



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Enrollment Reporting Site User Guide

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1. Logging In and Out and Navigating

The Enrollment Reporting Site is utilized by the NIH Collaboratory Trial teams to submit trial data every quarter. This includes enrollment figures, demographic information, and trial milestone data.

The reporting site allows trial teams to access and enter data for their trial only. NIH Pragmatic Trials Collaboratory Leadership has access to the reporting site to review and compare data for multiple trials side-by-side.

Note: The Enrollment Reporting Site is operated by Duke University and requires an active Duke sponsored account for access. It is the responsibility of the trial teams to identify individuals who require access to perform the reporting, or access the trial records for review. When individuals no longer require access, the account will be de-activated following notification to the NIH Pragmatic Trials Collaboratory team or the Enrollment Reporting Site administrator.

Logging In

Complete the following steps to log in to the UH3 Enrollment Reporting Site.

- 1 Access the tool by clicking on <https://uh3reporting.nihcollaboratory.org/> . Enter the site using your Duke credentials (NetID and password).
 - For trouble with your NetID or password, contact the Duke Helpdesk (by visiting <https://pwreset.oit.duke.edu/> or over the phone by calling the service desk at 919-684-2243).

The **Welcome** page opens in your computer's default browser. *Tip:* To save time accessing this site in the future, consider making it a shortcut in your browser.



WELCOME TO THE

NIH Collaboratory Trials Enrollment Reporting Site

This platform facilitates quarterly enrollment reporting to the NIH. NIH Collaboratory Trial teams input enrollment data via forms, enabling the NIH to review the data through reports and graphs, assessing study progress.



METRICS

NIH Collaboratory Trial teams submit enrollment and milestone forecasts before trial initiation and then provide quarterly data on enrollment, including participant race, ethnicity, and sex. These data allow tracking of enrollment progress and participant characteristics throughout the trial.

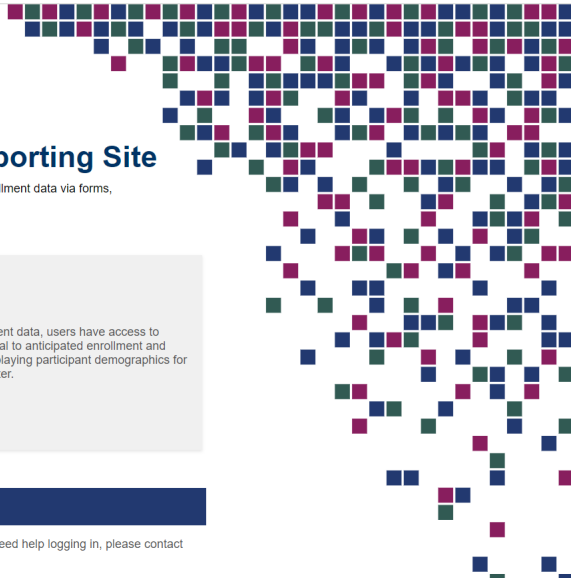


REPORTING

In addition to the raw enrollment data, users have access to visual reports comparing actual to anticipated enrollment and milestones over time and displaying participant demographics for a selected trial year and quarter.

LOG IN

Access is limited to designated members of the NIH Collaboratory Trial teams and NIH personnel. If you need help logging in, please contact NIH-Collaboratory@dm.duke.edu for assistance.



- 2 Click the **Login** button. The **Duke Log In** page appears.
- 3 Enter the **NetID** and **Password**.
- 4 Click the **Log In** button. The **Home** page appears.

Home Page



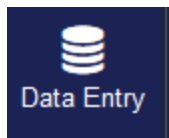
The topmost navigation tool is the dark blue **Menu Bar** across the top of the page. This bar contains four buttons: four on the left and one at the far right.



- **Home:** Returns you from any other page back to the **Home** page.
- **Data Entry:** Takes you to the page where your trial(s) can be selected for editing, or the Study Details page where users can navigate and edit data for the trial.
- **Reports:** Opens read-only graphical reports based on the trial data entered.
- **Healthy Equity Dashboard:** Opens additional read-only graphical reports to include the study status filter.
- **Log Out:** Ends the session and logs you out of the system.

Study Details Page

After clicking the **Data Entry** button on the **Home** page, the **Study Details** page for your trial appears if you work with only one trial.



If entering data for multiple studies, you will first be directed to a **Study Search** page. Click **Select** in the right column for the desired trial to be directed to the **Study Details** page.

Study Search			
<input type="text"/>			Show 10 entries
Acronym	Title	Principal Investigator	
Import Study Test	Import Study	John Smith	Select
TEST Study	Test 1.4.1	Test PI	Select
Showing 1 to 2 of 2 entries			Previous 1 Next

The **Study Details** page is the starting point for the data entry tasks in this guide. On the right is trial information currently in the system. On the left are links to access two **Forecast** pages, two **Actuals** pages, a **Milestones** page and a **Reports** page. The Enrollment Reporting Tool administrator will set up the trial, and the Study Coordinator/PI will then complete the details. Training will be provided when the trial team is ready for data entry.

Home | Data Entry | Reports | Health Equity Dashboard

Import Study Test

Forecast

- Enrollment
- Demographics

Actuals

- Enrollment
- Demographics

Milestones

Reports

Study Details

Title	Import Study
Acronym	Import Study Test
Principal Investigator	John Smith
Study Year	2017
Study Duration	4
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of Grant Award	2017-10-01
Target Number of Clinical Sites	5
Target Number of Practitioners	5
Total Enrollment	1,000
Timeline for Completing subject accrual	2018-08-03
Date of first subject activity/enrollment in clinical trial	2018-03-06
Study Status	
Expected Start Date	NA
Forecast Locked	No
Study Details Locked	No
Expected Milestones Locked	No
Actual Milestones Locked	No
Actual Enrollment & Demographics Locked	No
Last Updated	2021-06-18 11:32 EDT

Edit

Data Entry

The table below shows the timing of the data entry tasks to be completed by the trial team, and are described in Chapters 2-9. Four items are entered one time before trial enrollment begins, and three items are entered every quarter after enrollment begins.

Data entry task	When submitted for approval	Data to enter
-----------------	-----------------------------	---------------

Study Details	One time, before enrollment begins	Details of the trial
Forecast: Enrollment		Cumulative numbers
Forecast: Demographics		Cumulative numbers
Milestones: Expected Dates		Planned completion dates
Actuals: Enrollment	At the start of every quarter with data from the previous quarter	Cumulative numbers
Actuals: Demographics		Cumulative numbers
Milestones: Actual Dates		Actual completion dates

IMPORTANT: Be aware of two conditions that will *prevent* data entry:

After completing data for **Study Details, Forecast: Enrollment, Forecast: Demographics,** and **Milestones: Expected Dates**—and NIH personnel have approved your entries—these pages are **locked** for the duration of the study.

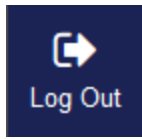
For **Actuals: Enrollment, Actuals: Demographics,** and **Milestones: Actual Dates**, data cannot be entered for the current quarter until *the first day of the next quarter*.

If edits need to be made to a locked page, the trial’s Principal Investigator or representative should contact the NIH Pragmatic Trials Collaboratory Coordinating Center (NIH-Collaboratory@dm.duke.edu).

Logging Out

Log out when finished entering data to free up network and server resources for the benefit of other users.

- 1 On any page, go to the right side of the **Menu Bar** and click the **Log Out** button. The **Duke Log Out** page appears.



Log Out

Are you sure you want to log out? This will also log you out of all Duke websites and services using your current login session.



- 2 Click **Log out** to end the connection to the Duke network.

2. Study Details

The first task is to enter details about your trial into the system. You can return at any time (before the trial is locked) to edit these fields if there is an error or update needed. On the **Study Details** page, click the **Edit** button at the bottom of the page.



Study Details	
Title	Import Study
Acronym	Import Study Test
Principal Investigator	John Smith
Study Year	2017
Study Duration	4
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of Grant Award	2017-10-01
Target Number of Clinical Sites	5
Target Number of Practitioners	5
Total Enrollment	1,000
Timeline for Completing subject accrual	2018-08-03
Date of first subject activity/enrollment in clinical trial	2018-03-06
Study Status	
Expected Start Date	NA
Forecast Locked	No
Study Details Locked	No
Expected Milestones Locked	No
Actual Milestones Locked	No
Actual Enrollment & Demographics Locked	No
Last Updated	2021-06-18 11:32 EDT



The **Edit Study** page appears.

The screenshot shows the 'Edit Study' form with the following fields and values:

- Title:** Import Study
- Acronym:** Import Study Test
- Principal Investigator:** John Smith
- Study Year:** 2017
- Study Duration:** 4
- ClinicalTrials.gov NCT ID#:** 11223355
- NIH Grant Number:** 55332211
- Date of Grant Award:** 2017-10-01
- Study Status:** (Dropdown menu)
- Target Number of Clinical Sites:** 5
- Target Number of Practitioners (if applicable):** 5 NA
- Total Enrollment (including anticipated loss/withdrawal):** 1000
- Timeline for Completing subject accrual:** 2018-08-03
- Date of first subject activity/enrollment in clinical trial (YYYY-MM-DD):** 2018-03-06
- If no active sites/subject, provide date trial is expected to begin:** NA

Buttons: Submit, Cancel

Study Year - should equal the year the trial expects to enroll

Date of first subject activity/ enrollment in clinical trial - date is a forecasted date


If no active sites/subjects, provide date trial is expected to begin - to be used when no subjects are being enrolled

Study Status – this information should reflect the status the trial is in currently in, not the one that has been completed

The **Edit Study** page is an editable form with several fields.

- 1 Complete as many fields as possible.

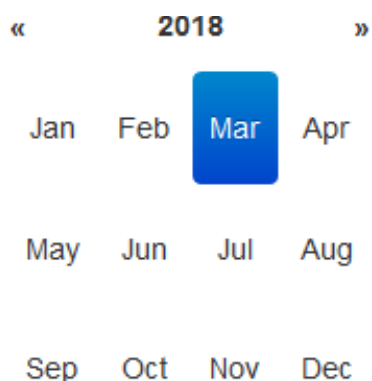
Note: Two fields in the second column have an **NA** (not applicable) checkbox. If the field does not apply to your trial, check the box.

- 2 Clicking in a date field (marked with a calendar icon ) opens an online calendar to select the date; users can also directly enter the date in the field using the format YYYY- MM-DD.

Note: The **Study Year** field is YYYY only.



- 3 By default, the online calendar shows the current month. To select a different year or month click the center-top area of the calendar (where the current month/year appears). The calendar changes to show the months in the current year. If you need a month within this year, click its abbreviation. After that month appears, click on the day.



- 4 If you need a different year, click the double arrows at the far top corners (» next year or « previous year). Click the desired month. After that month appears, click on the day.
- 5 After selecting a day, the calendar disappears and the field displays the full date.

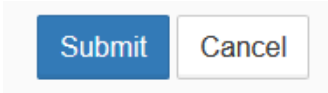
Note: An incorrect date format will display a red error message: **Please enter a valid date.**

The study duration can be changed once a trial commences, but not if data exists for that year. E.g., enrollment data exists for 5 years, the study duration can be changed to 6 years but not 4. If the system finds data for a year you are trying to change, the following error message appears.

