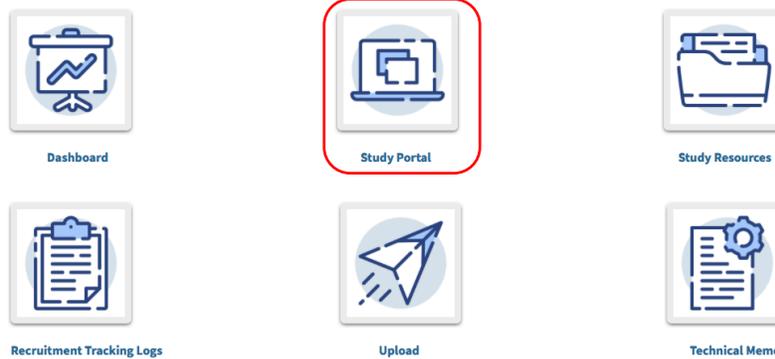The LIMBIC-CENC website provides access to the Prospective Longitudinal Study (PLS) Study Portal.

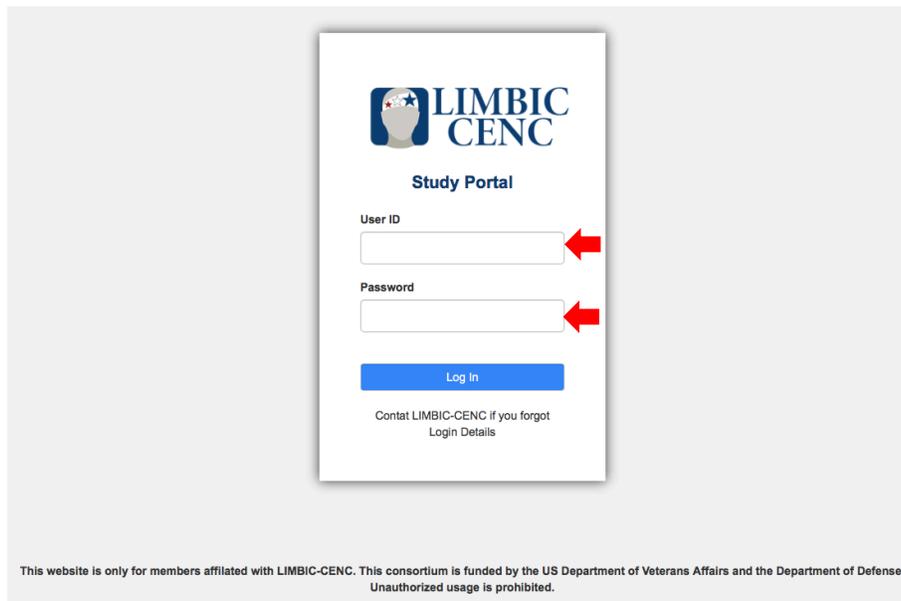To access the study portal, click on the "Study Portal" icon on the "Longitudinal Study Operations" page.

Login and Password Reset

Enter your username and temporary password and click on "Log in" to complete your login.

After your first login, you must change the temporary password provided to you by the DBC. To do so,

Click on the "Account" button in the upper right-hand portion of the screen. Then, click on "Change Password". Please make sure your new password meets all the requirements specified in Red

Contact LIMBIC-CENC Data and Biostatistics Core to request study portal account for new users.

Study Portal

On the landing page, you will see two modules:

- **Contact Information Management System (CIMS) Module:** This is the initial data entry point for the creation and storage of a participant's name and contact information

a. **Create Subject**

To add a new participant, click on 'Contact Information Management System' and then click on 'Create Subject'.

A Study ID is only assigned once a participant is enrolled/consented in the PLS and should be entered only once in the CIMS to create a record for the participant. **Participant IDs should not be reused**.

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System edit checks are in place to ensure that the participant IDs are unique within a site. The site coordinator will be able to fill in the details for the participant including preferred time of call, preferred phone number, date of Baseline visit and the Index date. Clicking on 'Create' will save the details.

