NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

UH3 Reporting Site User Guide

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1. Logging In and Out and Navigating

The UH3 Enrollment Reporting Site is used by the NIH Collaboratory Demonstration Project teams to submit study data on a quarterly basis, including enrollment data, inclusion (demographic) data, and study milestone data.

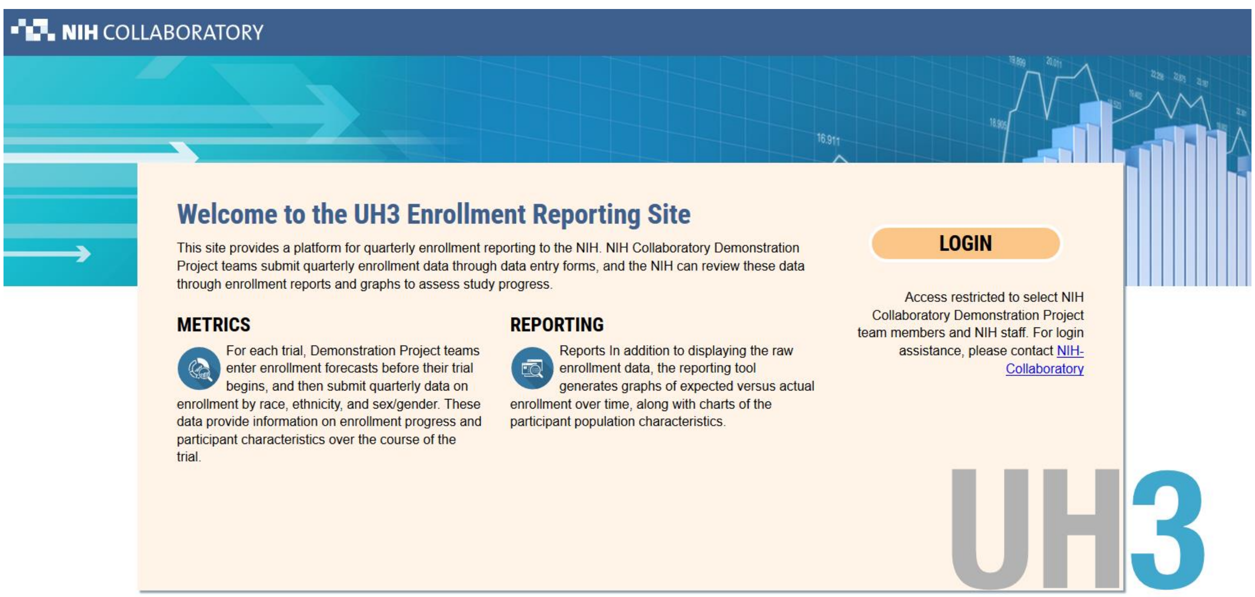
The reporting site allows study teams to access and enter project data for their project only. However, the NIH Collaboratory Leadership has access to the reporting site to review and compare data for multiple projects side-by-side.

Logging In

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

1 In the email you received from the Collaboratory Coordinating Center, click the link for the site located in the body of the email.

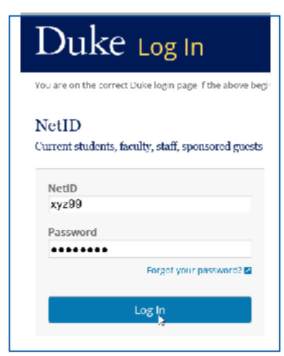
The **Welcome** page opens in your computer's default browser. *Tip:* To save time accessing this site in the future, consider making it a shortcut in your browser.



2 Click the **Login** button. The **Duke Log In** page appears.

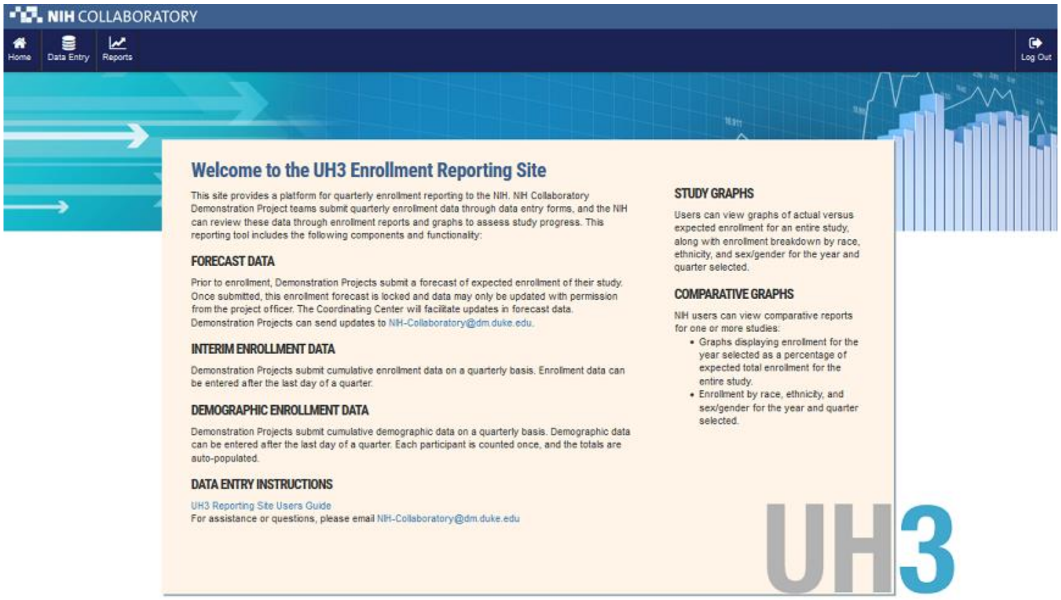
3 Enter the **NetID** and **Password** you received in the email.

4 Click the **Log In** button. The **Home** page appears.



Home Page

The text on the left summarizes the tasks to be completed.



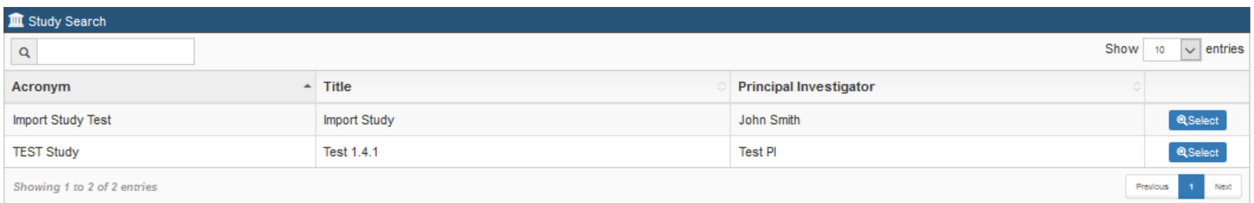
The topmost navigation tool is the dark blue **Menu Bar** across the top of the page. This bar contains four buttons: three on the left and one at the far right.

