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Introduction

The *CRC-Hub Study Designer* is an alternative to creating spreadsheets/documents that show the study schedule and to writing checklists on paper or in a document. It is for staff at clinical trial sites that work with paper to avoid having a computer between them and the patient. The CRC-Hub Study Designer is part of the CRC-Hub product.^[1] Throughout this document, 'Designer' is short for 'CRC-Hub Study Designer'.

To replace spreadsheets and other manually written documents the Designer supports:

- Defining the events in a study and optionally the details of their schedule. An event is typically a patient visit but it can be anything that needs to be done by site personnel
- Defining the checklist of things to do for each event.
- Generating a document(s) containing the schedule and checklists that can be printed or viewed online

Define Events and Their Schedule

Create or Select the Study

Clicking on the study name takes you to the pages where you can see the Study Design.

Name	Status	Therapeutic Area	Action
BE-X5	Planning	Oncology	
MK-3475-028	Active	Oncology	
XL-184-001	Active	Oncology	
AX-3476-001	Active	Hematology	
MK-2200-001	Complete	Hematology	

Define the Events

The study events/visits within the periods defines the overall structure.

The screenshot shows the CRCHub Study Designer interface. At the top, there's a navigation bar with the CRCHub logo, Home, Studies, Availability, and user icons (gear and MV). Below that is a breadcrumb navigation: Home > Studies > Study: XL-184-001. On the left, a sidebar displays study details: Name (XL-184-001), Title (Effect of Different Doses of SAR110894 on Growths in Patients With Mild to Moderate Cancerous Tumors), Status (Active), Phase (III), Therapeutic Area (Oncology), and Current Protocol (v1). The main content area is titled "Study Design". It shows a hierarchical structure of study periods and events. Under "STUDY PERIODS", there are two periods: "Period: Screening" and "Period: Treatment". "Period: Screening" contains five events: "Event: V1 run in", "Event: V2 rando", "Event: V2 run in", "Event: V1 rando", and "<+ events>". "Period: Treatment" contains one event: "Event: Treatment". There are also buttons for adding new periods and events.

The Designer makes it easy to create periods and their events [see video for details](#)

- Click the plus next to 'Study Periods' and enter the name
- Click the plus next to 'Events' and enter the name
- Click the \cong to make a smart copy of an event. The name is automatically incremented, e.g., 'V1' becomes 'V2' and scheduling dependencies are automatically duplicated and updated.
- Copy-and-Paste, Cut-and-Paste, or Drag-and-Drop one or more Events as needed
- Undo (ctrl-Z) and Redo (ctrl-Y) works here or anywhere else in the Designer

The goal is, if you know the schedule of events from the protocol, the Designer's understanding of study structure allows you to setup it faster than you could type the names into a document.

Define the Schedule

The Designer makes it easy to create complex schedules. In this example the 'V1 run in' visit is scheduled when 3 days after 'V1 rando' completes with a window of 2 days before or after. You are guided through schedule creation, e.g., when you get to the place showing 'when' you are given all the choices for when an event can be first scheduled and based on what you select other options are shown. It is like typing in Word or Excel if those tools *understood* clinical trials.

▼ EVENTS

Event: V1 run in

Alt-Name: Week - 4
Type: site
<Description>

▼ SCHEDULE

First scheduled: when V1 rando → completed + 3 days
with a window of: at most 0 day(s) before
 2 day(s) before
 2 day(s) after
 at most 0 day(s) after
and then repeats: <choose>
limited to this time of day: <choose>

