

sealed envelope™

CRF Builder

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Chapter 1

Overview

The CRF Builder is used to create an electronic case record form (CRF) for Red Pill. Visits, forms, fields and validation rules can be specified, and a Red Pill preview can be created at any time. The easy to use drag and drop interface allows researchers to build their CRF quickly.

Chapter 2

Getting started

To access the CRF builder [contact Sealed Envelope](#) for details. First you must create your CRF by completing the form requesting the trial name and your email address. Completing this form creates your CRF and sends you the unique URL (web address) to access your CRF in future. You can share this URL with your colleagues but be aware that anyone with the URL can edit the CRF.

Only one person should edit the CRF otherwise changes can be over-written!

Subject details and subject ID

At first your CRF will be empty except for a special *Subject details* visit. This visit contains the subject registration and withdrawal forms which are used by [Red Pill](#) to create subjects and mark them as withdrawn from follow-up.

You can change the wording associated with this visit, and its forms and fields but you cannot delete it or add other fields. You should edit the *Subject ID* field and check the field size is appropriate for your trial. The subject ID can be automatically generated — add this to your [list of customisations](#) if required.



::: Visit: Subject details

Timepoint: At any time

Visit date: The date the Subject registration form is added

 [Edit](#)

Forms

-  [Subject registration](#)
-  [Withdrawal](#)

Figure 2.1: Subject details visit

Edit a field

* indicates a required field

Field details

Label *

Field size

Figure 2.2: Editing subject ID

Add the first visit

Add the first visit using the *Add a visit* link. This will usually be a screening or baseline visit and you will probably want to enter the forms in Red Pill for this visit as soon as the subject is added to the database. To make the forms due immediately, set the *Visit is due* selection to *Subject details form is added*. See [visits](#) for more information.

Visit details

Label *

Baseline

Visit is due

Subject details form is added

+ (offset)

0 days

The offset from the date specified above at which this visit occurs, e.g.

- 0 days
- 4 months
- 2 years

Red Pill will use this offset to calculate the visit due date and mark overdue visits

Figure 2.3: Adding a baseline visit

Add forms

Next add forms to your visit using the *Add a form to this visit* link. The *Label* field is displayed in the Red Pill interface and the *Name* field is used to name the underlying database table. Because of this, names must be alphanumeric, start with a letter, and have a maximum length of 32 characters. The name is used when [downloading data](#) from Red Pill.

The *Repeatable* option should be selected only if you expect to enter multiple forms for the same subject, such as when recording adverse events or other events that may happen multiple times.

Add a form

* indicates a required field

Form details

Label *

Name *

This will be reflected in the form name in the database

Description

Repeatable

Yes

No

Can this form be entered multiple times for the same subject?

Subject entered form

Yes

No

Can subjects enter this form?

Figure 2.4: Adding a baseline form

The *Subject entered form* option indicates that the subject will be expected to complete the form themselves online using Red Pill's [Subject entered forms](#) feature. Talk to Sealed Envelope before selecting this option.

Add sections and fields

To add fields to a form you must first add a section. Sections are used to group fields visually on a form. A section can be repeatable to allow a set of questions to be recorded multiple times. This is useful for recording all concomitant medications on one form for instance.

Add a field using the *Add a field* link in the section. Choose the best field type to suit the data you want to collect. The *Label* field is displayed in the Red Pill interface and the *Name* field is used to name the underlying database column. Because of this, names must be alphanumeric, start with a letter, and have a maximum length of 32 characters. The name is used when [downloading data](#) from Red Pill.

Preview your CRF

Once you have created some visits and forms you may wish to preview the Red Pill application to check on how they will appear when in use. Go to the top level of your CRF and click the *Preview* link. You can generate a new preview based on your current CRF and then click the blue button to view the preview. You will need to add a subject using the link in the top menu bar first, and then you will see all your visits and forms. You can enter data and test that your forms are acting as you expected.

Field details

Field type *

Changing the field type will delete any rules on this field

Label *

Name *

This will be the name of the field in the database

Is this field required? *

Yes

No

Figure 2.5: Adding a date field

Form: Demographics

v1 **new** DemographicsVER1

Basic information about the subject

 [Edit form details](#)

::: Section: Demographics

 [Edit section](#)  [Duplicate](#)  [Delete](#)

○ **Date of examination** **DateOfExamination** date

DD/MM/YYYY

This field is **required**

This date **must be in the past**

 [Edit field](#)  [Add a rule](#)  [Duplicate](#)  [Delete](#)

○ **Sex** **Sex** category

○ **Date of birth** **DateOfBirth** date 

○ **Ethnicity** **Ethnicity** category

○ **If other, please specify** **OtherEthnicity** single line text **2 rules**

 [Add a field](#)

Figure 2.6: Viewing a form

Preview the Demo CRF

Preview revision 30

The preview is a fully functional Red Pill application based on your CRF. You will be logged in to the application with an administrator account.