✘ **Error: Quarterly study data exists. Cannot decrease the study duration.**

Submitting Your Updates

You may choose to make no edits to the data. However, if you choose to make edits and do not submit (navigate from the page or select **Cancel**), all data entry is lost.



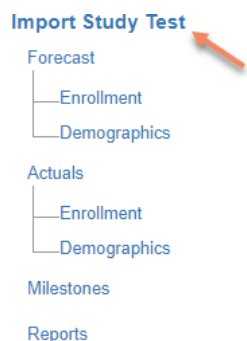
- 1 When finished, click the **Submit** button. You are returned to the **Study Details** page with a success message displayed across the top of the page. Your updates appear on the page.

✓ **Success: Study updated.**

- 2 Inform the trial’s Principal Investigator that this data entry task has been completed.

Returning to Study Details page

When navigating to other pages within the tool, (or if access to a single trial within the UH3 tool), the Study Details page is accessible for entry/review through the Data Entry icon at the top of the page, or through a link within the navigation pane.

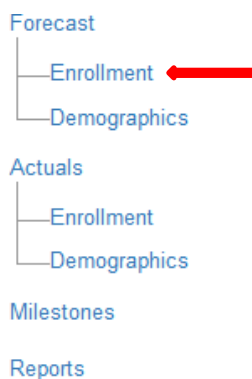


3. Forecasting Enrollment

Before enrollment starts, enter forecast (expected) enrollment numbers by quarter for the duration of the trial.

Please note that the Enrollment Reporting Site is based on the calendar year, so begin your forecasting entry with the calendar year and quarter that you expect enrollment to start. E.g., if you should start enrollment July 5, 2025, the year of trial enrollment (set as Study Detail: Study Year 2025) start is 2025, and the first numbers entered will be Q3, Year 1.

To begin, go to the **Study Details** page (or use the navigation pane if in the editing area of the system). In the left column, click **Enrollment** (under Forecast).



The **Enrollment Forecast** page appears.

Enrollment Forecast (All Numbers Are Cumulative)

		Total clinical sites with active subjects	Total practitioners randomized (if applicable)	Total subjects screened/contacted (if applicable)	Total active subjects (cumulative)	Total subject enrolled & lost, withdrawn, or opted out	Total subjects completing study
Year 1	Q1	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q2	<input type="text" value="8"/>	<input type="text" value="4"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q3	<input type="text" value="10"/>	<input type="text" value="5"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q4	<input type="text" value="12"/>	<input type="text" value="6"/>	<input type="text" value="4"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Year 2	Q1	<input type="text" value="18"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Year 3	Q1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Year 4	Q1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Q4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Important Notes

- 1 Enter forecast totals for the following six items as applicable for the duration of your trial:

- Total clinical sites with active subjects
- Total practitioners randomized (if applicable)
- Total subjects screened/contacted (if applicable)
- Total active subjects (cumulative)
- Total subjects enrolled & lost, withdrawn, or opted out
- Total subjects completing study

Note: The forecast enrollment numbers entered is cumulative, such that *each quarter’s number should not be a lower value than the previous quarter*. If a lower number is entered, an error message will be generated upon submission (see example below under Submitting Your Updates) to prompt a review of the values entered. The values however are saved to the system.

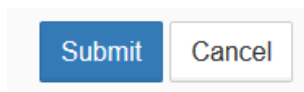
- 2 To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data. Below the table is an optional **Important Notes** area for users to enter explanatory information about the forecast. The text box will scroll if the text exceeds the size of the box. Changes to forecasting, after enrollment initiation, should be documented here. (Note: maximum 4,000 characters allowed).

Important Notes

1. Phase-In Period (April-May 2014) not included (will not count toward analysis)
 2. Reported Data begins with Intervention Period: June 2014 - Nov 2015
 3. Only patients who contribute person days to the trial are included. Thus, patients who stay in participating units less than 2 days are excluded.
 4. Reported data is estimated to be 75% accurate. Will update in the future following improved mapping with participating wards and actual data from the trial periods

Submitting Your Updates

If you made no edits—or decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page to return to the **Study Details** page or simply navigate from the page without selecting an option.



- 1 When finished, click the **Submit** button.

If the system finds a lower number than the previous quarter, you will receive a warning message. If you incorrectly added a lower number, correct the error and click **Submit** again.

! Warning: Study forecast updated. You have entered a value that is less than the previous quarter. Please review. X

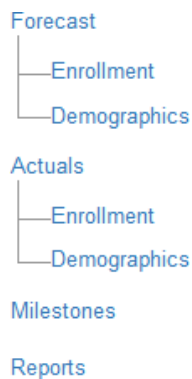
- 2 If there are no warnings, a success message is displayed across the top of the of the **Forecast** page.

✓ Success: Study forecast updated.

- 3 Inform the trial’s Principal Investigator that this data entry task has been completed.

4. Forecasting Demographics

Before enrollment initiates, enter forecast demographic numbers (i.e., demographic data associated with included trial subjects) for the duration of the trial. To begin, go to the **Study Details** page. In the left column, click **Demographics** (under Forecast).



The **Demographics Forecast** page appears.

Demographics Forecast

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	50	60	25	27	162
Asian	11	12	4	9	36
Native Hawaiian or Other Pacific Islander	5	6	2	4	17
Black or African American	55	59	33	37	184
White	50	48	8	5	111
More Than One Race	10	15	15	10000	10040
Total	181	200	87	10082	10550

- 1 Enter the forecast demographic totals for female and male for pertinent racial categories in the correct ethnic block. To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data. Enter zeros for fields in which no subjects are forecasted.
- 2 Review the forecast numbers (the system totals the cells in rows and columns).

Note: the total for demographics should be the same as your final cumulative active subject’s enrollment forecasted total. E.g., if the active subjects final enrollment is 2,000 subjects, then the demographics should total 2,000 subjects.

Submitting Your Updates

If you decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page. In addition, migrating from the page in the browser prior to submitting also discards your entries.

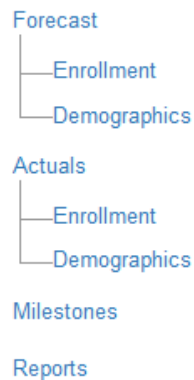
- 1 When finished, click the **Submit** button, a success message is displayed across the top of the **Demographics Forecast** page.

✓ **Success: Study Demographic Forecast updated.**

- 2 Inform the trial’s Principal Investigator that this data entry task has been completed.

5. Actual Demographics

To begin, go to the **Study Details** page. In the left column, click **Demographics** (under Actuals).



The **Demographics Actuals** page appears.

Cumulative Demographic Enrollment for Active Bathing to Eliminate (ABATE) Infection
 ABATE
 Susan Huang, MD, MPH

Year: 4 (2017)
 Quarter: 4

Click on the choose file button below to upload data for the year and quarter
 No file chosen

Cumulative Demographic Enrollment

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More Than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Last Modified Date: 2019-10-09 11:43 EDT

- 1 Enter the actual demographic totals for female and male for pertinent racial categories in the correct ethnic block. To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data. Enter zeros for fields in which no subjects are forecasted.
- 2 Review the actual numbers (the system totals the cells in rows and columns).
- 3 It is also possible to upload your entries by using the [ActualDemographicsUploadTemplate](#) which can be accessed by clicking on the link located below the trial name at the top of the demographics screen.

ActualDemographicsUploadTemplate.xls. Once the values are populated into the template navigate to the upper left-hand side of the reporting window. Under the investigator’s name you will be able to select **Choose File**. Navigate to the location

of the locally saved template file and select **Open**. User will see the name of the file next to the **Choose File** button.

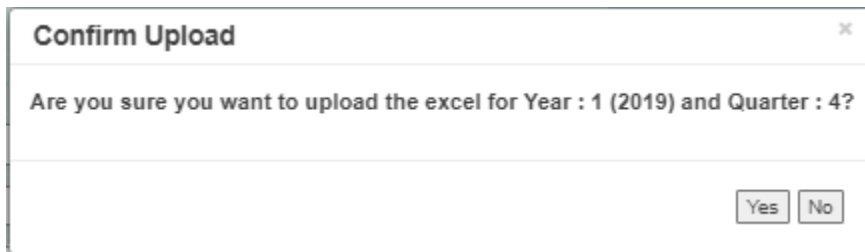
SAMPLE [ActualDemographicsUploadTemplate](#)

Racial Categories	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity		
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown
American Indian/Alaska Native									
Asian									
Native Hawaiian or Other Pacific Islander									
Black or African American									
White									
More Than One Race									
Unknown or Not Reported									

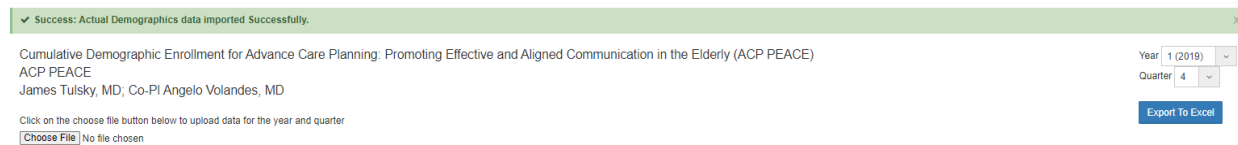
Click on the choose file button below to upload data for the year and quarter

ActualDemo... Template.xls

Select Upload. A new pop-up window will appear asking you to confirm the upload of the file for the specific year and quarter. Select **Yes**. Ensure that the file is uploading to the correct year and quarter.



A green banner will appear at the top of the reporting screen indicating the upload was successful.



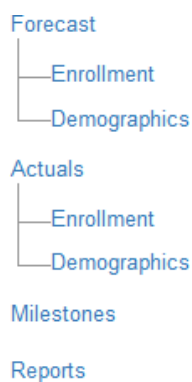
3 User can also export the report by navigating to the upper right-hand side of the screen and selecting the **Export to Excel** button. The file will download locally on your machine for retrieval.

Year

Quarter

6. Milestones: Expected Dates

Before enrollment initiates, enter expected completion dates for major milestones for the duration of the trial. If you are on a page pertaining to your trial, click **Milestones** in the left column to begin. If you are in the reports section of the web site, return to the **Study Details** page (select Data entry or if you have rights to a single trial, a link is provided on the reports navigation pane) to return to data entry pages. In the data entry navigation pane, select **Milestones**.



The **Milestones** page appears containing 27 milestones with fields for **Expected Date**, **Actual Date**, and **Comments**.

Milestone (high-level milestones are denoted by *)	Expected Date	Actual Date	Comments
UG3 Award Date ⓘ <i>Abbreviated Name: UG3 Award Date</i>	<input type="text"/>	<input type="text"/>	Testing
UH3 Award Date* ⓘ <i>Abbreviated Name: UH3 Award Date</i>	<input type="text"/>	<input type="text"/>	
Award Date* ⓘ <i>Abbreviated Name: Award Date</i>	<input type="text"/>	<input type="text"/>	
Trial Registration ⓘ <i>Abbreviated Name: Trial Reg</i>	<input type="text"/>	<input type="text"/>	

1. Enter expected completion dates in the **Expected Date** field for all milestones. Use the online calendar or enter the date directly in the format YYYY-MM-DD. If any milestone does not apply to your trial, indicate this in the **Comments** field.

Note: For a brief description of each milestone, hover the cursor over the information icon ⓘ, or refer to the table below for a full description.

