download as CSV

Click an entry to display the form and visit name.

Search: [   ]

Patient ⇕	Site ⇕	A	B	C	D
RV10001	Luton	🟩🟩🟩	🟥🟥🟥🟥🟥		
RV18001	Luton	🟩🟩🟩	🟥🟥🟥🟥🟥		

Figure 8.1: Overdue forms detail

Overdue forms

View a detailed list

Summary by site

Key ▮ Form completed ▮ Form overdue ▮ Form missing ▮ Patient withdrew ▮

Number and percentage of forms by status excluding forms not yet due.

Site					
Luton	6	12	0	0	0
	33%	67%	0%	0%	0%
Total	6	12	0	0	0
	33%	67%	0%	0%	0%

Figure 8.2: Overdue forms summary

Chapter 9

Viewing forms

Forms are viewed by clicking on the **View** link next to the selected form shown on the patient details screen. The most recent version of the form is displayed. If the form has been edited a history bar will be shown, allowing past versions of the form to be displayed. Changes to the form compared to the previous, older, revision are highlighted in yellow. The exception to this is repeating sections within forms - changes to these are not highlighted.

Figure 9.1: Viewing a form that has been edited

Chapter 10

Sites

Trial sites (centres) must be added to the system before adding a patient or randomising, completing forms, updating a code list, or creating investigator accounts. Sites must also have their status set to either *Authorised to recruit patients* or *Recruiting patients* before patients can be added. The site number may be used in some trials to create a patient identifier of the form SSNNN where SS is the site number and NNN is a sequential number (either within or across sites).

Administrators can add sites by clicking on the **Contacts** link in the left-hand sidebar, followed by the **New site** link.

Note that sites **may not be deleted** once they are referenced by another record in the database (e.g. when a patient form has been completed for a patient at that site).

The contacts help contains some more information on managing contacts.

Figure 10.1: Adding a new site

Chapter 11

Contacts

Clicking on the **Contacts** link in the the left-hand sidebar takes the user to the trial contact pages. The user can click on the **A-Z** links to restrict contacts by name.

In addition a search facility is available in the top right hand corner of the page. This can be used for a general search through the contacts by typing in a name or address into the search box. Alternatively the associated drop down bar may be used to find contacts of a chosen type, such as investigators, sites or other organisations. Exact matches are generated by enclosing search terms in double quotes. Exact match searches are case sensitive whereas normal searches are not.

Clicking on a contact or submitting a search that returns just one contact will cause more detailed information about that contact to be displayed on the right hand side of the screen.

Adding contacts

Contacts can be added by clicking on the **New person**, **New organisation**, or **New site** links that appear near the top of the page. A form will be displayed appropriate to the type of contact. Completing the form and clicking the submit button will create the new contact.

Once the contact is created additional information such as addresses, phone numbers and email addresses may be added to the contact. This is achieved by first viewing the contact, then clicking on the **Address**, **Number**, or **Email** links shown above the contact details.

Contact events can be added with the **Event** link. Contact events are useful for recording notes of conversations, meetings or other events. Records of monitoring visits can also be added to site contacts.

Links are used to create relationships between different contacts. Related people or organisations are shown when viewing the details of a contact. At least one side of the link must

Figure 11.1: List of contacts starting with B

Figure 11.2: Viewing details of a contact

Figure 11.3: Creating a new person contact

involve an organisation - two people may not be linked. To add a link view a contact and use the **Link** link to pick the related contact.

Editing contacts

To edit a contact it must first be viewed. The contact may then be edited by clicking on its name in the right-hand panel. Similarly, additional information may be edited by simply clicking on it. Use the contact's **[Delete]** link to delete the record from the database.

Figure 11.4: Adding additional information to an existing contact

Chapter 12

Queries

Queries are intended to be used by administrators to raise questions about the form data for investigators to answer and for investigators to notify administrators of any issues they are aware of in completed forms. Queries can be linked generally to a patient, or more specifically to a particular form for a patient. Queries may only be closed by administrator users. Investigators can create new queries and add messages to existing queries.

Opening queries

A query can be opened either on the patient details panel or when viewing a form, by clicking on the **Create a query** link. The query must be given a title and an initial message. To link the query to a specific Form, choose the appropriate form from the related form drop-down control. Once it has been created, the query will be shown on the patient details panel and form specific queries will also be shown when viewing the form. In addition, if a form has an open query attached, an amber question mark symbol appears next to the form name in the patient details panel.

