

3.4.1 OpenClinica Navigation

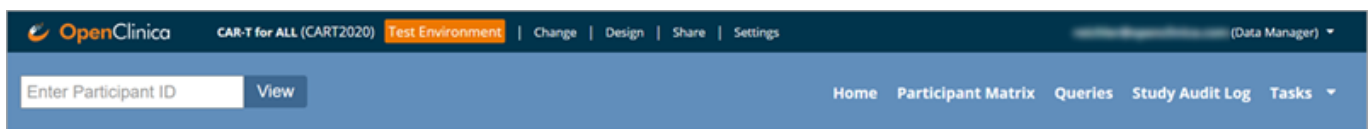
There are two main areas in OpenClinica:

- **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AVAILABLE in test UNPUBLISHED in production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

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

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AVAILABLE in test UNPUBLISHED in production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

Alex's Study

AVAILABLE in test UNPUBLISHED in production

Test Study
Study ID: Alex23
Study Type: Observational
Expected Enrollment: 100
Expected Duration: 01-Jun-2021 to 01-Jun-2022

Share

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

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

OpenClinica 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\$trailing\$000\$

OpenClinica CAR-T Study (CART2019)

Settings User Roles Modules

User Roles

Role	Description	Access	Actions
CEC (Data Entry Person - STUDY)	CEC	Unassigned Forms, Eligibility, Enrollment, Review, Expected ID	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.	Unassigned Forms, Eligibility, Enrollment, Assignment, Enrollment, All Report, Links	Edit
Coder (Data Manager - STUDY)	Coding	Unassigned Forms, CTDR, 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.	Unassigned Forms	Edit
Study Monitor (Monitor - STUDY)	Study-level role with permission to view and SDV records; add, update, and close queries; extract data.	Unassigned Forms, Control, Coding, Case Manager, Assignment, Enrollment, CCR and SDV, Unassigned Forms, Expected ID, Enrollment, Eligibility, CTDR, Evaluator A, Evaluator B, Evaluator C, Evaluator D, Evaluator E, Evaluator F, Evaluator G, Evaluator H, Evaluator I, Evaluator J, Evaluator K, Evaluator L, Evaluator M, Evaluator N, Evaluator O, Evaluator P, Evaluator Q, Evaluator R, Evaluator S, Evaluator T, Evaluator U, Evaluator V, Evaluator W, Evaluator X, Evaluator Y, Evaluator Z, CCR and Both Adjustments, Enrollment, 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.	Unassigned Forms	Edit

OpenClinica 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.mvtrial.net/>
URL for TEST Environment: <https://stf01test.mvtrial.net/>

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 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	111223333	Study Viewer	User	Available	17-Jun-18:43
Andrea	Flathers	afathers-SMON	afathers-SMON@openclinica.com	OpenClinica	111223333	Study Monitor	User	Available	17-Jun-18:42

Sites

Name	ID	Lead Investigator	IRB Approval Date	Expected Start Date	Expected Number of Participants	Site Location	Primary Contact	Created (UTC)	Updated (UTC)	Status	Actions
Dana-Farber	DF	Dr. Farber			100	Boston		16-Sep-2019 16:44	10-Feb-2020 02:02	Available	Edit
Waltham	WAL	Dr. Wall	05-Apr-2020	06-Apr-2020	100	Waltham, MA 02451		06-Apr-2020 11:45	14-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

OpenClinica CAR-T Study (CART2019)

Library Management Form Template Table Design

Informed Consent

Informed Consent

Source Documents

Event Demo

Approved for publication by Ben Baumann. Signed on 2021-07-19 10:56AM

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