Event: V2 rando

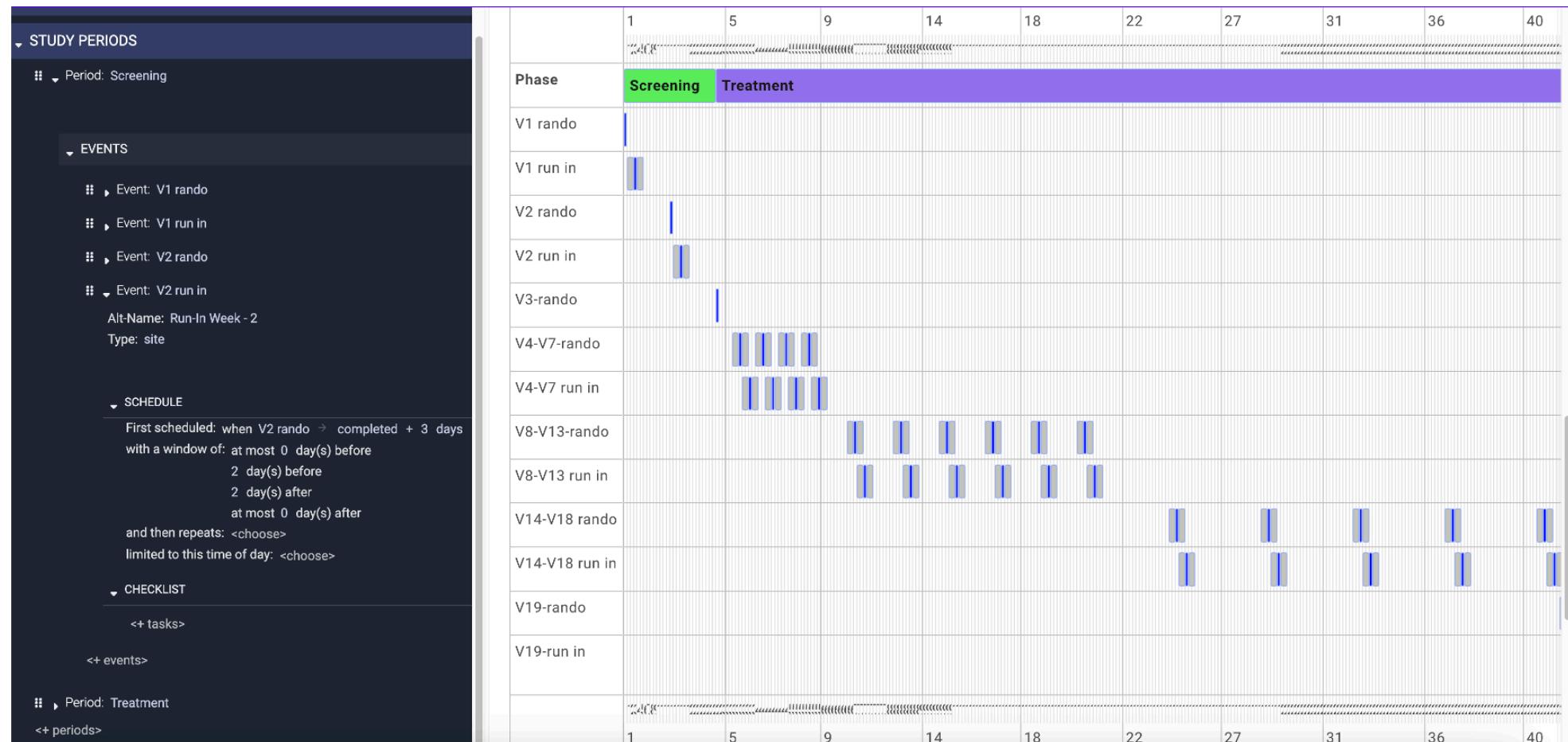
Event: V2 run in

Event: V1 rando

<+ events>

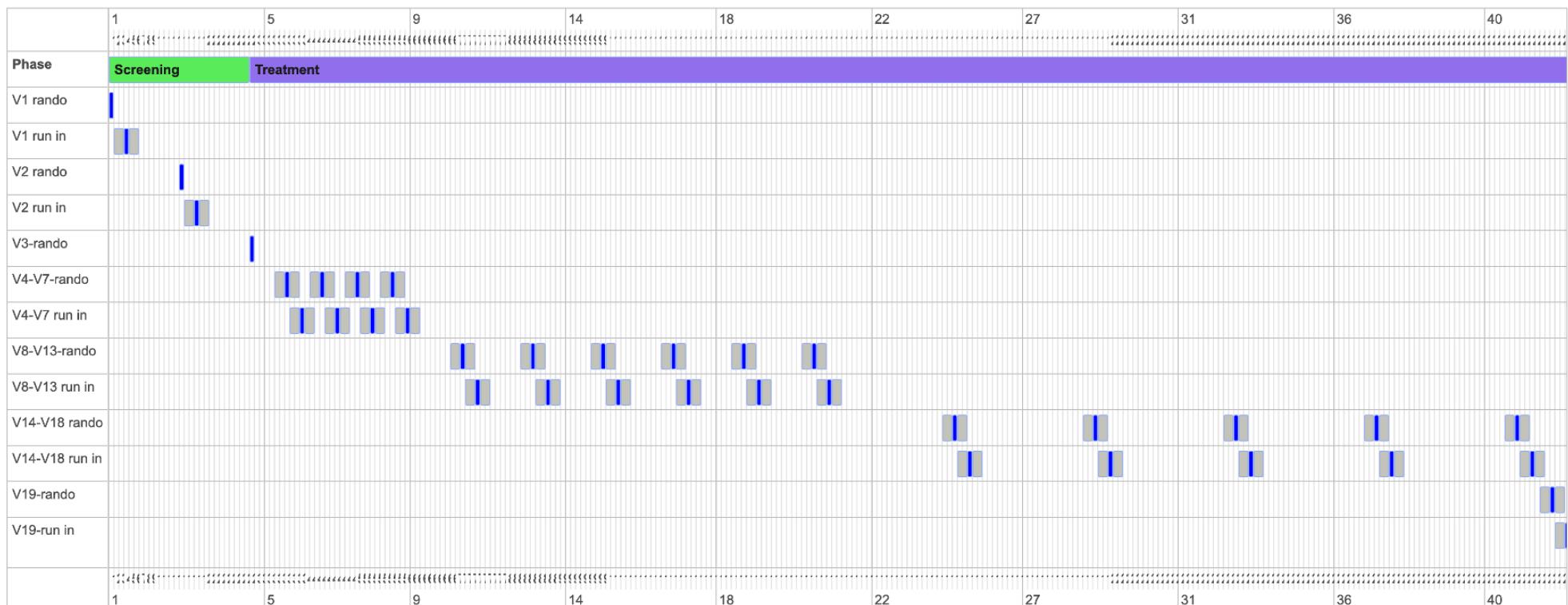
View Schedule Charts

Accurately creating anything but a simple study schedule is hard because of things like dependencies between visits, repeating visits, and overlapping windows. The Designer allows you to immediately view a chart of the schedule that you can zoom and scroll through. You can seamlessly move back and forth between