

Chapter 1: Getting Started

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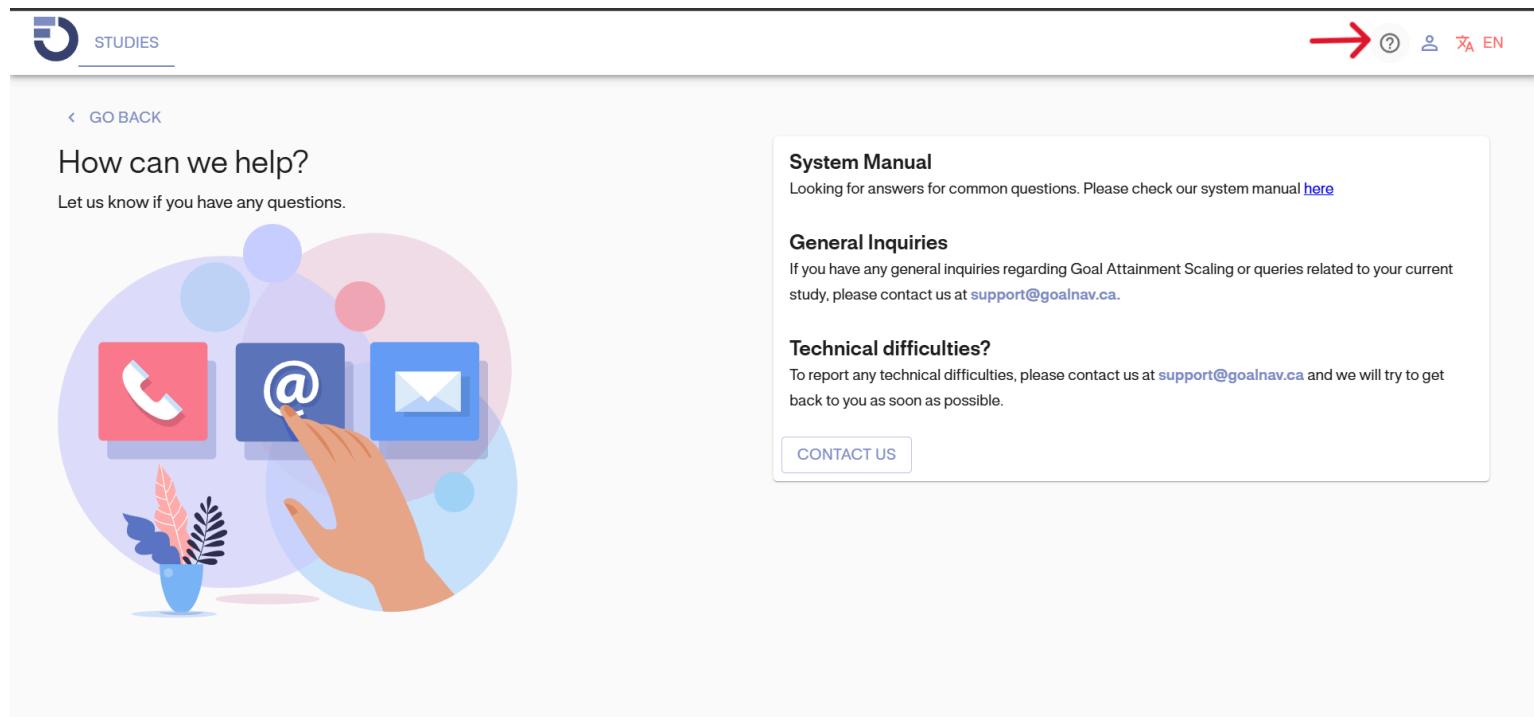
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1 [Help](#)

Help

You can easily get assistance by clicking on the help icon. This will direct you to our help page, where you'll find quick access to the help email, a general version of the system assets (excluding any study specifics), and a "Contact Us" page.



The screenshot shows a help page with the following elements:

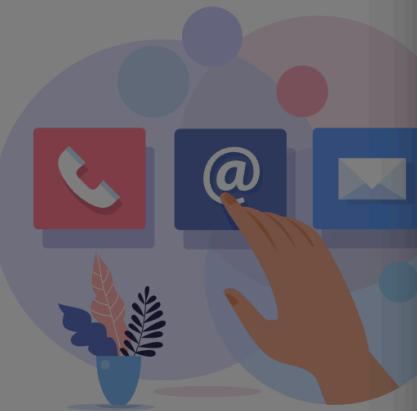
- Header:** Includes a logo for "STUDIES", a red arrow icon, a help icon, a user icon, and language options (EN).
- Section 1: How can we help?** Features a hand pointing at an '@' icon on a blue button, surrounded by a circular graphic with icons for a phone, email, and a small plant.
- Section 2: System Manual** (with a red arrow pointing to it): Text: "Looking for answers for common questions. Please check our system manual [here](#)".
- Section 3: General Inquiries**: Text: "If you have any general inquiries regarding Goal Attainment Scaling or queries related to your current study, please contact us at support@goalnav.ca".
- Section 4: Technical difficulties?**: Text: "To report any technical difficulties, please contact us at support@goalnav.ca and we will try to get back to you as soon as possible." A "CONTACT US" button is located below this section.

Click on "Contact Us" button to create a support ticket. If you have any study related questions, you may also use your study specific email for assistance.

GO BACK

How can we help?

Let us know if you have any questions.



Contact Us

Title

Please check our system manual [here](#)

Description

Goal Attainment Scaling or queries related to your current
nav.ca.

UPLOAD IMAGE

Email

CANCEL SEND

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- 1 [Minimum Requirements](#)
 - a [Mobile/Tablet Minimum Specifications](#)
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Minimum Requirements

GoalNav uses a web-based interface that requires an internet connection. GoalNav was tested using Google Chrome version 80 and supports many web browsers such as Microsoft Edge, Apple Safari, and more. Please allow popups from GoalNav in your web browser.

Mobile/Tablet Minimum Specifications

- Operating System:
 - iOS/iPadOS 16.4
 - Android 13

Laptop/Desktop Minimum Specifications

- CPU: 64bit processor
- RAM: 4 GB
- Graphics card: Microsoft DirectX 9 graphics device with WDDM driver.
- Operating System:
 - Windows 10
 - macOS Catalina (10.15)

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- 1 [How to Log In](#)
 - a [GoalNav® Account Sign-in](#)
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How to Log In

GoalNav® Sign-in and Log-in Instructions

To start using the GoalNav® system, access it through your assigned study domain. It should look similar to this:

[domain].goalnav.ca

The study domain can be found in the GoalNav training document provided when gaining access to GoalNav. If you cannot find it, please contact us using your study-specific email.

If you use the URL: “goalnav.ca” you will be redirected to enter your domain:

If you are uncertain about your GoalNav domain, click on “What’s my domain” to see instructions for locating it.



Enter your GoalNav Domain to
login.



CONTINUE

→ [What's my domain?](#)



What's my GoalNav Domain?

<https://company.goalnav.ca>

↑
It's
this!

Look at the address bar when you are logged in to GoalNav (or ask a colleague, since you are not logged in). The text just before .goalnav.ca is your domain.

GREAT THANKS!

Enter GoalNav domain in the text field, next to ".goalnav.ca"

This will take you to the GoalNav® Login Page

Please ensure you have completed your training on Goal Attainment Scaling and the GoalNav® system prior to conducting your first GAS interview.

[GoalNav® Account Sign-in](#)

After entering the GoalNav domain, you will be prompted to enter an email address. Enter your email and click Next.



Sign In

Email *

NEXT

Note: If your organization has chosen to allow signing into GoalNav with a work account via Single Sign On (SSO), after clicking Next on the email prompt you will be redirected to your organization's login page. Login as you normally would with your work account, and you will be redirected back to GoalNav once done. You are not required to create a GoalNav account if signing in this way.

If you have a password set for the account, enter the password in the password field and then click "Sign In".



Sign In

demo@gmail.com

Password *

A password input field with a small lock icon in the top right corner.

SIGN IN

[Forgot password?](#)

[Don't have an account? Sign Up](#)

If you have your 2 Factor authentication enabled, the site will redirect you to complete 2 factor authentication by asking for a code sent on your preferred authentication source. Enter the code in the text box and then click on "VERIFY".



Authentication Code

#####

VERIFY

A message was sent via SMS to +*****7609 with your authentication code. Enter the code in the form above to verify your identity.

If you no longer have access to this device, contact support for help accessing your account.

Common Sign-in Issues

If you have not been authorized to use the GoalNav® system by the GoalNav® team, the following message will display.



Access Denied: Contact your Study Admin

It looks like you currently do not have access to any Study or Workspace in the system. If you believe this is a mistake, please contact your study administrator or get in touch with us at support@gaoalnav.ca

Please contact the email listed and our team will review the issue. If you are having trouble signing-in, or if you have forgotten your password, please contact us at support@gaoalnav.ca

IN THIS CHAPTER

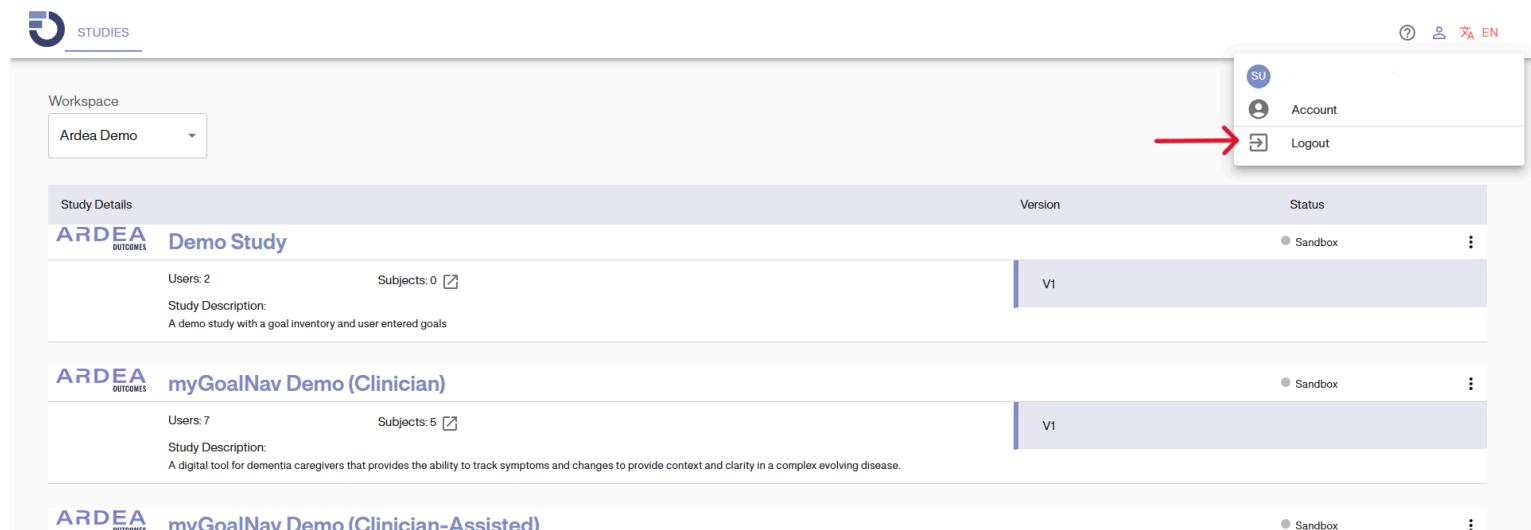
1 How to Log Outa Log out of the GoalNav® system

How to Log Out

Log out of the GoalNav® system

Click on the user icon . It will open a dropdown menu.

Click on “Logout” to logout from the site.



The screenshot shows the GoalNav system's user interface. At the top, there is a navigation bar with a logo, 'STUDIES', and other links. Below this is a 'Workspace' dropdown set to 'Ardea Demo'. The main content area displays two study entries under the 'ARDEA OUTCOMES' heading:

Study Details	Version	Status
Demo Study Users: 2 Subjects: 0  Study Description: A demo study with a goal inventory and user entered goals	V1	Sandbox
myGoalNav Demo (Clinician) Users: 7 Subjects: 5  Study Description: A digital tool for dementia caregivers that provides the ability to track symptoms and changes to provide context and clarity in a complex evolving disease.	V1	Sandbox
myGoalNav Demo (Clinician-Assisted)		Sandbox

A red arrow points to the 'Logout' option in the user dropdown menu, which is part of a sub-menu that also includes 'Account' and 'SU'.

Note: It should be common practice to log out of the system after you have finished every session. Do not wait for the system to log you out automatically.

Chapter 2: GoalNav Basics

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Home Screen

Study Details

After signing in to the GoalNav® system, you will be redirected to the study details page as outlined below.

On this page, you will see the details of your study which includes:

- Study Details
- Study Version number
- Study Status ('published' for active ongoing studies, "sandbox" for training studies)

The screenshot shows the GoalNav Home Screen with the following details:

- Workspace:** Ardea Demo
- Study Details:**
 - ARDEA OUTCOMES Demo Study**: Version V1, Status Published. Description: A demo study with a goal inventory and user entered goals. Users: 4, Subjects: 0.
 - ARDEA OUTCOMES myGoalNav Demo (Clinician)**: Version V1, Status Sandbox. Description: A digital tool for dementia caregivers that provides the ability to track symptoms and changes to provide context and clarity in a complex evolving disease. Users: 9, Subjects: 6.
 - ARDEA OUTCOMES myGoalNav Demo (Clinician-Assisted)**: Version V1, Status Sandbox. Description: A digital tool for dementia caregivers that provides the ability to track symptoms and changes to provide context and clarity in a complex evolving disease. Users: 10, Subjects: 5.
 - ARDEA OUTCOMES myGoalNav Demo (RWE)**: Version V1, Status Sandbox. Description: A digital tool for dementia caregivers that provides the ability to track symptoms and changes to provide context and clarity in a complex evolving disease. Users: 11, Subjects: 2.
- Buttons:** NEW STUDY, HELP, LOGOUT, LANGUAGE (EN)

Additional Features

- Access your user account or log out of the system
- Change the language of the GoalNav® system if study requires

- The ‘STUDIES’ button will always return you to your study details home page.