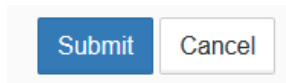
2. Review the entries for accuracy.

Milestone * = high-level milestone	Abbreviated Name	Summary
UG3 Award Date	UG3 Award Date	The date UG3 Awarded (from the NIH website).
UH3 Award Date *	UH3 Award Date	Date UH3 Awarded (from the NIH website).
Award Date	Award Date	The date R01 or other funding mechanisms awarded (other than UG3/UH3 mechanism) [from the NIH website]
Trial Registration	Trial Reg	Date the Trial was registered with www.clinicaltrials.gov by the legally responsible entity.
Protocol Approved for Implementation	Protocol App. For Implem.	Date initial protocol is considered final by the NIH.
IRB Approval	IRB Appr.	Date of IRB approval for study implementation.
Statistical Analyses Plan Finalized	SAP Final	Date of final SAP entry completed and locked.
First Site Activated Date	1st Site Act.	Date drug/device is shipped to the first site, OR the date that the first site is considered ready to enroll subjects.
First Patient Enrolled *	1st Pt. Enroll	Date the first patient is enrolled by a site.
Last Patient Enrolled	Last Pt. Enroll	Date the last patient is enrolled by a site. Enrollment in the study is complete.
Last Day for Intervention *	Last Day for Interv.	Date of the last day of intervention, i.e. the day intervention is turned off or stopped measuring.
End of Outcome Observation Period	End of Outcome Obs. Period	Date of last day of the primary outcome observation period.
Key Data Available	Key Data Avail.	Date when data is available to assess the primary objective; Table 1, Primary Exposure and Endpoint Data Available.
Secondary Endpoint Data Available	Sec. Endpt. Data Avail.	Date when data is available to assess secondary objectives and/or other details.
All Data Available *	All Data Available	Complete data package; ancillary, explanatory.
Database Lock *	DBL	Date the primary endpoint database is considered “locked”.
Final Statistical Analysis *	FSA	Date that pre-approved tables, figures, and modeling are complete.
Topline Results Report*	Topline Report	If applicable, the date when topline results get generated. If not applicable, please indicate so in the Comment field.
Topline Results (or Full Results) to Health System Partners	Topline to HS Partners	If applicable, when results go to health system partners. Do they have to approve results before further sharing? If not applicable, please indicate so in the Comment field.
Topline Results to	Topline to	Date when the topline results are available

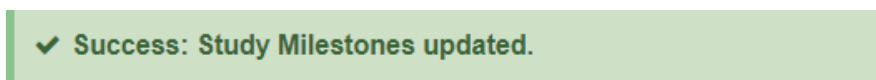
Note: Both the **Abbreviated Name** and the designation of a **high-level milestone** pertain to the **Milestone Report** (details in “11. Reports”).

Submitting Your Updates

You may choose to make no edits to the data. However, if you choose to make edits and do not submit (navigate from the page or select **Cancel**), all data entry is lost.



- 1 When finished, click the **Submit** button. You are returned to the **Milestones** page with a success message displayed across the top of the page.



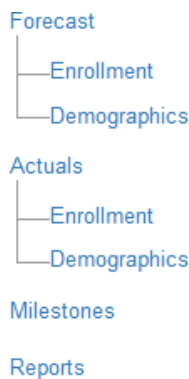
- 2 Inform the trial’s Principal Investigator that this data entry task has been completed.

7. Reporting Enrollment

As the trial progresses, trial teams will enter the total actual enrollment numbers for the reported quarter and answer five questions.

Note: This data entry is to be completed during the 3-week window at the beginning of every quarter. The data entered are from the *previous quarter* (i.e., the reported quarter).

To begin, go to the **Study Details** page. In the left column, click **Enrollment** (under Actuals).



The **Enrollment Activity** page appears. Data is entered in the **Actual Total** column.

Note 1: The numbers in the **Expected Total** column are prepopulated with data from the Forecast Enrollment Report (see “11. Reports”) and cannot be modified in this table.

Note 2: Please inform the Enrollment Reporting Site administrator to lock the data when

ready – following review of data following database lock and curation (verification of data). If any locked information needs to be edited, please contact the Enrollment Reporting Site administrator, and ensure approvals for the changes by either trial PI or NIH Program Officer.

Enrollment Activity Table

	Q1 Reporting Date Jan 1 - Mar 31		Q2 Reporting Date April 1 - June 30		Q3 Reporting Date July 1 - Sep 30		Q4 Reporting Date Oct 1 - Dec 31	
	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total
Effective Date of Data	2020-04-06		2020-04-07				2017-10-19	
Locked	No		No		No		<input checked="" type="checkbox"/>	
Total clinical sites with active subjects	3	9	8	16	10		12	<input type="text" value="40"/>
Total practitioners randomized (if applicable)	4		4		5		6	<input type="text" value="1"/>
Total subjects screened/contacted (if applicable)							4	<input type="text" value="72155"/>
Total active subjects (cumulative)								<input type="text" value="82155"/>
Total subject enrolled & lost, withdrawn, or opted out								<input type="text" value="9486"/>
Total subjects completing study								<input type="text" value="25748"/>

If any of this information has changed, please contact your program officer

- 1 In the upper right, using the drop-down list, select the specific year and quarter for which you are reporting trial data. The table changes with each selection and allows you to **edit only the quarter selected**. Current and previous quarters are editable. In the event that previous quarters are locked, please contact the Enrollment Reporting Site administrator NIH Pragmatic Trials Collaboratory or email (NIH-Collaboratory@dm.duke.edu) for assistance.

Year Quarter

- 2 In the **Effective Date of Data** field, enter today’s date (YYYY-MM-DD) or use the online calendar to select today.

	Q1 Reporting Date Jan 1 - Mar 31
Effective Date of Data	<input type="text"/>
Locked	<input type="checkbox"/>
	Expected Total Actual Total

- 3 Enter **Actual Total** numbers as of this reported quarter as follows (i.e., total cumulative number up to this point in the trial):
 - **Total clinical sites with active subjects:** This is the number of clinical sites with active subjects as of this reported quarter.

- **Total practitioners randomized (if applicable):** This is the cumulative number of practitioners participating in enrollment activities as of this reported quarter.
- **Total subjects screened/contacted (if applicable):** This is the cumulative number of new subjects that were screened or contacted as of this reported quarter. This number may be the same or higher than the previous quarter's Actual Total. If the number entered is lower than the previous quarter's, an error will be generated when you submit (see next page).

Note: If no new subjects were screened or contacted during this quarter, enter the same number as the previous quarter. If the trial is not screening or contacting subjects per the design, leave null (or enter zero) for the current and subsequent quarters.

- **Total active subjects (cumulative):** This is the total number of cumulative subjects enrolled as of this reported quarter.
 - **Total subjects enrolled & lost, withdrawn, or opted out (cumulative):** This is the total number of cumulative subjects lost, withdrawn, or opted out as of this reported quarter.
 - **Total subjects completing study (cumulative):** This is the total number of cumulative subjects completing the trial as of this reported quarter.
- 4 Scroll down to answer the five questions at the bottom of the page using the drop-down list (No/Yes). These must be completed for each quarter. If you answer **Yes** to any question, a text field opens to enter a required explanation.
 - 5 Use the optional **Comments** text box under the questions to add further information (maximum 4,000 characters). The comments box is not associated to a specified year and quarter. Any notes entered in the comments box will be visible for each year and quarter selected.

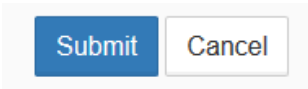
Please explain if quarterly enrollment activity is behind schedule and if corrective action has been taken	
1. Any change to IRB status of the trial? (If Yes, please provide further comments)	Yes <input type="button" value="v"/> <input type="text"/>
2. Any new sites or sites that are no longer participating? (If Yes, please provide further comments)	No <input type="button" value="v"/>
3. Any protocol changes? Changes to demographic/exclusion criteria? (If Yes, please provide further comments)	No <input type="button" value="v"/>
4. Any budgetary concerns or anticipation of carrying over 25% of funds? (If Yes, please provide further comments)	No <input type="button" value="v"/>
5. Any changes to key personnel efforts >25%? (If Yes, please provide further comments)	No <input type="button" value="v"/>
Comments <input type="text"/>	



6 Review the edits for accuracy.

Submitting Your Updates

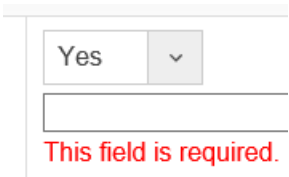
If you decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page to clear your edits.



1 When finished, click the **Submit** button.

If enrollment data entered is lower than a previous quarter, you will receive a warning. The entered data is saved, but it is recommended that you review your data entries. If any question has an error, red text appears to explain the error.

! Warning: Actual Enrollment data updated. You have entered a value that is less than the previous quarter. Please review and then enter Actual Demographics data when ready. X



2 If there are no errors, a success message displayed across the top of the

Actuals Enrollment page.

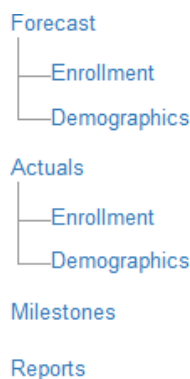
✓ **Success: Actual Enrollment data updated. Please enter Actual Demographics data.**

- 3 Inform the trial’s Principal Investigator that this data entry task has been completed.

8. Reporting Demographics

As the trial progresses, trial teams will enter actual demographic data (race, ethnicity, and sex) for enrolled subjects. This data is to be completed within the first three weeks of each new quarter using *final data from the previous quarter*.

To begin, go to the **Study Details** page. In the left column, click **Demographics** (under Actuals).



The **Cumulative Demographic Enrollment** page appears. The **Cumulative Demographic Enrollment** table is for reporting the demographic breakdown of the *total number* of subjects accrued (e.g., total enrolled this quarter plus previous quarters).

Cumulative Demographic Enrollment

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian/Alaska Native	31	22	0	3	2	0	2	0	0	60
Asian	462	369	0	14	10	0	14	14	0	883
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	3403	2496	0	36	30	0	138	140	0	6243
White	16051	13476	9	2183	1889	1	757	632	1	34999
More Than One Race	104	76	0	5	6	0	3	1	0	195
Unknown or Not Reported	440	438	0	2593	2251	0	211	205	0	6138
Total	20491	16877	9	4834	4188	1	1125	992	1	48518

1. In the upper right, select the specific year and quarter you are reporting from the drop-down list. The table changes with each selection. Future quarters, if selected, do not allow data entry.

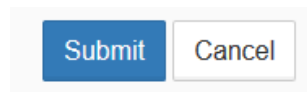
Year Quarter

2. Enter the number of females and males for the reported quarter in their respective racial categories and the correct ethnic block. If you do not know the demographic breakdown of a particular subject, enter that number in the **Unknown or Not Reported** row. Enter zeros for fields that are not applicable. To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data.
3. Review the entries for accuracy. The values entered in this **Cumulative Demographic Enrollment** table should equal the cumulative subjects *accrued* during the reported quarter plus previous quarters.

Note: If the Total column on the far right does not populate the total number of subjects per racial category, please clear your browser cache and refresh the page.