trying different ways to express the schedule and seeing if it's correct. The following shows a chart with repeating visits that have complex dependencies.



This chart shows the entire study duration so only some of the study weeks are displayed on the axis.

Study Timeline

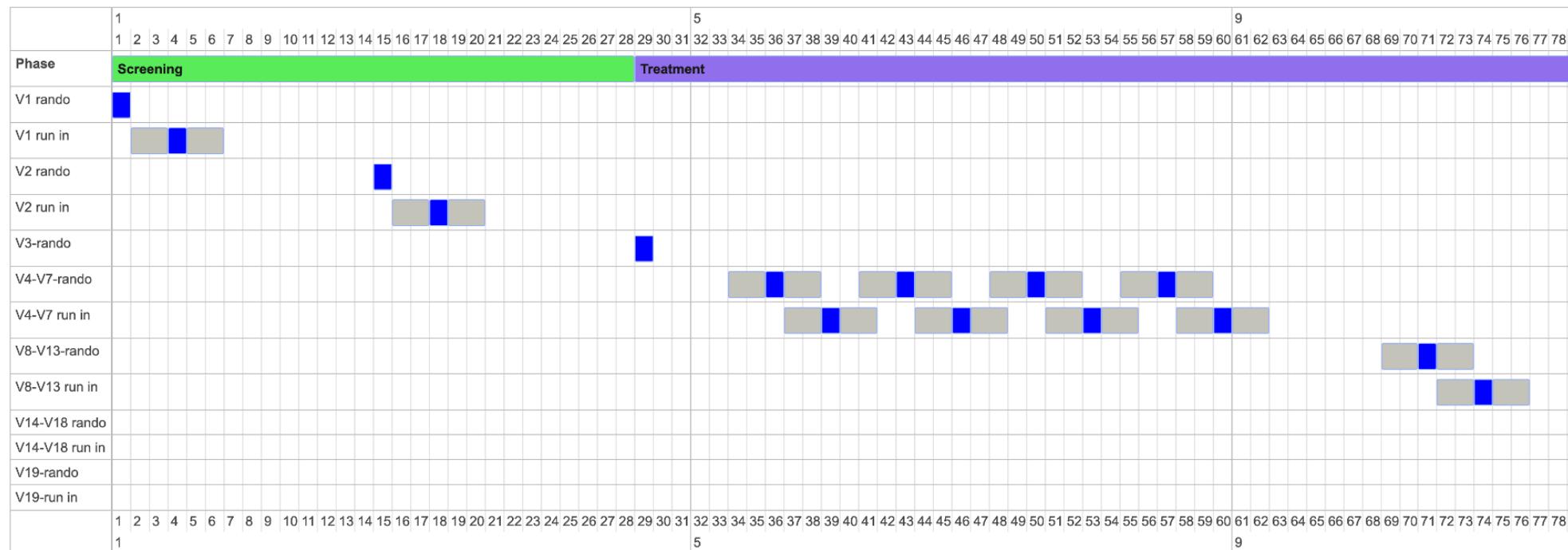


█ Scheduled time of an Event/Visit

Window before and after a Scheduled Event/Visit

Zooming in on the Study Timeline shows study days and study weeks.