Previews will be automatically deleted after 1 month! This will delete any test data that you have entered.

You can regenerate your preview at any time.

Generating a new preview will destroy the preview of revision 30 and any test data that you have entered.

Your CRF is currently at revision #30.


Generate a new preview

Figure 2.7: Preview page

Demographics

Demographics

Date of examination *


dd/mm/yyyy

Sex *

Male

Female

Height *

cm. Number (up to 3 digits)

Date of birth *



dd/mm/yyyy

Figure 2.8: Preview a form

Chapter 3

Forms and sections

A [visit](#) contains forms. Each form is used to collect data on a subject. We recommend forms are kept relatively short, since in [Red Pill](#) the whole form must be entered and saved in one go (although drafts are saved to allow partial entry). It may help users performing data entry to split long forms in your paper CRF into several forms in the eCRF.

Add a form

Add a form by navigating to the visit and using the *Add a form to this visit* link. The *Label* field is displayed in the Red Pill interface and the *Name* field is used to name the underlying database table. Because of this, names must be alphanumeric, start with a letter, and have a maximum length of 32 characters. The name is used when [downloading data](#) from Red Pill. The *Description* field is displayed under the form label when viewing or editing the form in Red Pill.

The *Repeatable* option should be selected only if you expect to enter multiple forms for the same subject, such as when recording adverse events or other events that may happen multiple times.

The *Subject entered form* option indicates that the subject will be expected to complete the form themselves online using Red Pill's [Subject entered forms](#) feature. Talk to Sealed Envelope before selecting this option.

Add a form

* indicates a required field

Form details

Label *

Name *

This will be reflected in the form name in the database

Description

Repeatable

Yes

No

Can this form be entered multiple times for the same subject?

Subject entered form

Yes

No

Can subjects enter this form?

Save

Cancel

Figure 3.1: Adding a baseline form

Other forms

Due: at any time [Mark as data missing](#)

Serious Adverse Events	Add		
Serious Adverse Events (#1)		View	Edit
Serious Adverse Events (#2)		View	Edit
Withdrawal	Add	View	Edit

Figure 3.2: Repeat entry forms

Add a section

To add fields to a form you must first add a section. Sections are used to group fields visually on a form. A section can be *repeatable* to allow a set of questions to be recorded multiple times. This is useful for recording all concomitant medications on one form for instance. Repeating sections are denoted with a circular arrow icon.

Sections can also be used to present multiple questions in a grid with *Likert scale* responses. Every field within a Likert scale section must be a category field with the same categories.

Once you've added a section, you are ready to start [adding your fields](#).

::: Section: Hospital admissions

[Edit section](#) [Duplicate](#) [Delete](#)

- **Did your child stay at hospital overnight during the last 7 days?** `StayAtHospitalOvernight`
yes/no
- If 'Yes' please provide details below: `explanation`

[+ Add a field](#)

::: Section: Hospital admissions [↻](#)

[Edit section](#) [Duplicate](#) [Delete](#)

- **Name of hospital** `NameOfHospital` single line text
- **Reason for visit** `ReasonForVisit` single line text
- **Date of admission** `DateOfAdmission` date
- **Date of discharge** `DateOfDischarge` date

[+ Add a field](#)

Figure 3.3: Adding a repeating section

Hospital admissions

Did your child stay at hospital overnight during the last 7 days? (reset)

Yes
 No

If 'Yes' please provide details below:

Hospital admissions

Hospital admissions

Name of hospital
 Bath

Reason for visit
 High temperature

Date of admission
 04/01/2017
dd/mm/yyyy

Date of discharge
 05/01/2017
dd/mm/yyyy

[Edit](#) [Delete](#) 

Hospital admissions

Name of hospital
 Bath

Reason for visit
 Surgery

Date of admission
 07/01/2017
dd/mm/yyyy

Date of discharge
 09/01/2017
dd/mm/yyyy

[Edit](#) [Delete](#) 

[Add Hospital admissions](#)

Figure 3.4: A form with subforms

Satisfaction of Care

Overall care

On a scale of 0-10 (0 being least 10 being most), how satisfied are you with:

	0	1	2	3	4
Your overall care? *	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The continuity of your care? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Your supportive care? *	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Figure 3.5: A Likert scale section

Chapter 4

Fields

Once you've added a [form and section](#) you can add a field using the *Add a field* link in the section. There are several field types to choose from depending on the type of data you are collecting.