IN THIS CHAPTER

1 User Profile

- a User Account : User Profile
- b User Account: Security (Change Password)

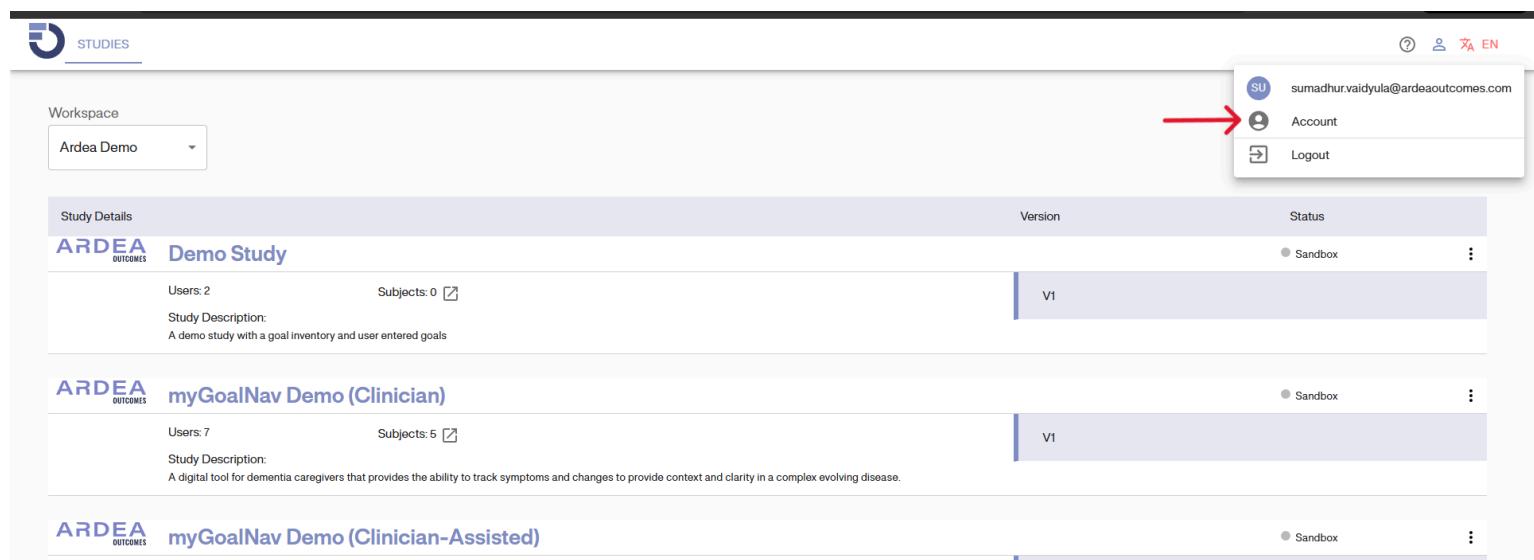
User Profile

Your user account can be accessed via the navigation panel at the top of the screen on the homepage.

User Account : User Profile

Your user profile page contains all your personal information. You may fill this out at any time. This information is important in case the GoalNav® team must contact the user.

Click on the user icon  . It will open a dropdown menu.



The screenshot shows the GoalNav interface. At the top right, there is a user icon with a red arrow pointing to a dropdown menu. The dropdown menu contains the following items: a blue circular icon with 'SU', the email address 'sumadhur.vaidyula@ardeaoutcomes.com', the text 'Account', and a 'Logout' button.

Study Details

Study	Version	Status
ARDEA OUTCOMES Demo Study	V1	Sandbox
ARDEA OUTCOMES myGoalNav Demo (Clinician)	V1	Sandbox
ARDEA OUTCOMES myGoalNav Demo (Clinician-Assisted)		Sandbox

User Account: Security (Change Password)

In your user account, you can also select security settings. These settings allow you to change or update your password.

[GO BACK](#)

Account Settings

[PROFILE](#)[SECURITY](#)

User Profile

First Name	Last Name	Organization
<input type="text"/>	<input type="text"/>	<input type="text"/>
Street Address		
<input type="text"/>		
Country *	Region *	
<input type="text"/>	<input type="text"/>	
City	Postal Code	
<input type="text"/>	<input type="text"/>	
Phone Number *	Fax Number	
<input type="text"/>	<input type="text"/>	

Enter your current password, and then choose new password to change it.

Security

Change Password

Current Password

New Password

- ! Must be at least 8 characters long
- ! Must have at least one lowercase character
- ! Must have at least one uppercase character
- ! Must have at least one numeric character
- ! Must have at least one special character (!@#\$%^&*)

Confirm New Password

- ! Both passwords must match.

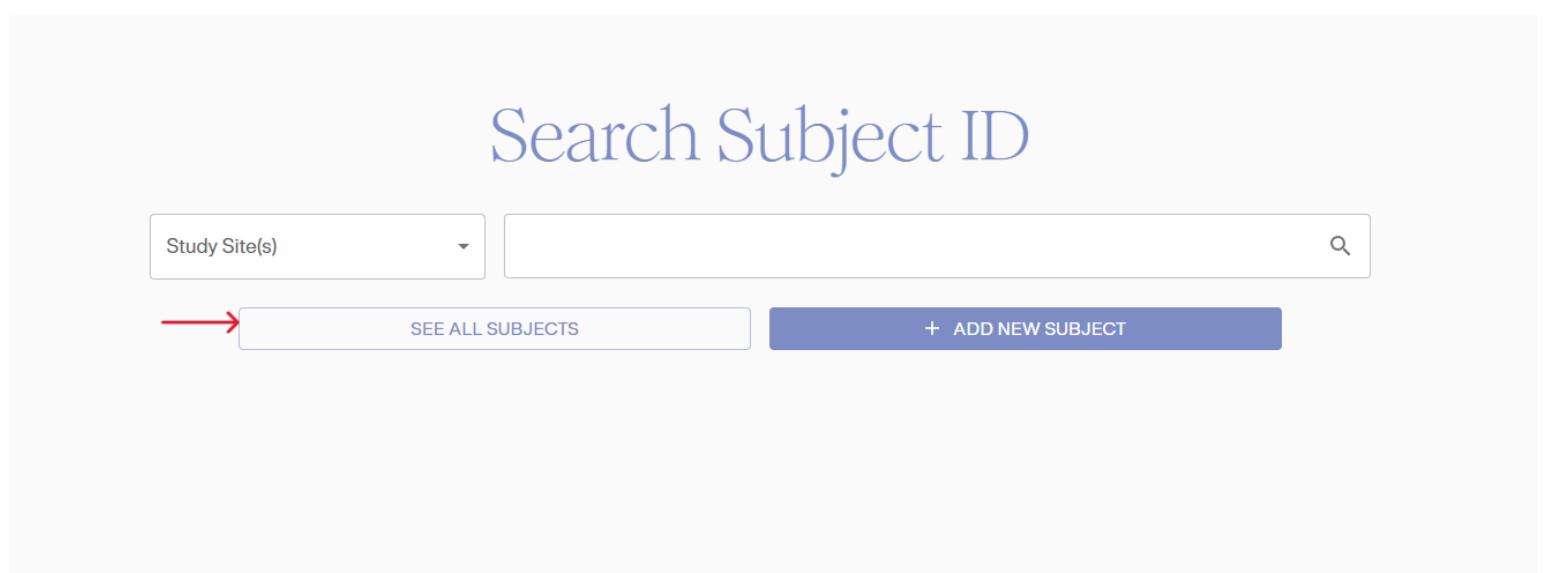
IN THIS CHAPTER

1 Subject Matrixa Additional Features

Subject Matrix

In the homescreen page, click on your study to access the study. You will first be taken to the “Search Subject” page where you can access the subject matrix. We will review how to add a subject in the GoalNav: Data Entry section

Click on the “SEE ALL SUBJECTS” to access the Subject Matrix.



The Subjects Matrix will be displayed, containing all the information for each subject. This matrix tracks the progress of visits completed by each subject using various icons. Each record is labeled with the Subject ID, and clicking on it will open the Subject Details Dashboard.

Study Site(s)		Search Subject ID		Scheduled Visits										Unscheduled Visits	
Subject ID	Subject Status	Added Date		Baseline	Monthly Follow Up 1	Monthly Follow Up 2	Monthly Follow Up 3	Monthly Follow Up 4	Monthly Follow Up 5	Monthly Follow Up 6	Checkin				
1223434	⌚	Tuesday, December 21, 2021		✓	✓	📅	📅	📅	📅	📅	📅	⌚			...
1234	⌚	Wednesday, May 18, 2022	⌚	⌚	📅	📅	📅	📅	📅	📅	📅	⌚			...
1339	⌚	Thursday, April 29, 2021	⌚	⌚	📅	📅	📅	📅	📅	📅	📅	⌚			...
KS23	⌚	Wednesday, June 12, 2024	⌚	📅	📅	📅	📅	📅	📅	📅	📅	⌚			...
test1	⌚	Monday, November 22, 2021	✓	📅	📅	📅	📅	📅	📅	📅	📅	⌚			...

Additional Features

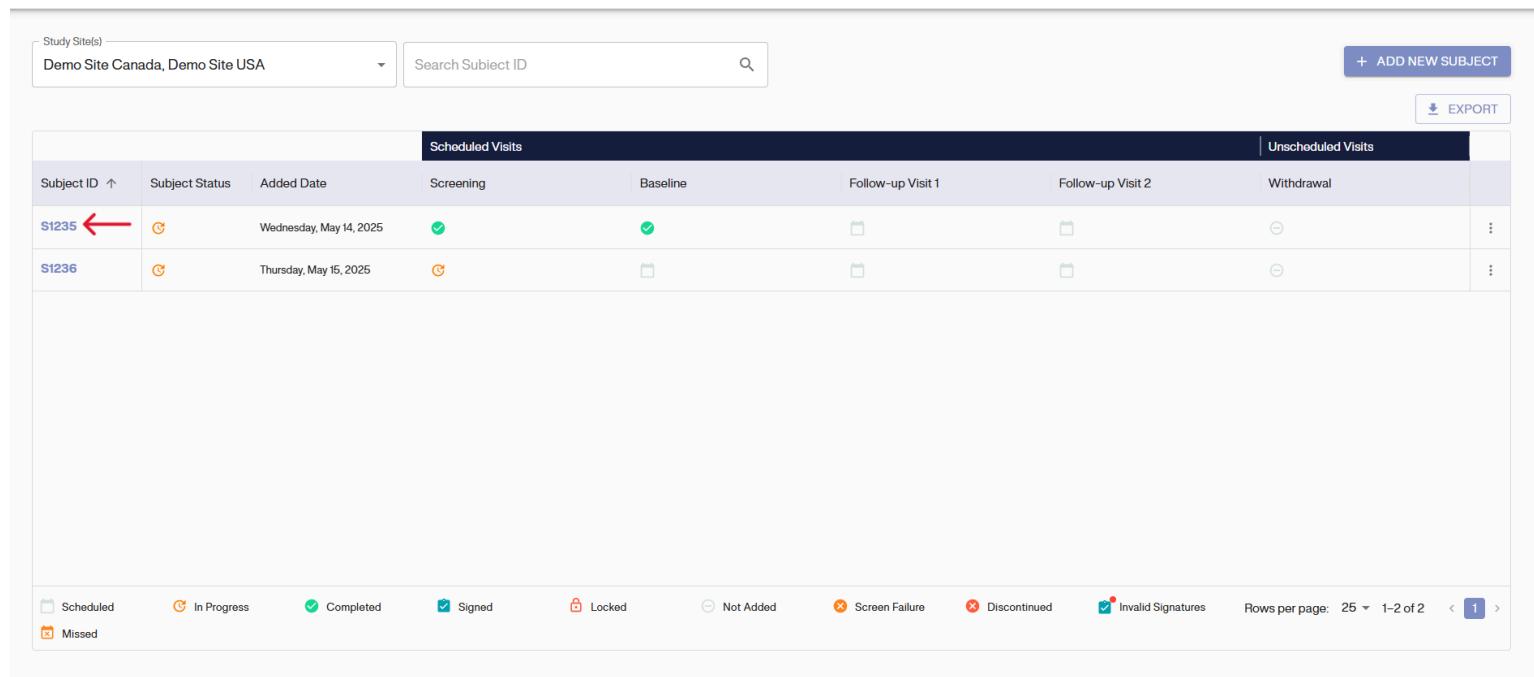
- Export Subject Matrix using the Export button on the top.
- Clicking on the options icon (three dot icon) on individual record row, will provide more actions to perform on subject such as View Subject, Sign subject based on user role.

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1 [Subject Details Page](#)a [Icons Legend Section](#)

Subject Details Page

To navigate to the Subject Details Dashboard, click on the subject Id from the Subject Matrix.



The screenshot shows the Subject Details Page. At the top, there are search filters for 'Study Site(s)' (Demo Site Canada, Demo Site USA) and 'Search Subject ID', and buttons for '+ ADD NEW SUBJECT' and 'EXPORT'. Below is a table titled 'Scheduled Visits' with the following data:

Subject ID ↑	Subject Status	Added Date	Scheduled Visits				Unscheduled Visits	
			Screening	Baseline	Follow-up Visit 1	Follow-up Visit 2	Withdrawal	
S1235 		Wednesday, May 14, 2025						
S1236		Thursday, May 15, 2025						

At the bottom, there is a legend for visit status icons: Scheduled (calendar), In Progress (orange circle), Completed (green checkmark), Signed (checkmark), Locked (padlock), Not Added (minus sign), Screen Failure (red X), Discontinued (red X), Invalid Signatures (red X with dot), and Missed (calendar with red X). There are also buttons for 'Rows per page' (25), '1-2 of 2', and a page number '1'.

Then, you will be able to view your subject's visits and associated forms.

On the **left side of the page**, you will find a table containing:

- Visit name
- Visit start date (start of data entry)
- Visit status ▪ Form name(s)
- Date of last update to the form
- Form status

The status of the visit and forms may differ if you have more than one form to fill out during each visit.

Subject: S1235

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Wednesday, May 14, 2025 at 9:27 PM ADT	✓	GAS Assessment	Wednesday, May 14, 2025 at 9:47 PM ADT	✓
Baseline	Wednesday, May 14, 2025 at 9:48 PM ADT	✓	GAS Assessment	Wednesday, May 14, 2025 at 9:52 PM ADT	✓
Follow-up Visit 1		📅	GAS Assessment		📅
Follow-up Visit 2		📅	GAS Assessment		📅

📅 Scheduled ⌚ In Progress ✓ Completed ✓ Signed 🔒 Locked ✗ Invalid Signatures ✗ Missed ✓ Source Data Verified



Subject ID	S1235	⋮
Screening	✓	▲
Baseline	✓	▲
Follow-up Visit 1		▲
Follow-up Visit 2		▲
+ Add Visit		
Signatures		



The study menu will remain on every visit page and can be collapsed using the arrow. Icons may appear within the study menu to signify visit statuses.

> ARDEA OUTCOMES
Subject ID
S1235
⋮

- Screening ✓ ▲
- Baseline ✓ ▲
- Follow-up Visit 1 ▲
- Follow-up Visit 2 ▲
- + Add Visit
- ✓ Signatures

Icons Legend Section

The icons legend section at the bottom of the Subject Details Dashboard serves as a helpful guide for users to understand the meanings of the various icons used throughout the interface. Each icon

represents a specific action, status, or feature related to the subjects being monitored or analyzed.

Subject ID ↑	Subject Status	Added Date	Visit 2 (Baseline)	Visit 4 (Week 12)	Visit 6 (Completion)	Withdrawal	
S0000	⌚	Thursday, July 24, 2025	✓	✓	📅	⌚	⋮

Scheduled In Progress Completed Signed Rows per page: 25 ▾ 1-1 of 1 < >

Locked Not Added Screen Failure Discontinued

Invalid Signatures Missed

IN THIS CHAPTER

1 Print Forms

Print Forms

If you need to print the GAS scale form for any reason, first navigate to the GAS form in the appropriate visit. Next, click the 'Print' icon for each page. See example of printing a baseline visit below.