Study Timeline



View Schedule Tables

The timeline of study events can also be viewed as a table with the same seamless moving back and forth between the schedule and the table.

OPTIONS

STUDY PERIODS

B → Period: Screening

EVENTS

II → Event: V1-mando
Alt-Name: Rando Week - 4
Type: site

SCHEDULE

First scheduled: Study Start - 4 weeks
with a window of: at most 0 day(s) before
0 day(s) after
0 day(s) after
at most 0 day(s) after
and then repeats: <choose>
Limited to this time of day: <choose>

CHELIST

II → Task: Task 1
++ tasks++

II → Event: V1-run-in

II → Event: V2-mando

II → Event: V2-run-in
++ events++

B → Period: Treatment

EVENTS

II → Event: V3-mando

II → Event: V4-V7-mando

II → Event: V8-V13-mando

II → Event: V8-V13-run-in

II → Event: V14-V18-mando
Alt-Name: Special Alt Name
Type: site

SCHEDULE

First scheduled: when V8-V13-mando is completed + 4 weeks
with a window of: at most 0 day(s) before
2 day(s) before
2 day(s) after
at most 0 day(s) after
and then repeats: 4 times
Limited to this time of day: <choose>

CHELIST

++ tasks++

ERRORS	SEARCH	SIMULATION			
Study Timeline Table					
Visit Name	Alternative Name	Phase	Window (-)	Day/Date	Window (+)
V1-mando	Rando Week - 4	Screening	0	-27	0
V1-run-in	Run-In Week - 4	Screening	2	-24	2
V2-mando	Rando Week - 2	Screening	0	-13	0
V2-run-in	Run-In Week - 2	Screening	2	-10	2
V3-mando	Study Start	Treatment	0	1	0
V4-V7-mando	Rando V1	Treatment	2	8	2
V4-V7-run-in	Run-In V1	Treatment	2	11	2
V4-V7-mando	Rando V2	Treatment	2	15	2
V4-V7-run-in	Run-In V2	Treatment	2	18	2
V4-V7-mando	Rando V3	Treatment	2	22	2
V4-V7-run-in	Run-In V3	Treatment	2	25	2
V4-V7-mando	Rando V4	Treatment	2	29	2
V4-V7-run-in	Run-In V4	Treatment	2	32	2
V8-V13-mando	Rando V1	Treatment	2	43	2
V8-V13-run-in	Run-In V1	Treatment	2	46	2
V8-V13-mando	Rando V2	Treatment	2	57	2
V8-V13-run-in	Run-In V2	Treatment	2	60	2
V8-V13-mando	Rando V3	Treatment	2	71	2
V8-V13-run-in	Run-In V3	Treatment	2	74	2
V8-V13-mando	Rando V4	Treatment	2	85	2
V8-V13-run-in	Run-In V4	Treatment	2	88	2
V8-V13-mando	Rando V5	Treatment	2	99	2
V8-V13-run-in	Run-In V5	Treatment	2	102	2
V8-V13-mando	Rando V6	Treatment	2	113	2
V8-V13-run-in	Run-In V6	Treatment	2	116	2
V14-V18-mando	Special Alt Name	Treatment	2	141	2
V14-V18-run-in	V14-V18-run-in	Treatment	2	144	2
V14-V18-mando	Special Alt Name (2)	Treatment	2	169	2
V14-V18-run-in	V14-V18-run-in (2)	Treatment	2	172	2
V14-V18-mando	Special Alt Name (3)	Treatment	2	197	2
V14-V18-run-in	V14-V18-run-in (3)	Treatment	2	200	2
V14-V18-mando	Special Alt Name (4)	Treatment	2	225	2
V14-V18-run-in	V14-V18-run-in (4)	Treatment	2	228	2
V14-V18-mando	Special Alt Name (5)	Treatment	2	253	2
V14-V18-run-in	V14-V18-run-in (5)	Treatment	2	256	2
V19-mando	V19-mando	Treatment	2	260	2
V19-run-in	V19-run-in	Treatment	2	263	2

A variety of table formats can be supported, e.g., visits of different types shown side-by-side instead of one longer table. Events can be given alternative names that automatically reflect counts of repeating visits, e.g., 'V14-V18 run in (2)' for the second occurrence of a visit in the 'V14-V18 run in' repetitions.

Define Checklists

A *checklist* defines the tasks to be done during a visit. The Designer makes it easy to create checklists of things to do at any visit/event.