> Note that creating a query or re-opening a closed query linked to a CRF will cause the CRF to be marked as not validated.

Adding messages

Messages may be added to queries by investigators or administrators, forming a conversation thread. Administrators can close a query when the issue has been resolved. Administrators

Figure 12.1: Creating a new query

may also re-open a closed query by setting the action to 'Reopen' when adding a new message to it.

Figure 12.2: Viewing an open query

When viewing a query, printing the web-page will display an extra box that asks the investigator to write their response, with signature and date. This may be useful for the site's own records or workflow.

Email notifications

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

Query ID 2: Gender?

Code Immediate Invasive Strategy | Randomised 14 Jun 2010 16:28 | Luton (Site #1), United Kingdom

Current status: Open

Superuser (ID 1) on 12 Jul 2010 at 11:31:33 AM	Action: Open
Why the change from male to female?	

Superuser (ID 1) on 12 Jul 2010 at 11:33:56 AM	Action: None
Because there was a mix up with another patient with a similar name	

Please write your response above then sign and date.

Investigator name:

Investigator signature:

Date:

Mon, 12 Jul 2010 11:47:34 +0100 | 0.0.0

Figure 12.3: Response box shown when printing a query

- On creation: all administrators, and all investigators at the same site as the patient the query relates to;
- On update: all users who have participated in the query - that is the user who created the query and any user who has added a message to the query.

The format of the notification email is:

```
From: Sealed Envelope <automated@sealedenvelope.com>
Subject: [Trialname] Query updated
Date: Thu, 22 Oct 2009 15:43:22 +0100
To: joe@trialsite.org,admin@trialcentre.org

A query "Confirm date of birth" has just been updated by Joe Bloggs (ID 8). You can
    view the query here:

  https://www.sealedenvelope.com/Trialname/query/view/3


Note, this message was auto-generated on Thu 22 Oct 2009 15:43 Europe/London (GMT
    +0100).
```

Listing queries

A list of queries grouped by site is displayed by clicking on the **Queries** link in the left-hand sidebar. 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.

Chapter 13

Patient attachments

If patient attachments are enabled for your trial you can upload documents associated with a patient for storage in the patient's CRF.

> Note: It is **essential** that you do not upload documents containing personally identifiable patient information.

The specification page will list details of the maximum file size allowed for an individual attachment and the proportion of the space you have available for attachments that has been used.

Attachments

Attachments are enabled for this trial. You can upload, download, and delete attachments to a patient CRF. Individual attachments can have a maximum file size of 100.0 MB.
You have used 0% of the 5.0 GB space you have available for storing attachments.

Figure 13.1: Attachments information

Permissions

Every role with access to the patient view may download the attachments. Investigators can upload new attachments, and Administrators can delete existing attachments.

Uploading attachments
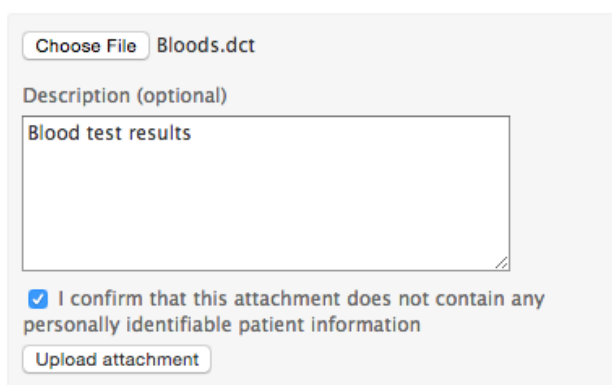
The patient record will have an Attachments section with a link to **Upload an attachment**. Following the link takes you to the Attachments page for that patient, and a form where you can specify the file to upload along with an optional description.

Figure 13.2: Uploading an attachment

Submitting the form will store the attachment in the patient's CRF.

Viewing and downloading existing attachments

Once attachments have been uploaded for a patient the patient view will display a link to download the attachment.

The Attachments page will contain a table detailing the attachments for that patient.

Attachments

Figure 13.3: An attachment listed in the patient view

Existing attachments

Attachment	Size	Uploaded by	Uploaded at	Description	Delete
Bloods.dct	1.4 kB	Jon Ramsey (ID 57)	25 Sep 2015 12:56	Blood test results	Delete

Figure 13.4: Table of attachment details

Deleting an attachment

Administrators can delete existing attachments. To delete an attachment follow the **Delete** link from the table on the Attachments page. This will take you to a confirmation page where clicking the **Delete attachment** button will remove the attachment from the patient's CRF.