Follow-up Visit 1



GAS Assessment



General Info



Visit Date *



2025-05-16

Required

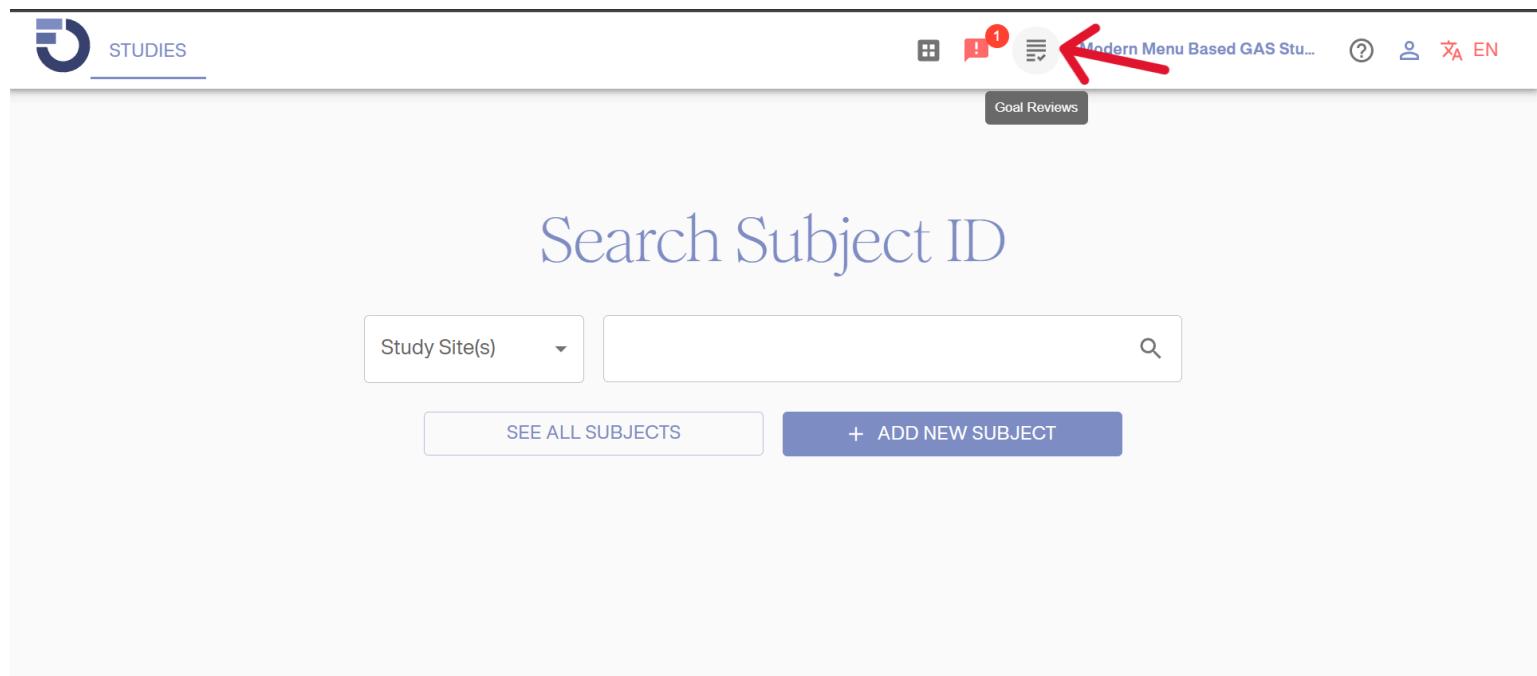


Goal Count

3

Goal Reviews

To access Goal Reviews section, click on the icon for goal reviews from the top navigation bar as shown in the image below.



Here, in this section, you will be able to see all the goal reviews. Goal reviews can also be exported into a csv file by clicking the “EXPORT” button. This will download the csv file into your device.

Goal Reviews

User	Subject Key	Visit	Review Date	Final Rating	Status	Latest Acknowledge Date	Form Edited After R...	EXPORT
andrew.whitlo...	S0000	Visit 2 (Bas...	Thursday, August 14, 2025 at 10...	Excellent	0 of 2 ackn...		No	

Denotes all feedback acknowledged Total Rows: 1

Chapter 3: Using GoalNav as a Data Entry

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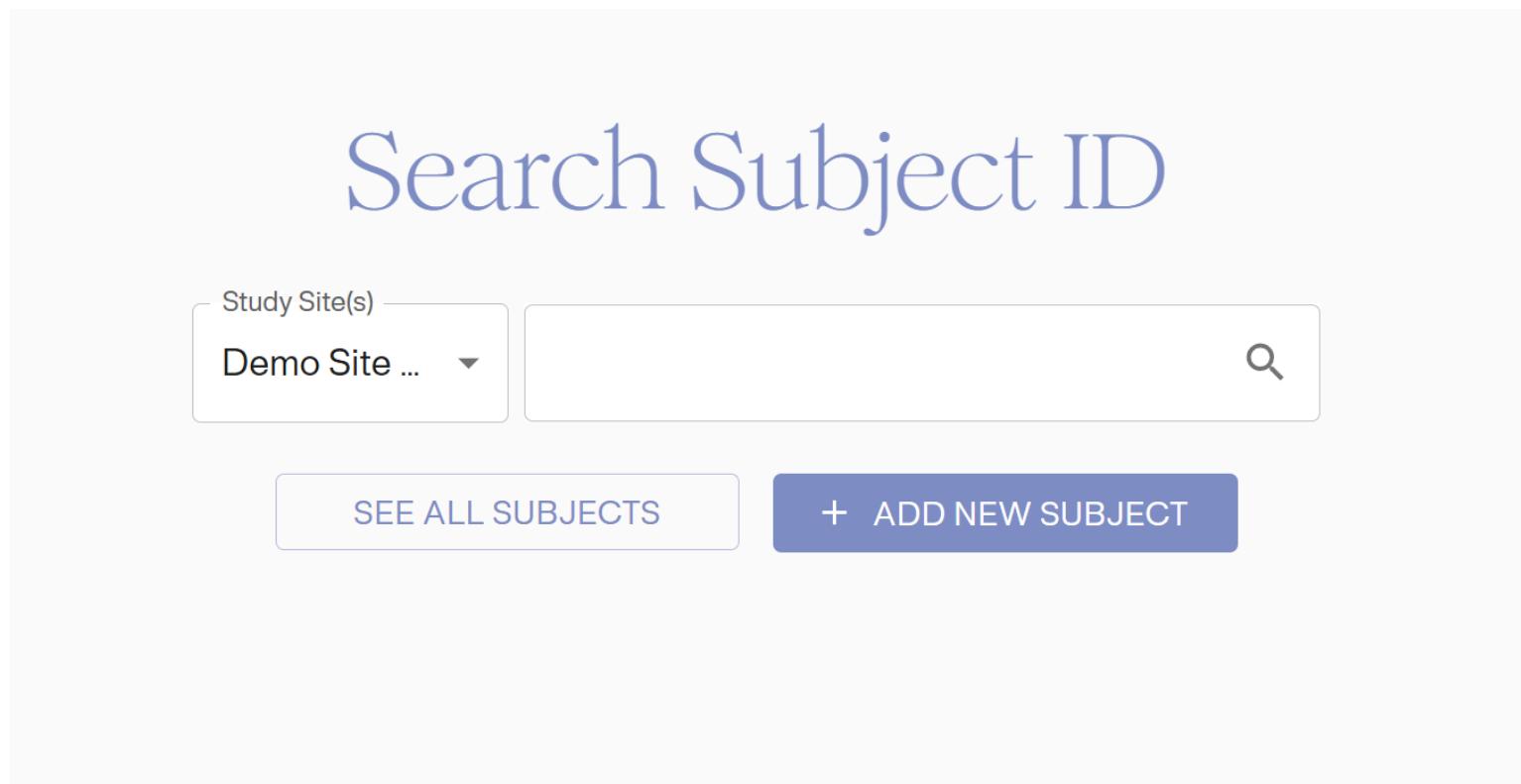
- [Add Subjects](#)
- [Visits](#)
- [Comments](#)
- [Changes to Forms](#)
- [Missed Visit](#)
- [Signatures](#)
- [Source Data Verification](#)
- [Manage Queries](#)

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1 [Adding Subjects](#)

Adding Subjects

If a subject has not yet been added to the system, you can do so by clicking '+ ADD NEW SUBJECT'.



Study Site(s)

Demo Site ...

SEE ALL SUBJECTS

+ ADD NEW SUBJECT

You are required to enter your subject's ID and Study Site. Please double check you are entering the correct subject information before clicking 'ADD SUBJECT'. You will also note the study version if your study has more than one version.

Add Subject

Subject ID

S1235

Study Site

101 - Demo Site Canada

[CANCEL](#)[ADD SUBJECT](#)

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[Privacy Policy](#) [Terms of Service](#)

Once a subject is added or selected, click on “SEE ALL SUBJECTS” to be taken to the subject details Dashboard.

The screenshot shows a table of subjects with the following data:

Subject ID	Subject Status	Added Date	Scheduled Visits				Unscheduled ...	
			Screening	Baseline	Follow-up Vis...	Follow-up Vis...	Withdrawal	
S1235		Wednesday, May 21, 2025						
S1236		Thursday, May 15, 2025						
S1237		Tuesday, May 20, 2025						

Legend at the bottom:

- Subject Added
- View Subject
- Scheduled
- In Progress
- Completed
- Signed
- Screen Failure
- Discontinued

Bottom right: Rows per page: 25 ▾ 1-4 of 4

Click on the Subject ID in blue to access the Subject Details Dashboard for that subject or click on “VIEW SUBJECT” on the green pop-up status which appears on the screen after creating a subject.

Scheduled Visits							Unscheduled ...	
Subject ID ↑	Subject Status	Added Date	Screening	Baseline	Follow-up Vis...	Follow-up Vis...	Withdrawal	
S1235		Wednesday, May 21, 2025						
S1236		Thursday, May 15, 2025						
S1237		Tuesday, May 20, 2025						

Scheduled In Progress Completed Signed
 Screen Failure Discontinued

Rows per page: 25 ▾ 1–4 of 4 < 1 >

Subject Added View Subject

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 - d [Unscheduled Visits](#)
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 - b [Data collection for studies with Separate Screening and Baseline Visit](#)
 - a [Screening Visit: GAS Assessment Form Data Entry](#)
 - a [Identify Goals](#)
 - b [Build GAS Scales](#)
 - c [Rank Goals \(Optional - Study Dependent\)](#)
 - d [Save Form](#)
 - b [Baseline Visit](#)
 - a [Identify Goals](#)
 - b [Build GAS Scales](#)
 - c [Rank Goals](#)
 - c [Data collection for studies with a combined Screening/ Baseline visit.](#)
 - d [Follow-up Visits](#)
 - a [Enter Subject's Current Status](#)
 - b [Subject and GAS Interviewer Rating](#)
 - c [GAS Interviewer Comments & Saving the Data](#)

Visits

Study visits in GoalNav can be accessed through the study menu on the right side of the subject details page.

Screening Visit:

To access the Screening Visit page, click on the visit labeled “Screening.”

Screening

May 14, 2025
Do you want to start Screening?

This is the screening visit.

[ADD TO CALENDAR](#) [MARK VISIT MISSED](#) [START](#)

Subject ID
S1235

GAS Assessment

- 1 Identify Goals
- 2 Build GAS Scales
- 3 Rank Goals



Search [Search](#)

[+ Other](#)

Screening
Baseline
Follow-up Visit 1
Follow-up Visit 2
+ Add Visit
Signatures

To start the Screening visit, click on the start button on the visit details page.

May 14, 2025
Do you want to start Screening?

This is the screening visit.

[ADD TO CALENDAR](#) [MARK VISIT MISSED](#) [START](#)

→

Baseline Visit:

To access the Baseline Visit page, click on the visit labeled “Baseline.”

GO BACK

Baseline

May 14, 2025
Do you want to start Baseline?

This is the baseline visit.

[ADD TO CALENDAR](#) [MARK VISIT MISSED](#) [START](#)

Subject ID
S1235

Screening
Baseline
Follow-up Visit 1
Follow-up Visit 2
+ Add Visit
Signatures

GAS Assessment

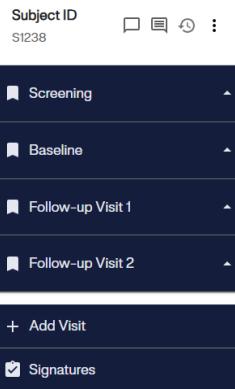
This form has been pre-filled with the previous GAS data. You are free to make changes.

1 Identify Goals 2 Build GAS Scales 3 Rank Goals

To start the Baseline visit, click on the start button on the visit details page.

Follow-up Visits

To access the follow-up visit page, click on the appropriate follow-up visit. The names of these follow-up visits may vary per study therefore, your study menu may look different.

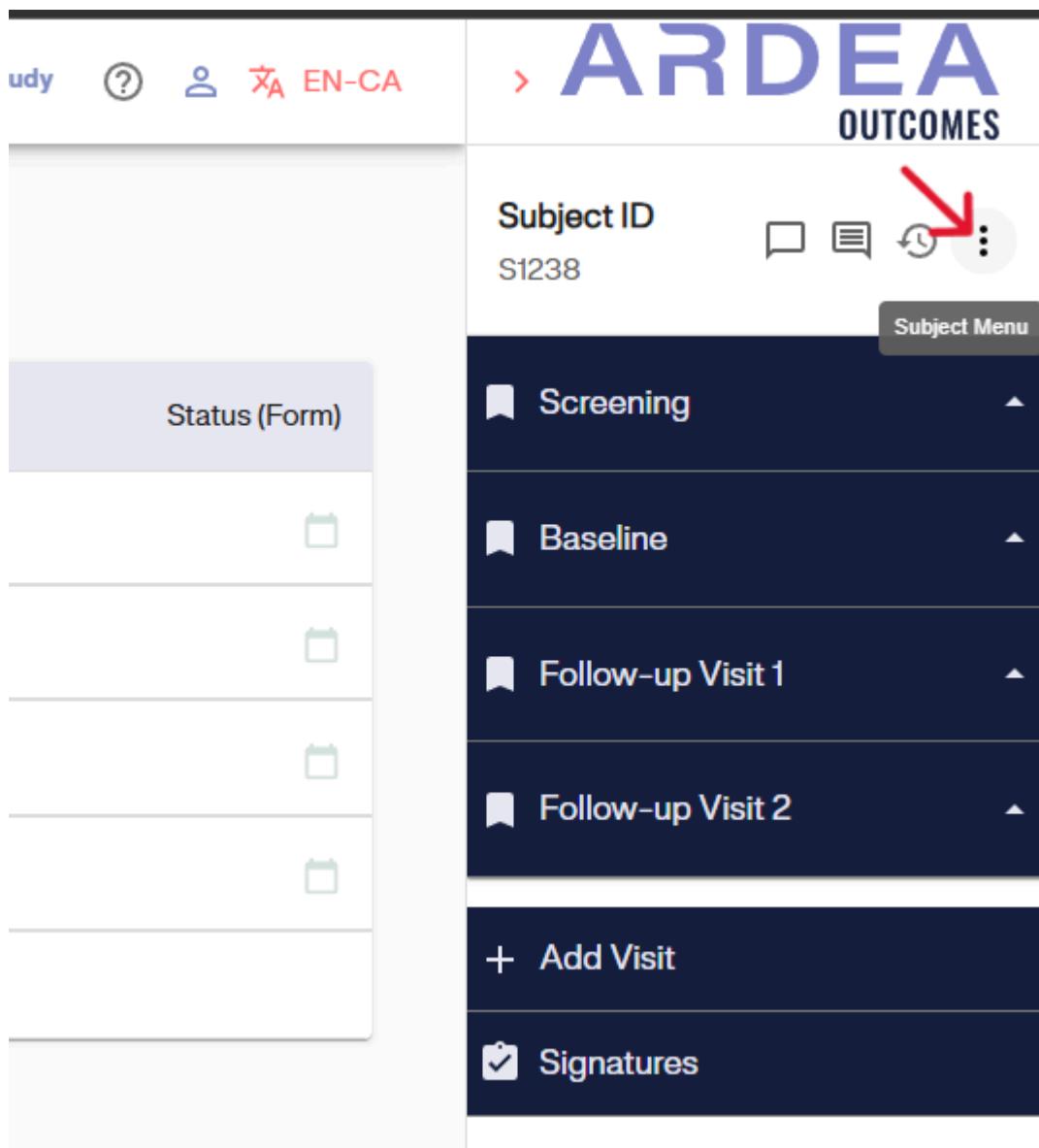


Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening			GAS Assessment		
Baseline			GAS Assessment		
Follow-up Visit 1			GAS Assessment		
Follow-up Visit 2			GAS Assessment		

Scheduled
 In Progress
 Completed
 Signed
 Locked
 Invalid Signatures
 Missed
 Source Data Verified

Unscheduled Visits

To add an unscheduled visit, click the 3-dot icon on the Subject Menu and select 'Add visit'.