STUDY PERIODS

Period: Screening

EVENTS

Event: ICF (1A)

Alt-Name:

Type: site

SCHEDULE

CHECKLIST

Task: Informed Consent

Task: Patient History and Medication Review

Task: Patient Assessments and Procedures

Task: Patient Eligibility Review

<+ tasks>

Event: Screening (1B/1C)

■ ► Event: BAE (2A)

■ ► Event: BAE (2B)

<+ events>

■ ► Period: Treatment

Checklists are shared and standardized rather than custom created in something like a spreadsheet, document, or notebook. To start, only a minimum can be captured, e.g., just a list of tasks to be done in a visit as shown above for the Informed Consent visit.

Steps

The steps that describe the details of how to do a task can be added.

☰ Event: ICF (1A)

Alt-Name:

Type: site

▶ SCHEDULE

▼ CHECKLIST

☰ Task: Informed Consent

The purpose of this task is to obtain informed consent from the patient. This will involve discussing the study with them, then an internal medical discussion to determine their eligibility to move forward.

▼ STEPS

☰ Step: Obtain Informed Consent

☰ Step: Record Consent Decision

☰ Step: Inform Internal Medical Personnel

<+ steps>

☰ Task: Patient History and Medication Review

☰ Task: Patient Assessments and Procedures

☰ Task: Patient Eligibility Review

<+ tasks>

Step Details

Details about each step can be added.

Event: ICF (1A)

Alt-Name:

Type: site

► SCHEDULE

▼ CHECKLIST

■ ■ Task: Informed Consent

The purpose of this task is to obtain informed consent from the patient.

This will involve discussing the study with them, then an internal medical discussion to determine their eligibility to move forward.

▼ STEPS

■ ■ Step: Obtain Informed Consent

- Explain the study details, including purpose, procedures, risks, and benefits to the patient
- Obtain informed consent from the patient, ensuring they understand and agree to the study terms
- [Optional] Discuss with the patient about the possibility of using their data for future research

► REFERENCES

► SYSTEMS

► PEOPLE

■ ■ Step: Record Consent Decision

■ ■ Step: Inform Internal Medical Personnel

<+ steps>

Details about each step can include things like referenced documents or people to contact. This is particularly useful when the checklist is viewed online because you can click on the links to references or contacts.

Event: ICF (1A)

Alt-Name:

Type: site

SCHEDULE

CHECKLIST

Task: Informed Consent

The purpose of this task is to obtain informed consent from the patient.

This will involve discussing the study with them, then an internal medical discussion to determine their eligibility to move forward.

STEPS

Step: Obtain Informed Consent

- Explain the study details, including purpose, procedures, risks, and benefits to the patient
- Obtain informed consent from the patient, ensuring they understand and agree to the study terms
- [Optional] Discuss with the patient about the possibility of using their data for future research

REFERENCES

SYSTEMS

PEOPLE

Step: Record Consent Decision

Step: Inform Internal Medical Personnel

<+ steps>

Save or Print Study Design

By the press of a button, some or all of the chart and table views of the schedule and the checklist are saved as a document. The document can be printed to support using the studies printed data collection forms.

The study design as a document contains the following sections.

Table of Contents Section

The printable document starts with a table-of-contents. Not all the sections in the document are populated in this example, e.g., there are no checklists for the Treatment period. There is no requirement that you fill them all. You might start with just the first few and add details as you do real visits.

Study 123ABC

Author: Mike Vogel CRC Manager

Date: 09/20/2024

▼ Study Timeline

- [Table](#)
- [Chart](#)

▼ Screening Period

▼ ICF (1A)

- Task: Informed Consent
- ▼ Step 1 - Obtain Informed Consent
 - REFERENCES
 - PEOPLE
- ▼ Step 2 - Record Consent Decision
 - REFERENCES
- ▼ Step 3 - Inform Internal Medical Personnel
 - PEOPLE

▼ Screening (1B/1C)

- Task: Patient History and Medication Review
- ▼ Step 1 - Review with Patient
 - REFERENCES
 - PEOPLE
- ▼ Step 2 - Internal Medical Review
 - PEOPLE
- Task: Patient Assessments and Procedures
- Task: Patient Eligibility Review
- BAE (2A)
- BAE (2B)

▼ Treatment Period

- Randomization (3A)
- [Dose Admin \(3A\)](#)