Please note that 'Time Zone' refers to the time zone in which the participant is located; however, the 'Preferred Time of Call' selections should be in Eastern Standard Time (EST), regardless of the selected time zone.
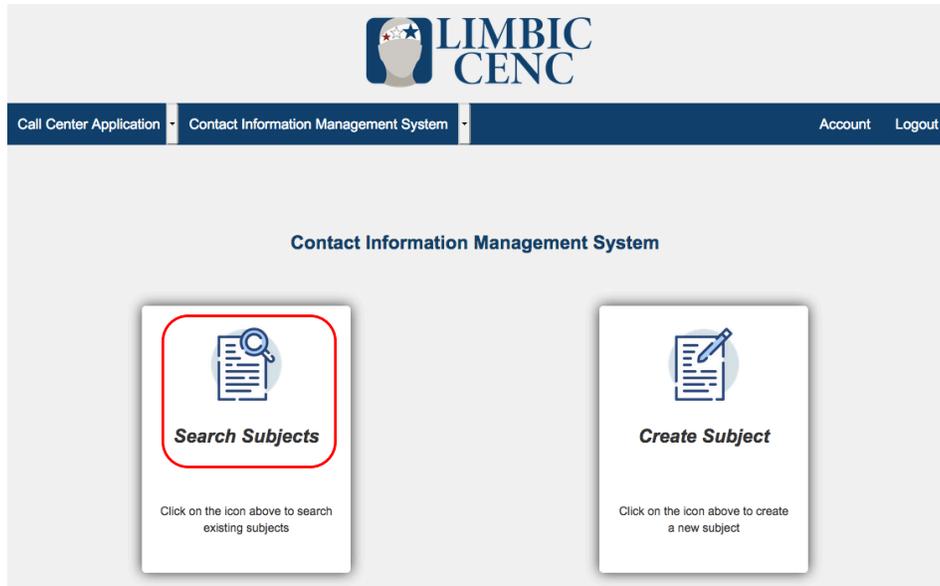

Contact Information management System- Create Subject system edit checks:

- Subject ID must be valid and unique

- Subject ID, first name, last name, primary phone number, and baseline date are required and can't be blank

- You may leave the index date blank if you don't have the information when creating the subject; however, this field is required, and you must enter the date as soon as the participant is indexed. Records marked with * are missing the Index Date.

- Only alphabetical entries are acceptable for first and last name.

- Phone numbers must be valid

- Index date can't be after the Baseline Date

- The BTACT must be scheduled within 14 days of the Baseline date.

b. **Search Subject**

Information saved on the CIMS Create Subject page will also be available for Call Center users. Both the site Coordinator and Call Center staff can make changes to participants' contact information and the most up-to-date information will be displayed in CIMS to maintain consistency of information. To update the participant information:

Click on the 'Search Subjects' button

Search for the participant using first name, last name, or subject ID and Click on the Subject ID to open the subject profile page.

Update the participant details and click on 'Edit Contact Information' to save the changes. You will be able to update all the details for the participant except for Subject ID, Baseline Date, and Index Date, which will be locked as soon as you create a new subject.

Once the site coordinator updates the contact information, an email notification will be sent to the Call Center users notifying them of the change.