> Note: Deleted attachments are removed from the filesystem so you cannot undo this action.

Figure 13.5: Deleting an attachment

Running out of space

Please contact us at support@sealedenvelope.com if you are running out of space for storing attachments.

Chapter 14

Reports

Various reports summarising data-entry and randomisation activity and site status are available by clicking on the **Reports** link in the left-hand sidebar. Clicking on a report title displays the report compiled from the live database so that it is always up to date. Report data can be downloaded as a plain text comma separated value file by clicking on the **Download as CSV** link. Reports may also be sorted by clicking on a column heading or filtered by entering search terms into the search box.

Figure 14.1: Viewing a report

Chapter 15

Downloads

CRF data may be downloaded in either CSV or Stata fixed format via the **Download** link in the left-hand sidebar. The download page shows a list of forms in the CRF and provides links to download the data for each form individually or for all forms (as a zip file).

CSV format

The data for each form is provided in comma separated value format, which is a plain text file that can be opened in many spreadsheet or Statistical programs. The first row contains a header with the question labels for each column.

Every file contains a patient identifier field so that data stored in different forms can be linked together.

Stata format

The data for each form is provided in Stata fixed format, which is a plain text file format with a dictionary 'header' that describes the format of the rows. Each row contains information from one saved form with a patient identifier field to identify the patient record it belongs to. The data can be easily imported into Stata using the infile command.

For example, to import the withdrawal data the following infile command would be used in Stata:

```
infile using SeWithdrawal.dct, clear
compress
```

Form data downloads

CSV files

These CSV format datasets can be imported into Excel, Numbers, Google docs, R etc.
Download form data:

- Randomisation
- Interviewers questions
- CSRI
- Patient Questions
- Satisfaction of Care
- Concomitant medications
- Patient information
- ECG results
- Patient Questions
- Interviewers questions
- CSRI
- Patient Questions
- Satisfaction of Care
- Withdrawal
- Serious Adverse Events

Download all data

Stata files

These datasets are ASCII (text) data in fixed format with a dictionary and can be imported into Stata using the `infile` command:

```
infile using SeWithdrawal_StudyCompletion.dct, clear
compress
```

where `SeWithdrawal_StudyCompletion.dct` is the full filesystem path to the downloaded file. The compress command is recommended to reduce the storage space allocated to each variable.

Figure 15.1: Form data download page

	A	B	C	D	E	F
1	id	Parent patient. F	User who create	User who last up	Timestamp for r	Date & time of la
2	1		1 Jacob Benfield (	Jacob Benfield (	29/04/2014 15:0	29/04/2014 15:0
3	2		3 Jacob Benfield (	Jacob Benfield (	29/04/2014 15:0	29/04/2014 15:0

Figure 15.2: Viewing CSV file in spreadsheet

where `SeWithdrawal.dct` is the full filesystem path to the downloaded file. The `compress` command is recommended to reduce the storage space allocated to each variable.