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

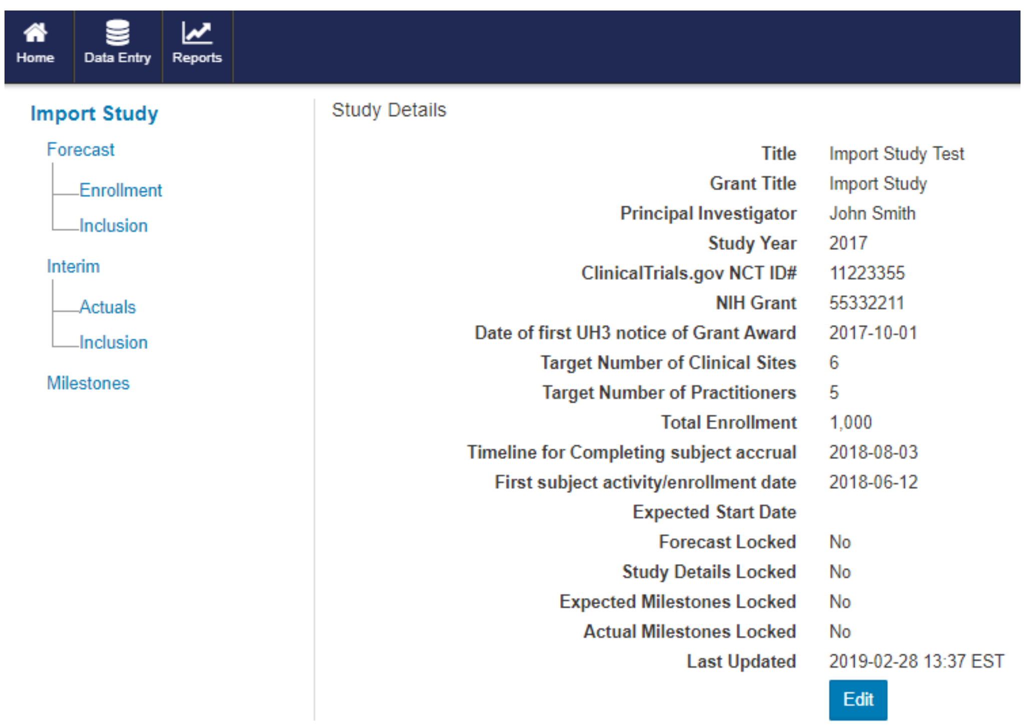
Study Details Page

After clicking the **Data Entry** button on the **Home** page, the **Study Details** page for your Study appears if you work with only 1 study.

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



The **Study Details** page is the starting point for the data entry tasks in this guide. On the right is study information currently in the system. On the left are links to access two **Forecast** pages, two **Actuals** pages, a **Reports** page and a **Milestones** page.



Data Entry

The table below shows the timing of the data entry tasks to be completed by the study team, and are described in Chapters 2-8. Four items are entered one time before study enrollment begins, and three items are entered every quarter after enrollment begins.

Chapter	Data entry task	When submitted for approval	Data to enter
2	**Study Details**	One time, before enrollment begins	Details of the study
3	**Forecast: Enrollment**		Cumulative numbers
4	**Forecast: Demographics**		Cumulative numbers
5	**Milestones: Expected Dates**		Planned completion dates
6	**Actuals: Enrollment**	At the start of every quarter with data from the previous quarter	Cumulative numbers
7	**Actuals: Demographics**		Cumulative numbers
8	**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.

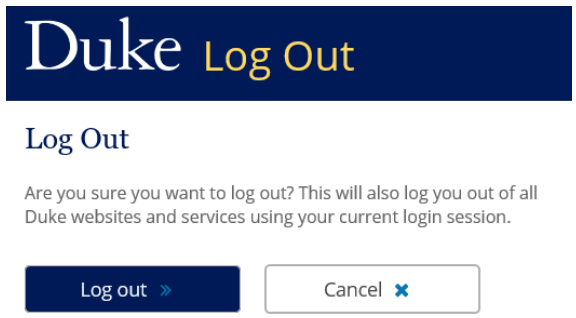
For **Actuals: Enrollment, Actuals: Demographics,** and **Milestones: Actual Dates**, data cannot be entered for the current quarter until *the first 2 weeks of the next quarter*.

If edits need to be made to a locked page, the study's Principal Investigator should contact the 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.

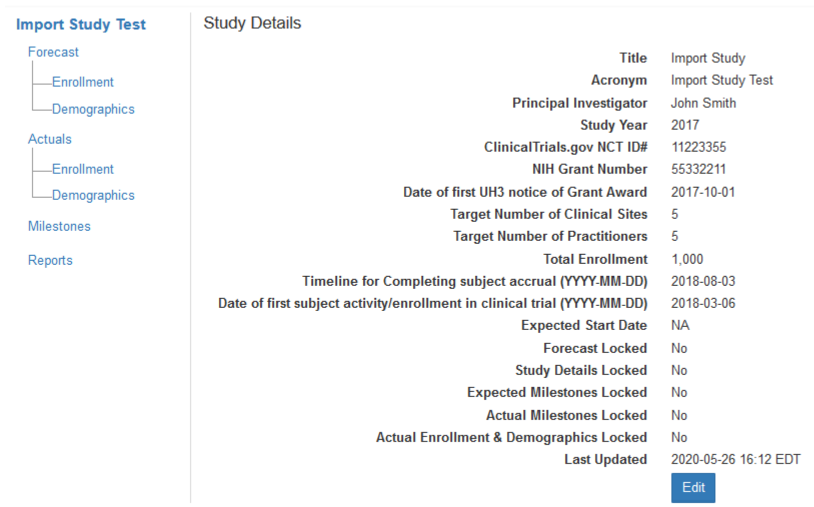
1 On any page, go to the right side of the **Menu Bar** and click the **Log Out** button. The **Duke Log Out** page appears.



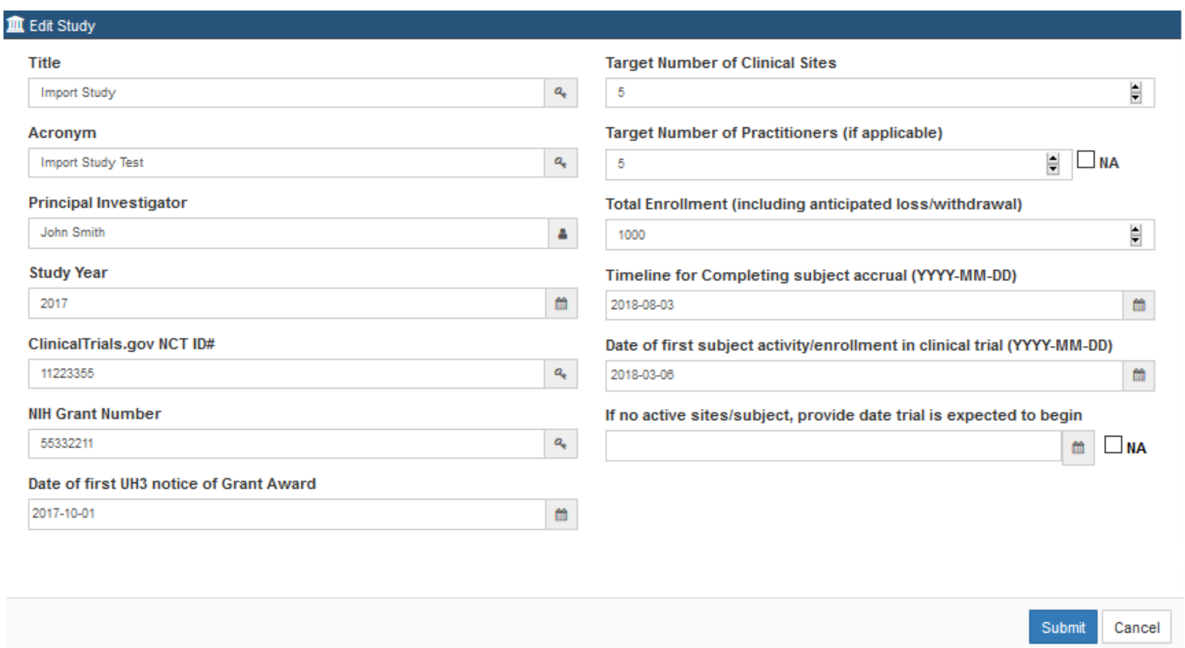
2 Click **Log out** to end the connection to the Duke network.

2. Study Details

The first task is to enter details about your study into the system. You can return at any time (before the study 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.



The **Edit Study** page appears.



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

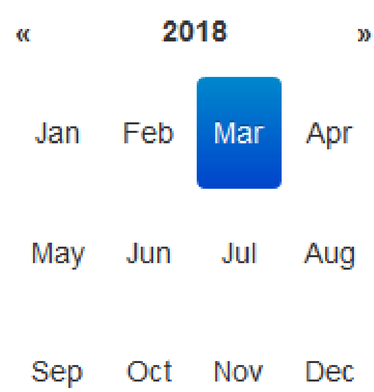
1 Complete as many fields as possible.