Then select the type of visit from the drop down and click on 'ADD VISIT'.

Form Name	Last Updated	Status (Form)
GAS Assessment	Tuesday, May 20, 2025 at 9:35 PM ADT	✓
GAS Assessment	Wednesday, May 21, 2025 at 6:17 PM ADT	✓
GAS Assessment		📅
GAS Assessment		📅

 Invalid Signatures  Missed  Source Data Verified

 GAS Assessment Wednesday, May 21, 2025 at 6:17

Add Visit

Select Visit

Withdrawal

Withdrawal

CANCEL + ADD VISIT

Entering Data into Visit Forms

Data Collection visits

Depending on your study configuration, there may be different methods for completing the data collection forms and visits. In studies with separate Screening and Baseline Visits, the data should be entered during the Screening Visit, and the data entered will be pre-populated in the Baseline Visit. You have the option to adjust or modify this data during the Baseline Visit.

For studies that combine the Screening and Baseline Visits into one visit “Screening/Baseline”, all data collection will take place during this initial visit.

Data collection for studies with Separate Screening and Baseline Visit

SCREENING VISIT: GAS ASSESSMENT FORM DATA ENTRY

Identify Goals

To enter data into the GAS assessment form for the screening visit, the first step is to identify the goals. Here, you can select goals from the goal inventory options or by using the search bar at the top to look for specific keywords. If you find that any identified goal is not present in the list, there is an option to choose “Other” and enter a custom goal.

Note: Not all studies include a goal inventory therefore you may only be required to add a custom goal.

[GO BACK](#)

Screening GAS Assessment

1 Identify Goals 2 Build GAS Scales 3 Rank Goals

Search ←

Other ←

<input type="radio"/> Forming and fostering relationships
<input type="radio"/> Being present with loved ones
<input type="radio"/> Participating in social activities
<input type="radio"/> Depression
<input type="radio"/> Mood changes
<input type="radio"/> Freedom of choice

→ Forming and fostering relationships

Once the goals are identified, click on Next to move to next step.

<input type="radio"/> Depression	×
<input type="radio"/> Participating in social activities	×
<input type="radio"/> Being present with loved ones	×
<input type="radio"/> Forming and fostering relationships	×

← NEXT

Enter the date of your visit by typing in the format (YYYY-MM-DD) or by selecting a date from the calendar icon located on the right side of the text field.

Identify Goals Build GAS Scales Rank Goals

General Info

Visit Date * Required

2025-05-14 Calendar icon

Goal Count Info icon

4 Edit icon

Next, enter the attainment level descriptions in the goal scale for each of the identified goals as shown in the image below. Repeat this process for all the goals selected.

Anxiety

Much more than expected * Required

Good sleep throughout the week X A +2

Somewhat more than expected * Required

Good sleep for 5 days in the week X A +1

Expected level of outcome / goal level * Required

Good sleep for 4 days in a week X A 0

Somewhat less than expected / baseline level * Required

Good sleep for 2 days in a week X A -1

Much less than expected * Required

Struggled with throughout the week X A -2

Rank Goals (Optional - Study Dependent)

Finally, rank goals from most importance to least important. Some studies may include a skip rank option.

rank them, click the "skip rank" button.  SKIP RANKING

Most important

 Hobbies	
 Anxiety	
 Work/school performance	

Least important

◀ BUILD GAS SCALES SAVE

Enter the ranks by dragging and dropping each goal to sort them from Most Important (top) to Least Important (bottom).

Most important

 Anxiety	
 Hobbies	
 Work/school performance	

Least important

◀ BUILD GAS SCALES SAVE

If your study does not include ranking, the ranking section will not appear on your screen.

Save Form

Once you have correctly entered all of the data into the 'Goal Attainment Scaling' form, click the 'Save' button as shown below. Once the form has been saved, you will see the saved logo appear at the bottom of the screen (as shown below):



Depression



Being present with loved ones



Forming and fostering relationships



Least important

[← BUILD GAS SCALES](#)

Saved!



SAVE

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If you have another form to fill out at the visit, navigate to the form in the study menu and follow the same instructions for entering data and saving the form.

BASELINE VISIT

To begin, navigate to the study menu and select the Baseline visit. Then, click on the Start Baseline form.

If your study includes separate Screening and Baseline visits, the GAS assessment form within the Baseline visit will automatically be filled with goals, goal scales, and rankings (if applicable) that were added during the Screening visit. During the Baseline visit, you have the option to add new goals, remove existing goals, or edit the descriptions for attainment levels of current goals. Moreover, all follow-up visits that include GAS forms will utilize the updated Goal Attainment rubric established during the Baseline visit.

Baseline



GAS Assessment



This form has been pre-filled with the previous GAS data. You are free to make changes.

1

Identify Goals

2

Build GAS Scales

3

Rank Goals

Search



Other

 Forming and fostering relationships Being present with loved ones Participating in social activities Depression Mood changes[Identify Goals](#)

The Identify Goals section of the GAS assessment form for Baseline visit will have all the pre-populated values entered during the Screening Visit. If required, you may update the goals by adding or removing goals. Do not touch any goals you want to keep. Once you are finished, click on “Next” to continue.

Sensory sensitivity

Hobbies

Anxiety

Work/school performance

NEXT

Build GAS Scales

The next Section to complete is Section 2: Build GAS Scales. Here you will find all the prepopulated attainment levels for the goal scales set during the Screening Visit. However, the date of the baseline visit will not be pre-populated. Select the date of Baseline Visit.

General Info

Visit Date * Required

yyyy-mm-dd

Goal Count

3

First, scroll down to find the goal scales and the pre-filled attainment levels. Review these items, and if necessary, you can make modifications during the baseline visit as well. Ensure you complete the data entry for any newly added goals during this visit. Once you have finished all the goal scales, click “Next.”

Much more than expected *	Required
Good sleep throughout the week (Can update here during Baseline Visit)	+2 <input checked="" type="checkbox"/> A
Somewhat more than expected *	Required
Good sleep for 5 days in the week	+1 <input checked="" type="checkbox"/> A
Expected level of outcome / goal level *	Required
Good sleep for 4 days in a week	0 <input checked="" type="checkbox"/> A

Rank Goals

The ranks of the goals will be set to default order of selection or with the order in which it was ranked during the Screening visit. The ranks can be re-assigned at Baseline visit as well. Click on “Save” once the ranks of goals are satisfactory.

Most important

-  Hobbies ⋮
-  Anxiety ⋮
-  Work/school performance ⋮

Least important

Data collection for studies with a combined Screening/ Baseline visit.

Studies with a combined screening/baseline visit will simply use the same visit and GAS assessment form to enter data for screening and baseline. To start the visit with a single goal-setting visit (Screening/ Baseline visit), click on the designated Screening/Baseline visit. Click on “START” to start the visit.

Screening/Week 1 Day 1 Goal Attainment Scaling

Form:

Section 1: Identify Goals

Have the participant or caregiver identify goals (symptoms or challenges) that are meaningful and important to them. Once goals have been identified, give each goal a title (1-3 words).

Section 2: Build GAS Scales

Each goal scale should be developed separately.

Step 1: Describe the Participant's Baseline Status (-1)

Have the participant describe their current status with respect to the identified goal. Facilitate the discussion by having the participant/caregiver identify the precise nature of the symptoms or challenges by using examples from their everyday life.

Step 2: Set the Goal (0)

Have the participant/caregiver identify how they would like their baseline to improve. Use SMART concepts to ensure that the goal is realistic, reasonable and achievable within the time-frame of your study.

Step 3: Set Additional Attainment Levels: Better (+1, +2) and Worse (-2) Attainment Levels

Guide the participant/caregiver to set the (+1) somewhat better and (+2) much better attainment levels. Complete the scale by having them identify the (-2) much worse than the goal attainment level.

Document who has set the GAS Scale (subject or caregiver).

Return to this form to make any necessary changes during the Week 1 Day 1 visit when finalizing goals.

[ADD TO CALENDAR](#)

[MARK VISIT MISSED](#)

[START](#)

To complete the screening visit, follow the same instructions as outlined earlier. For the baseline visit, return to the “Screening/Baseline visit” and update the necessary details. Use the same instructions as before. You can add or remove goals, modify goal scales as needed, create new goal scales, and update rankings if applicable. Remember to click “Save” at the end of each data entry.

Note: The data collected in Baseline form and the text fields may appear differently based on the configuration of study.

Somewhat Better than the Goal *

Required

+1

The Goal *

Required

0

Baseline Status

-1

Much Worse than the Goal *

Required

-2

[← IDENTIFY SYMPTOMS](#)[ADD ANOTHER GOAL](#)[SAVE](#)

Follow-up Visits

Using the study menu on the right side of your subject overview screen, navigate and select the appropriate follow-up visit.

All follow-up visits will follow the same format for entering data. Click 'start' to begin the visit.

GO BACK

Follow-up Visit 1

May 20, 2025
Do you want to start Follow-up Visit 1?

This is the first follow-up visit.

[ADD TO CALENDAR](#) [MARK VISIT MISSED](#) [START](#)

GAS Assessment



Subject ID
S1236

- Screening
- Baseline
- Follow-up Visit 1

Form: GAS Assessment

- Follow-up Visit 2
- + Add Visit
- Signatures

Enter the date of Follow-up Visit.

Follow-up Visit 1



GAS Assessment



General Info



Visit Date *

2025-05-16



Required

Goal Count

3

After you scroll down you will find the Goal Attainment Scaling Follow-up Form.

ENTER SUBJECT'S CURRENT STATUS

A description of the subject's current status in relation to each individual goal should be entered into the text box 'Subject's Current Status' within the specific goal tab. Enter data in the subject's own words as much as possible.

Anxiety

Document the participant's current status in relation to the goal area

Enter Current Status here



文A

Rating *

SUBJECT AND GAS INTERVIEWER RATING

Then, rating needs to be selected by clicking on the radio button next to the appropriate goal attainment level. The type of ratings may vary per study (e.g. subject, participant, caregiver, GAS interviewer, etc.)

Document the participant's current status in relation to the goal area.*

A

Rating *

Much more than expected

 Much more than expected:
Good sleep throughout the week +2

Somewhat more than expected

 Somewhat more than expected:
Good sleep for 6 days in the week +1

Expected level of outcome / goal level

 Expected level of outcome / goal level:
Good sleep for 4 days in a week 0

Somewhat less than expected / baseline level

 Somewhat less than expected / baseline level:
Good sleep for 2 days in a week -1

Much less than expected

 Much less than expected:
Struggled with throughout the week -2

Each goal will be filled out in the same way. Please repeat these steps for each goal. The following pages show how to fill out a Goal Attainment Scaling Follow-up Visit Form.

GAS INTERVIEWER COMMENTS & SAVING THE DATA

If applicable for your study, the GAS interviewer may include interviewer notes. Once all data has been entered for the follow-up visit, click “Save”. Remember to look for the green banner to ensure it has been saved.



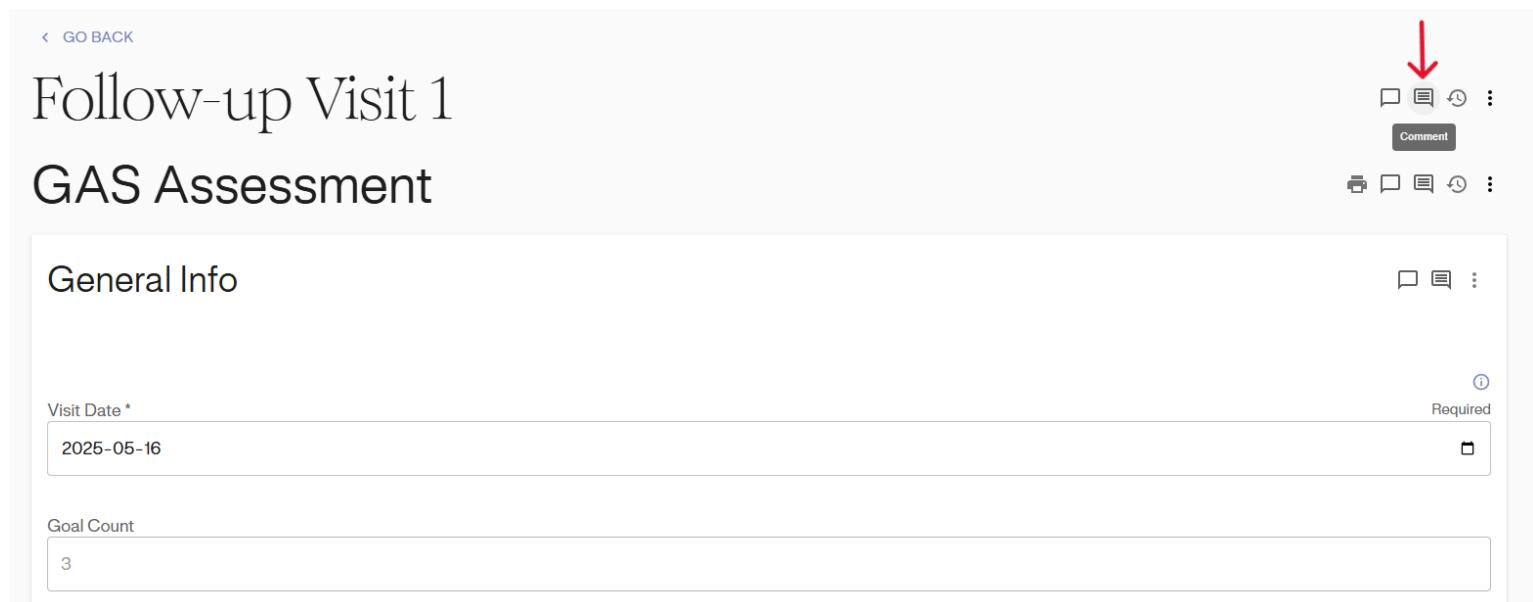
A screenshot of a web-based data entry form. At the top right is a 'SAVE' button with a blue background and white text. Below the main data entry area, a green banner displays the text 'Saved!' with a checkmark icon and a close button 'X'. The main area contains several input fields and dropdown menus for data entry. The entire interface is set against a white background with a light gray header bar.