- **Call Center Module:** This is used primarily by Call Center staff and for scheduling BTACT visits.
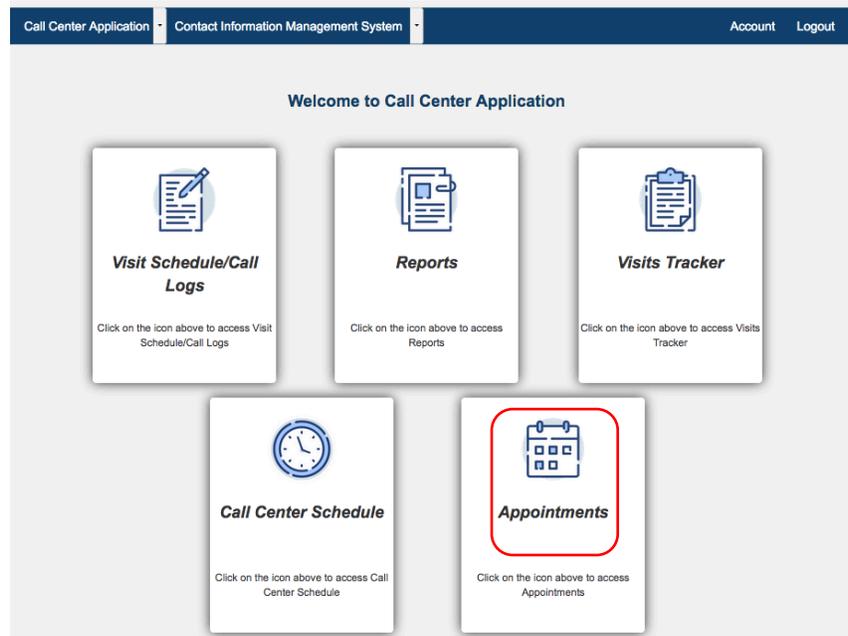
Scheduling BTACT Appointment

a. **Baseline BTACT**

After a new subject is created in the CIMS, the Baseline-BTACT can be scheduled using the 'Call Center Application' module. To do so, click on 'Call Center Application' button on the Study Portal homepage.

In the Call Center Application homepage, click on 'Appointments'

On the Appointments page, you can see Call Center availability before scheduling a BTACT. Each site can only view appointment details such as subject ID and visit type for participants within their sites and the solid green blocks (i.e., without appointment details) are BTACT and Annual Telephone appointments for other sites. Appointment in red are expired (i.e. out of window)
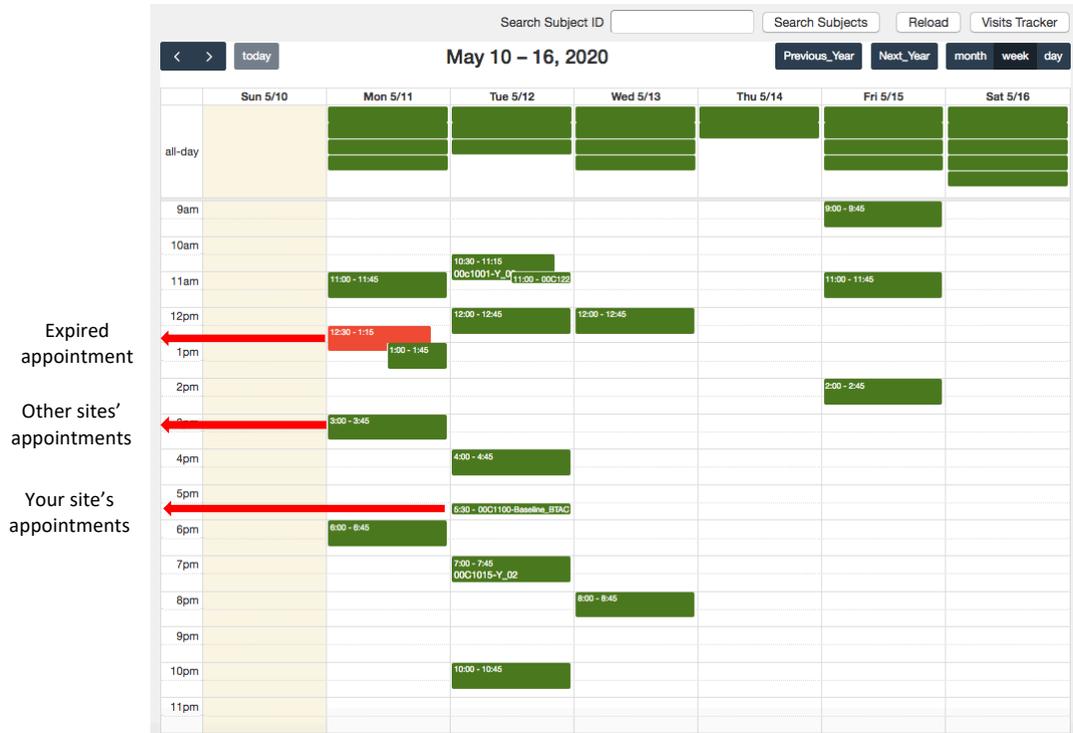
To schedule a BTACT, click on the plus icon at the top left corner of the page.
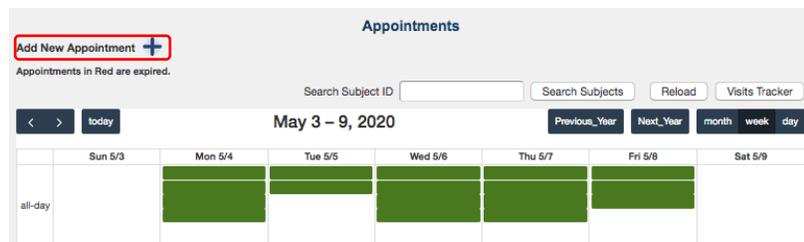
Add the 'Subject ID' and click 'Submit.