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



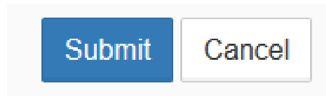
4 If you need a different year, click the double arrows at the far top corners (» next year or « previous year). Click the desired month. After that month appears, click on the day.

5 After selecting a day, the calendar disappears and the field displays the full date.

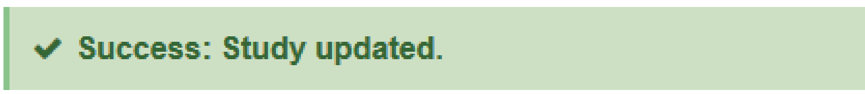
Note: An incorrect date format will display a red error message: Please enter a valid date.

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.



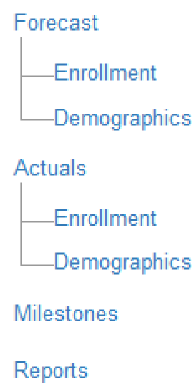
1 When finished, click the **Submit** button. You are returned to the **Study Details** page with a success message displayed across the top of the page. Your updates appear on the page.



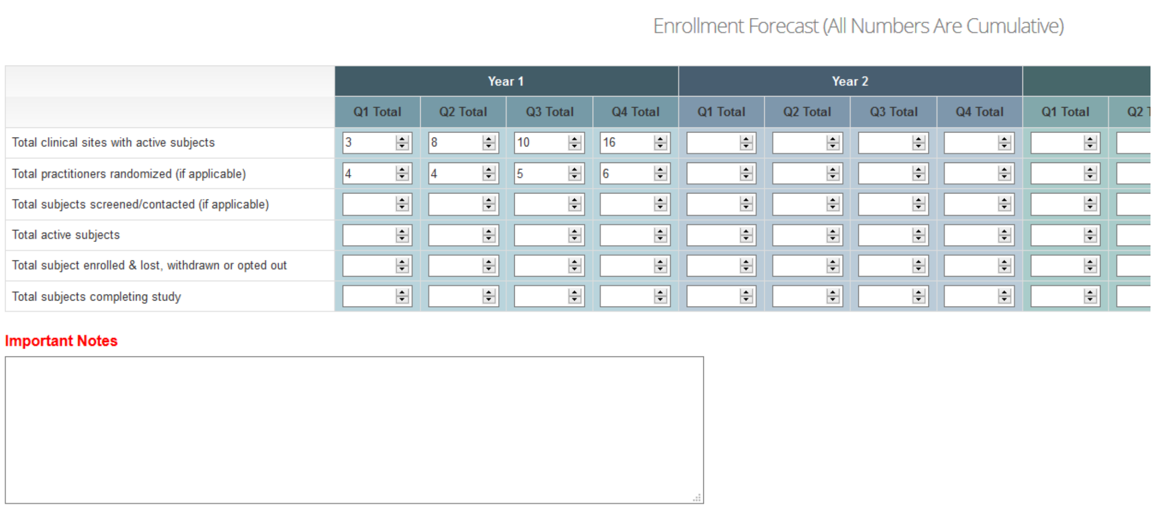
2 Inform the study's Principal Investigator that this data entry task has been completed.

3. Forecasting Enrollment

Before enrollment starts, enter forecast (expected) enrollment numbers by quarter for the duration of the study. To begin, go to the **Study Details** page. In the left column, click **Enrollment** (under Forecast).



The **Enrollment Forecast** page appears.


Enrollment Forecast (All Numbers Are Cumulative)

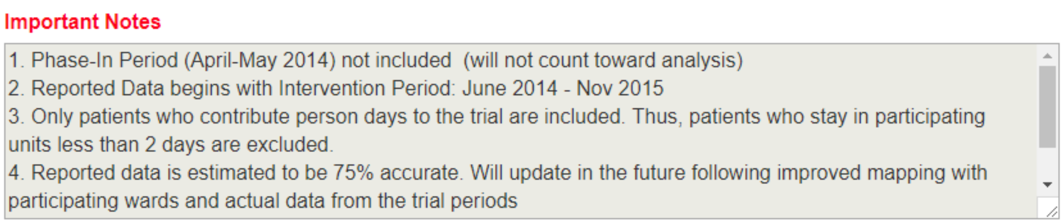
	Year 1				Year 2					
	Q1 Total	Q2 Total	Q3 Total	Q4 Total	Q1 Total	Q2 Total	Q3 Total	Q4 Total	Q1 Total	Q2 T
Total clinical sites with active subjects	3	8	10	16						
Total practitioners randomized (if applicable)	4	4	5	6						
Total subjects screened/contacted (if applicable)										
Total active subjects										
Total subject enrolled & lost, withdrawn or opted out										
Total subjects completing study										

Important Notes

1. Enter forecast totals for the following 6 items as applicable for the duration of your study:
   - Total number of clinical sites with active subjects
   - Total practitioners randomized (if applicable)
   - Total subjects screened/contacted (if applicable)
   - Total active subjects
   - Total subjects enrolled & lost, withdrawn, or opted out
   - Total subjects completing study

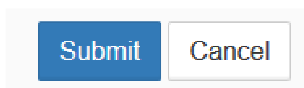
Note: The forecast enrollment numbers entered must be cumulative such that *each quarter's number is not lower than the previous quarter*. If a lower number is entered, an error will be generated when you submit (see example below under Submitting Your Updates).

2 To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data. Under 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 (maximum 4,000 characters).



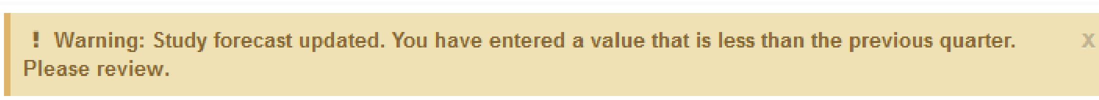
Submitting Your Updates

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.

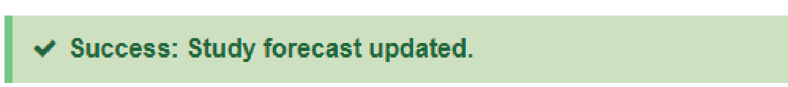


1 When finished, click the **Submit** button.

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.



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



3 Inform the study's Principal Investigator that this data entry task has been completed.

4. Forecasting Demographics

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

- Forecast
  - Enrollment
  - Demographics
- Actuals
  - Enrollment
  - Demographics
- Milestones
- Reports

The **Demographics Forecast** page appears.

Demographics Forecast

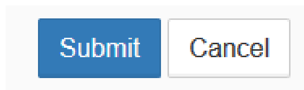
	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		
Racial Categories	Female	Male	Female	Male	Total
American Indian/Alaska Native	50	60	25	27	162
Asian	11	12	4	9	36
Native Hawaiian or Other Pacific Islander	5	6	2	4	17
Black or African American	55	59	33	37	184
White	50	48	8	5	111
More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

Submit Cancel

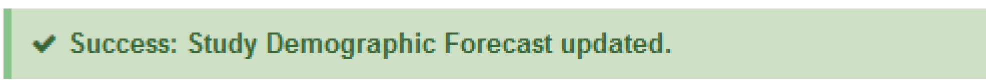
1. Enter the forecast demographic totals for female and male for pertinent racial categories in the correct ethnic block. To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data.
2. Review the forecast numbers (the system totals the cells in rows and columns).

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.



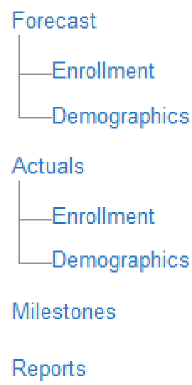
1. When finished, click the **Submit** button, a success message is displayed across the top of the **Demographics Forecast** page.