IN THIS CHAPTER

1 Comments

Comments

You can leave a comment by clicking the Comments icon.



Follow-up Visit 1
GAS Assessment

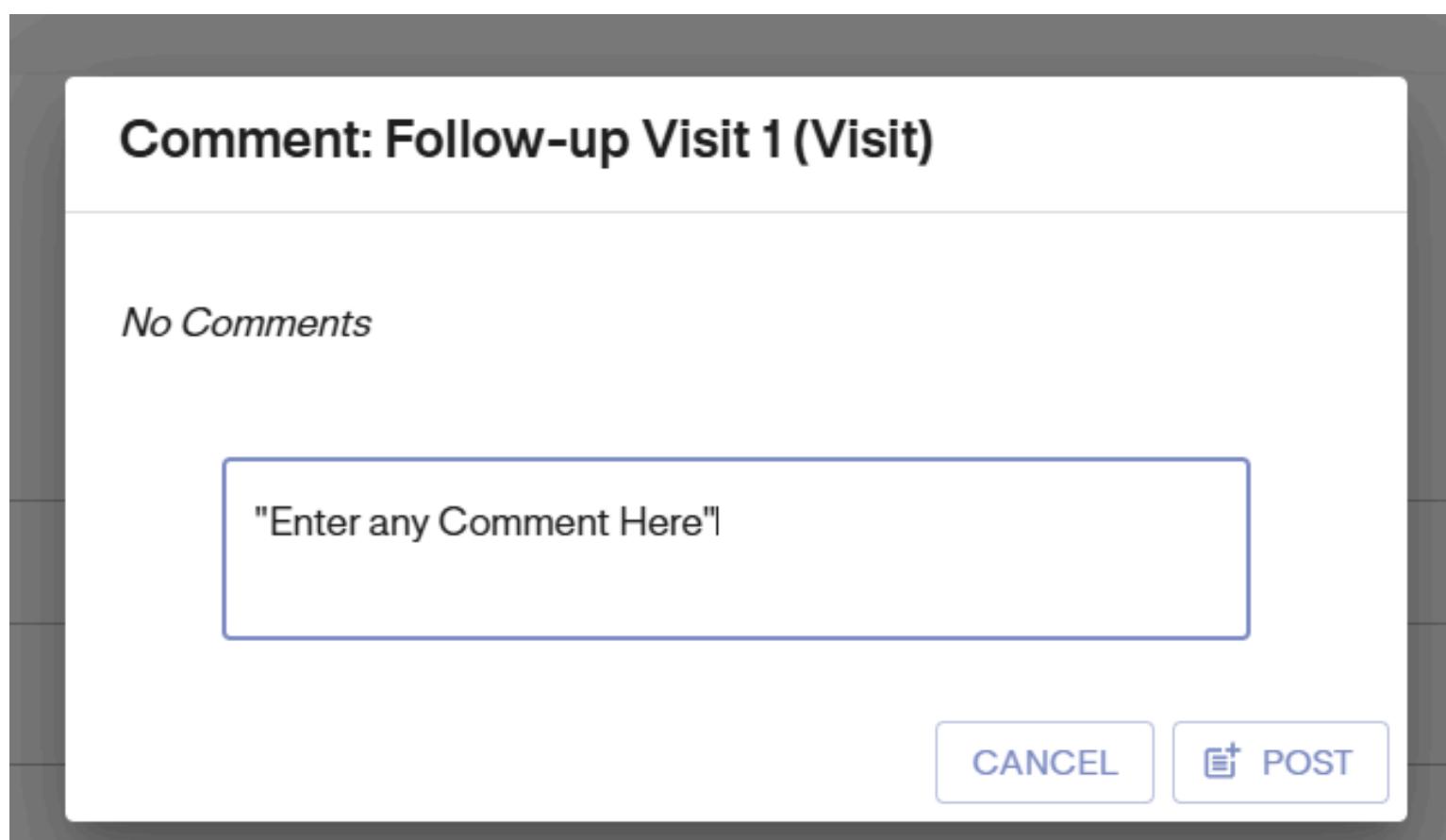
General Info

Visit Date * Required

Goal Count

Comment icon (highlighted with a red arrow)

A pop up window will appear with a text box to enter comment.



Comment: Follow-up Visit 1 (Visit)

No Comments

"Enter any Comment Here"

CANCEL POST

After posting your comment, the Comment icon next to that data field will turn blue. 

You can view comments by clicking on the blue Comment icon and delete them by clicking the Remove icon.

Follow-up Visit 1

GAS Assessment

Comment: Follow-up Visit 1 (Visit)

SU

Sumadburvaldyula

Tuesday, May 20, 2025 at 10:05 PM ADT

"Enter any Comment Here"



Remove

Add new comment

CANCEL

POST

IN THIS CHAPTER

1 Changes to Forms

Changes to Forms

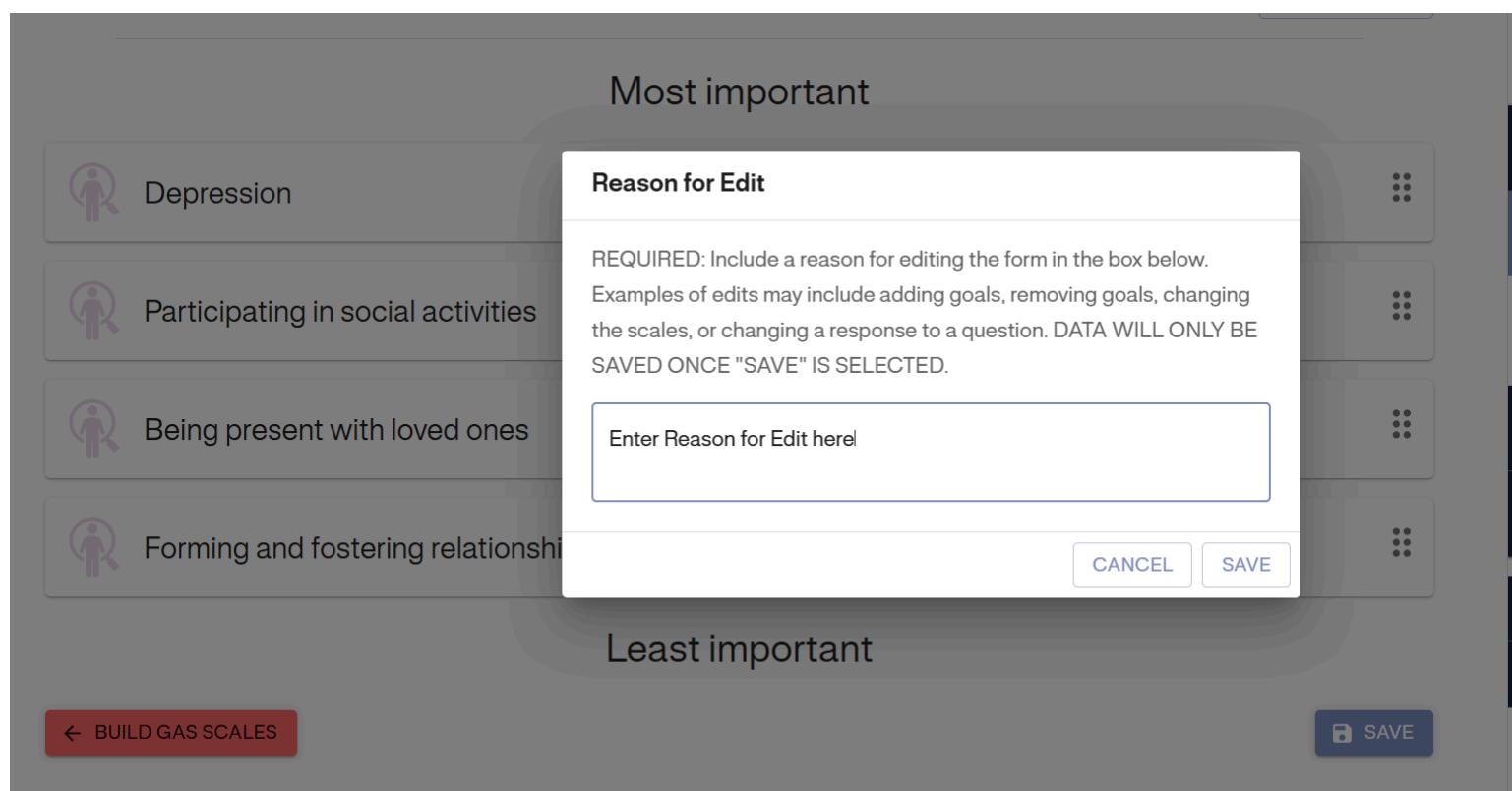
Data changes can be made within each form at any time until the study is locked. It is important to remember to press the 'Save' Button at the end of each form to ensure that your data is successfully saved. GoalNav® requires an active internet connection to save your data permanently. However, GoalNav® constantly auto saves your form data in your device storage with appropriate encryption, but it is only persisted in the current device you are using. In the event of loss of connectivity or in case of application crash, data can be recovered by visiting the same form using the same device and saving the form. The user will be reminded that the current data was recovered and not yet saved on GoalNav® servers. Users may also choose to clear the recovered data by using the 'Clear Recovered Values' button.

It is important to remember that data should only be changed in the following circumstances:

- Updating goals within the goal attainment scale form from screening to baseline
- An error was noted during data entry
- The wrong patient information was entered
- A monitor has a query that requires a change to the data
- Quality Assurance has requested changes to the subject's goal(s)

To make changes to any form, you simply click on the appropriate visit and form and make the change.

Once the change is made, you will be required to state why the change was made. Please make this as specific as possible. You are required to enter a reason and press save. If you press cancel, the data will remain on the screen but will not be saved in the system.



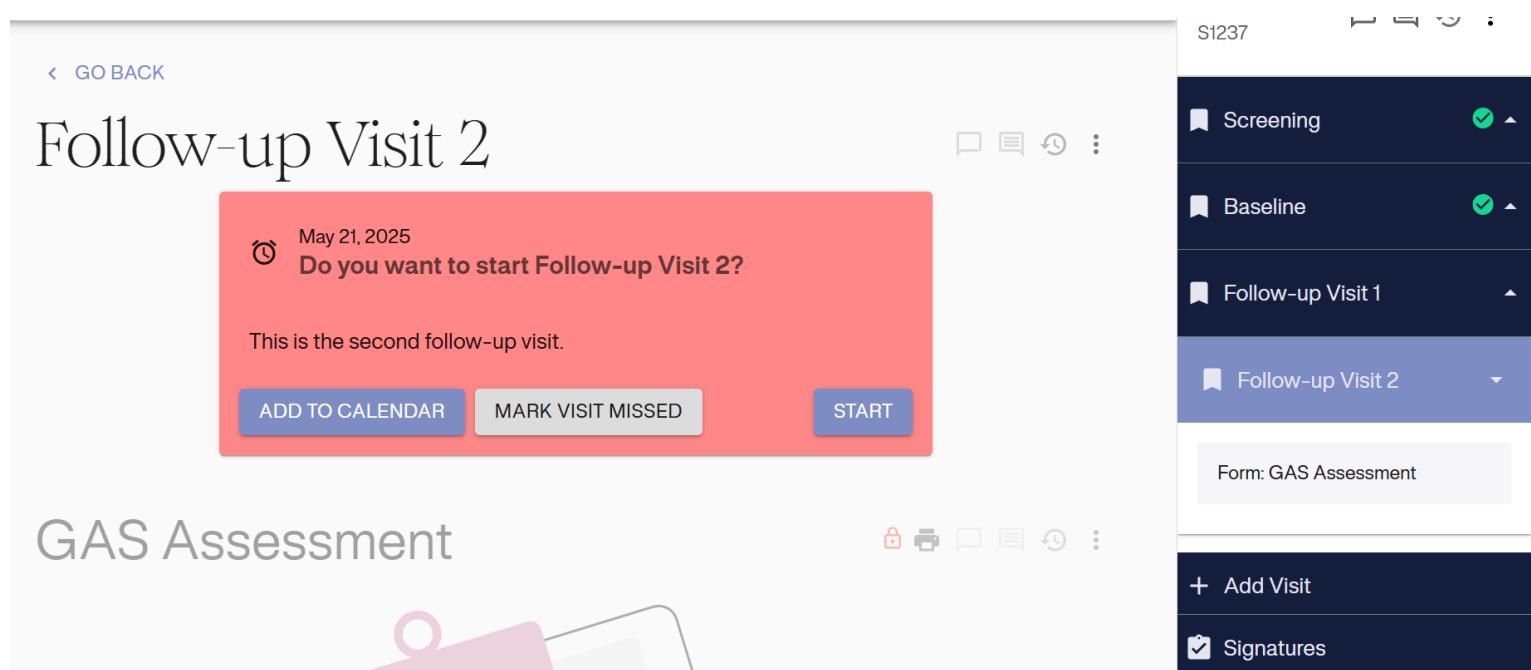
REMEMBER: Re-signing the data is required by all those responsible at their designated level each time changes are made. **Re-signing the data is required by all those responsible at their designated level each time changes are made.**

IN THIS CHAPTER

1 Missed Visits

Missed Visits

If a subject misses or skips a visit, you can continue entering available data by simply clicking the appropriate visit. Visits are not required to be entered in order, for example, you may begin the Week 32 visit even if there is no data for Week 16. Please include a comment in the missed visit that there was no data to be entered during the visit and the reason for the missed visit (if known).



The screenshot shows the GoalNav software interface. On the left, the main window displays a red overlay asking 'Do you want to start Follow-up Visit 2?' with a date of May 21, 2025. Below this, buttons for 'ADD TO CALENDAR', 'MARK VISIT MISSED', and 'START' are visible. The background shows the title 'Follow-up Visit 2'. On the right, a sidebar titled 'S1237' lists visit types: 'Screening' (checked), 'Baseline' (checked), 'Follow-up Visit 1' (unchecked), and 'Follow-up Visit 2' (checked). Below the visit list, a section for 'Form: GAS Assessment' is shown, along with buttons for '+ Add Visit' and 'Signatures'.