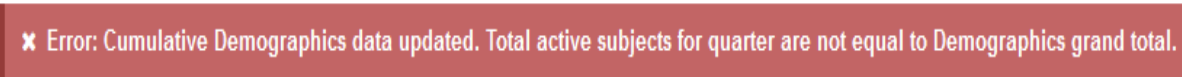
Submitting Your Updates

If you decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page to clear your edits.

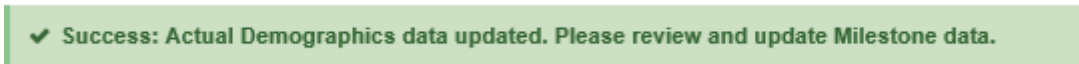


1. When finished, click the **Submit** button.

If the number of subjects entered in the Cumulative Demographics table does not match the total active subjects for same the year/quarter, you will receive a warning message. Review the numbers, correct the error and click **Submit** again.



2. If there are no errors, you will see a success message displayed across the top of the page with a reminder to review and update the Milestone data.

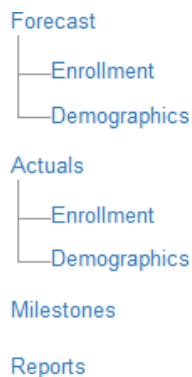


3. Inform the trial’s Principal Investigator that this data entry task has been completed.

9. Milestones: Actual Dates

As the trial progresses, trial teams will enter actual dates for milestones as they are

completed. Not all quarters will reach milestones, so there will be quarters when this page is not updated. To begin, click **Milestones** in the left column navigation pane.



The **Milestones** page appears.

Milestone (high-level milestones are denoted by *)	Expected Date	Actual Date	Comments
UG3 Award Date ⓘ <i>Abbreviated Name: UG3 Award Date</i>	<input type="text"/>	<input type="text"/>	Testing
UH3 Award Date* ⓘ <i>Abbreviated Name: UH3 Award Date</i>	<input type="text"/>	<input type="text"/>	
Award Date* ⓘ <i>Abbreviated Name: Award Date</i>	<input type="text"/>	<input type="text"/>	
Trial Registration ⓘ <i>Abbreviated Name: Trial Reg</i>	<input type="text"/>	<input type="text"/>	
Protocol Approved for Implementation ⓘ <i>Abbreviated Name: Protocol App. For Implem.</i>	<input type="text"/>	<input type="text"/>	

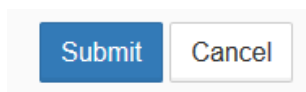
- 1 Enter actual completion dates in the **Actual Date** field for completed milestones. Use the online calendar or enter the date directly in the format YYYY-MM-DD. Use the **Comments** field to add information if necessary.

Note: For a brief description of each milestone, hover the cursor over the information icon ⓘ or refer to the table in Chapter 6 for a description.

- 2 Review the entries for accuracy.

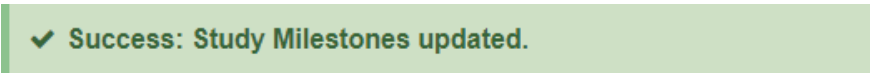
Submitting Your Updates

If you decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page to clear your edits.



- 1 When finished, click the **Submit** button. You will be provided a success

message displayed at the top of the page to know that the entries were saved.



- 2 Inform the trial’s Principal Investigator that this data entry task has been completed.

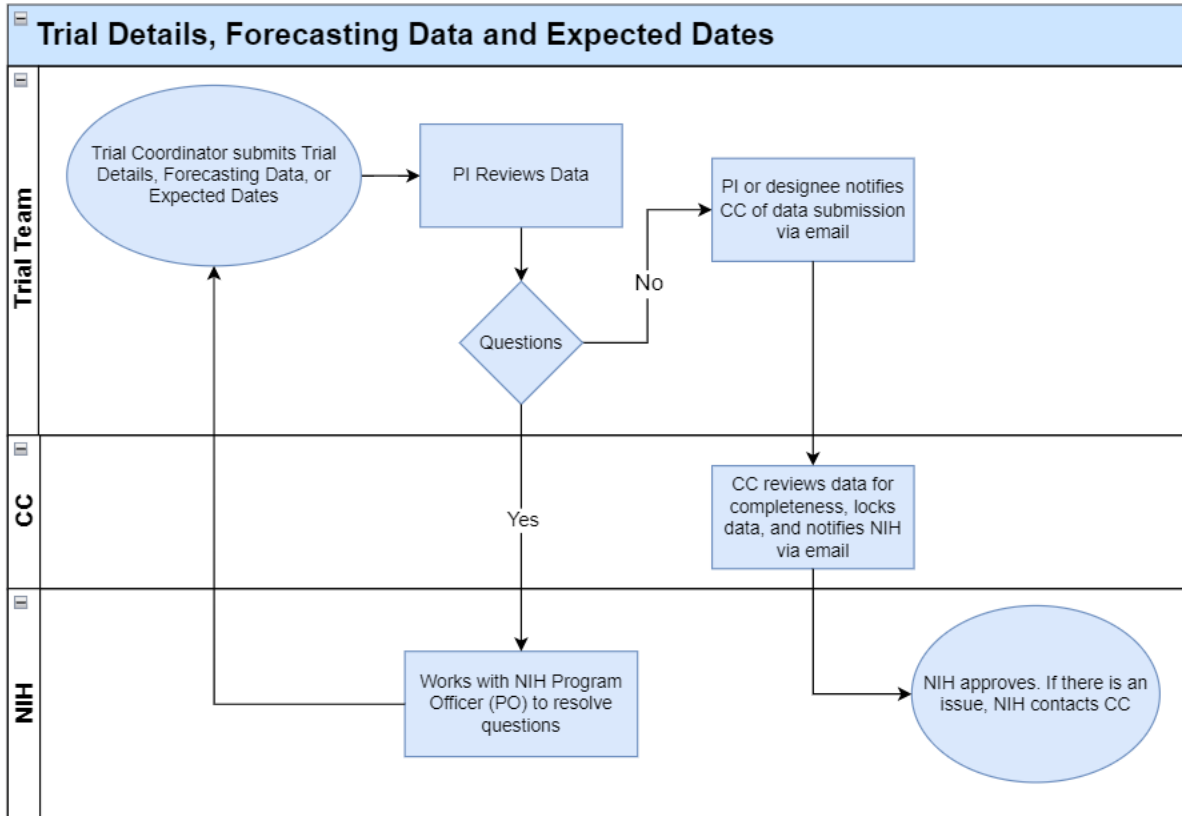
10. Data Entry and Approval

This chapter summarizes the data entry tasks and approval timing.

When submitted for approval	Data entry item
One time, before enrollment begins: These <i>forecast tasks</i> are to be completed within the first three quarters after the Award Date milestone, but no later than the First Patient Enrolled Date milestone.	Study Details
	Forecast: Enrollment
	Forecast: Demographics
	Milestones: Expected Dates
Every quarter: These <i>interim tasks</i> are to be completed at the beginning of every quarter using actual data from the previous quarter.	Actuals: Enrollment
	Actuals: Demographics
	Milestones: Actual Dates

Data to Submit One Time Before Enrollment

The flowchart shows this process.



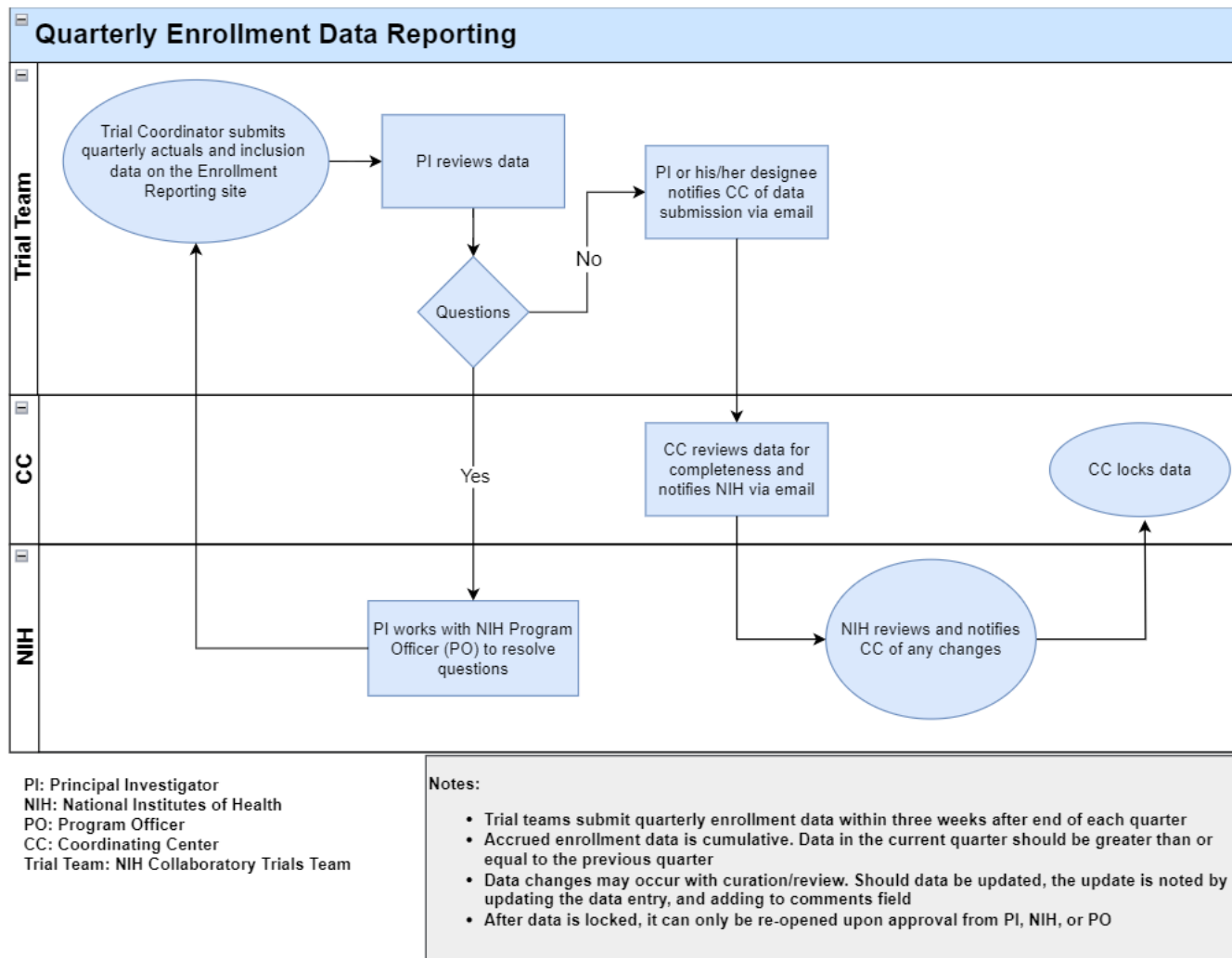
PI: Principal Investigator
NIH: National Institutes of Health
PO: Program Officer
CC: Coordinating Center
Trial Team: NIH Collaboratory Trials

Notes:

- All items on this chart to be completed before enrollment begins
- Trial teams submit trial details and forecast data within first two quarters from the trial start date

Data to Submit at the Start of Every Quarter

The flowchart shows this process.



Review and Approval

All data submitted by the trial teams must be reviewed and approved by the trial’s Principal Investigator. If there are any exceptions to providing enrollment reporting data or questions about the data, the PI should contact the trial’s NIH Program Officer.