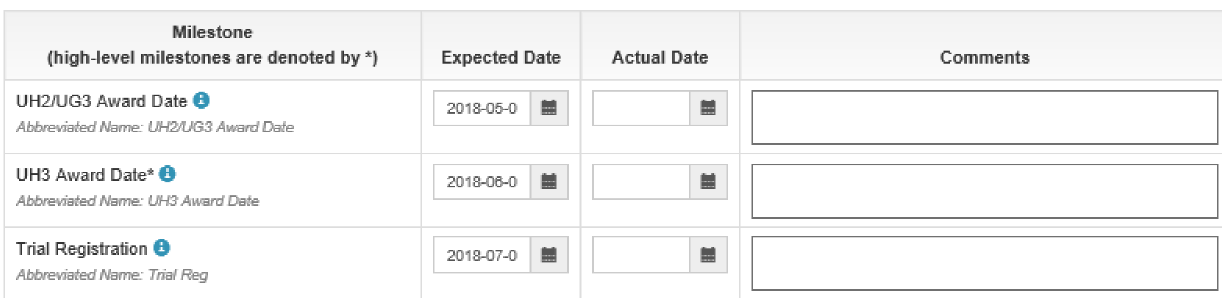
2. Inform the study's Principal Investigator that this data entry task has been completed.

5. Milestones: Expected Dates

Before enrollment starts, enter expected completion dates for major milestones for the duration of the study. If you are on a page pertaining to your study, click **Milestones** in the left column to begin. If you are in another section of the web site, go to the **Study Details** page. In the left column, click **Milestones**.



The **Milestones** page appears containing 26 milestones with fields for **Expected Date, Actual Date**, and **Comments**.



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 study, 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.

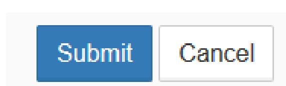
Milestone * = high-level milestone	Abbreviated Name	Summary
UH2/UG3 Award Date	UH2/UH3 Award Date	The date UH2/UG3 Awarded (from the NIH website).
UH3 Award Date *	UH3 Award Date	Date UH3 Awarded (from the NIH website).
Trial Registration	Trial Reg	Date the Trial was registered with www.clinicaltrials.gov by the legally responsible entity.
Protocol Approved for Implementation	Protocol App. For Implem.	Date initial protocol is considered final by the NIH.
Initial IRB Approval (UH3 Phase Implementation)	Initial IRB Appr.	Date of the first site IRB approval of the main trial (UH3) [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 do 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

Milestone * = high-level milestone	Abbreviated Name	Summary
Leadership/SC and Other Stakeholders	Leadership/SC/ Stakeholders	for the Study Leadership/Steering Committee.
Topline results to Investigators/Sites	Topline to PI/Site	Date that the topline results are available for the Study Investigators/sites.
Topline Results to Public via Press Release (if done)	Topline Press Release	If applicable, the date that the topline results are available to the public (i.e., press release). If not applicable, please indicate so in the Comment section.
Full Results to Public *	Full Results to Pub.	Date that the full results are available for the public.
First Presentation Results *	1st Present. Results	Date of the first public presentation of the primary endpoint data.
Main Manuscript Submitted	Main MS Sub.	Date the primary endpoint manuscript is submitted for publication.
Main Manuscript Accepted *	Main MS Accept.	Date the primary endpoint manuscript is accepted for publication.
Clinicaltrials.gov Reporting	CT.gov report	Date is the date reported in clinicaltrials.gov as complete with results or project terminated.

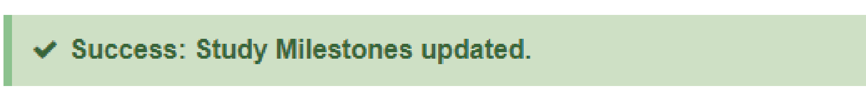
Note: Both the **Abbreviated Name** and the designation of a **high-level milestone** pertain to the **Milestone Report** (details in "10. Reports").

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 **Study Details** page with a success message displayed across the top of the page.



2 Inform the study's Principal Investigator that this data entry task has been completed.

6. Reporting Enrollment

As the study progresses, study teams will enter the total actual enrollment numbers for the reported quarter and answer 5 questions.

Note: This data entry is to be completed during the 2-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).

- Forecast
  - Enrollment
  - Demographics
- Actuals
  - Enrollment
  - Demographics
- Milestones
- Reports

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 "10. Reports") and cannot be modified in this table.

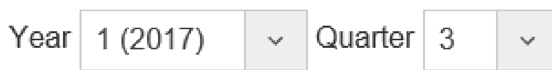
Note 2: If any locked information needs to be edited, please contact the NIH Program Officer for approval to unlock and edit the data.

Enrollment Activity

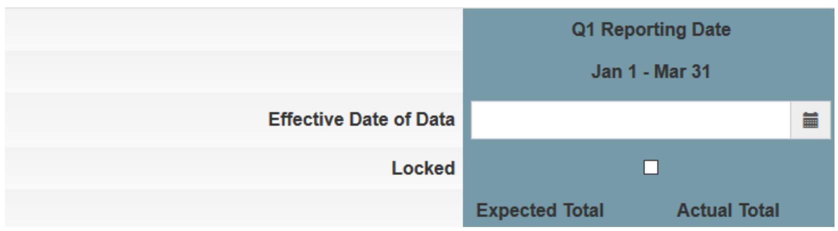
	Q1 Reporting Date Jan 1 - Mar 31		Q2 Reporting Date April 1 - June 30		Q3 Reporting Date July 1 - Sep 30		Q4 Reporting Date Oct 1 - Dec 31	
Effective Date of Data			2017-08-06		2017-10-01			
Locked	No		No		☐		No	
	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total	Expected Total	Actual Total
Total clinical sites with active subjects			1	2	2	2	3	
Total practitioners randomized (if applicable)			1	3	2	3	3	
Total subjects screened/contacted (if applicable)	16		17	4	18	4	19	
Total active subjects	32		33	5	34	5	35	
Total subject enrolled & lost, withdrawn or opted out	48		49	6	50	6	51	
Total subjects completing study	64		65	7	66	7	67	

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 study data. The table changes with each selection and allows you to edit only the quarter selected. Only the current and previous quarters are editable. In the event that previous quarters are locked, please contact NIH Collaboratory or email (NIH-Collaboratory@dm.duke.edu) for assistance



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



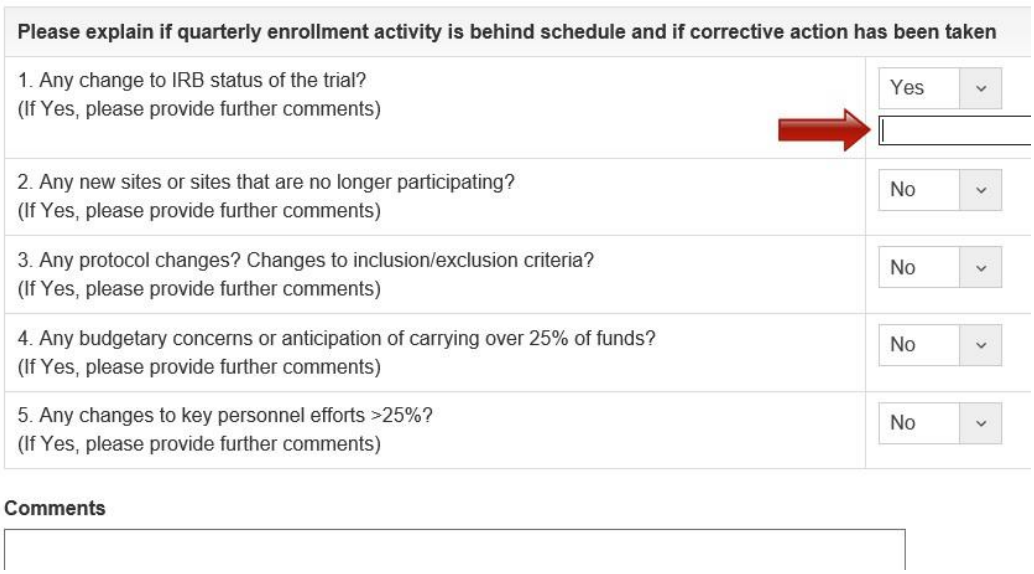
3 Enter **Actual Total** numbers as of this *reported quarter* as follows (ie, total number up to this point in the study):

- **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 number of practitioners participating in enrollment activities as of this reported quarter.
- **Total subjects screened/contacted (if applicable):** This is the 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 study is not screening or contacting subjects per the design, enter zero for the current and subsequent quarters.
- **Total active subjects:** This is the total number of active subjects as of this reported quarter.
- **Total subjects enrolled & lost, withdrawn, or opted out:** This is the total number of subjects lost, withdrawn, or opted out as of this reported quarter.
- **Total subjects completing study:** This is the total number of subjects completing the study as of this reported quarter.