IN THIS CHAPTER

- 1 [Signatures](#)
- 2 [Signature Records](#)
 - a [Add Signatures](#)
 - b [Viewing Signatures from Signatures Tab](#)
 - c [Invalid Signatures](#)
 - a [Invalid Signature: Re-signing a Visit or a Subject](#)

Signatures

Signature Records

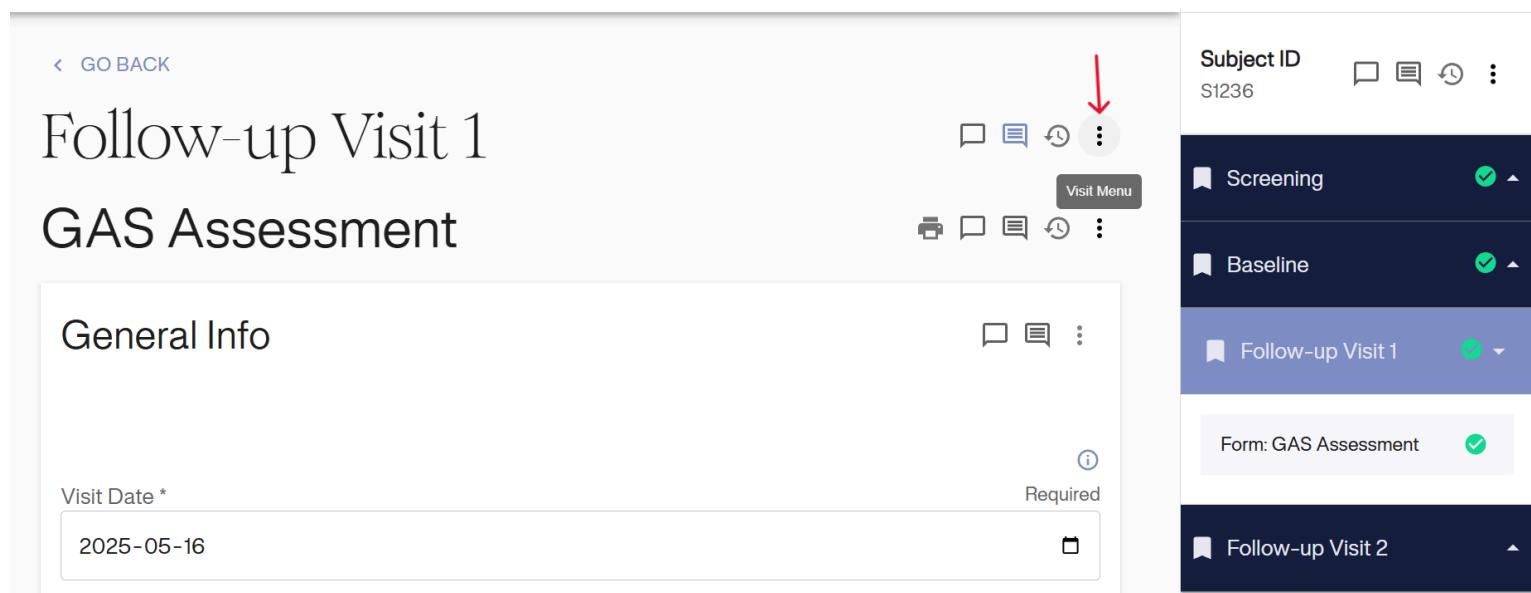
Add Signatures

Once a visit has been completed, you may be required to provide a digital signature, depending on your study requirements.

Signatures at the Subject Level: The PI is generally responsible for signing the subject level if required.

Sign Visit Example:

To sign the visit, click on the 3 dots on the right side of the Goal Attainment Scaling form.



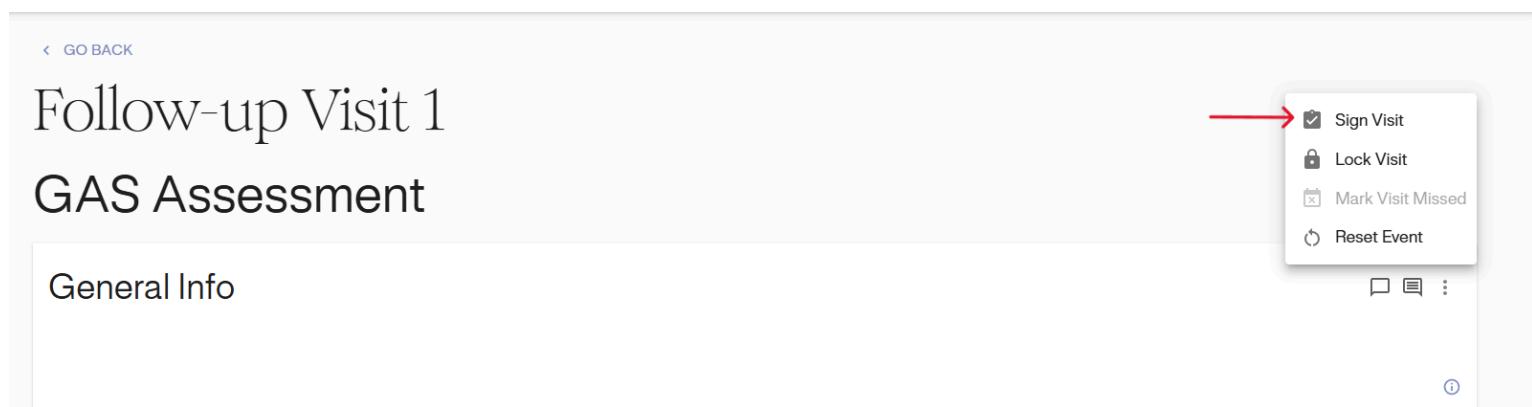
The screenshot shows the GoalNav software interface for a 'Follow-up Visit 1 GAS Assessment'. The main screen displays 'General Info' with a 'Visit Date *' field set to '2025-05-16' and a 'Required' status. To the right, a 'Visit Menu' icon (three dots) is highlighted with a red arrow. The 'Subject ID' is listed as 'S1236'. A sidebar on the right shows a history of visits: 'Screening', 'Baseline', 'Follow-up Visit 1' (selected), and 'Follow-up Visit 2'. A 'Form: GAS Assessment' section is also visible.

You may note that there are other similar icons present on the page. Those icons represent:

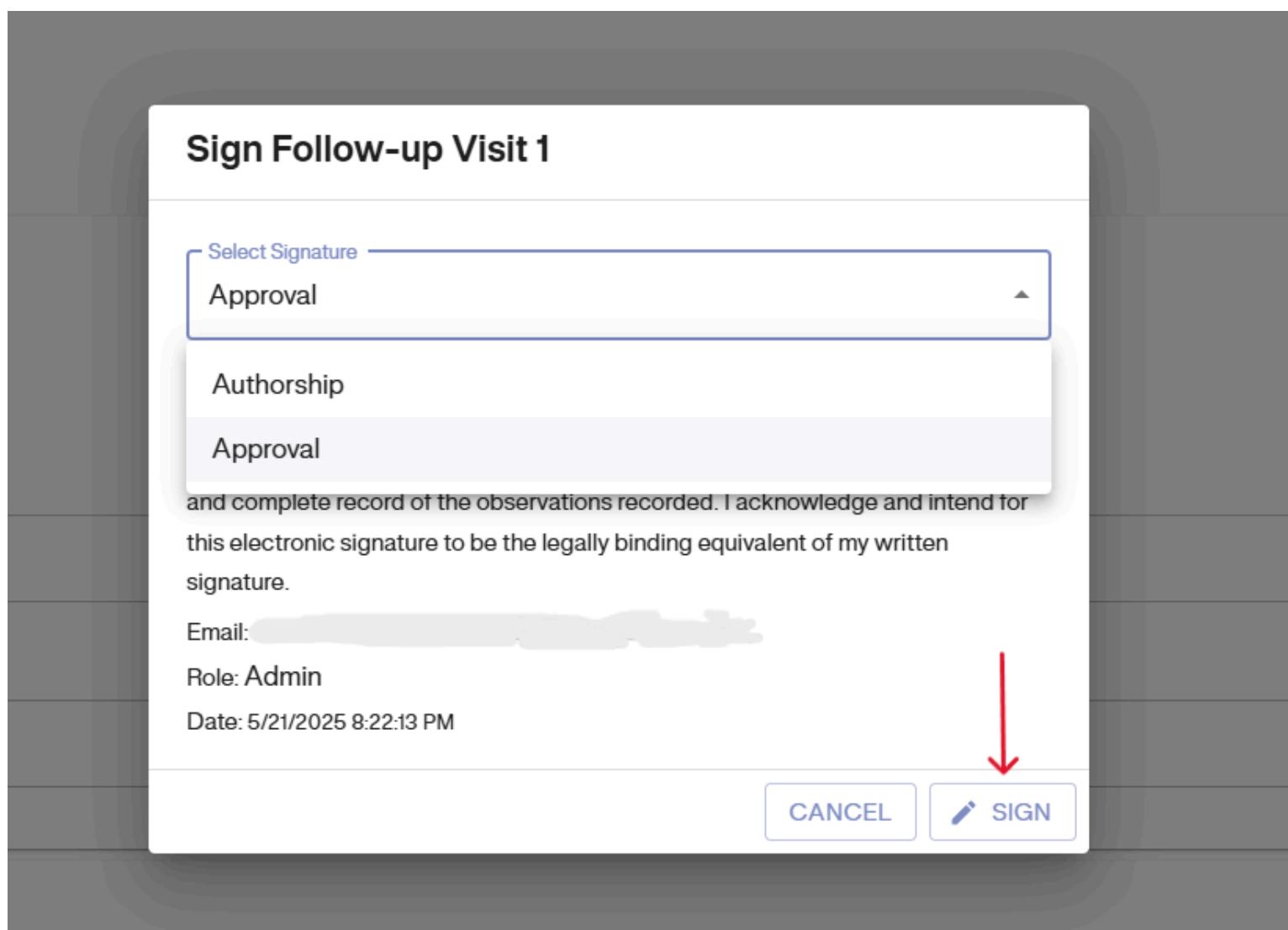
- Signatures at the form level (3 dots above the form visit signature)

- Subject level (3 dots next to the subject ID in the study menu)

All signatures (form, visit, subject) can be done following the same format as outlined below.



Once you click on 'sign visit', you will be required to re-enter your login information to verify your identity. Once authenticated, you will see a window to select the type of signature Authorship or Approval. Select the relevant option and then click on "Sign" button.



Once the form has been signed, a green pop-up with status 'Signature Added' will appear in the bottom left of the screen and a blue notepad icon will be added right next to the visit name to indicate that the visit has been signed.

Follow-up Visit 1

GAS Assessment



General Info



Visit Date *

2025-05-16

Required

Goal Count

3

Hobbies



Document the participant's current status in relation to the goal area *

Signature added.



Required



In the Subject Details Dashboard, the visit will reflect the signed icon, once they are signed on the visit level as required by the study

Subject: S1236

Back to Subject(s)

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Thursday, May 15, 2025 at 7:38 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:33 PM ADT	✓
Baseline	Tuesday, May 20, 2025 at 8:50 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:41 PM ADT	✓
Follow-up Visit 1	Tuesday, May 20, 2025 at 9:49 PM ADT	✓  	GAS Assessment	Tuesday, May 20, 2025 at 10:00 PM ADT	✓
Follow-up Visit 2			GAS Assessment		
 Scheduled  In Progress  Completed  Signed  Locked  Invalid Signatures  Missed  Source Data Verified					

If you edit the forms, your signature will be invalidated and an invalid signature icon will appear on signature panel. You must resign the form each time you make a change to the data.

Viewing Signatures from Signatures Tab

The signatures page can be accessed by clicking on the 'signatures' tab on the study menu.

Signatures

Subject

Role	User	Signature	Date
------	------	-----------	------

Visits

Role	User	Signature	Date
------	------	-----------	------

Forms

Role	User	Signature	Date
------	------	-----------	------



On this page, you can see any items that have been signed, as well as individual visits and forms that have been completed and their status.

Your signature will be overwritten if any changes are made to the form. You must re-sign the form every time a change has been made.

Not all studies require signatures on every level. Please refer to CRA for information on what is required for signatures in your study.

Invalid Signatures

There are different consequences for changing data depending on what signatures have been added to the system.

Changes to data at the form level: If any changes are made to the data once a signature has been added to the form, the signature panel for visit will then **become invalidated** (as seen in the screenshot below vs an invalid signature at the visit or subject level as seen in the red below). You are required to re-sign the form once data has been changed if required for your study. The signature panel under forms will then be updated appropriately.

Invalid signatures at the visit or subject level: If any user makes a change to a form within a visit after that visit has been signed all signatures for that visit will be marked as invalid on the signatures tab.

Invalid signatures at the subject level: If any user makes a change to a form, starts a visit, or resets a visit after the subject has been signed, all signatures at the subject level will be marked as invalid on the signatures tab (red panel would then show up at the subject level).

An invalid signature is an indication to the signing user that the data has changed and requires review.

Signatures

Subject

Role	User	Signature	Date
------	------	-----------	------

Visits

Role	User	Signature	Date
Screening			
Baseline			
Follow-up Visit 1			

Admin

louise@theverdict.ca

Approval

Wednesday, May 21, 2025 at 8:22 PM ADT



Forms

Role	User	Signature	Date
GAS Assessment(Screening)			
GAS Assessment(Baseline)			
GAS Assessment(Follow-up Visit 1)			

INVALID SIGNATURE: RE-SIGNING A VISIT OR A SUBJECT

A user can re-sign a visit or subject if their current signature has been marked as invalid. Re-signing will update the signature based on the currently entered data and make it valid again.

The signature button will be replaced with “Re-sign visit”.

Follow-up Visit 1

GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

...

Subject ID: S1236

Screening (Valid)

Baseline (Valid)

Follow-up Visit 1 (Valid)

Form: GAS Assessment (Valid)

Follow-up Visit 2

+ Add Visit

Signatures

IN THIS CHAPTER

1 Source Data Verification

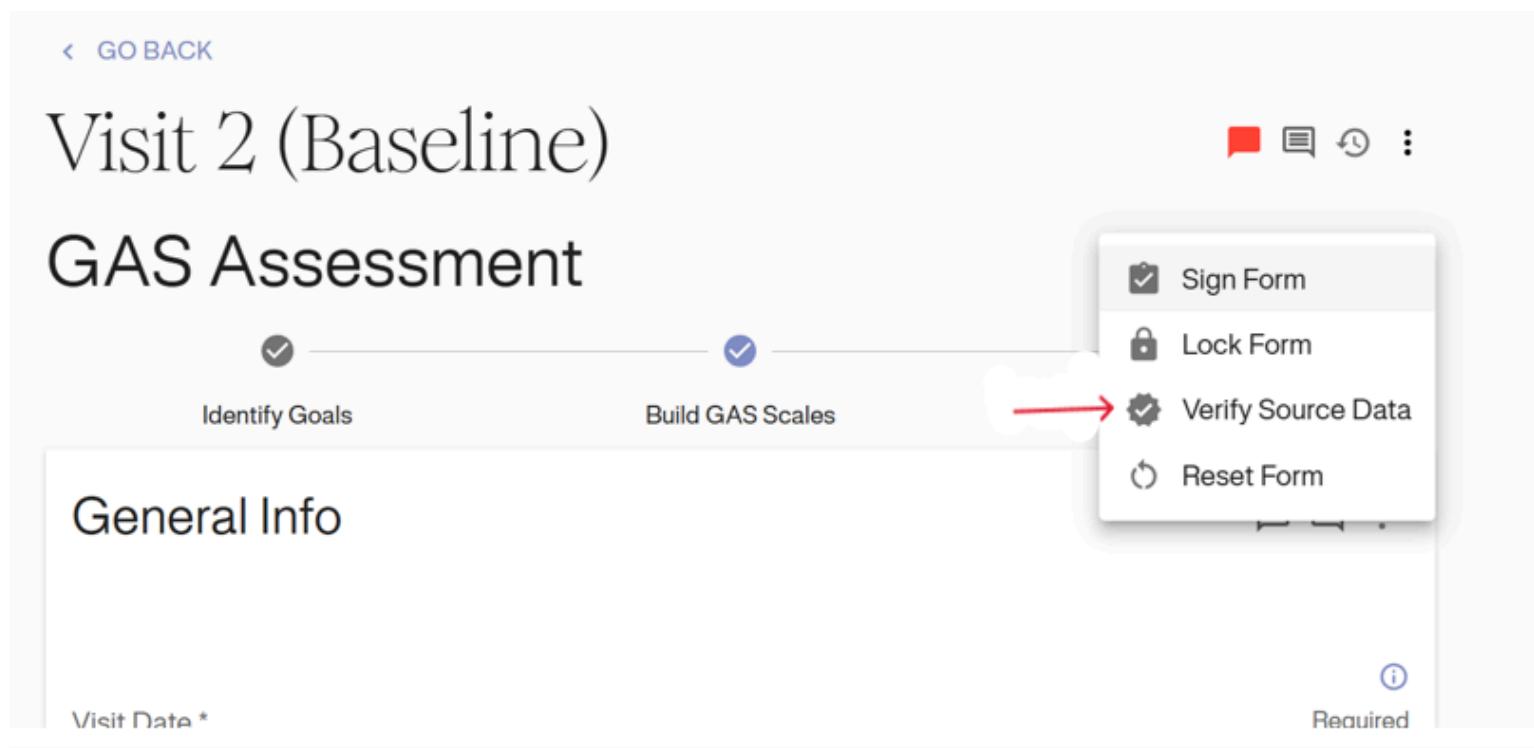
Source Data Verification

NOTE: This section only applies for those studies that allow source data verification to be completed by the sites alternate GAS interviewer.