IMPORTANT: After Forecast data is locked, it can only be reopened with approval from NIH. Trial teams should communicate their need to change forecasting to the NIH Pragmatic Trials Collaboratory Coordinating Center.

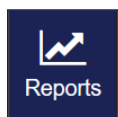
Contacting the NIH Pragmatic Trials Collaboratory Coordinating Center

For questions or comments about the Enrollment Reporting site, send an email to the NIH Pragmatic Trials Collaboratory at NIH-Collaboratory@dm.duke.edu, and your message will be triaged to the appropriate person for response.

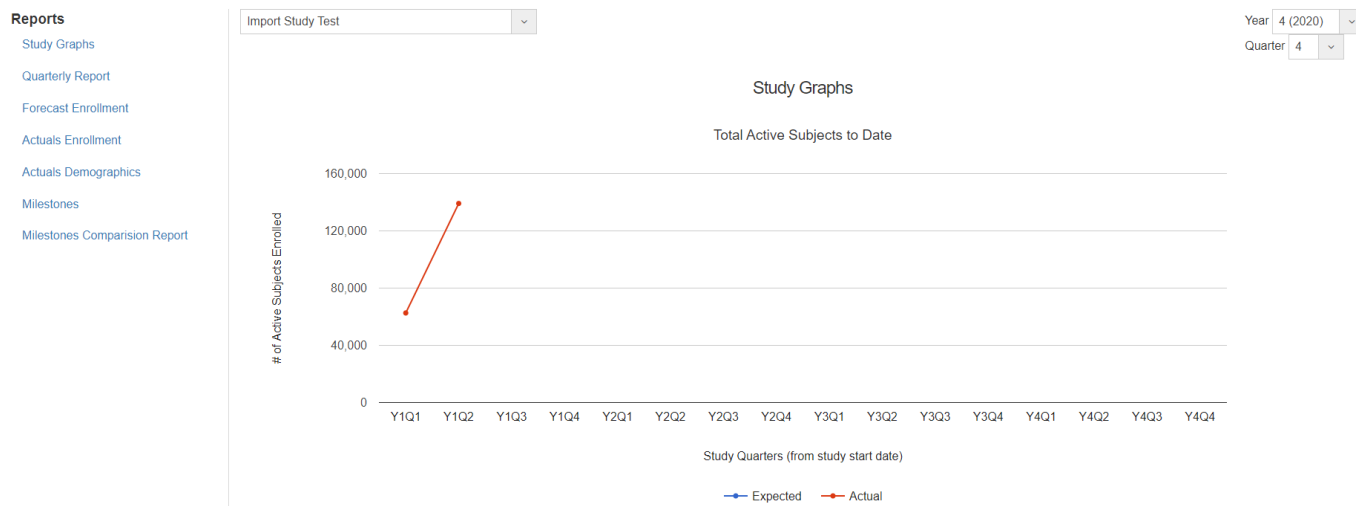
11. Reports

Although not part of the core tasks of the PI and Study Coordinator, displaying reports can help to visualize trends or issues in the data. These reports are a graphical representation of the information currently in the system for your trial. Certain members of the NIH Pragmatic Trials Collaboratory Coordinating Center, NIH Pragmatic Trials Collaboratory Leadership, and NIH have access to the reports in the UH3 tool.

From any page, click the **Reports** button on the **Menu Bar**. Reports are also available as a link on the Left navigation page while editing the trial, for the Study Coordinators and PIs.



By default, the **Study Graphs** report appears with columns on the left for links to all reports.



Selection Control

If you have access to more than one trial, select the desired trial from the dropdown.



For **Study Graphs, Quarterly, Forecast, and Actuals** reports, select the year and quarter from the drop-down lists in the upper right. This is the time period that will apply to the report.

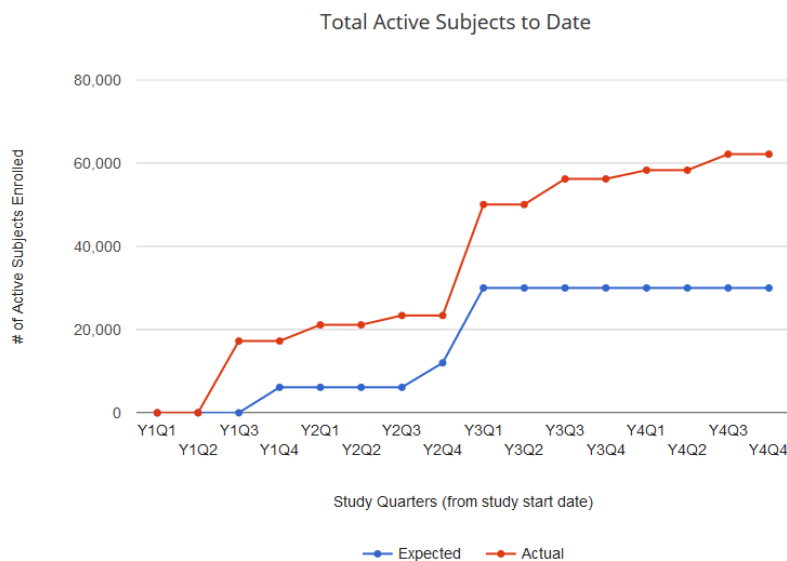
Year Quarter

Study Graphs

If data is available for the selected time period, four different graphs (described below) will appear on the **Study Graphs** page. (If a graph does not appear, data has not been submitted for the selected time period.)

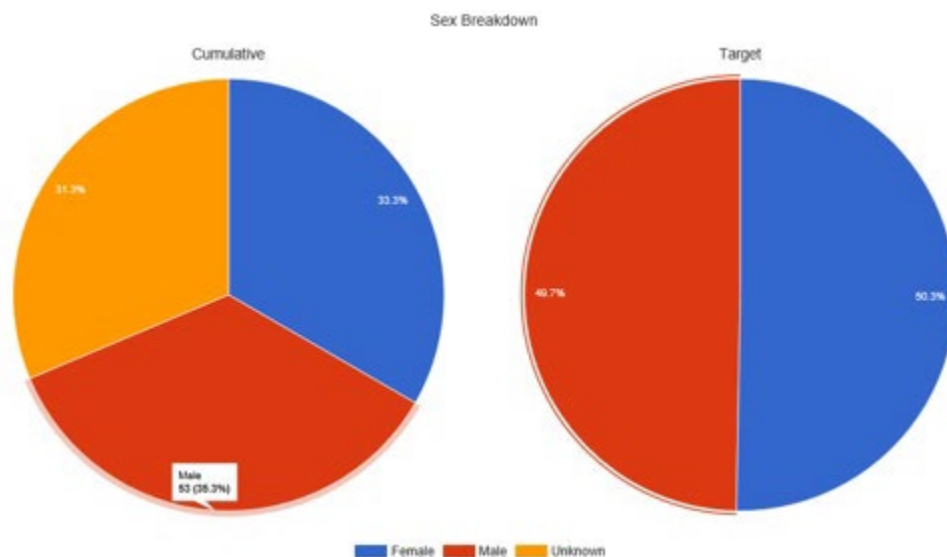
IMPORTANT: The top graph, **Total Active Subjects to Date**, is always cumulative for your entire trial to date. This line graph does not change with your selected time period; however, the other graphs on this page are affected by the selected time period.

Total Active Subjects to Date: This graph is cumulative. The line chart always shows expected (blue) versus actual (red) enrollment numbers for the entire project, up to the present. The blue line, taken from Forecast data, is complete and does not change over the entire life of the project. The red line grows as trial teams enter enrollment numbers at the start of each quarter. For actual numbers, hover over a dot; a tool tip appears with additional information.

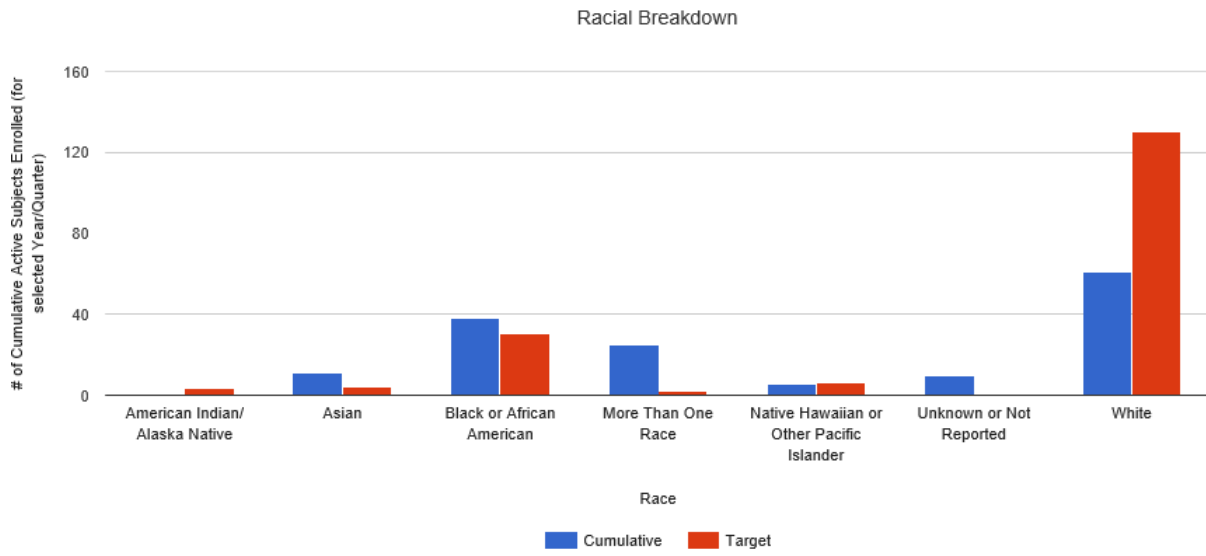


Sex Breakdown: The pie chart on the left (**Cumulative**) divides the total number of subjects enrolled in the selected time period into percentages known to be male (red), female (blue), or unknown/unreported (yellow). Similarly, there is a sex breakdown for the forecasted demographics (**Target**). To view actual numbers, hover the cursor over any part of a chart; a tool tip appears with more information including the actual numbers for the enrollment selected.