Type

Single line text

Use for descriptive data such as initials, medication name or adverse event. A maximum of 80 characters are allowed.

Paragraph text

Use for recording longer descriptions or notes. There is no limit to the amount of text that may be stored.

Number

Use for recording numbers. Decimal places and whether the number can be negative are controlled by the **format** option. For instance **###** format allows positive integer numbers from 0 to 999 only.

Field details

Field type *

Single line text ▾

Changing the field type will delete any rules on this field

Label *

Initials

Is this field required? *

Yes

No

Is this field personally identifiable information? *

Yes

No

Personally identifiable information is encrypted when stored

Field size

3

Help

Help text for this field

Save

Cancel

Figure 4.1: Adding a text field

Field details

Field type *

Paragraph text

Changing the field type will delete any rules on this field

Label *

Notes on medication response

Name *

NotesOnMedicationResponse

This will be the name of the field in the database

Figure 4.2: Adding a para field

-#.## allows numbers from -9.99 to 9.99. Both hard and soft ranges can also be specified for number fields to limit values or warn of unusually low or high values.

Field type *

Number

Changing the field type will delete any rules on this field

Label *

Age

Name *

age

Figure 4.3: Adding a number field

Date

Use for recording dates in *dd/mm/yyyy* format. Options are available to limit dates to past dates (which includes today) or future dates.

Yes/No

Use for recording boolean data.

Field details

Field type *

Changing the field type will delete any rules on this field

Label *

Name *

This will be the name of the field in the database

Is this field required? *

- Yes
 No

Is this field personally identifiable information? *

- Yes
 No

Personally identifiable information is encrypted when stored

The date should be in the past

- Yes
 No

The date should be in the future

- Yes
 No

Figure 4.4: Adding a date field

Field details

Field type *

Changing the field type will delete any rules on this field

Label *

Name *

Figure 4.5: Adding a yesno field

Category

Use for recording a category such as sex or ethnic group. Categories are specified with a semi-colon separated list of values. Categories are presented as a drop-down select control in Red Pill unless the field is required and has 3 or fewer values. In this case the category will be presented as radio buttons.

Clock time

Use for recording the time of an event in 24 hour clock format (e.g. 19:50).

Elapsed time

Use for recording durations in hours and minutes (e.g. 36:30).

Explanation

Used to add arbitrary text to a form. Does not store data.

Label

The label is shown on the form in Red Pill above the control for entering data. It is the question or information sought.

Name

The name field is used to name the underlying database column. Because of this, names must be alphanumeric, start with a letter, and have a maximum length of 32 characters. The name is used when [downloading data](#) from Red Pill.

Field details

Field type *

Category

Changing the field type will delete any rules on this field

Label *

Sex

Name *

Sex

This will be the name of the field in the database

Is this field required? *

Yes

No

Is this field personally identifiable information? *

Yes

No

Personally identifiable information is encrypted when stored

Categories

Male; Female

Semi-colon separated list of possible values, e.g. 'Yes; No; Unsure'.

Figure 4.6: Adding a category field

Field details

Field type *

Changing the field type will delete any rules on this field

Label *

Name *

This will be the name of the field in the database

Figure 4.7: Adding a clock field


Field details

Field type *

Elapsed time 

Changing the field type will delete any rules on this field

Label *

Duration of surgery 

Name *

DurationOfSurgery

This will be the name of the field in the database

Figure 4.8: Adding a elapsed field

General information

Initials*

Notes on medication response

Age*

years. Number (up to 3 digits)

Date form completed*

dd/mm/yyyy

Patient died?

Sex*
 Male
 Female

Marital status

Please make sure timings are accurate

Time operation started*

hh:mm

Duration of surgery*

hh:mm

Figure 4.9: Viewing a form

Required

All field types except explanation can optionally be set as required. The user will see an error message for this field if they skip it when entering data in Red Pill.

Personally identifiable information (PII)

Fields can optionally be set as PII. The value will be [encrypted](#) when stored in the Red Pill database.

Help

Help can be added to any field to provide instructions or additional context to the user. The help is shown in a popup on the form in Red Pill. You can add **bold** to emphasize words in the help by surrounding them with asterisks **like this**.