A visit completed on a paper form must be entered into GoalNav® by the GAS interviewer who completed the visit. The alternate GAS interviewer at the site must verify that the data has been entered accurately into GoalNav® and complete a Source Data Verification signature. GoalNav® does not allow any user who authored the data in GoalNav®, to perform SDV on the same data.

Follow these steps below to complete a source data verification signature:

The following is an example of a GAS interviewer completing source data verification for a baseline visit GAS assessment form. Click on the options icon (:) next to the name of the Baseline form. Locate “VERIFY SOURCE DATA” from the dropdown and click on it.



This will authenticate the user. The “Added Source Data Verification” status will be displayed at the bottom of the screen, and a blue tick icon will appear right next to the form, as shown below.

Visit 2 (Baseline)

✖️ 📄 ⏲ ⏴

GAS Assessment

➡️⚙️🖨️📄📅🕒⋮



Identify Goals



Build GAS Scales



Rank Goals

General Info

📄📅⋮

Visit Date *

ⓘ Required

Added Source Data Verification



IN THIS CHAPTER

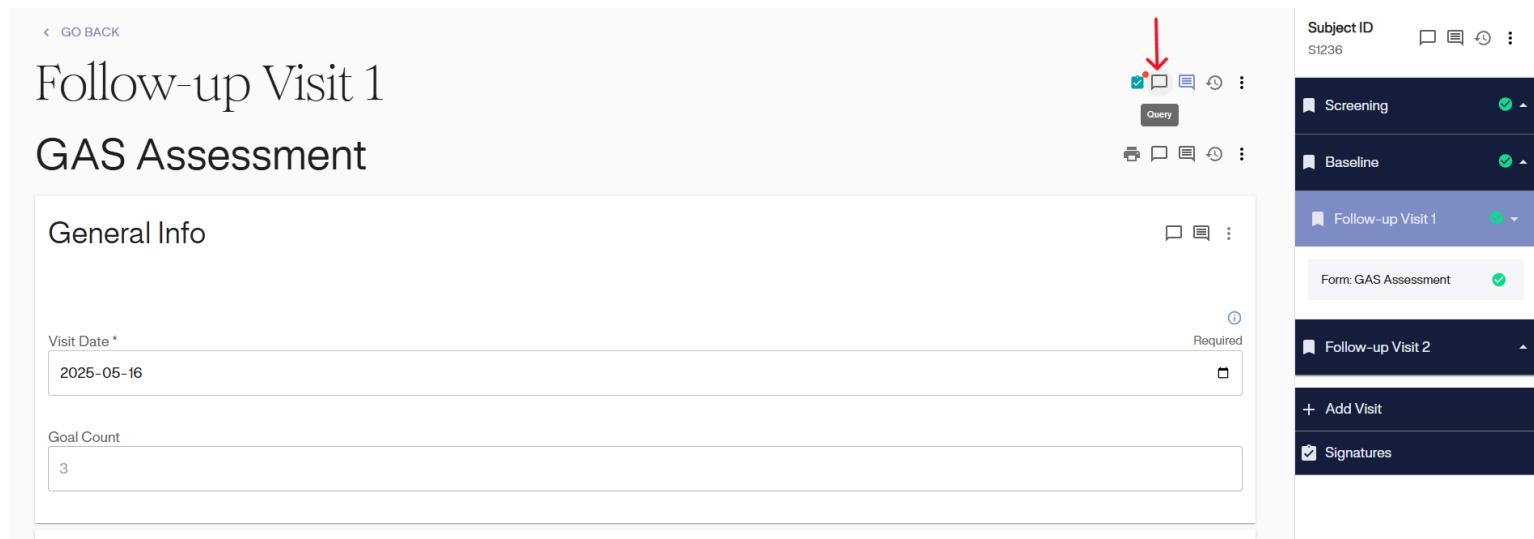
1 Managing Queries

- a Create a GoalNav® Query
- b View All GoalNav® Queries
- c Respond to GoalNav® Queries
- d Close Queries

Managing Queries

Create a GoalNav® Query

To create a new GoalNav® query on the visit level, click on the blank dialogue box icon right next to the name of the visit.



Follow-up Visit 1
GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

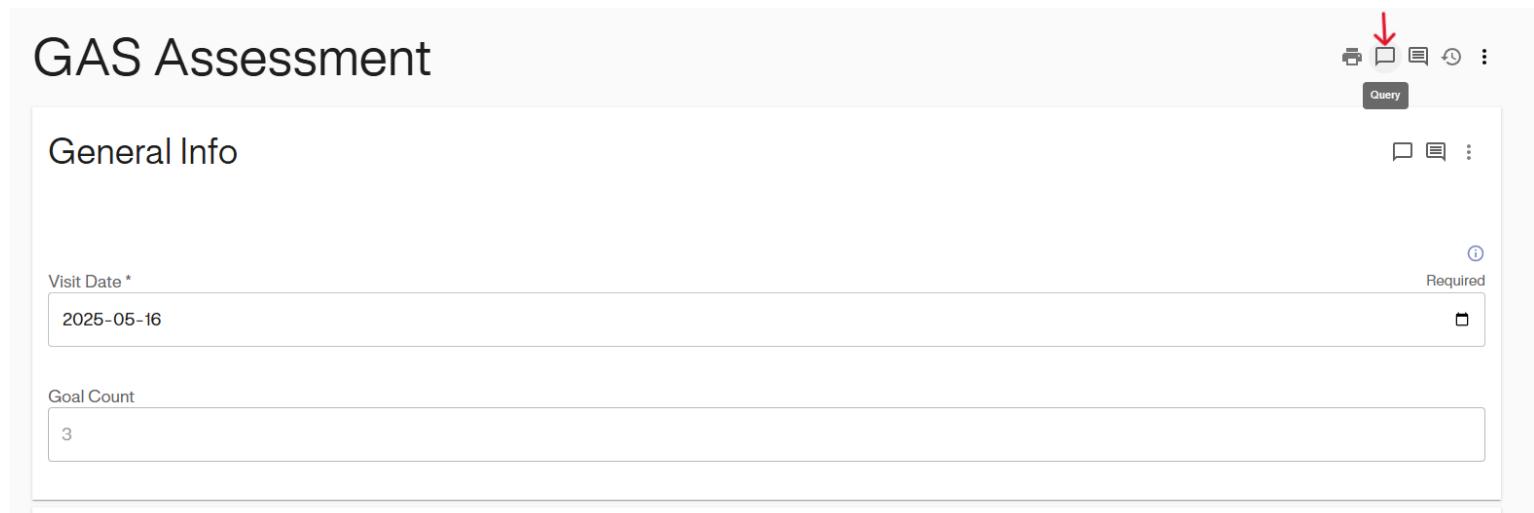
Subject ID: SI236

Screening, Baseline, Follow-up Visit 1 (selected), Follow-up Visit 2

Form: GAS Assessment

Add Visit, Signatures

To create a new GoalNav® query on the form level, click on the blank dialogue box icon right next to the name of the form.



GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

To create a new GoalNav® query on the section level, click on the blank dialogue box icon at the top of the form section.

General Info

Visit Date * Required

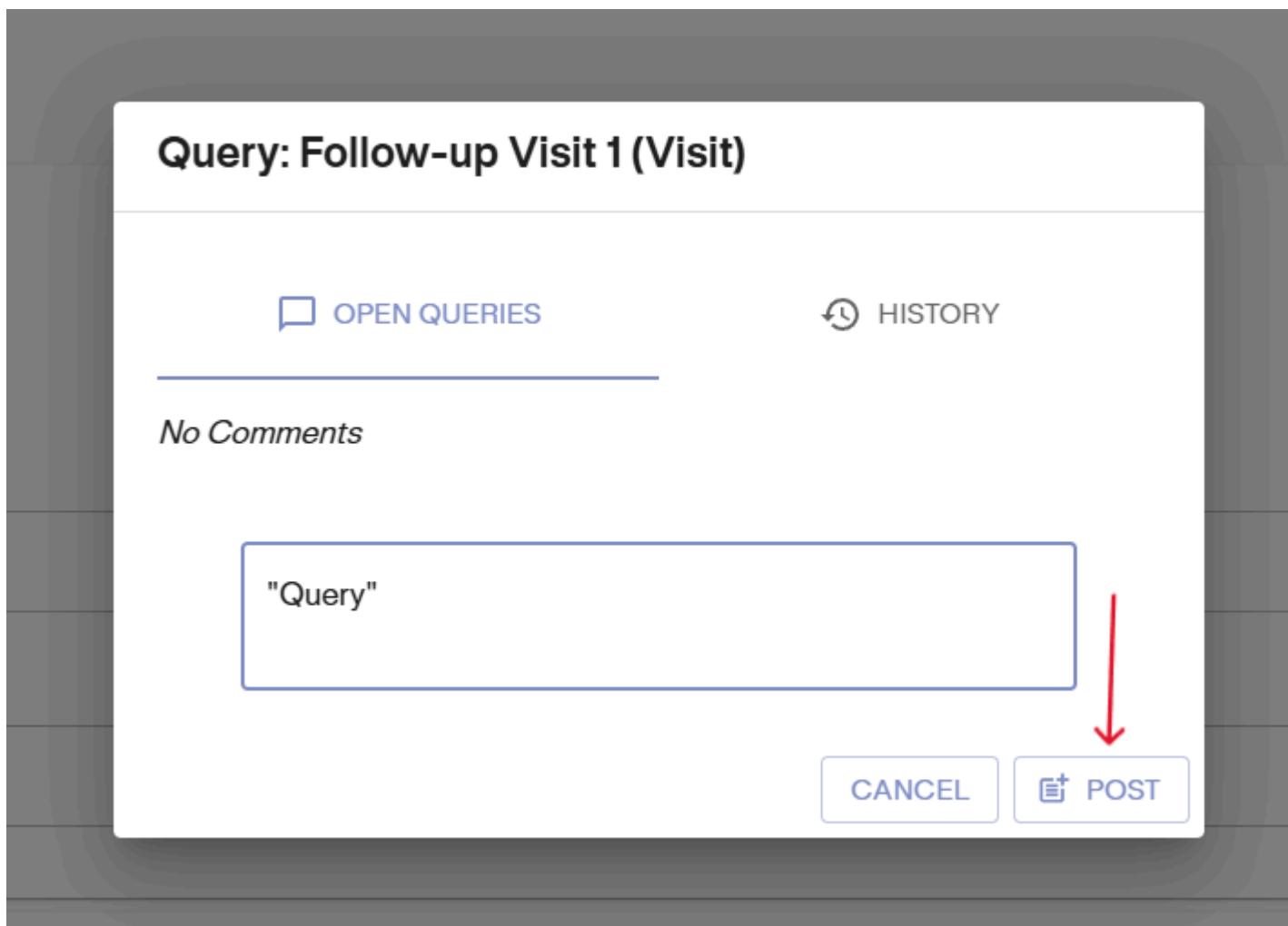
2025-05-16

Goal Count

3

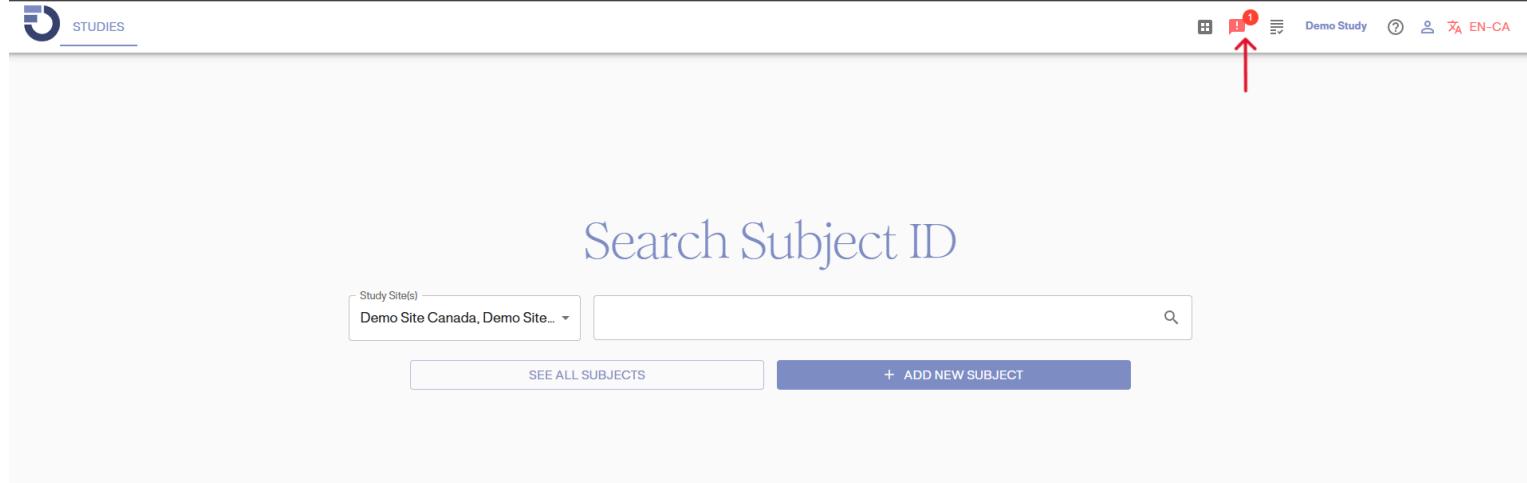
Query

Click the icon to open a pop-up window. Here, start a new query thread in GoalNav® for the selected subject and visit. In the text box, enter the query. Then, click the “Post” button to submit it. When a new query is posted, the author of the visit will be notified.