In the new window that pops up, enter the date, time (in EST), and visit note (if any) and click 'Submit'.

You should receive an 'Appointment Created Successfully' message and the appointment should appear on the calendar.

b. Follow-up BTACT

To schedule a BTACT for a comprehensive follow-up visit, you must provide the 'Actual Visit Date' first. The Actual Visit Date entered in the study portal for a visit must be the same as the Actual Visit Date entered in the Visit Gateway form in Medidata.

On the Call Center Application Module, click on 'Visit Schedule/Call Logs' icon.
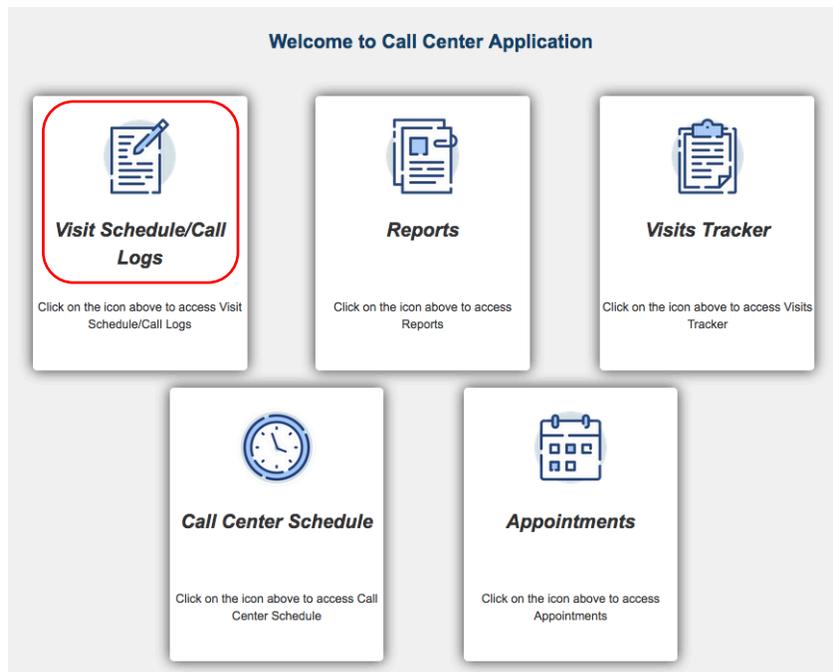
Search for the subject using the first name, last name, or subject ID. For example, if subject 00C1009 has just completed the Y-3 comprehensive visit, in 'Visit Schedule/Call Logs' page, search for 00C1009.

Next, click on the subject ID and all the visits for this subject will populate. Enter the date that the participant completed the Y-3 Comprehensive visit under the 'Actual Visit Date' column and click on the update icon.