Example

Some interview data has been downloaded in Stata fixed format. There are two rows below the dictionary header because only data on two patients have been entered so far:

```
dictionary {
  long id
  long patientId `"Parent patient. Foreign key: patient table.id"'
  str244 userIdentifier `"User who created row"'
  str244 lastUserIdentifier `"User who last updated row"'
  str244 created `"Timestamp for row creation"'
  str244 updated `"Date & time of last update to row"'
  str244 reasonForEdit `"Reason for editing row"'
  str244 notes `"Notes"'
  str244 validationOverrides `"Justifications for overriding validation"'
  str244 validationStatus `"Validation status"'
  str244 validationNotes `"Validation notes"'
  str244 question1 `"Form details — Site number. Number (up to 3 digits)"'
  str244 question2 `"Form details — Participant number. Number (up to 3 digits)"'
  str244 question3 `"Form details — Date CRF completed. dd/mm/yyyy"'
  str244 question4 `"Questions — Sex"'
  str244 question5 `"Questions — Marital status"'
  str244 question6 `"Questions — If other, please specify"'
  str244 question7 `"Questions — Ethnicity"'
  str244 question8 `"Questions — Employment status"'
  str244 question9 `"Questions — Current or most recent job"'
  str244 question10 `"Questions — Highest level of education completed"'
  str244 question11 `"Depression — Have you had any previous episodes of depression?"'
  str244 question12 `"Depression — If so, how many. Number (up to 5 digits)"'
  str244 question13 `"Depression — Duration of current episode in weeks. Number (up to
    5 digits)"'
  str244 question14 `"Depression — Are you using any treatments for depression at the
    moment?"'
  str244 question15 `"Depression — Treatment/Medication Name"'
  str244 question16 `"Depression — Treatment/Medication Name [additional fields as
    needed]"'
  str244 question17 `"AUDIT — How often do you have a drink containing alcohol?"'
  str244 question18 `"AUDIT — How many drinks containing alcohol do you have on a
    typical day when you are drinking?"'
```

```
    str244 question19 `"AUDIT - How often do you have six or more drinks on one occasion
      ?"'
    str244 question20 `"AUDIT - How often during the last year have you found the you
      were not able to stop drinking once you had started?"'
    str244 question21 `"AUDIT - How often during the last year have you failed to do
      what was normally expected from you because of drinking?"'
    str244 question22 `"AUDIT - How often during the last year have you needed a first
      drink in the morning to get yourself going after a heavy drinking session?"'
    str244 question23 `"AUDIT - How often during the last year have you had a feeling of
       guilt or remorse after drinking?"'
    str244 question24 `"AUDIT - How often during the last year have you been unable to
      remember what happened the night before because you had been drinking?"'
    str244 question25 `"AUDIT - Have you or someone else been injured as a result of
      your drinking?"'
    str244 question26 `"AUDIT - Has a relative or friend or a doctor or another health
      worker been concerned about your drinking or suggested you cut down?"'
    str244 question27 `"ECOG - ECOG performance status"'
    str244 question28 `"Treatment Expectation - Name of treatment"'
    str244 question29 `"Treatment Expectation - To what extent do you think you will
      improve if you receive this treatment?. Number (up to 5 digits)"'
    str244 question30 `"Treatment Expectation - Have you ever received this treatment
      before?"'
    str244 question31 `"Treatment Expectation - If yes, please provide further detail
      about the effect of the treatment on yourself"'
    str244 dateEntered "Date entered study"
    str244 dateWithdrew "Date withdrew"
    str244 siteName "Site"
    str244 countryName "Country"
    str244 identifier "Patient identifier"
    str244 visit "Visit"
}
1 1 "Jacob Benfield (ID 813)" "Jacob Benfield (ID 813)" "2014-04-29 15:03:09"
    "2014-04-29 15:03:09" "" "" "{}" "Not validated" "" "010" "100" "28/4/2014" "Male"
    "Married" "" "White" "Employed" "Landscape gardener" "A level (or equivalent)" "Yes
    " "2" "15" "No" "" "" "1.  Monthly or less" "2.  5 or 6" "0 - Never" "0 - Never" "0
     - Never" "0 - Never" "0 - Never" "0 - Never" "0 - No" "0 - No" "0 = Fully Active,
    able to carry on all pre-disease performance without restriction" "Paracetamol"
    "34" "No" "" "2014-04-10" "" "Luton" "United Kingdom" "RV10001" "Baseline"
2 3 "Jacob Benfield (ID 813)" "Jacob Benfield (ID 813)" "2014-04-29 15:05:08"
    "2014-04-29 15:05:08" "" "" "{}" "Not validated" "" "010" "180" "29/4/2014" "Female
    " "Partner - Living with" "" "Indian" "Self employed" "Vet" "Degree" "No" "" "19" "
    No" "" "" "0.  Never" "0. 1 or 2" "0 - Never" "" "" "" "" "" "0 - No" "0 - No" "1 =
      Restricted in physically strenuous activity but ambulatory and able to carry out
```

```
work of a light or sedentary nature, e.g., light house work, office work" "
Paracetamol" "0" "No" "" "2014-04-10" "" "Luton" "United Kingdom" "RV18001" "
Baseline"
```