4 Scroll down to answer the 5 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.

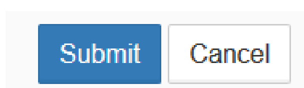
5 Use the optional **Comments** text box under the questions to add further information (maximum 4,000 characters). The Comments Box is not associated to a specified year and quarter. Any notes entered in the Comments box will be visible for each year and quarter selected.



6 Review the edits for accuracy.

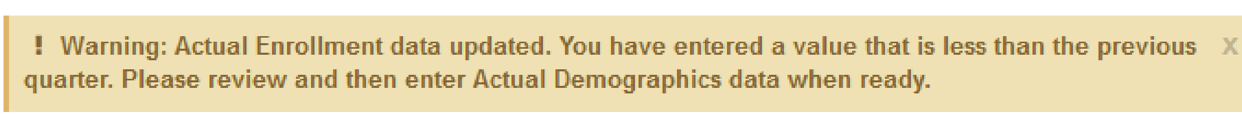
Submitting Your Updates

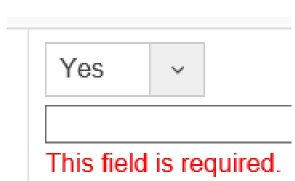
If you decide for any reason to discard your edits this session (they will not be retrievable)—click the **Cancel** button at the bottom of the page to clear your edits.



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.





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 study's Principal Investigator that this data entry task has been completed.

7. Reporting Demographics

As the study progresses, study teams will enter actual demographic data (race, ethnicity, and gender) for enrolled participants. This data is to be completed within the first 2 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).

Forecast
- Enrollment
- Demographics

Actuals
- Enrollment
- Demographics

Milestones

Reports

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

Cumulative Demographic Enrollment

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
Racial Categories	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	Total
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

Submit Cancel

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.

   Year 1 (2017) Quarter 3

2. Enter the numbers for female and male 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**

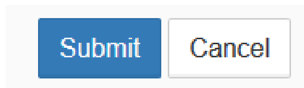
row. To update an existing number, put the cursor in the field, delete the existing data, and enter the updated data.

3. Review the entries for accuracy. The values entered in this **Cumulative Demographic Enrollment** table should equal the participants *accrued* during the reported quarter plus previous quarters.

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

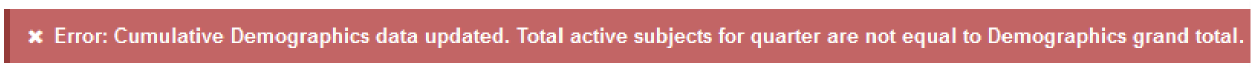
Submitting Your Updates

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 participants 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.

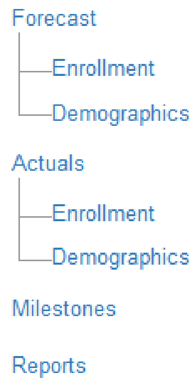


2 If there are no errors, you are returned to the **Study Details** page with a success message displayed across the top of the page.

3 Inform the study's Principal Investigator that this data entry task has been completed.

8. Milestones: Actual Dates

As the study progresses, study 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.



The **Milestones** page appears. For the first 2 weeks of a new quarter, this page displays the **Actual Date** for milestones completed in the *previous quarter*. At the end of the first 2 weeks of the quarter, this page is locked again.

Milestone (high-level milestones are denoted by *)	Expected Date	Actual Date	Comments
UH2/UG3 Award Date *Abbreviated Name: UH2/UG3 Award Date*	2017-06-01	2017-07-03	
UH3 Award Date* *Abbreviated Name: UH3 Award Date*	2017-06-13	2017-07-03	Waiting for HB 221 tp pass for funding/app
Trial Registration	2017-08-08	2017-09-04	

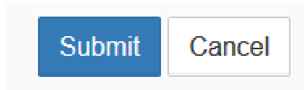
1 Enter actual completion dates in the **Actual Date** field for completed milestones. Use the online calendar or enter the date directly in the format YYYY-MM-DD. Use the **Comments** field to add information if necessary.

   Note: For a brief description of each milestone, hover the cursor over the information icon or refer to the table in Chapter 5 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 are returned to the **Study Details** page with a success message displayed at the top of the page.

2 Inform the study's Principal Investigator that this data entry task has been completed.

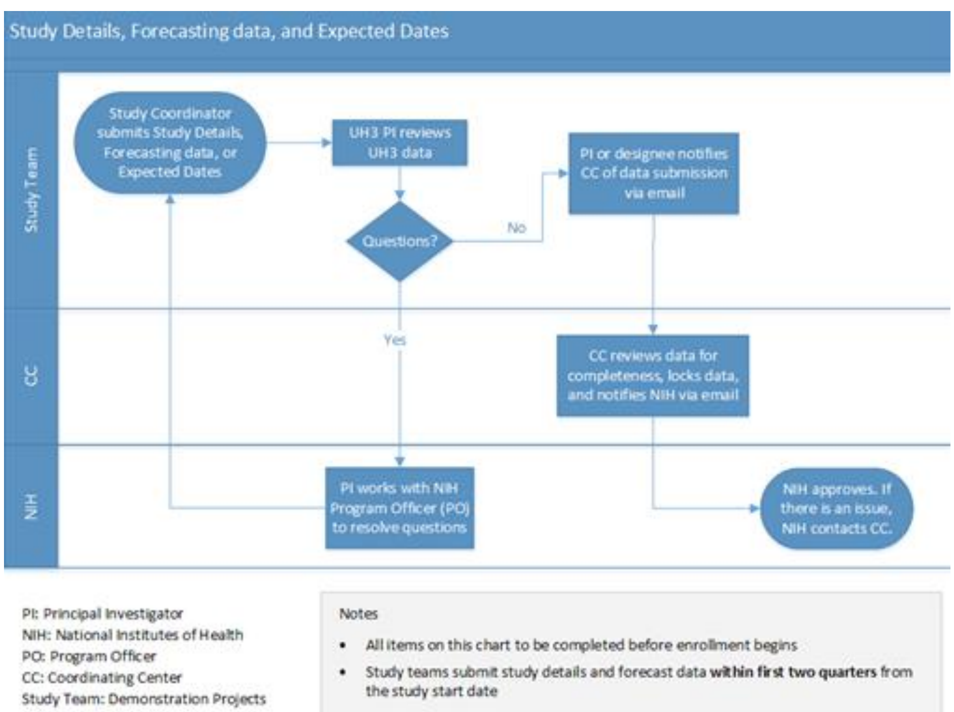
9. Data Entry and Approval

This chapter summarizes the data entry tasks and approval timing.

