

## 3.4.1 OpenClinica Navigation

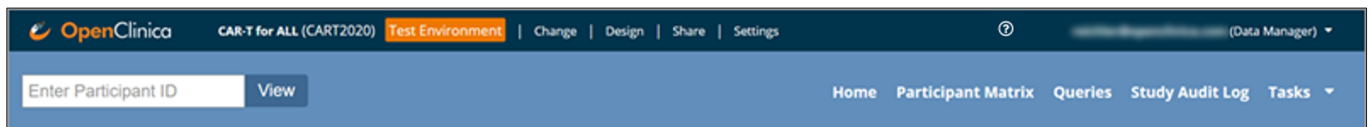
There are two main areas in OpenClinica:

- **Study Runner:** the part of the system where your studies are carried out
- **Study Build System:** where studies are configured, then published to Study Runner

### Study Runner:

All users can access Study Runner, but the home screen you will see depends on your user role, as does access to certain features. Features in Study Runner include:

- The **Home** screen, which can be the **Welcome** screen, **Participant Matrix**, or **Source Data Verification** screen (depending on role)
- The **Participant Details** screen
- The **Queries** screen
- The **Study Audit Log**
- The **Tasks** menu and associated tasks
- The **User** menu
- **Quick Access** links to queries assigned to you and recently accessed Participant information



The Header Bar Displays:

- Top Row (from left to right):
  1. The Study Name and Study ID
  2. If you are in the test environment it will display a banner to the right of the study id. This space will be empty in the production environment.
  3. The **Change**, **Share**, and **Settings** buttons. (Only users who are **Data Managers** and **Administrators** see the **Design** button.)
  4. Your user id and the downward arrow that will open your user menu, the contents of which depend on your specific role.
- Second Row (from left to right):
  1. Participant ID Search/Lookup
  2. Links to menus and certain areas within Study Runner

### Study Build System:

Only **Data Managers** and **Administrators** can access the **Study Build System**. This includes the following screens, which are presented in detail throughout this guide.

OpenClinica My Studies

**Ray's OC4UM Demo Study**

● AVAILABLE in test ○ UNPUBLISHED in production

A study to QC user manual and capture images.  
Study ID: ray01  
Study Type: Other  
Expected Enrollment: 100  
Expected Duration: 07-Jun-2021 to 30-Jun-2021

Design Share Go

**CAR-T Study**

● AVAILABLE in test ● AVAILABLE in production

A Phase IIB, double-blind, multi-center study of CAR-T cell therapy in adults with acute lymphoblastic leukemia.  
Study ID: CART2019  
Study Type: Interventional, Phase II  
Expected Enrollment: 400  
Expected Duration: 20-Aug-2019 to 31-Dec-2020

Design Share Go

**Target Study**

● AVAILABLE in test ○ UNPUBLISHED in production

This is for a mock migration.  
Study ID: Target  
Study Type: Interventional, Phase III  
Expected Enrollment: 100  
Expected Duration: 16-Jun-2021 to 16-Jun-2023

Share Go

**Alex's Study**

● AVAILABLE in test ○ UNPUBLISHED in production

Test Study  
Study ID: Alex123  
Study Type: Observational  
Expected Enrollment: 100  
Expected Duration: 01-Jun-2021 to 01-Jun-2022

Share Go

**SV0527**

○ UNPUBLISHED in test ○ UNPUBLISHED in production

SV0527  
Study ID: SV0527  
Study Type: Observational  
Expected Enrollment: 100  
Expected Duration: 08-Oct-2020 to 30-Nov-2021

Share Go

**PAB 18**

● AVAILABLE in test ● AVAILABLE in production

PAB Study 18 Stack 13.3  
Study ID: PAB18  
Study Type: Interventional, Phase I  
Expected Enrollment: 100  
Expected Duration: 01-Jun-2018 to 31-Dec-2025

Share Go

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CAR-T Study (CART2019)

Settings User Roles Modules

**Study Settings**

ID: CART2019  
Name: CAR-T Study  
Description: A Phase IIB, double-blind, multi-center study of CAR-T cell therapy in adults with acute lymphoblastic leukemia  
Type: Interventional  
Phase: Phase II  
Expected Number of Participants: 400  
Disable adding new participants when expected number is reached: No  
Expected Start Date: 20-Aug-2019  
Expected End Date: 31-Dec-2020

**Participant ID Settings**

Method of Creation: System-generated  
ID Template: %SiteID%\$site\$ParticipantCount+1\$zeroing\$000\$