Next, you will receive an update successful confirmation followed by a message asking you if you want to navigate to the Appointments module to schedule the BTACT. If you click 'Yes', you are re-directed to the Call Center calendar where you can schedule the Y-3 BTACT for this subject and the remaining steps are identical to the Baseline BTACT instruction outlined above.

Email Notifications and Follow-up Action Items:

a. Difficult to Contact (DTC):

The Call Center staff will perform a review of all cases in Study Portal and identify difficult-to-reach subjects on a daily basis. Once participants are marked difficult-to-contact, the respective site coordinators will receive an email notification for each subject when they are added to the DTC list.

Cases marked as DTC include:

- Participants who have received 10 call attempts with one contact number provided in CIMS

- Participants who have 2 or more numbers in CIMS who have received 15 or more call attempts

- Participants whose windows will be closing within the next 30 days

Below is an example of the DTC email notification:
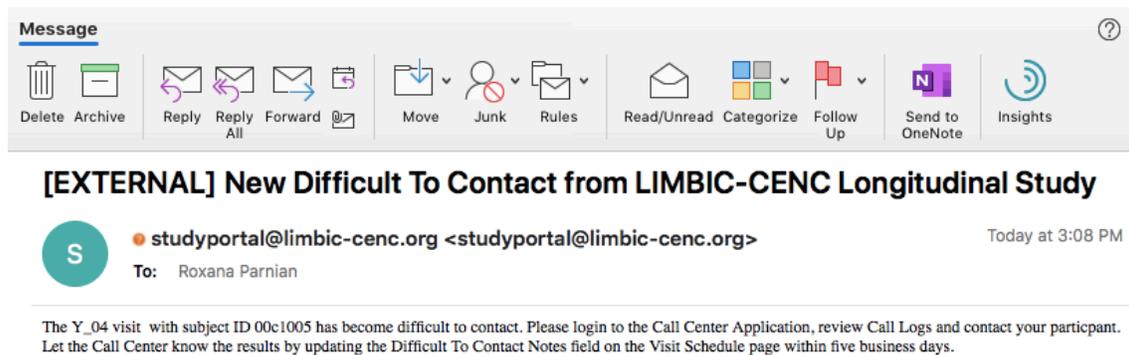
Once you receive a DTC email for a subject, you have 5 business days to provide an update/response to the Call Center staff by updating the DTC notes in the study portal. To do so, go to 'Visit Schedule/Call Logs' page and search for the subject.

Open the subject's visit page and update the DTC column for the respective visit year and click on the update icon.

Visit Schedule

Show 10 entries   Search:

Subject ID	Visit Type	Visit Window Start	Visit End Date	Status	DTC	DTC Notes	Actual Visit Date	Update
⊕ 00c1005	*Baseline_BTACT*	5/8/2019	7/7/2019	Expired	☐		05/08/2019	🔄
⊕ 00c1005	Y_04	4/1/2020	8/1/2020	In Progress	☑	secondary phone # added in CIMS		🔄
⊕ 00c1005	Y_05_BTACT	4/1/2021	10/1/2021	Upcoming	☐			🔄

Once you confirm that you would like to update the DTC notes, you will receive an update successful message.

If the site does not update the DTC notes in the study portal within 5 business days, a follow up email will be sent out to site coordinators and the participant will be taken off of DTC and contact attempts will resume once a week. If a follow up email is sent to your site, you must respond both to the email and complete the updates in the application.

   b.   **Wrong Number Notification:**

 If the Call Center cannot reach a participant due to an outdated or invalid contact information in CIMS, the participant will be marked as wrong number and the site staff will receive an email notification asking them to update/correct the participant's contact information within 5 business days.