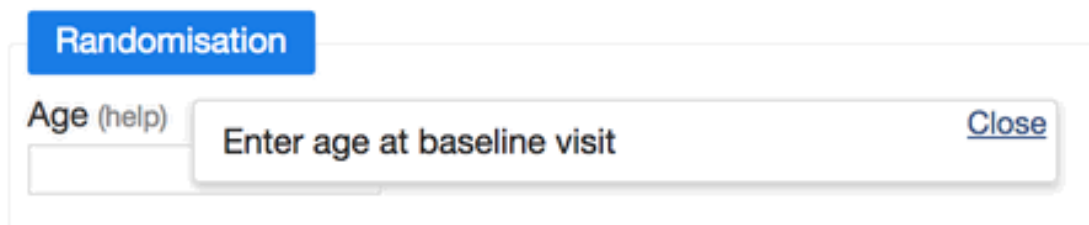


Figure 4.10: Field with help

Other options

Other options such as field size, number format, hard and soft ranges are shown depending on the field type chosen.

Chapter 5

Visits

Visits in Red Pill organise forms in the CRF into logical groupings. Mostly the visits will correspond to real world visits the subject makes, such as baseline and follow-up visits. They can also be used to group forms that are completed on demand (such as adverse events and other clinical events), and to sub-divide stages of a long real world visit (such as in hospital).

Visit dates

Within each visit you can optionally assign one of the date fields to be a *visit date*. The field chosen must be collected on a form in the visit, and it's recommended this field is **required**. If you set a visit date, it will be used on the Red Pill [visit summary report](#). This report shows, by site, how many subjects have completed this field, the range of dates entered, and an estimate of the number of subjects per month completing the visit date. As subjects accrue and move through the trial the report provides an overview of the flow of subjects through each stage.

Due dates

Visits can be scheduled by defining time-points when they become due. When visits are scheduled they show up on the Red Pill [overdue forms page](#) and due dates are shown in the [subject details](#) with overdue forms highlighted in red.

Visit details

Label *

Baseline

Visit is due

Subject details form is added

+ (offset)

0 days

The offset from the date specified above at which this visit occurs, e.g.

0 days

4 months

2 years

Red Pill will use this offset to calculate the visit due date and mark overdue visits

Visit date

Date of examination

This date will be used in the Red Pill visit summary report

Figure 5.1: Editing a baseline visit

Baseline

Due: 1 Dec 2017 [Mark as data missing](#)

Demographics

[Add](#) [View](#) [Edit](#)

Randomisation

[Add](#) [View](#) [Edit](#)

3 month follow-up

Due: 1 Mar 2018 [Mark as data missing](#)

Telephone contact 3m

[Add](#) [View](#) [Edit](#)

Home visit - extra

Due: Only if ulcer remains unhealed after 6 weeks

Home visit

[Add](#)

Figure 5.2: Schedule in Red Pill

The time-point when a visit is due is set in the visit details. The **Visit is due** dropdown allows any date in the CRF to be selected. It also includes the date forms were added to Red Pill. For example, a baseline visit could become due 0 days after the subject details form is added. This would mean as soon as the subject is added to the database, all baseline forms would become due.

An offset field allows visits to become due a defined period after the visit date. For example, a 3 month follow-up visit might be set to become due 3 months after the randomisation form is added (i.e. date of randomisation). Or an in-hospital form might become due 3 days after date of surgery. Even if you're not sure exactly when a visit will become due (e.g. a discharge visit), it is worth setting an offset to highlight visits that are outstanding after the visit would normally be expected to have taken place.

Edit visit

* indicates a required field

Visit details

Label *

Visit is due

+ (offset)

The offset from the date specified above at which this visit occurs, e.g.

0 days

4 months

2 years

Red Pill will use this offset to calculate the visit due date and mark overdue visits

Figure 5.3: 3 month visit

It is also possible to use arbitrary text to define when the visit is due. For example, you might describe an optional visit as due only if certain criteria are met. These text labels will be displayed in Red Pill but due dates will not be calculated and the visit will not appear on the [overdue forms page](#).

Visit details

Label *

Home visit - extra

Visit is due

as specified in the text field below 

Only if ulcer remains unhealed after 6 weeks

A label describing when the visit is due, e.g.

At discharge

Figure 5.4: Unscheduled visit

Chapter 6

Repeating form or repeating section?

A [form](#) can be *repeatable* to allow the same form, such as an adverse event form, to be recorded multiple times for the same subject.

But a single form can also contain a repeating *section* which also allows a set of questions to be answered multiple times for the same subject. So when designing your electronic CRF, you may have to choose between these two options for recording repeating questions.

How they are the same

- Repeating forms and repeating sections both allow a set of questions to be recorded multiple times for the same subject

How they are different

- Each completed **repeating form** is shown in the [subject details section of Red Pill](#) with a sequence number when viewing a subject. This makes it easy to see how many have been recorded.