When submitted for approval	Data entry item	Chapter
One time, before enrollment begins: These *forecast tasks* are to be completed within the first 3 quarters after the **UH3 Award Date** milestone, but no later than the **First Patient Enrolled Date** milestone.	Study Details	**2**
	Forecast: Enrollment	**3**
	Forecast: Demographics	**4**
	Milestones: Expected Dates	**5**
Every quarter: These *interim tasks* are to be completed at the beginning of every quarter using actual data from the previous quarter	Actuals: Enrollment	**6**
	Actuals: Demographics	**7**
	Milestones: Actual Dates	**8**

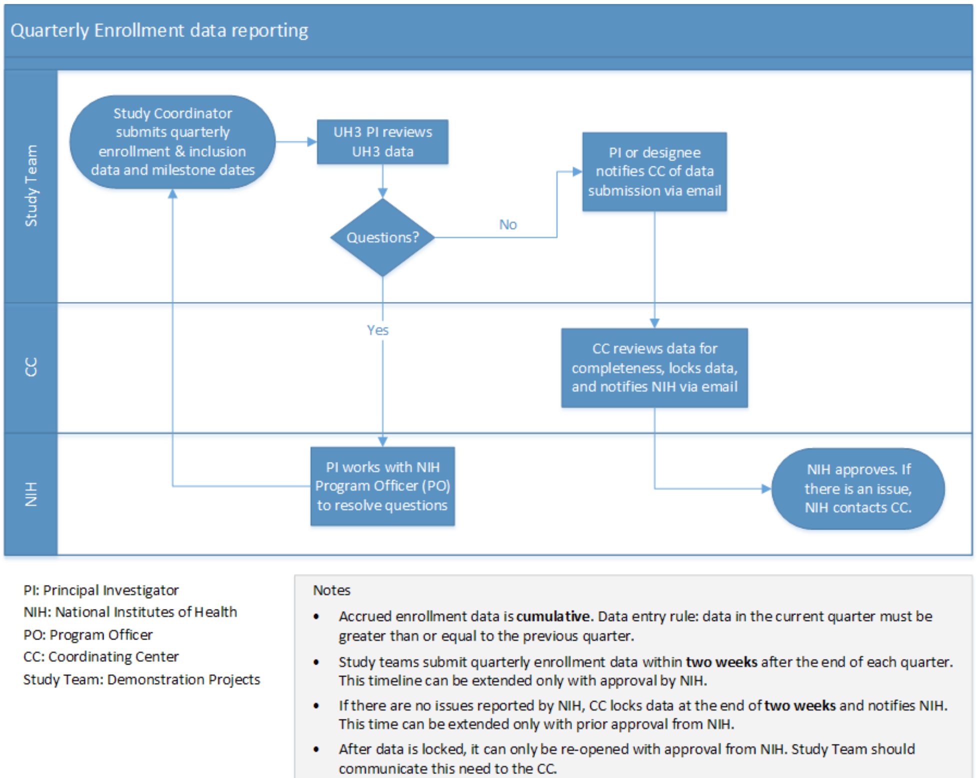
Data to Submit One Time Before Enrollment

The flowchart shows this process.



Data to Submit at the Start of Every Quarter

The flowchart shows this process.



Review and Approval

All data submitted by the Demonstration Projects must be reviewed and approved by the study's Principal Investigator. If there are any exceptions to providing UH3 reporting data or questions about the data, the PI should contact the study's NIH Program Officer.

IMPORTANT: After Forecast data is locked, it can only be reopened with approval from NIH. Study teams should communicate their need to the CC.

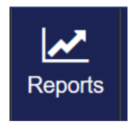
Contacting the NIH Collaboratory Coordinating Center

For questions or comments about the UH3 reporting environment, send an email to the Collaboratory at NIH-Collaboratory@dm.duke.edu, and your message will be triaged to the appropriate person for response.

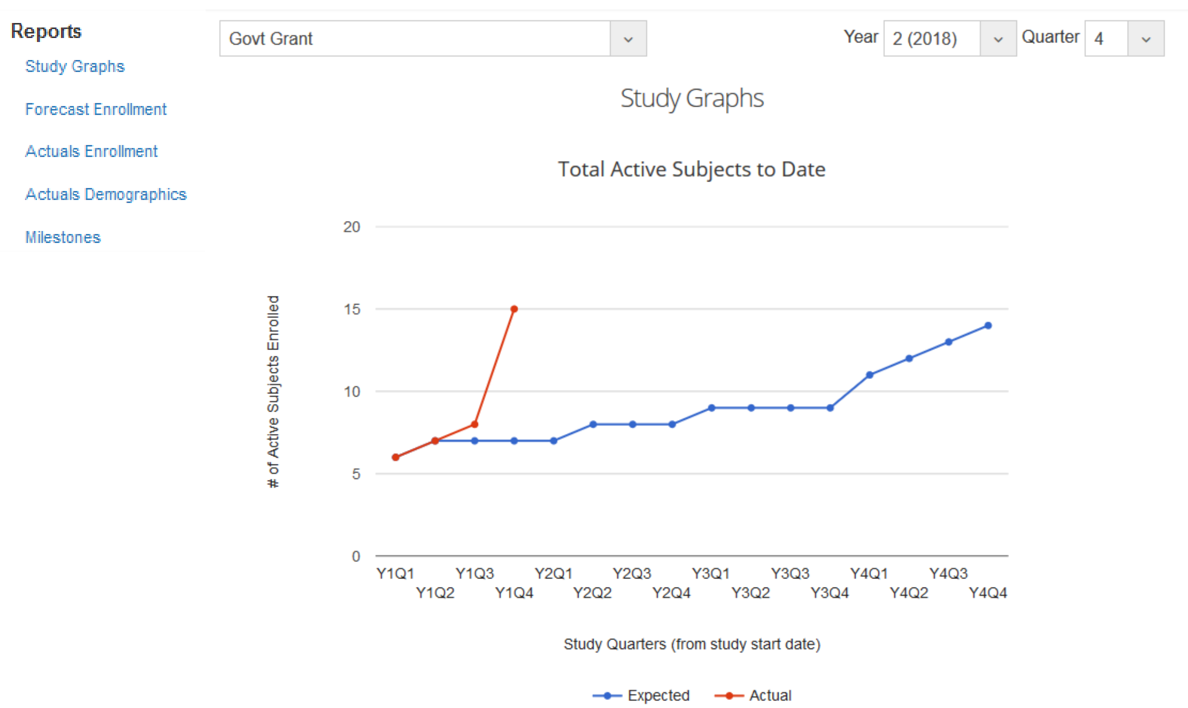
10. Reports

Although not part of the core tasks, displaying reports can help to visualize trends or issues in the data. These reports are a graphical representation of the information currently in the UH3 system for your study.

From any page, click the **Reports** button on the **Menu Bar**.



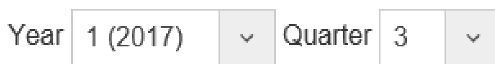
By default, the **Study Graphs** page appears with columns on the left for links to the reports.



Selection Control

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

For **Study Graphs, 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.