Below is an example of the wrong number email notification:
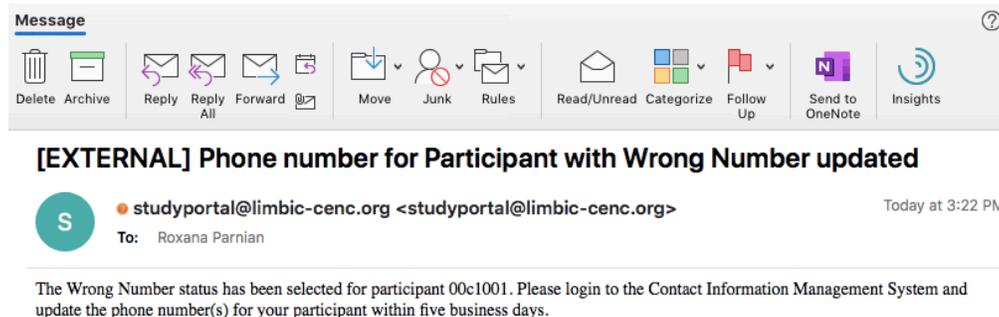
If the site does not respond within 5 business days, a follow up email will be sent out to site coordinators and the participant will remain wrong number until the site provides updated contact information. If updated contact information is not provided, the participant will be placed on the DTC list when they are 30 days out from the window end date and the sites will be asked again to reconfirm the participant's contact information.

   c.   **Pending Withdrawal Notification:**

If a participant expresses that they no longer wish to participate in the PLS, or request that they be withdrawn, the Call Center staff will assign a status of "Pending Withdrawal". Then, the site coordinators will receive an email notification asking them to confirm the withdrawal, complete an End of Study (EOS) form in Medidata, and update the 'Site Contact Notes' in CIMS.

Below is an example of Pending Withdrawal email notification:
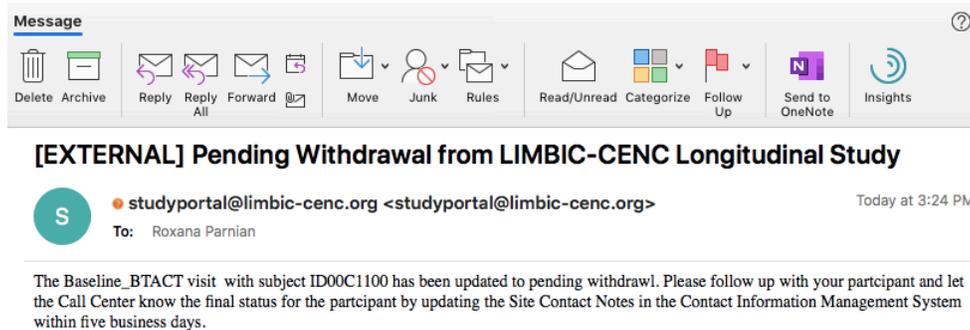
If the site does not respond to the Pending withdrawal notification within the 5 business days, a follow up email will be sent out to site coordinators. In the event that the site coordinator is unable to contact the participant during the 5 business days to confirm their desire to no longer participate in the study, the participant's visit will be marked as expired (when the visit window ends) or final refusal and the Call Center will contact the subject when their next call window opens. If the site confirms the participant's desire to continue with the study, the call center will resume contact with participant and change the status from 'Pending Withdrawal'.

Follow-up procedures based on visit status:

**In the event that sites are unable to reach a participant and/or complete the updates requested within 5 business days, they should inform the call center of the failed attempts by updating the DTC Notes and/or the site contact notes **

d. **Visit Completion**

Upon completion of the BTACT and Annual Telephone Follow-up visits, an email notification will be sent to the respective site staff for reimbursement purposes. Below is an example of visit completion email notification.
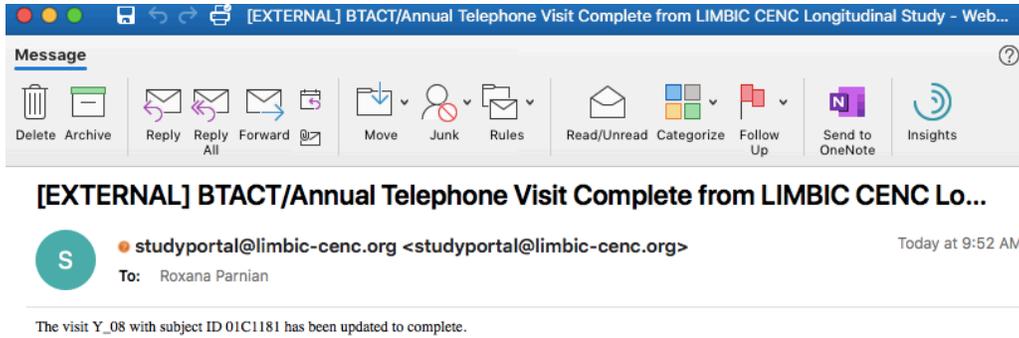
Generating In-person Visit Report:

Site staff can use the 'Report' module to pull comprehensive in-person visit reports. To do so, under the Call Center Application, click on the 'Reports' icon.
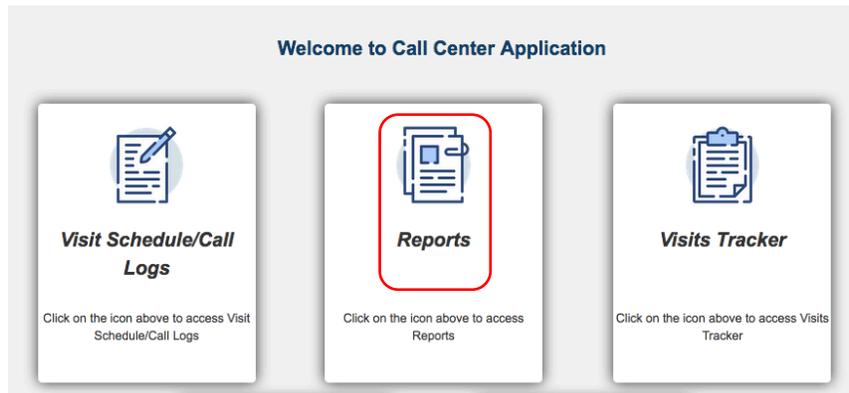

In the report module page, select 'In-person' for the visit type and indicate the date range for which you would to pull the report. You can also pull a visit report for an individual subject by searching by the subject ID. Once you select your search criteria, click on the 'Run Visit Report' and the report will be displayed.
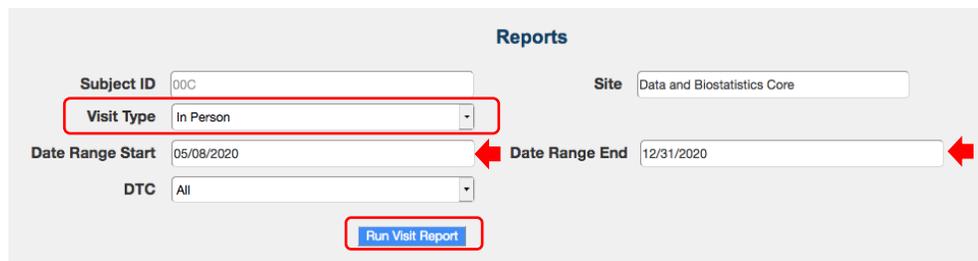
You can export the report as an excel file by clicking on 'Download Excel Report'

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Reports

Subject ID	00C		Site	Data and Biostatistics Core
Visit Type	In Person			
Date Range Start	05/08/2020		Date Range End	12/31/2020
DTC	All			

Run Visit Report

Download Excel Report

Visits

Show 100 entries   Search:

Subject ID	Visit Year	Visit Window Start	Visit Window End	Days Till Visit Window End
00C1000	Baseline_IN_PERSON_VISIT	4/30/2020	6/29/2020	51
00C1002	Baseline_IN_PERSON_VISIT	04/28/2020	6/27/2020	49
00c1003	Baseline_IN_PERSON_VISIT	05/01/2020	6/30/2020	52
00C1010	Baseline_IN_PERSON_VISIT	04/21/2020	6/20/2020	42
00c1011	Baseline_IN_PERSON_VISIT	05/01/2020	6/30/2020	52