The data is imported and compressed, and the output from Stata's `describe` command can be seen in the screenshot. The variable names and variable descriptions have been picked up automatically from the dictionary header.


```
  obs:           2
  vars:          48
  size:      1,078 (99.9% of memory free)

               storage  display   value
variable name   type    format    label    variable label

id              byte    %12.0g
patientId       byte    %12.0g             Parent patient. Foreign key: patient table.id
userIdentifier  str19   %19s              User who created row
lastUserIdent~r str19   %19s              User who last updated row
created         str19   %19s              Timestamp for row creation
updated         str19   %19s              Date & time of last update to row
reasonForEdit   str1    %9s               Reason for editing row
notes           str1    %9s               Notes
validationOve~s str2    %9s               Justifications for overriding validation
validationSta~s str13   %13s              Validation status
validationNotes str1    %9s               Validation notes
question1       str3    %9s               Form details - Site number. Number (up to 3 digits)
question2       str3    %9s               Form details - Participant number. Number (up to 3 digits)
question3       str9    %9s               Form details - Date CRF completed. dd/mm/yyyy
question4       str6    %9s               Questions - Sex
question5       str21   %21s              Questions - Marital status
question6       str1    %9s               Questions - If other, please specify
question7       str6    %9s               Questions - Ethnicity
question8       str13   %13s              Questions - Employment status
question9       str18   %18s              Questions - Current or most recent job
question10      str23   %23s              Questions - Highest level of education completed
question11      str3    %9s               Depression - Have you had any previous episodes of depression?
question12      str1    %9s               Depression - If so, how many. Number (up to 5 digits)
question13      str2    %9s               Depression - Duration of current episode in weeks. Number (up to 5
                                            digits)
```

Figure 15.3: Interview data imported into Stata

Category variables are stored as strings so can be tabulated without needing variable labels. Category variables can be encoded if storage space is an issue.

Conversion notes

During conversion into Stata download format, note the following changes that are made to the data:

- All strings are truncated at 244 characters
- Newlines are replaced by spaces
- Double quotes are replaced by single quotes

Figure 15.4: Interview data imported into Stata

- Dates and times are imported as strings in Stata. Stata's data conversion functions can be used as required to convert the strings to Stata's native datetime format.

Chapter 16

Audit trail

Clicking the **Log** link in the left-hand sidebar displays the audit trail. The most recent 100 lines are shown by default; click the 'Show all' button to see the entire log. The audit trail is a plain text file which can be copied and pasted into a local text file if required (click 'Show all' first). From version 9.6 onwards there is also a button to download the audit trail. This log records all significant events and changes to the data including:

- Data entry and editing of forms
- Creation and adding messages to queries
- Creation and editing of contacts
- Randomisations
- Movement of blocks within code lists
- Unblinding
- Downloads from the system such as reports in CSV format, CRF data, code list and the audit trail itself

An example extract from a log is shown below. The items shown in each row of the log are (from left to right):

- IP address of the user who initiated the event
- Name and user ID of the user
- URL
- Server date and time (including GMT offset)
- Notice level - usually this will be "INFO (6)"
- Message

Where applicable, the message contains information on the data before and after the event. Some events might generate several related messages - such as an explanatory note

Audit trail

Show all   Download

This log captures all notable events and changes to the data. Only the 100 most recent lines are shown.

100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/contact/add/Site" [2015-05-22T11:12:05+01:00] INFO (6): Row
inserted to contact: {"id":null}
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/contact/add/Site" [2015-05-22T11:12:05+01:00] INFO (6): Row
inserted to organisation: {"id" : "1","countryId" : "136","name" : "Western Eye Hospital ","type" : "site","notes":null}
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/contact/add/Site" [2015-05-22T11:12:05+01:00] INFO (6): Row
inserted to site: {"id" : "1","siteNumber" : "1","status" : "authorised to recruit patients"}
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/contact/add/Site" [2015-05-22T11:12:05+01:00] INFO (6):
Added contact Western Eye Hospital (Site #1), United Kingdom
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/crf/reviewadd/SeEntry/0" [2015-05-22T11:14:10+01:00] INFO
(6): Row inserted to crfSeEntry: {"id" : "1","patientId" : "1","identifier" : "001","userIdentifier" : "Andrea Amin (ID 118 -
Administrator)","lastUserIdentifier" : "Andrea Amin (ID 118 - Administrator)","siteId" : "1","created" : "2015-05-22
11:14:10","updated" : "2015-05-22 11:14:10","reasonForEdit":null,"notes":null,"validationOverrides" : "{}","validationStatus" :
"Not validated","validationNotes":null,"dateEnteredStudy" : "2015-04-22"}
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/crf/reviewadd/SeEntry/0" [2015-05-22T11:14:12+01:00] INFO
(6): Added form Study entry for Patient 001
100.2.3.4 "Andrea Amin (ID 118 - Administrator)" "/redpill/trialname/crf/reviewadd/DemographicData/1" [2015-05-
22T11:29:32+01:00] INFO (6): Row inserted to crfDemographicData: {"id":null,"patientId" : "1","userIdentifier" : "Andrea Amin
(ID 118 - Administrator)","lastUserIdentifier" : "Andrea Amin (ID 118 - Administrator)","created" : "2015-05-22