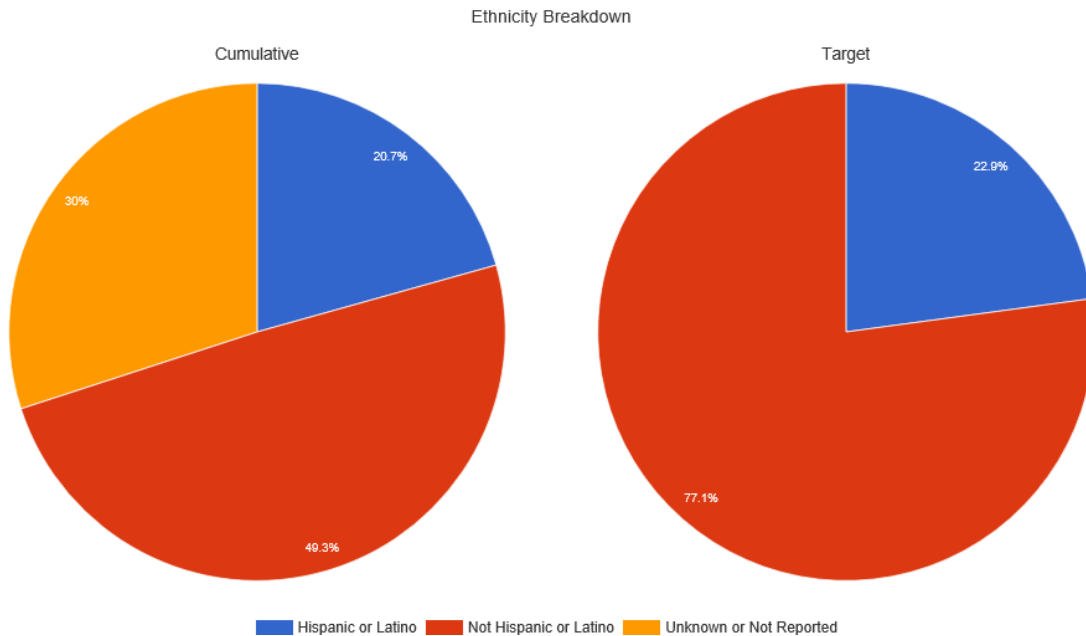
NOTE: If there is no Target information (entered in Forecasted Demographics), “No data” is displayed on the report. If there no Actuals Demographics data entered for the selected Year/Quarter, the Sex Breakdown (and Ethnicity Breakdown below) will display “No data”. For the line/bar charts, the graphs plot show only data that is available from the system.



Racial Breakdown: This bar chart plots the total number of subjects enrolled in the selected time period with the forecasted totals (**Target**) against five racial categories, as well as a more-than-one-race category and an unknown/unreported category. For actual numbers, hover over a bar; a tool tip appears with more information.



Ethnicity Breakdown: These pie charts divide the total number of subjects enrolled in the selected time period into a percentage known to be Hispanic or Latino (blue), not Hispanic or Latino (red), or unknown/unreported (yellow). For actual numbers, hover over any part of a chart; a tool tip appears with additional information.



Quarterly Report

Select **Quarterly Report** in the left column of the **Reports** page.

Reports

Study Graphs

Quarterly Report

Forecast Enrollment

Actuals Enrollment

Actuals

Demographics

Milestones

Milestones

Comparison Report

If data is available for the selected time period, four graphs (*Total Active Subjects to Date*, *Sex Breakdown*, *Racial Breakdown*, and *Ethnicity Breakdown*) and three tables (*Forecast Enrollment* and *Cumulative Demographic Enrollment*) will appear on the **Quarterly Reports** page. (If a graph does not appear, data has not been submitted for the selected time period.) This is the report submitted to the NIH by the coordinating center. The addition of information from the Study Details is provided, and page breaks added for printing through the browser.

NOTE: Chrome or IE browsers setting the scale to 80% is the recommended for printing the report. The report can be saved through the browser by selecting the print to .pdf function.

Forecast Enrollment Report

Select **Forecast Enrollment** in the left column of the **Reports** page.

Reports

- [Study Graphs](#)
- [Quarterly Report](#)
- [Forecast Enrollment](#)
- [Actuals Enrollment](#)
- [Actuals](#)
- [Demographics](#)
- [Milestones](#)
- [Milestones](#)
- [Comparison Report](#)

Project Summary: This section displays study details.

Forecast Report

Principal Investigator	John Smith
Acronym	Import Study Test
Title	Import Study
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of Grant Award	2017-10-01

Enrollment Forecast Table: This table shows forecast (expected) enrollment numbers by quarter for each study year. This forecast information was provided by the trial team at trial start-up.

Enrollment Forecast (All Numbers Are Cumulative)

		Total clinical sites with active subjects	Total practitioners randomized (if applicable)	Total subjects screened/contacted (if applicable)	Total active subjects (cumulative)	Total subject enrolled & lost, withdrawn, or opted out	Total subjects completing study
Year 1	Q1	4	3		6	2	6
	Q2	5	3		6	2	6
	Q3	6	3	5	7	2	6
	Q4	6	5	7	7	9	6
Year 2	Q1	7	7	8	7	34	6
	Q2	7	8	9	8	56	6
	Q3	7	9	10	8	66	6
	Q4	8	9	12	8	90	6
Year 3	Q1	8	9	15	9	90	6
	Q2	9	9	16	9	90	6
	Q3	10	9	89	9	90	6
	Q4	11	9	90	9	90	6
Year 4	Q1	12	9	90	11	90	6
	Q2	13	9	90	12	90	6
	Q3	14			13		6
	Q4	15			14		6

Important Notes

Actuals Enrollment Report

Select **Actuals Enrollment** in the left column of the **Reports** page.

Reports

- Study Graphs
- Quarterly Report
- Forecast Enrollment
- Actuals Enrollment
- Actuals
- Demographics
- Milestones
- Milestones
- Comparison Report

Selection Control: By default, the selected time period shown at the top of the page will auto-populate the fields in this report. Users can select a different time period using this control.

Year Quarter

Project Summary and Study Plan: This section displays study details and study plan.

Year
 Quarter

Actuals Enrollment Report

Principal Investigator	John Smith
Acronym	Import Study Test
Title	Import Study
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of Grant Award	2017-10-01

Study Plan	
Target Number of Clinical Sites	5
Target Number of Practitioners (if applicable)	5
Total Enrollment (including anticipated loss/withdrawal)	1,000
Timeline for Completing subject accrual	2018-08-03
Date of first subject activity/enrollment in clinical trial (YYYY-MM-DD)	2018-03-06
If no active sites/subject, provide date trial is expected to begin	NA

Enrollment Activity: Numbers in the **Expected Total** column are auto-populated from the Forecast Report. The **Actual Total** column numbers, entered by the trial team each quarter (see “6. Reporting Enrollment”), appear in the table when submitted, and will be seen in the table for the entire year (all quarters). If an **Actual Total** column is empty, then there is no data available for that quarter.

Enrollment Activity Table

	Q1 Reporting Date		Q2 Reporting Date		Q3 Reporting Date		Q4 Reporting Date	
	Jan 1 - Mar 31		April 1 - June 30		July 1 - Sep 30		Oct 1 - Dec 31	
Effective Date of Data	2021-04-13		2021-04-13		2021-04-13		2021-04-13	
Locked	No		No		No		No	
	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total
Total clinical sites with active subjects	2	2	2	2	2	2	2	2
Total practitioners randomized (if applicable)	0		0		0		0	
Total subjects screened/contacted (if applicable)	130	130	130	130	130	130	130	130
Total active subjects (cumulative)	85	90	85	90	85	90	85	90
Total subject enrolled & lost, withdrawn, or opted out	0		0		0		0	0
Total subjects completing study	0		0	5	0	5	0	5

IF ANY OF THIS INFORMATION HAS CHANGED, PLEASE CONTACT YOUR PROGRAM OFFICER

Question and Explanation: The display in this section varies depending on the selected time period, and identifies key changes in the trial that could affect reports. The five questions are worded in such a way that a **No** answer indicates no change from the previous quarter. A **Yes** answer contains a text field for explanation.

1. Any change to IRB status of the trial?	No
Comments	
2. Any new sites or sites that are no longer participating?	Yes
Comments	One site dropped because it was sold by HCA
3. Any protocol changes? Changes to inclusion/exclusion criteria?	No
Comments	
4. Any budgetary concerns or anticipation of carrying over 25% of No funds?	
Comments	
5. Any changes to key personnel efforts >25%?	No
Comments	

Comments

Reported data is estimated to be 75% accurate. Data will be updatec dataset is finalized.

Actuals Demographics Report

Select **Actuals Demographics** in the left column of the **Reports** page.

- Reports**
- Study Graphs
 - Quarterly Report
 - Forecast Enrollment
 - Actuals Enrollment
 - Actuals Demographics
 - Milestones
 - Milestones Comparison Report

Selection Control: By default, the selected time period shown at the top of the page will auto-populate the fields in this report. Users can select a different time period using this control.

When first entering a trial report, the default is the current reporting period (if enrolling) or the last enrolling period (if enrollment has completed).

Year Quarter

Project Summary: This section displays trial details.

Principal Investigator	John Smith
Acronym	Import Study Test
Title	Import Study
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of Grant Award	2017-10-01

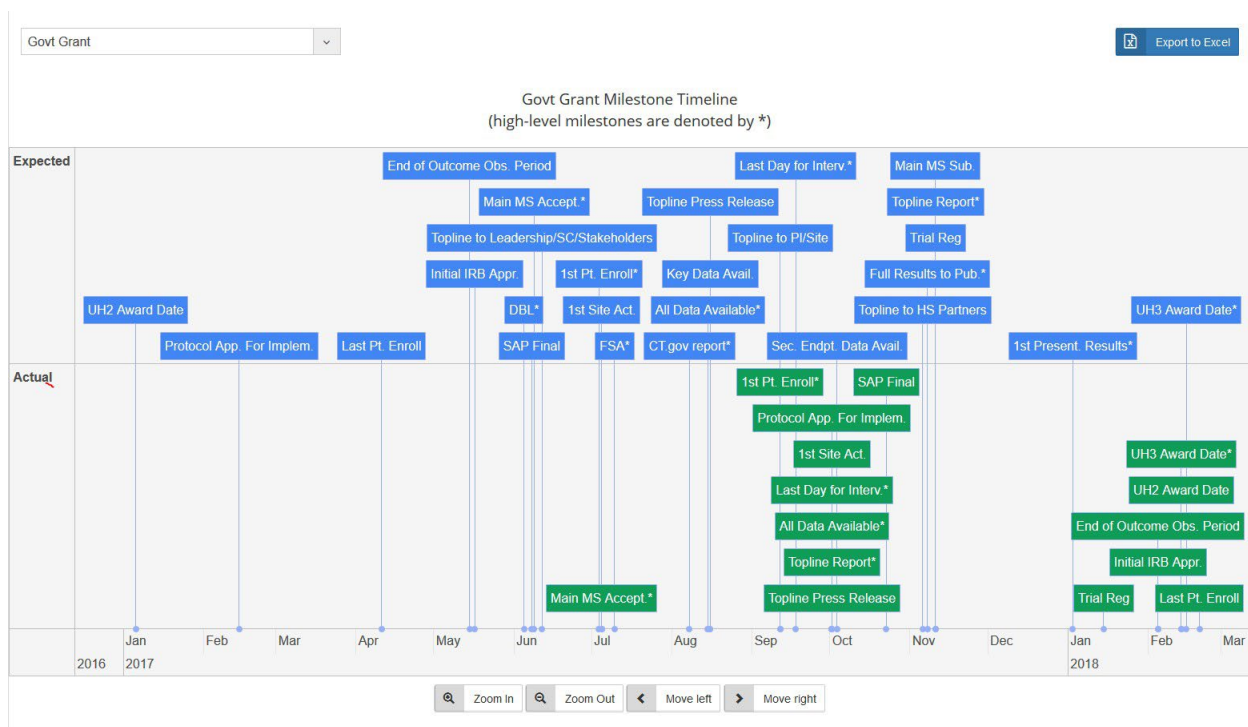
Cumulative Demographic Enrollment Table: This table divides the number of subjects during the selected time period into racial and ethnic categories. These numbers *are cumulative* from one quarter to the next.