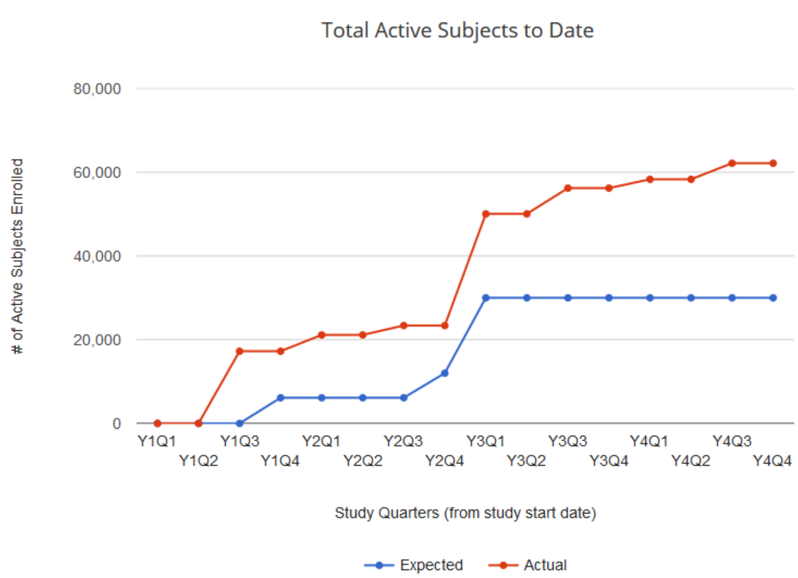


Study Graphs

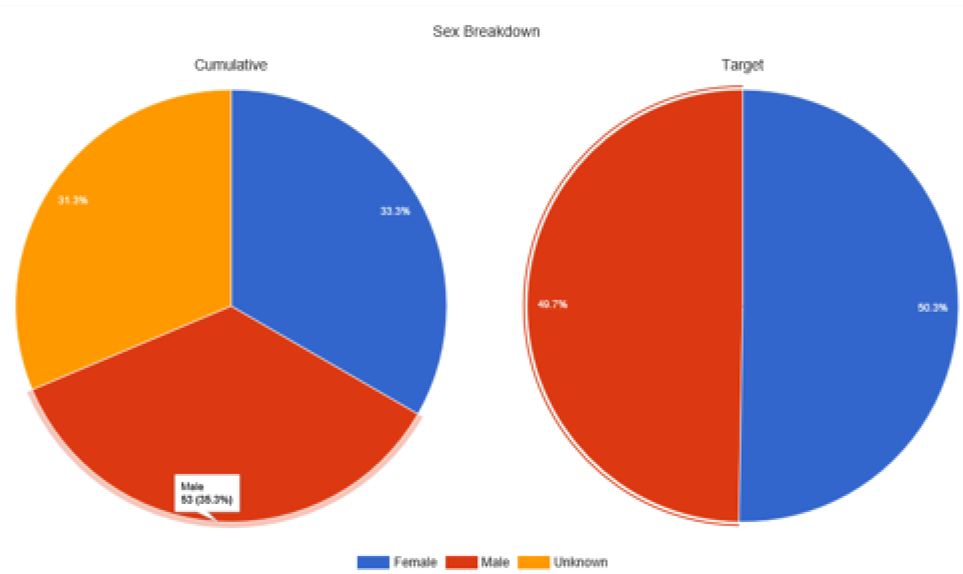
If data is available for the selected time period, four different graphs (described below) will appear on the **Study Graphs** page. (If a graph does not appear, data has not been submitted for the selected time period.)

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

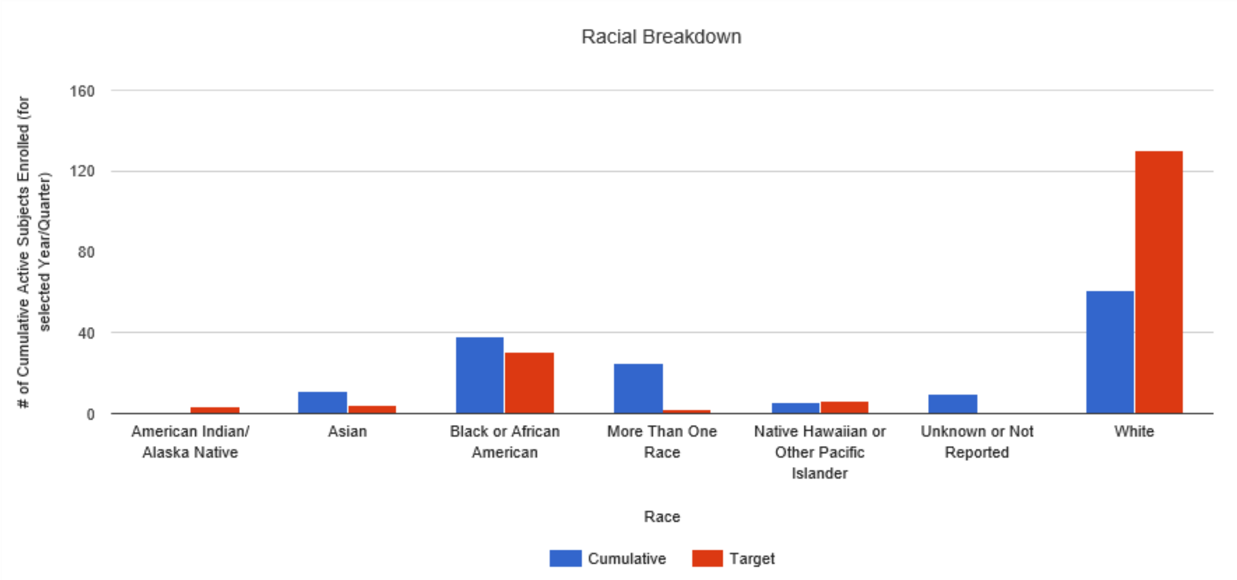
Total Active Subjects to Date: This graph is cumulative. The line chart always shows expected (blue) versus actual (red) enrollment numbers for the entire project, up to the present. The blue line, taken from Forecast data, is complete and does not change over the entire life of the project. The red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



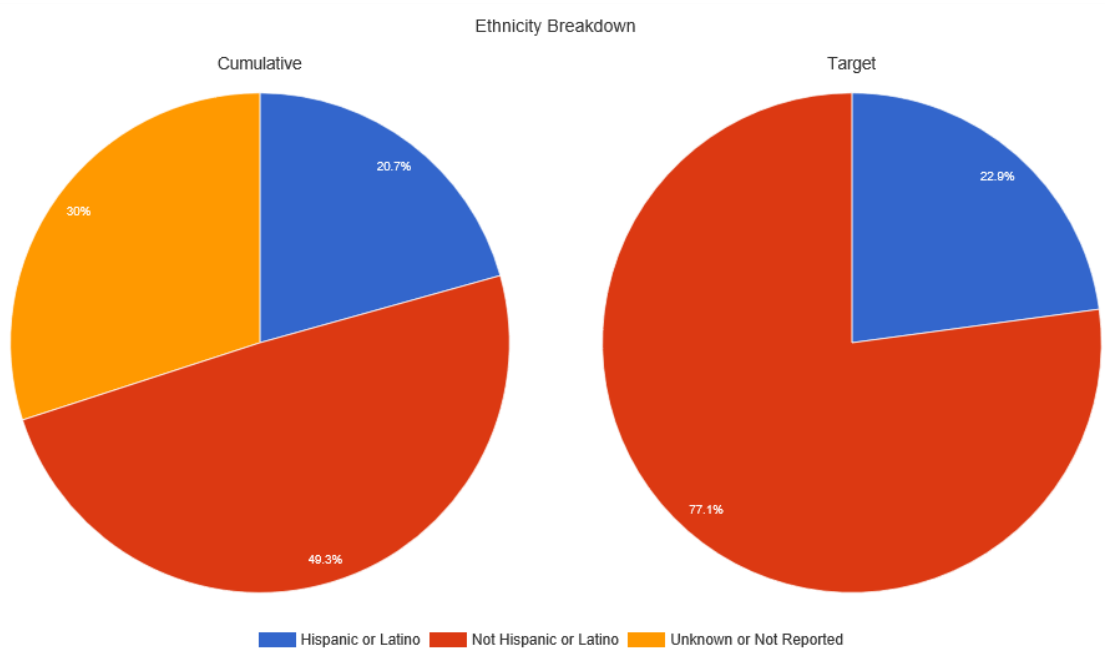
Sex Breakdown: The pie chart on the left (**Cumulative**) divides the total number of subjects enrolled in the selected time period into percentages known to be male (red), female (blue), or unknown/unreported (yellow). Similarly, there is a gender breakdown for the forecasted demographics (**Target**).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



Racial Breakdown: This bar chart plots the total number of subjects enrolled in the selected time period and 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.

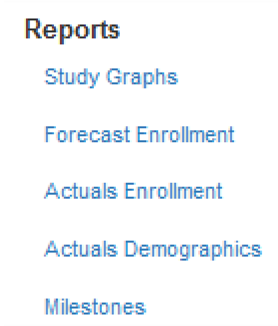


Ethnicity Breakdown: These pie charts divide the total number of subjects enrolled in the selected time period into a percentage known to be Hispanic or Latino (blue), not Hispanic or Latino (red), or unknown/unreported (yellow). For actual numbers, hover over any part of a chart; a tool tip appears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



Forecast Enrollment Report

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



Project Summary: This section displays study details.