Figure 16.1: Audit trail

```
"Edited form Eligibility Criteria Check At Recruitment for Patient SDN01"
```

plus a change in the data:

```
"Row in crfBaselineEligibilityCriteria for: {"id" : "1"}, changed From: {"updated" :
    "2014-10-22 17:45:47","reasonForEdit":null ..."
```

Example extract

```
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/crf/reviewadd/
    BaselineEligibilityCriteria/1" [2014-10-22T17:45:47+01:00] INFO (6): Row inserted
    to crfBaselineEligibilityCriteria: {"id":null,"patientId" : "1","userId" : "1","
    lastUserId" : "1","created" : "2014-10-22 17:45:47","updated" : "2014-10-22
    17:45:47","reasonForEdit":null,"notes":null,"diagnosisOfIpfOrNsip" : "No","
    rhcMeanPap" : "Yes","ageRange" : "No","dateWrittenInformedConsentGiven" :
    "10\/08\/2008","validationStatus":null,"validationNotes":null}
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/crf/reviewadd/
    BaselineEligibilityCriteria/1" [2014-10-22T17:45:47+01:00] INFO (6): Added form
    Eligibility Criteria Check At Recruitment for Patient SDN01
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/crf/reviewedit/
    BaselineEligibilityCriteria/1" [2014-10-22T17:48:40+01:00] INFO (6): Row in
    crfBaselineEligibilityCriteria for: {"id" : "1"}, changed From: {"updated" :
    "2014-10-22 17:45:47","reasonForEdit":null,"unstableUnderlyingLungDisease":null,"
    anySeriousComorbidity":null,"systolicBp":null}, To: {"updated" : "2014-10-22
    17:48:40","reasonForEdit" : "Adding some more answers","
```

```
    unstableUnderlyingLungDisease" : "No","anySeriousComorbidity" : "Yes","systolicBp"
    : "No"}
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/crf/reviewedit/
    BaselineEligibilityCriteria/1" [2014−10−22T17:48:40+01:00] INFO (6): Edited form
    Eligibility Criteria Check At Recruitment for Patient SDN01
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/contact/add/Individual" [2014−08−13
    T10:37:45+01:00] INFO (6): Row inserted to contact: {"id":null}
1.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/contact/add/Individual" [2014−08−13
    T10:37:45+01:00] INFO (6): Row inserted to individual: {"id" : "52","title":null,"
    lastName" : "Kinnear","firstName" : "James","jobTitle" : "Layman","responsibility":
    null,"notes":null,"type" : "individual","qualifications":null,"regNo":null,"cv" :
    "0","cvDate":null,"delegationLogReceived" : "0","delegationLogReceivedDate":null}
100.2.3.4 "Simon Admin (ID 2)" "/redpill/trialname/contact/add/Individual" [2014−08−13
    T10:37:45+01:00] INFO (6): Added contact James Kinnear
```

Chapter 17

Settings

A settings page is available to administrators that allows some features to be turned on or off to suit the requirements of your trial. Changes to settings are recorded in the audit trail. There are some common settings (see below) and you may also have some trial specific settings. The settings page was introduced in Red Pill 9.6.0.

Figure 17.1: Settings page

Review step

The review step is turned on by default and introduces an intermediate step when saving forms. The user is required to review the form data and enter their password to confirm the information is correct before the data is saved to the database. The process is described in the data entry section. Since investigator accounts normally do not have privileges to enter data once it is saved, the review step can help to prevent errors which would then require a query to resolve.

However, you may prefer to turn this review step off. In this case the form is saved immediately with no intermediate review page. This could be preferable, for instance, if you have data entry staff entering paper CRFs into a Red Pill database.

> Note the review step is always enabled for randomisation forms

Patient delete

The ability to delete patients is turned off by default. Deleting a patient will also remove all their CRF data, randomisation data and queries. The deleted data is shown in the audit trail but the action cannot be undone. You should consider very carefully whether to turn this feature on and use it. We recommend it is used only in exceptional circumstances.