Cumulative Demographic Enrollment

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian/Alaska Native	321	248	0	49	35	0	16	30	1	700
Asian	1,695	1,235	0	13	3	0	40	39	2	3,027
Native Hawaiian or Other Pacific Islander	141	106	0	8	8	0	4	4	3	274
Black or African American	1,319	1,382	0	21	29	0	43	49	4	2,847
White	24,345	20,164	3	3,221	2,542	1	841	843	5	51,965
More Than One Race	0	0	0	0	0	0	1	1	6	8
Unknown or Not Reported	334	351	0	946	792	0	721	647	7	3,798
Total	28,155	23,486	3	4,258	3,409	1	1,666	1,613	28	62,619

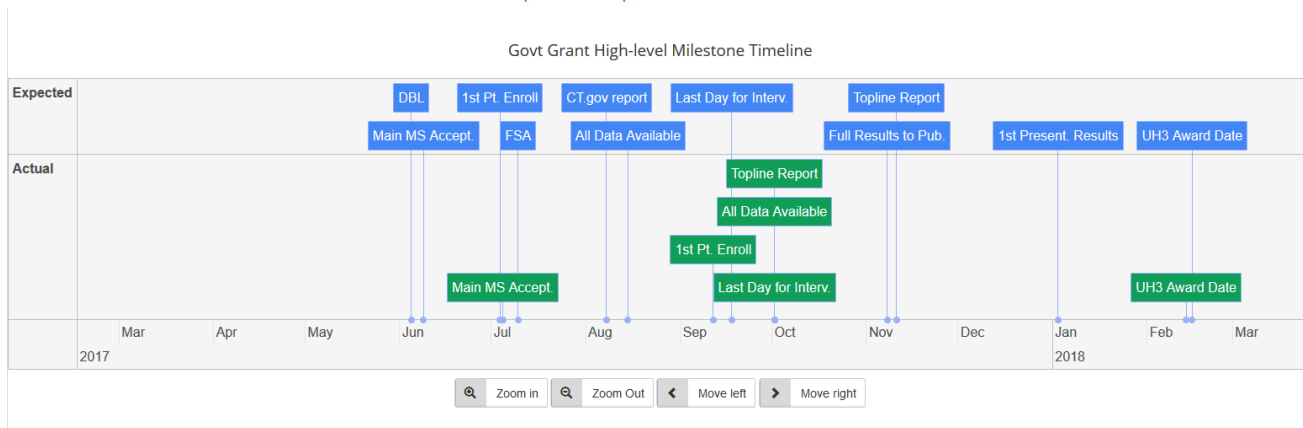
Milestones Report

Select **Milestones** in the left column of the **Reports** page.



Reports

- Study Graphs
- Quarterly Report
- Forecast Enrollment
- Actuals Enrollment
- Actuals Demographics
- Milestones Comparison Report



About the Two Graphs

The two graphs share the same design. In both, the **Expected Dates** are blue and the **Actual Dates** are green. Refer to the table in Chapter 6 for the abbreviated names of milestones with their full name and description.

Milestone Timeline: The top graph shows the Expected Dates (blue) compared with the Actual Dates (green) of all milestones (including high-level milestones).

High-Level Milestone Timeline: The bottom graph shows the high-level milestones, denoted by asterisks.

Across the bottom of each graph is a timeline, based on the earliest and latest dates on the **Milestones** page. Users can zoom in to enlarge the graph. To adjust your view, use one of the following controls (note: your computer’s hardware/software configuration may affect use):

- The four buttons underneath each graph.



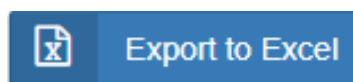
- The scroll wheel on a mouse. Click anywhere inside the graph, then roll up/down

as needed.

- A touchpad enabled system. Tap anywhere inside the graph. Then expand or contract the space between two fingers.

With a mouse or touchpad, drag and drop any place in the graph to move the graphic to the left or right.

Export to Excel: Click the **Export to Excel** button in the upper right. The system creates an Excel (extension .xls) file and sends it to your computer's downloads folder. Columns in the spreadsheet include Milestone name (high-level ones are marked by an asterisk), abbreviated name, milestone definition, expected date, actual date, and comments. Using the Excel program, you can print or save this information.



Milestones Comparison Report

Select **Milestones Comparison Report** in the left column of the **Reports** page.

Selection Control: If you have access to more than one trial, select the desired trial from the dropdown.

The **Milestones Comparison Report** allows the user to compare a minimum of one set of milestones (two different milestone fields) with up to a maximum of four sets of milestones based on the date that was entered for that particular milestone.

1. Select the two milestones to be evaluate, to get the absolute value in days, the average, standard deviation and median in days.

Note: The dates used for this report come from the dates entered in the **Milestones** page in the **Actual Date** field column. In the event that the either one of the fields are missing a date, the value brought back the absolute value in days will be blank and the value brought back for average, standard deviation and median in days will be 0.

Select Milestone 1 Select Milestone 2

Select Milestone 1 Select Milestone 2

Select Milestone 1 Select Milestone 2

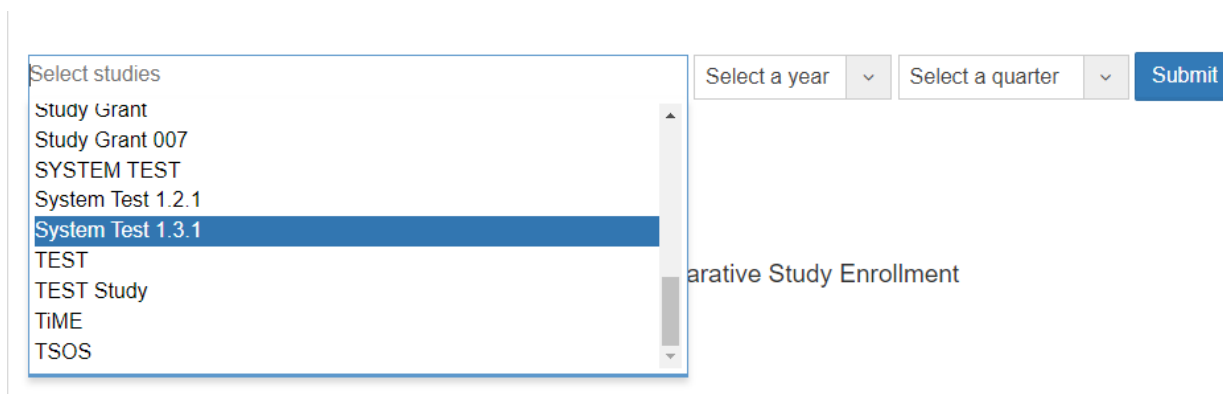
Select Milestone 1 Select Milestone 2

Comparative Graphs Report

NIH Pragmatic Trials Collaboratory leadership have the opportunity to view Comparative Reports, which provides visualizations across studies for a specified year (e.g., Year 2) and quarter (Quarter 2), regardless of the actual calendar year the trial started. The graphics are normalized to show enrollment actuals and demographic breakdown. Trial teams will only be able to view their own trial data and **WILL NOT** be able to compare information across studies. The screenshots below are based on leadership views of the report; trial teams will only be able to see your own site related information.

Note: The graphs will be rendered only for trials with data for the selected quarter/year.

Selection Control: Select studies in the selection window, the Year and quarter, then submit.

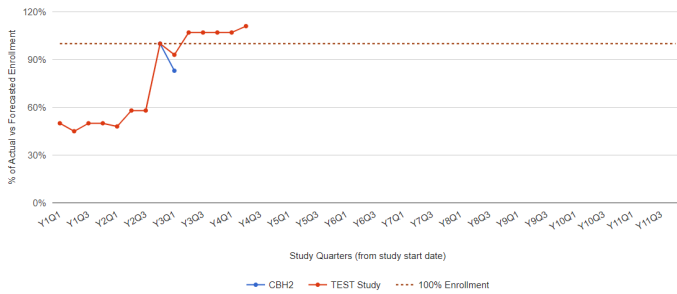


The report will be rendered as shown.

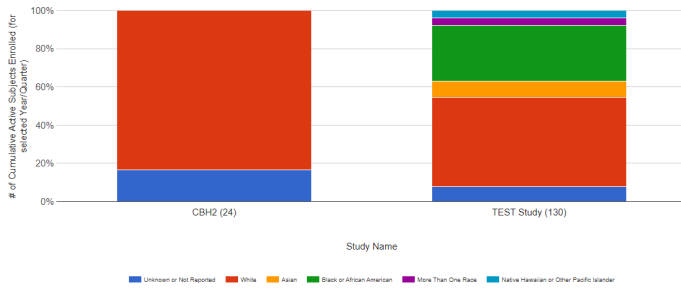
Comparative Graphs

CBH2 TEST Study Year 2 Quarter 4 Submit

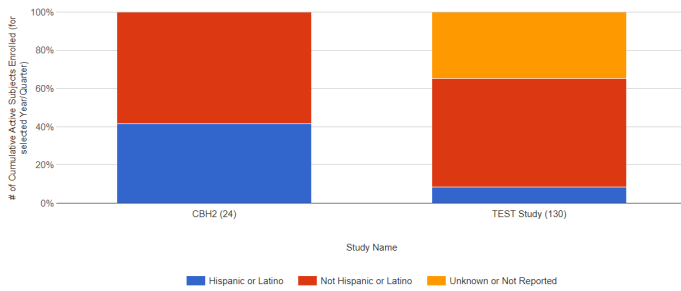
Comparative Study Enrollment



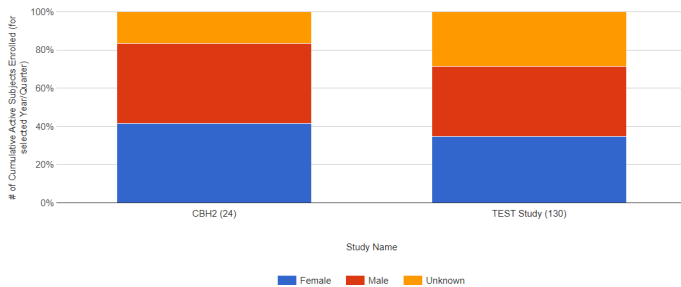
Comparative Racial Breakdown



Comparative Ethnicity Breakdown



Comparative Sex Breakdown



12. Health Equity Dashboard

The purpose of the Health Equity Dashboard reports are a graphical representation of the sex, race and ethnicity currently in the reporting system for your trial. Certain members of the NIH Pragmatic Trials Collaboratory Coordinating Center, NIH Pragmatic Trials Collaboratory Leadership, and NIH have access to the reports in the reporting tool across the trials while the Study Coordinators and PIs will only have access to their own trial(s).

These are aggregate numbers from the start of the trial up to the year and quarter selected. If you have access to more than one trial, it does not matter if one trial is in their 1st year while the other trial is in their 5th year, the aggregate number will be from start up to the year and quarter selected for reporting.

From any page, click the **Health Equity Dashboard** button on the **Menu Bar**.



Demographic Comparative Graphs Report

NIH Pragmatic Trials Collaboratory leadership have the opportunity to view Comparative Graph Reports, which provides visualizations across studies for a specified year (e.g., Year 2) and quarter (Quarter 2), regardless of the actual calendar year the trial started. The graphics are normalized to show enrollment actuals and demographic breakdown.

Select **Demographic Comparative Graphs** in the left column of the **Health Equity Dashboard** page.