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CAR-T Study (CART2019)

Settings User Roles Modules

**User Roles**

Role	Description	Access	Actions
CEC (Data Entry Person - STUDY)	CEC	Unmanaged Forms, [Evaluator A], [Evaluator B], Review, Suspended [X]	Edit
Clinical Research Coordinator (Clinical Research Coordinator - SITE)	Site-level role with permission to create, view, edit, and remove records; add and update queries; import data.	Unmanaged Forms, [Eligibility], [Consent], [Assignment], [Enrollment], [All Report], [Links]	Edit
Coder (Data Manager - STUDY)	Coding	Unmanaged Forms, [CTD], [Coding], [All Report]	Edit
Data Entry Person (Data Entry Person - STUDY)	Study-level role with permission to create, view, edit, and remove records; add and update queries; import data.	Unmanaged Forms	Edit
Study Monitor (Monitor - STUDY)	Study-level role with permission to view and SOV records; add, update, and close queries; extract data.	Unmanaged Forms, [Consent], [Coding], [Data Manager], [Assignment], [Enrollment], [CTD and SOV], [Consent], [Suspended], [Eligibility], [CTD], [Evaluator A], [EAC ID], [EAC], [Evaluator B], [CIC], [Evaluator A and B], [CIC and Both Adjustments], [Suspended], [EAC], [Evaluator B and SOV], [All Report], [Links]	Edit
Study Viewer (Viewer - STUDY)	Study-level role with permission to view records; no permission to modify data, add or update queries, or extract data.	Unmanaged Forms	Edit

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CAR-T Study (CART2019)

● PRODUCTION Environment ● TEST Environment  
Status: Available Change Status  
Share by inviting people and adding sites to the study. Jump to Publish History

**People**

First	Last	Username	Email	Organization	Phone	Role	Type	Status	Created (UTC)
Andrea	Flathers	afathers+SVIEW	afathers+SVIEW@openclinica.com	OpenClinica	1112223333	Study Viewer	User	Available	17-Jun-18:43
Andrea	Flathers	afathers+SMON	afathers+SMON@openclinica.com	OpenClinica	1112223333	Study Monitor	User	Available	17-Jun-18:42

**Sites**

Name	ID	Lead Investigator	IBB Approval Date	Expected Start Date	Expected Number of Participants	Site Location	Primary Contact	Created (UTC)	Updated (UTC)	Status	Actions
DanaFarber	DF	Dr. Farber			100	Boston		16-Sep-2019 16:44	10-Feb-2020 02:02	Available	Edit
Watham	WAL	Dr. Wall	05-Apr-2020	06-Apr-2020	100	Watham, MA 02451		06-Apr-2020 11:45	16-Aug-2020 20:48	Available	Edit

**Publish History**

Revision	User	Date (UTC)
201	Elizabeth Prager	21-Apr-2021 15:49
200	Elizabeth Prager	21-Apr-2021 15:22
199	Ben Baumann	02-Sep-2020 01:52
4	Bryan Farrow	16-Sep-2019 16:54
3	Bryan Farrow	16-Sep-2019 16:37
2	Bryan Farrow	16-Sep-2019 15:58
1	Bryan Farrow	16-Sep-2019 15:53

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CAR-T Study (CART2019)

Settings User Roles Modules

**Participate**

With OpenClinica Participate, you have total control over when forms are available for each subject, and the data is captured in real time. The underlying audit trail offers objective evidence that the subjects completed the forms in the timeframe dictated by the protocol. Learn more

Status: Active  
URL for PRODUCTION Environment: https://stf01.myclinical.com/ URL for TEST Environment: https://stf01test.myclinical.com/ Deactivate

**Insight**

Intelligent, visual reporting of all your data has arrived. OpenClinica's Insight module turns data into analytics and action. Learn more

Status: Active Deactivate

**Randomize**

OpenClinica's Randomize module allows you to conveniently randomize from within your OpenClinica study. Full configuration support and training provided. Learn more

Status: Active Deactivate

OpenClinica Status: Revision 198

CAR-T Study (CART2019)

Library Management Form Template Table Design Share Publish Go

**Informed Consent**

Informed Consent + Add a form

**Source Documents**

Source Document + Add a form

**Demo Event**

+ Add an event

Functional approval by Kate Lambert. Signed on 2024-11-06 3:15PM

Approved for publication by Paul Bowen. Signed on 2025-02-10 1:28PM

Not valid unless obtained from the OpenClinica document management system on the day of use.