> We **strongly discourage** using the patient delete feature on randomised patients because all randomised patients must be accounted for.

If a patient was randomised in error mark them as such rather than deleting the record.

Randomisation

Randomisation systems and Red Pill systems with a randomisation form can turn randomisation on or off (). This may be useful, for instance, if offline randomisations have been carried out due to the Sealed Envelope website being unavailable.

This is a global setting - to stop randomisation at a specific site, edit the site contact and set the status to something other than *Authorised to recruit patients* or *Recruiting patients*.

Chapter 18

Specification

The specification for a Red Pill application can be viewed by clicking the **Specification** link on the left-hand sidebar. The specification is only accessible to administrator users. It shows the following information where relevant:

- Names of forms that can be completed multiple times per patient.
- The timetable used by the form scheduling feature, if enabled.
- Form completion prompts shown to the user when certain criteria are met.
- Whether any of the forms can be patient self-completed, and information about custom text shown to the patient in the invitation email and after logging in.
- Details on randomisation method used, treatment groups, allocation ratio, strata, code list length, randomisation limit, data collected at randomisation (where relevant).
- Format of randomisation and unblinding email notifications
- User account privileges.
- Library version numbers.
- Server type (staging / production), review step setting and patient delete setting.

There may also be extra custom information specific to the study.

Chapter 19
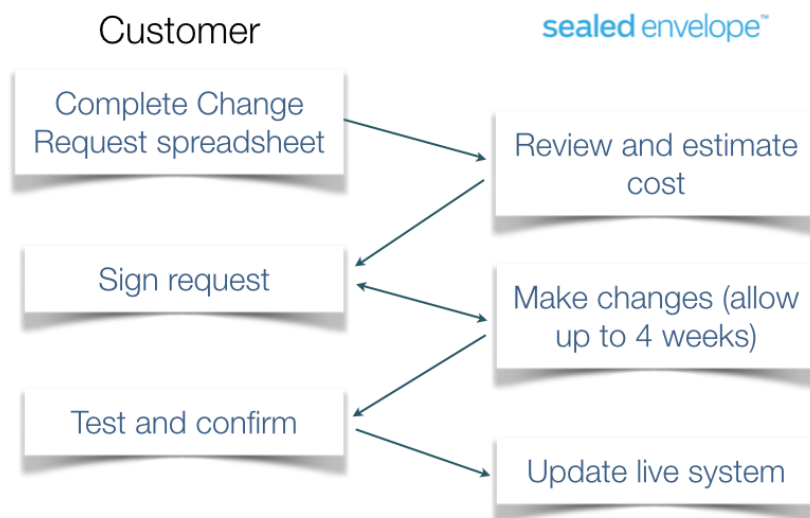
Making changes to the specification

Figure 19.1: Flowchart for change request process

Once a Red Pill or randomisation system is in production, changes to the forms or other aspects of the system can only be done through a documented change control process. To initiate this process please download and complete a Change Request spreadsheet [Excel file].

The Change Request Log will require you to complete the following information:

Change # Sequential change number 1, 2, 3, …
Visit Name of visit, e.g. *Baseline*
Form Name of form, e.g. *ECG results*
Item / Question The question to be added or changed, eg. *1. ECG - Has a baseline ECG been taken?*
Change type One of:

- New form
- New field
- Change field
- Other change

New or revised forms and fields might be required due to a change in the protocol or a mistake in the original specification. Other changes include changes to validation rules or user permissions etc.

If new field, please record response required When adding new fields, please list what type of response is expected. Please choose from:

- Single line text
- Paragraph text - a text box allowing long text entries
- Encrypted text - a text box whose value will be stored in an encrypted format
- Number
- Date
- Yes/No
- Category - please list all categories eg, Mild; Moderate; Severe
- Clock time - the time of day in 24hr clock format (e.g. 13:15)
- Elapsed time - a duration in hours and minutes (e.g. 30:50)
- Explanation - explanatory text (e.g. The following questions are about your health)

Change description The actual change that is required in the eCRF. e.g. *The drop down menu is missing a category and should be updated to include new option in drop down menu*

Once you have completed the form, please send it to Sealed Envelope for review. Sealed Envelope will review your list of changes and provide you with an estimate of how long it will take to configure these changes and provide you with a cost estimate to fulfil your request.