Health Equity Dashboard

Demographic Comparative
Graphs

NIH Collaboratory Program
Reports

Selection Control: The main demographic fields are available for selection are race, ethnicity and sex. Users can select which field in the first box using these controls. It is possible to view the fields together based on a main selection and sub-selection, e.g. main selection will be race based on non-Hispanic males. Ensure the main demographic field is selected first and proceed to filter the one or both of the sub-fields as needed.

Select demographic to graph Select race Select ethnicity Select sex

The **Demographic Comparative Graph Report** allows the user up to a maximum of eight trials to include in the demographic comparative graph report. Users can select a different time period using this control to the right of the study box. When first navigating to this page, all selection fields will be blank. The screenshots below are based on leadership views of the report. Trial teams will only be able to view their own trial data and **WILL NOT** be able to compare data across trials.

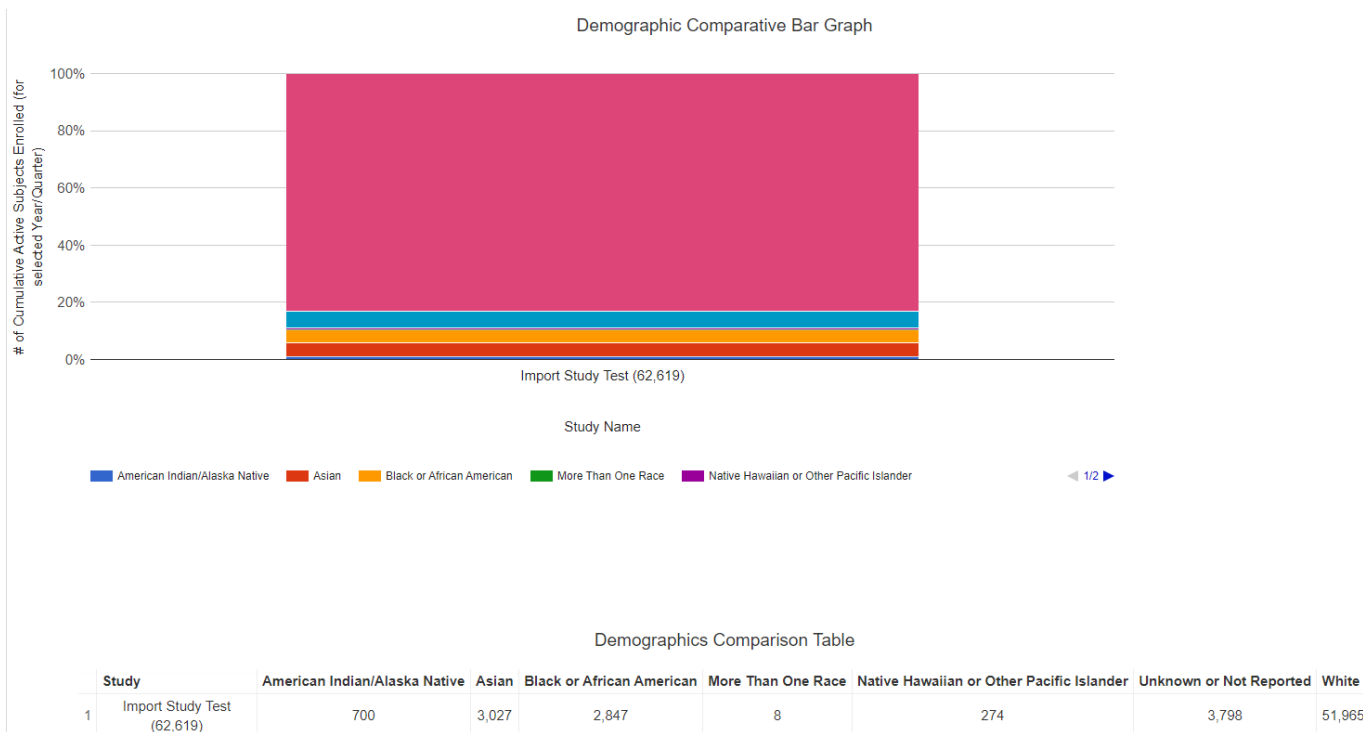
Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>	Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>
Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>	Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>
Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>	Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>
Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>	Select a study <input type="text"/> <input type="text"/> <input type="text"/> <input type="button" value="Reset"/>

1. Select the trial first and then proceed in entering the year and the quarter of interest.

Import Study Te Select a year Select a quarter

Note: The year and the quarter used can be trial specific and does not need to be the same if more than one trial is selected. The data is cumulative up to the year and quarter that is selected.

Demographic Comparative Graph Report: Each bar chart represents each trial based on the period selected. There is also a table below with each row representing each trial with the values displayed.



NIH Collaboratory Program Reports

This report allows the Study Coordinator to view aggregate data for all trials in which they have access using the study status field as a filter. The aggregate data will be based on when the report is generated. The study status information is based on the standard phases that the trial trials moves through. If you are responsible for more than one trial, all trials with the same study status will be aggregated in the report.

Select **NIH Collaboratory Program Reports** in the left column of the **Health Equity Dashboard** page.

Health Equity Dashboard

[Demographic Comparative Graphs](#)

[NIH Collaboratory Program Reports](#)

Selection Control: You can filter by any of the available status options by clicking on the search bar. It is possible to select more than one study status or leave the filter selection blank. If you leave the status selection field blank, the report that is run will select all of the study statuses.

Select Study Statuses (to see data for all the statuses, leave this blank and click submit)

- Pilot/Start-Up**
- Trial Initiation
- Site Activation
- Enrollment
- Follow-Up
- Data Availability
- Data Analysis
- Reporting (Internal)
- Reporting (Public)

Submit

Once the selection is made, a table will appear indicate which trial currently is included in the filter study status that was selected. In the left hand-side of the screen, you can also generate a PDF of the report.

Data Analysis **Submit** **Generate PDF**

Study Status Table (Collaboratory Program Report)

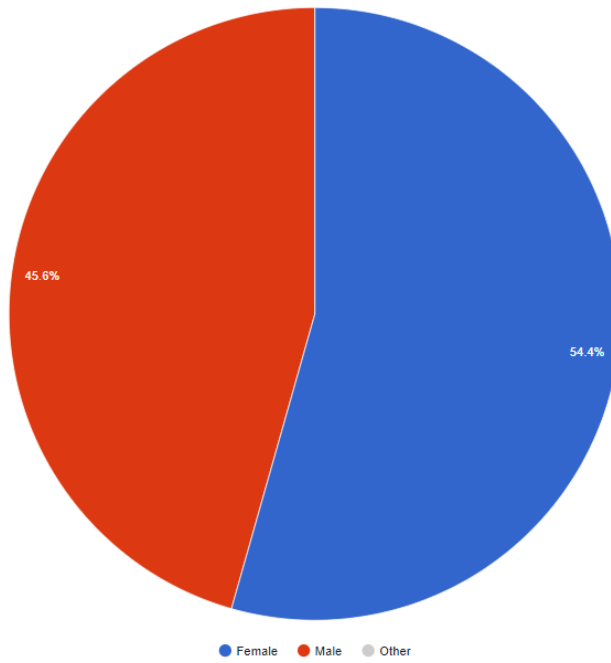
Study	Study Status
ABATE	Data Analysis

Cumulative Demographic Enrollment (Collaboratory Program Report)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian/Alaska Native	138	147	0	0	0	0	0	0	0	285
Asian	120	109	0	0	0	0	0	0	0	229
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	21,371	16,548	0	3	3	0	0	0	0	37,925
White	108,402	91,501	4	80	84	0	0	0	0	200,071
More Than One Race	0	0	0	0	0	0	64	56	0	120
Unknown or Not Reported	0	0	0	9,144	7,614	0	17,477	15,387	3	49,625
Total	130,031	108,305	4	9,227	7,701	0	17,541	15,443	3	288,255

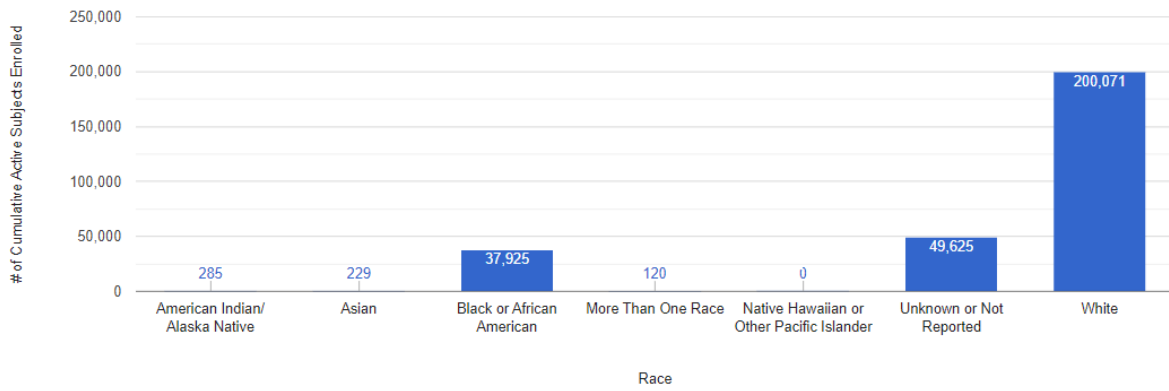
2024-08-08 21:30:38 UTC

Sex Breakdown (Collaboratory Program Report)



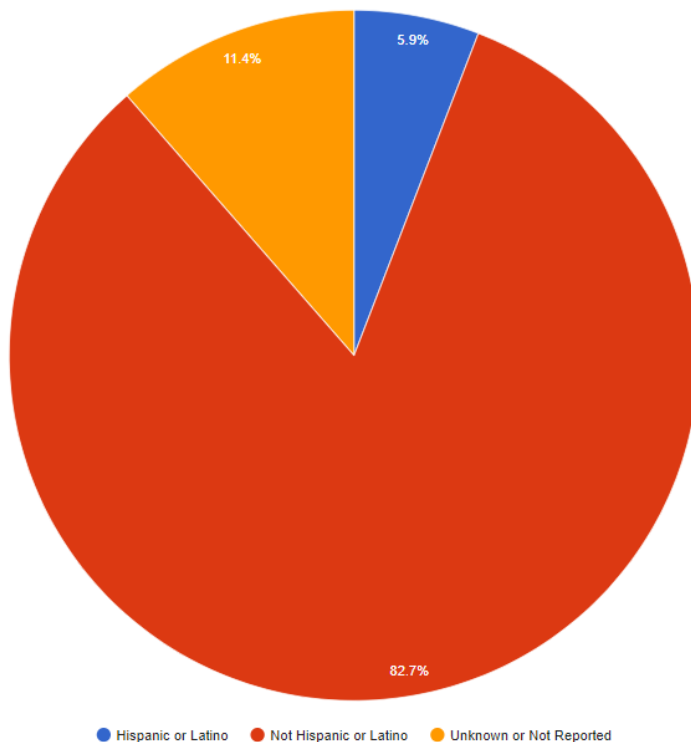
2024-08-08 21:30:38 UTC

Racial Breakdown (Collaboratory Program Report)



2024-08-08 21:30:38 UTC

Ethnicity Breakdown (Collaboratory Program Report)



2024-08-08 21:30:38 UTC

Note: Reports will be labeled Collaboratory Program Reports regardless of how many trials are being included in the report.