Forecast Report

Principal Investigator	John Smith
Grant Title	Import Study
Title	Import Study Test
ClinicalTrials.gov NCT ID#	11223355
NIH Grant	55332211
Date of first UH3 notice of Grant Award	2017-10-01

Enrollment Forecast Table: This table shows forecast (expected) enrollment numbers by quarter, divided into 4 years. This forecast information was provided by the study team at study start-up.

Enrollment Forecast (All Numbers Are Cumulative)

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

Important Notes

Actuals Enrollment Report

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

Reports

- Study Graphs
- Forecast Enrollment
- Actuals Enrollment
- Actuals Demographics
- Milestones

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 1 (2017) Quarter 3

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

Interim Report

Principal Investigator	John Smith
Acronym	Import Study Test
Title	Import Study
ClinicalTrials.gov NCT ID#	11223355
NIH Grant Number	55332211
Date of first UH3 notice 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 (YYYY-MM-DD)	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

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

Enrollment Activity: Numbers in the **Expected Total** column are auto-populated from the Forecast Report. The **Actual Total** column numbers, entered by the study 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	2018-04-02		2018-07-02		2018-10-08		2019-01-07	
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	4	4	4	4	4	4	4	4
Total practitioners randomized (if applicable)	2	4	2	4	2	4	2	4
Total subjects screened/contacted (if applicable)	20	15	20	15	20	15	20	15
Total active subjects	120	58	130	75	130	75	130	130
Total subject enrolled & lost, withdrawn or opted out	1	2	1	2	1	2	1	2
Total subjects completing study	200	55	200	55	200	55	200	55

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 study that could affect reports. The 5 questions are worded in such as 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 funds?	No
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
- Forecast Enrollment
- Actuals Enrollment
- Actuals Demographics
- Milestones

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 1 (2017) Quarter 3

Project Summary: This section displays study details.

Quarterly Enrollment Report

Principal Investigator	John Smith
Grant Title	Import Study
Title	Import Study Test
ClinicalTrials.gov NCT ID#	11223355
NIH Grant	55332211
Date of first UH3 notice of Grant Award	2017-10-01

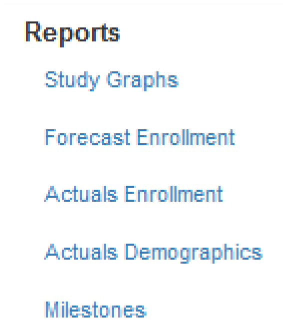
Cumulative Demographic Enrollment Table: This table divides the number of subjects during the selected time period into racial and ethnic categories. These numbers *are cumulative* from one quarter to the next.

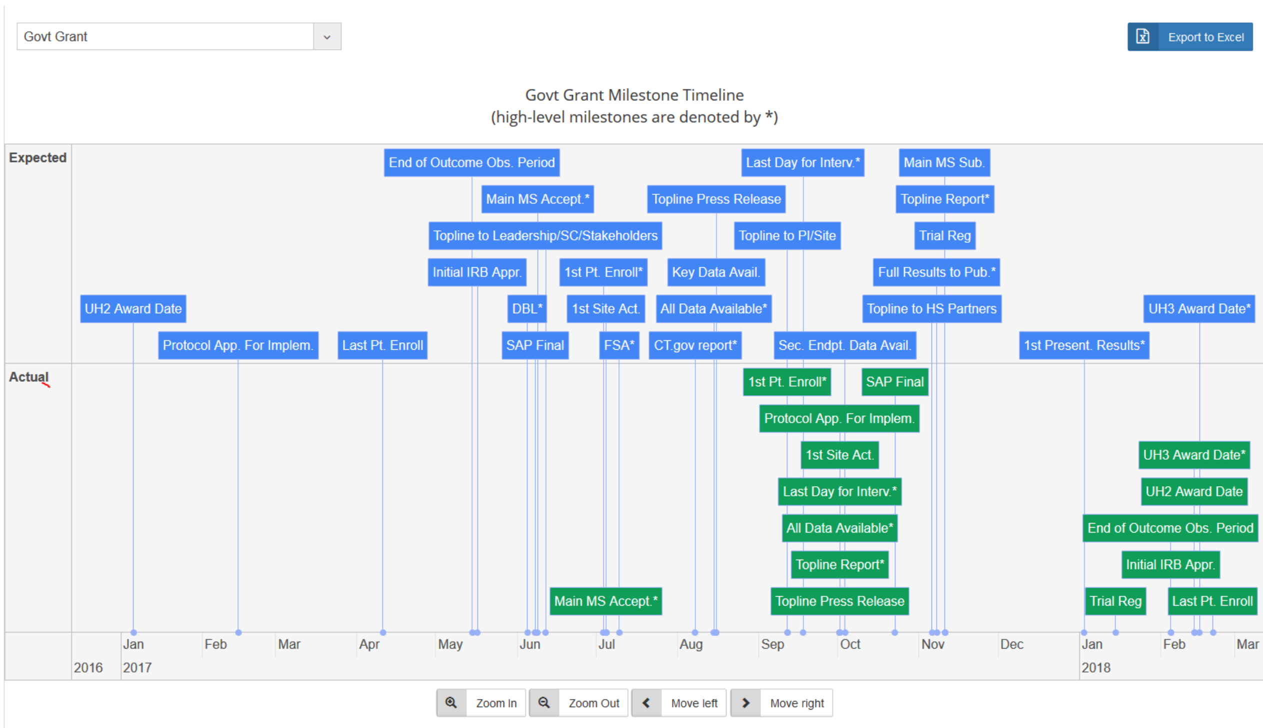
Cumulative Demographic Enrollment

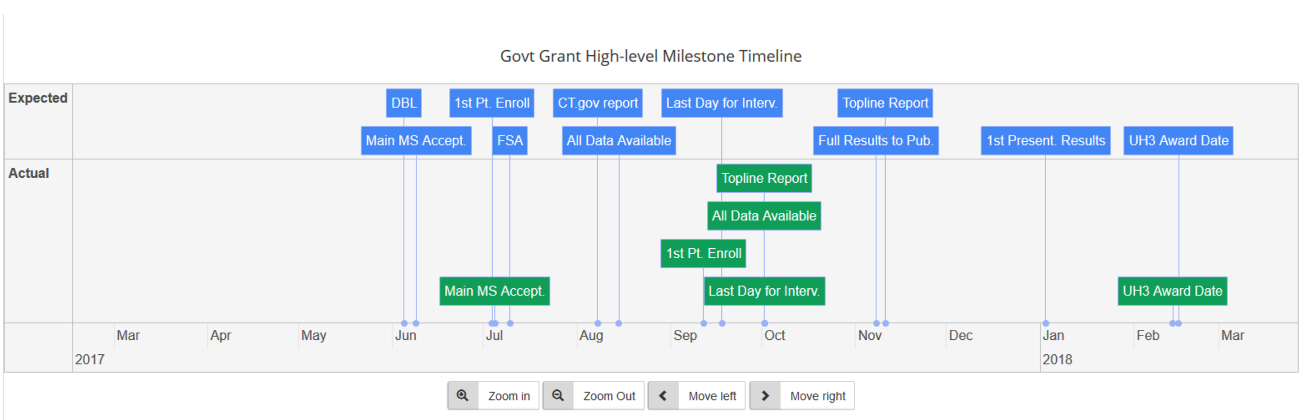
	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
Racial Categories	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	Total
American Indian/Alaska Native	321	248	0	49	35	0	16	30	1	700
Asian	1,695	1,235	0	13	3	0	40	39	2	3,027
Native Hawaiian 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.







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 5 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 that your computer's hardware/software configuration may affect their 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 on a laptop. 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.