- [Dose Admin \(3A\)](#)
- [Dose Admin \(3B\)](#)
- [Dose Admin \(3C\)](#)
- [Dose Admin \(3D\)](#)
- [Dose Admin \(3E\)](#)
- [PAC1 \(4A\)](#)
- [Dose admin/PAC1 \(3F/4B\)](#)
- [Dose admin/PAC1 \(3G/4C\)](#)
- [Dose admin/PAC1 \(3G/4C\)](#)
- [Dose admin/PAC1 \(3H/4D\)](#)
- [Dose Admin \(3G\)](#)
- [Dose Admin \(3H\)](#)
- [End of dose \(3I\)](#)
- [PAC2 \(4C\)](#)
- [PAC2 \(4D\)](#)

Timeline Section

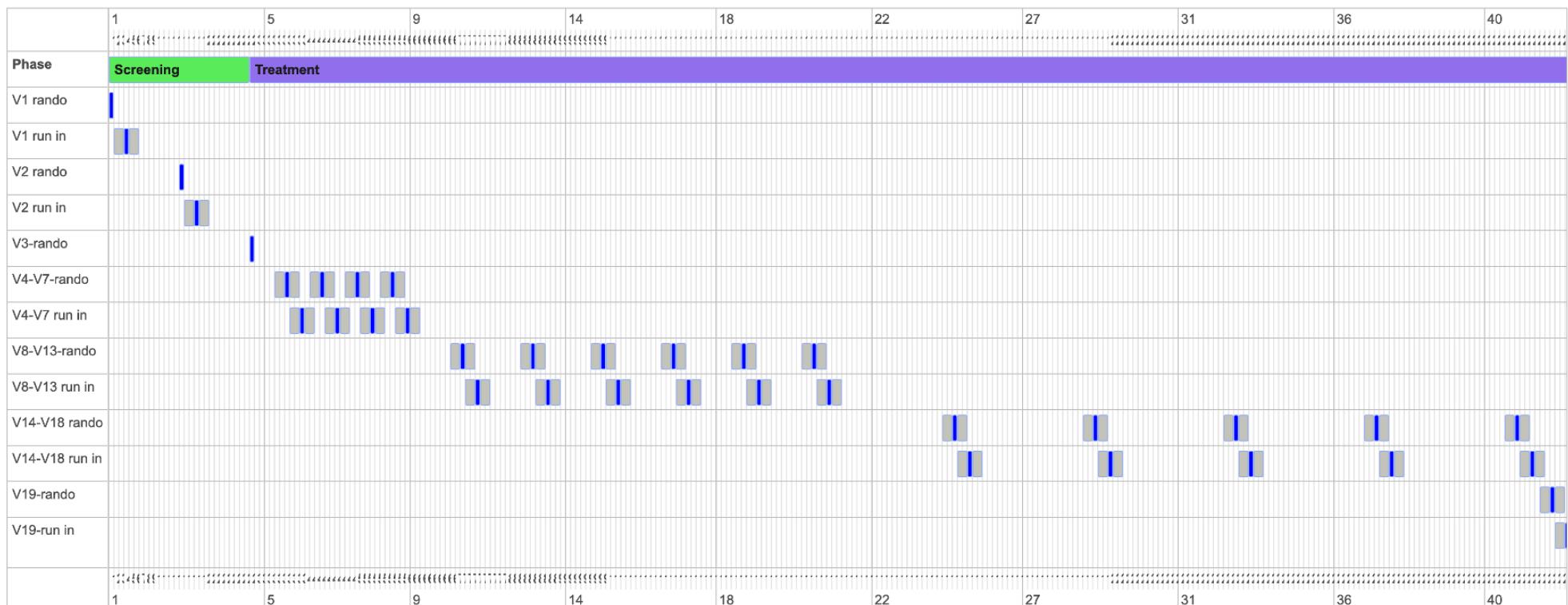
Study Timeline

Table

Visit Name	Alternative Name	Phase	Window (-)	Day/Date	Window (+)
ICF (1A)		Screening	0	-56	0
Screening 1B/1C		Screening	1	-55	1
BAE (2A)		Screening	0	-20	0
BAE (2B)		Screening	0	-6	6
Randomization (3A)		Treatment	0	1	0
Dose Admin (3A)		Treatment	2	29	2
Dose Admin (3B)		Treatment	2	57	2
Dose Admin (3C)		Treatment	2	85	2
Dose Admin (3D)		Treatment	2	113	2
Dose Admin (3E)		Treatment	2	141	2
PAC1 (4A)		Treatment	2	169	2
Dose admin/PAC1 (3F/4B)		Treatment	2	197	2
Dose admin/PAC1 (3G/4C)		Treatment	2	197	2
Dose admin/PAC1 (3G/4C)		Treatment	2	197	2
Dose admin/PAC1 (3H/4D)		Treatment	2	197	2

Dose Admin (3G)		Treatment	2	225	2
Dose Admin (3H)		Treatment	2	253	2
End of dose (3I)		Treatment	2	281	2
PAC2 (4C)		Treatment	2	316	2
PAC2 (4D)		Treatment	2	330	2
PAC3 (4E)		Treatment	2	407	2
PAC3 (4F)		Treatment	2	421	2
Follow up (5)		Treatment	5	421	5

Study Timeline



Checklists Section

Screening Period

ICF (1A)

The purpose of this task is to obtain informed consent from the patient. This will involve discussing the study with them, then an internal medical discussion to determine their eligibility to move forward.