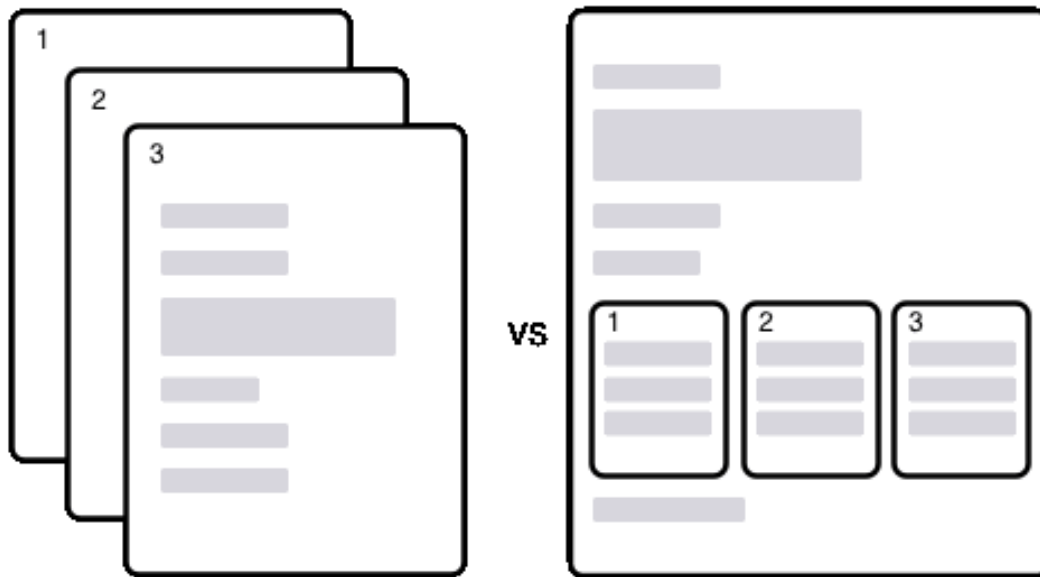


Figure 6.1: Repeating form vs section

Other forms

Due: at any time [Mark as data missing](#)

Serious Adverse Events

[Add](#)

Serious Adverse Events (#1)

[View](#) [Edit](#)

Serious Adverse Events (#2)

[View](#) [Edit](#)

Withdrawal

[Add](#) [View](#) [Edit](#)

A repeating form listed in the subject view

- Investigators can add another **repeating form** at any time. However, they can only add **repeating sections** once when adding the parent form. To add further sections they must later edit the form which requires the [investigator edit setting to be turned on](#).
- **Repeating sections** are displayed on a parent form as a series of panels. This makes it easy to see all responses at the same time.

Hospital admissions

Did your child stay at hospital overnight during the last 7 days? (reset)

Yes
 No

If 'Yes' please provide details below:

Hospital admissions

Hospital admissions

Name of hospital
 Bath

Reason for visit
 High temperature

Date of admission
 04/01/2017
 dd/mm/yyyy

Date of discharge
 05/01/2017
 dd/mm/yyyy

[Edit](#) [Delete](#) 

Hospital admissions

Name of hospital
 Bath

Reason for visit
 Surgery

Date of admission
 07/01/2017
 dd/mm/yyyy

Date of discharge
 09/01/2017
 dd/mm/yyyy

[Edit](#) [Delete](#) 

[Add Hospital admissions](#)

A form with a repeating section for hospital admissions

- With **repeating sections** you can include a leading question to ask whether any repeating sections are required. Sealed Envelope can add a [custom validator](#) to require none or at least one section to be completed depending on the answer given to the leading question.
- **Repeating sections** are stored in a [separate database table](#) from the parent form.

Recommendations

- Use repeating forms for events that can occur (unpredictably) at any time during the study
- If there are many questions to ask, repeating forms makes data entry easier and more manageable
- Repeating sections are useful for recording a limited set of questions at a particular visit, such as concomitant medications, information on family members or past hospital admissions. Consider adding a leading question to determine whether any repeating sections are expected and request a [custom validation rule](#) to enforce this.

Chapter 7

Customisation



Sealed Envelope can customise your Red Pill database to suit the requirements of your trial. Examples of the types of customisations that are commonly requested are:

- Hide forms for particular [user roles](#) or selected subjects (such as forms related to randomised treatment received)
- Create new user roles, such as a blinded account that does not see the randomised treatment group
- Send an email to administrators when a certain form in the CRF is completed
- Bespoke validation rules such as checking age based on date of birth
- Calculate fields, such as BMI based on height and weight

To request customisations please download and complete a [customisations form](#) and return it to Sealed Envelope when you have finished building your CRF.