First scheduled: when Last completed + 4 days
with a window of: at most 0 day(s) before
0 day(s) before
0 day(s) after
at most 0 day(s) after

and then repeats:

limited to this time of day:

Task: Informed Consent

- Informed Consent Completed

Step 1 - Obtain Informed Consent

- Explain the study details, including purpose, procedures, risks, and benefits to the patient
- Obtain informed consent from the patient, ensuring they understand and agree to the study terms
- [Optional] Discuss with the patient about the possibility of using their data for future research



REFERENCES

- Protocol - Consent Definition
- Protocol - Inclusion/Exclusion Criteria
- Consent Form
- Guidance on Research Use of Data

PEOPLE

- Patricia Bellweather (Patient Recruiter) pbellweather@mail.com 509.555.3419

Step 2 - Record Consent Decision

- File the signed consent form in the patients clinical study folder
- Scan the signed consent form into the EHR system
- Record the signed consent into the EDC system

REFERENCES

- Record Keeping Guidelines
- Epic EHR (Robot Script Available)
- Medidata EDC (Robot Script Available)

Step 3 - Inform Internal Medical Personnel

- Email Patricia with the result of the consent
- Inform Rachel and Mark about the patient consent

PEOPLE

- Patricia Bellweather (Patient Recruiter) pbellweather@mail.com 509.555.3419
 - Rachel Auchliff (Site Rater) rauchliffe@mail.com 957.555.2323
 - Mark Davis (Clinical Trial Administrator) mdavis@mail.com
-

Benefits

While conducting a patient visit:

- The checklist can serve as guidance for details of things to be done in or after the visit as well as how to fill the paper or electronic data collection forms.
- The schedule chart can be used to review the patients timeline and schedule future visits

Paper or electronic versions of checklists are particularly helpful when:

- Working on a new study
- Covering for someone or someone is covering for you
- As living SOPs that can be reviewed with monitors, sponsors, or IRBs

View Patient Charts

The Designer also allows entry of the dates of patients visit and dates when the patient isn't available. A patient chart can be generated showing this information.

PATIENTS

⋮ Patient: MV

▼ VISITS

V1 rando completed on day 09/30/2024 □

V1 run in completed on day 10/02/2024 □

V2 rando completed on day 10/05/2024 □

<+ patientVisits>

▼ NOT AVAILABLE

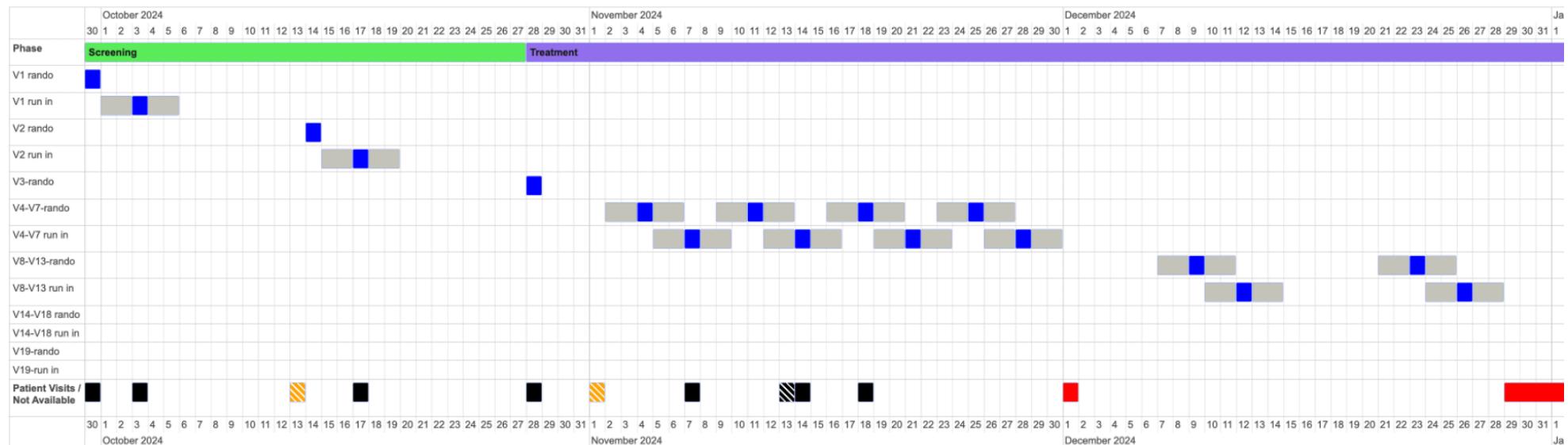
10/24/2024 □ thru: 11/05/2024 □

02/24/2024 □ thru: <choose>

<+ dates>

⋮ Patient: SHD

⋮ Patient: GM

Study Timeline

- █ Scheduled time of an Event/Visit
- Window before and after a Scheduled Event/Visit
- Date patient visit occurred on the scheduled date
- Date patient visit occurred in the scheduled window
- Date patient visit occurred outside the scheduled window
- Date(s) the patient is unavailable

View Staff Availability Charts

The availability of staff or other resources can be entered and included on the charts. The following shows a study schedule with staff availability.

STAFFING

Number of CRCs Normally Available: 5

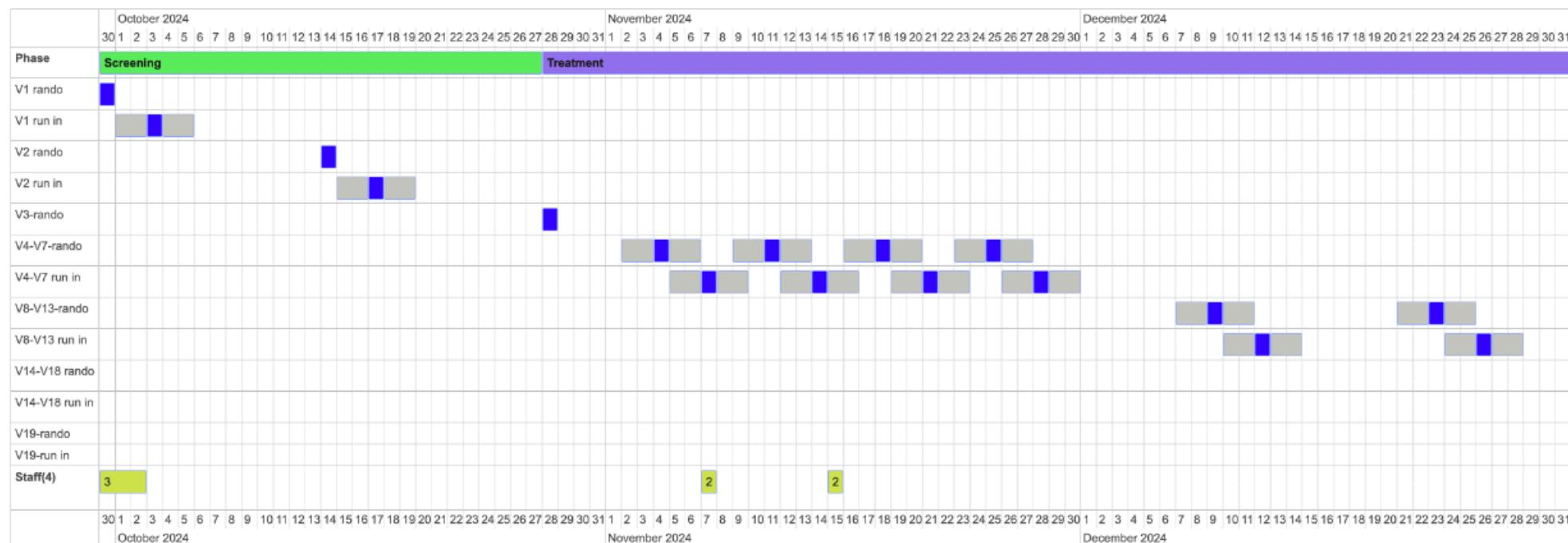
Staffing Level Changes:

Staff: 3 on: 10/24/2024 ☐ thru: <choose>

Staff: 4 on: 11/01/2024 thru: 11/15/2024

<+ staffLevels>

Study Timeline



2 Staff(#) - '(#)' is the total amount of staff available for the study. The number in the box is the staff on that date. The full staff is available on any date without a box with a number

1. This document describes using the Designer. The full CRC-Hub product is for sites that want to be guided on a computer, rather than paper, through the tasks done for a study. When used with the full CRC-Hub, the Designer generates the study specific web site and checklists of tasks. The full CRC-Hub features are not the focus here. ↵