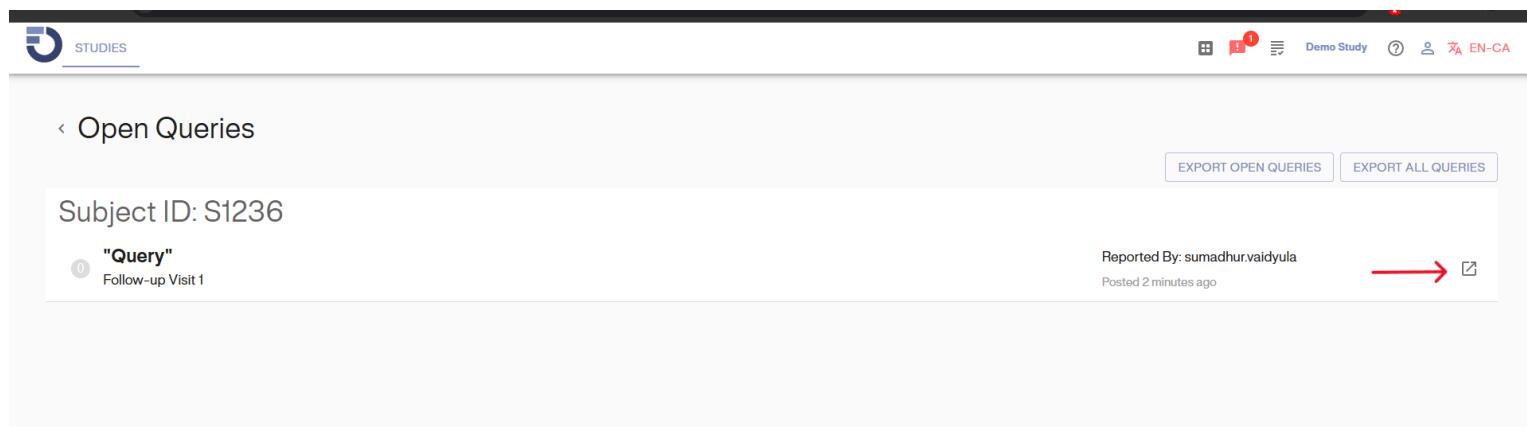


[View All GoalNav® Queries](#)

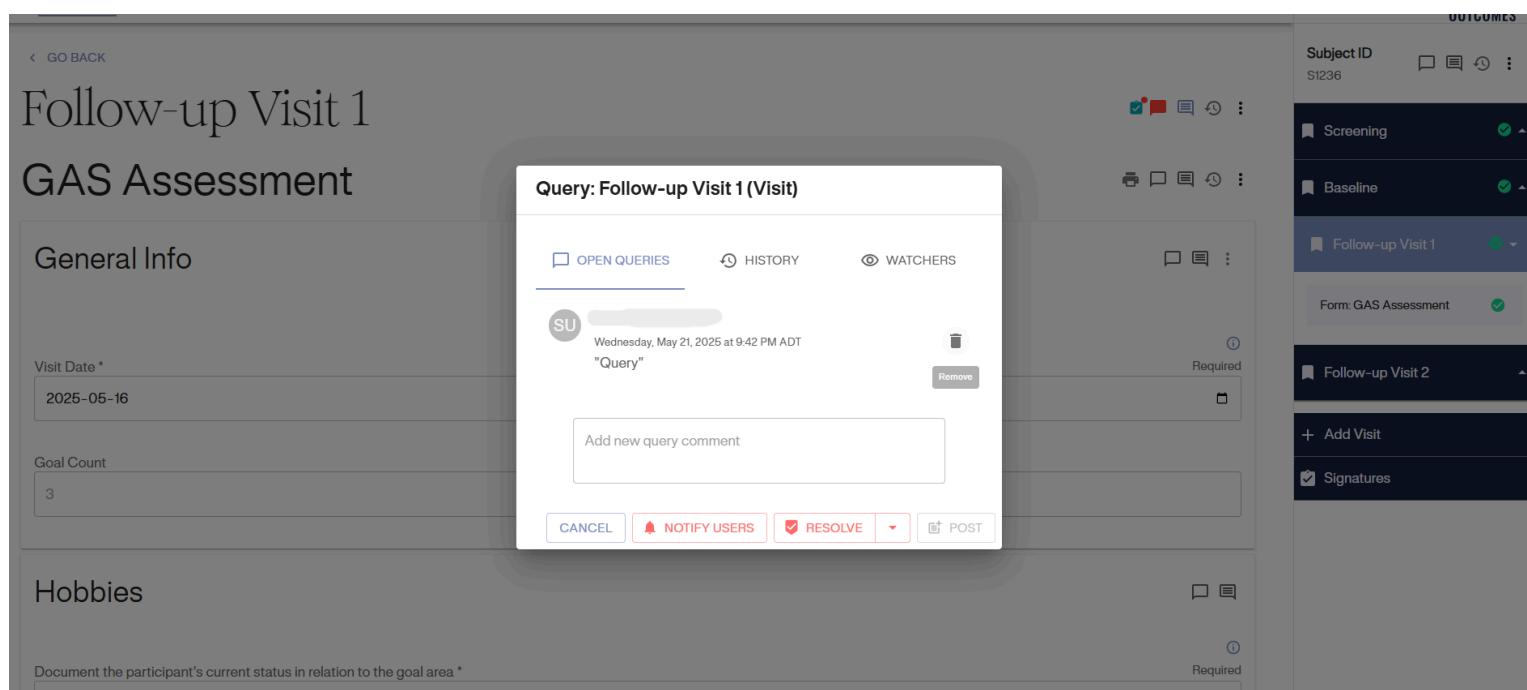
To view all open queries in GoalNav®, click the dialogue icon, which will be highlighted in red when unresolved queries are present within the study.



Click on the dialogue icon button, as shown in the image above, to display all open queries on the page, as highlighted in the image below. Click the link icon (the arrow icon) on the right-hand side of each query, to be directed to that specific query thread. For example, the first query is selected for viewing in this case.

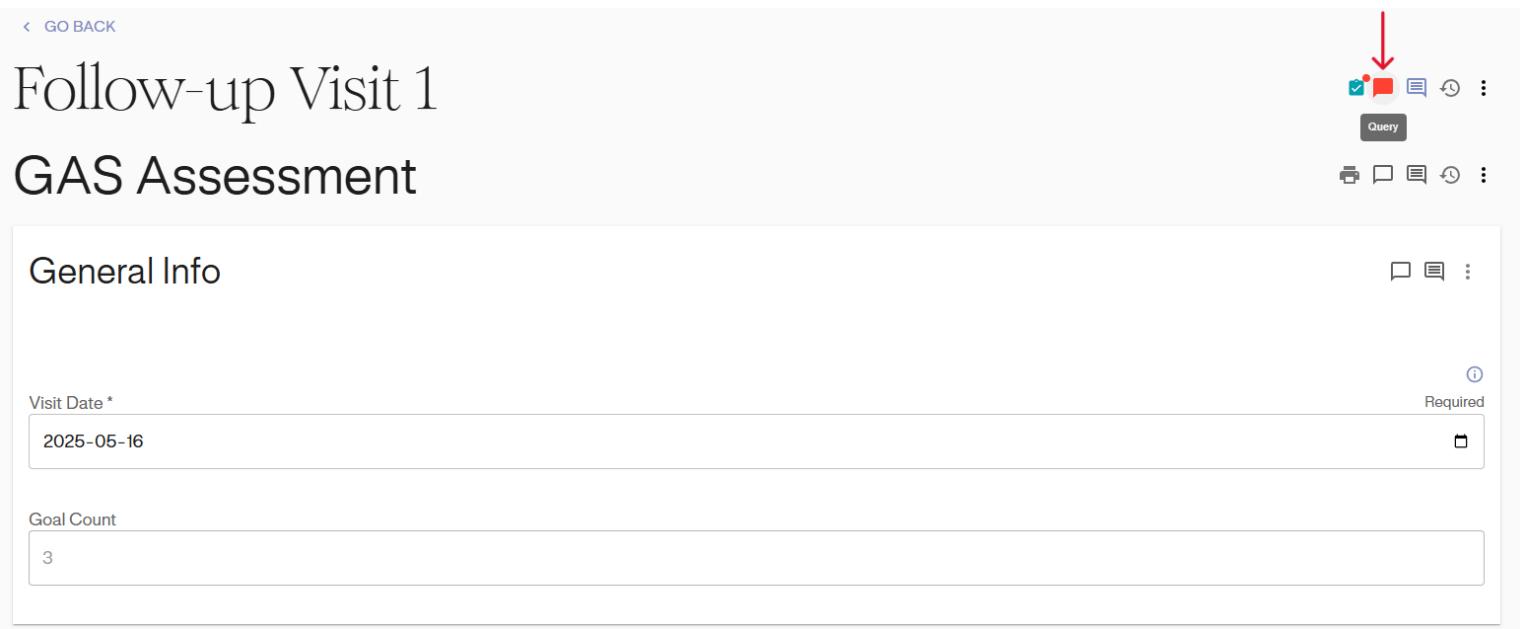


Click the link icon to open a pop-up window to display the visit, form, or form section where the query was created, including the entire query thread.



Respond to GoalNav® Queries

To respond to a query thread in GoalNav®, first navigate to any visit that has an open query. Alternatively, click the dialogue icon in the top bar and select the appropriate query thread to access the Query page. To view the query, click on the red dialogue box icon. Please be aware that a red dialogue icon next to the visit name, form name, or form section name indicates there is an active query for that visit.



GO BACK

Follow-up Visit 1

GAS Assessment

General Info

Visit Date * Required

2025-05-16

Goal Count

3

Query

Print

Print

Print

Print

Click on the red dialogue icon to open a pop-up window that displays the active query thread. In the text box, enter the answer to the query. Click on “Post” to post the response. Posting a response will notify the author of the data and any users who have previously responded/participated in the query thread.

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



"Answer to Query"

CANCEL

 NOTIFY USERS

 RESOLVE



 POST



Close Queries

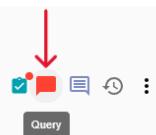
Once an answer to a query is accepted and validated, click the "Resolve" button to close the query. Once "Resolve" is selected, the resolved query will disappear. Note: The Data Monitors should only close queries they created themselves or those that have been resolved. They should not close any unanswered queries. To close a query, follow the instructions below:

Click on the Query Icon on the visit details page.

[GO BACK](#)

Follow-up Visit 1

GAS Assessment



General Info

Visit Date *

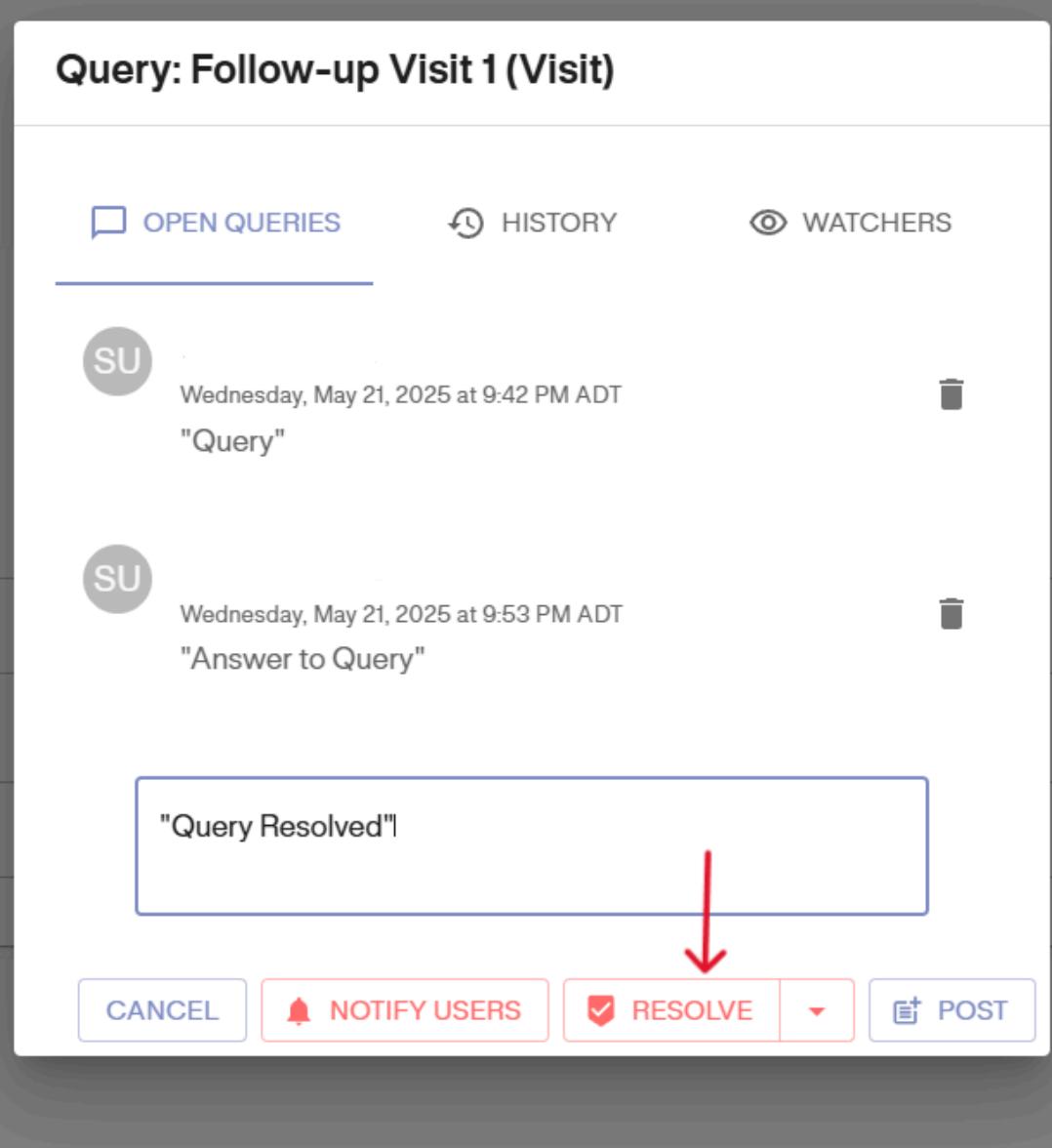
2025-05-16

 Required

Goal Count

3

This opens the existing query thread with the initial query and subsequent replies. Click on the “Resolve” button to close the query. A query can also be closed without a resolution. To do so, click the arrow icon next to the “Resolve” button. This opens a dropdown menu with an option labeled “Unresolvable.” Click on this option to close the query with an “Unresolvable” status.



Closing query with an unresolvable status:

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



SU

Wednesday, May 21, 2025 at 9:53 PM ADT

"Answer to Query"



 CANCEL

 NOTIFY USERS

 RESOLVE



 POST

Unresolvable

Chapter 4: Using GoalNav as an Investigator

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 - a [Add Signatures](#)
 - b [Viewing Signatures from Signatures Tab](#)
 - c [Invalid Signatures](#)
 - a [Invalid Signature: Re-signing a Visit or a Subject](#)

Signature Records

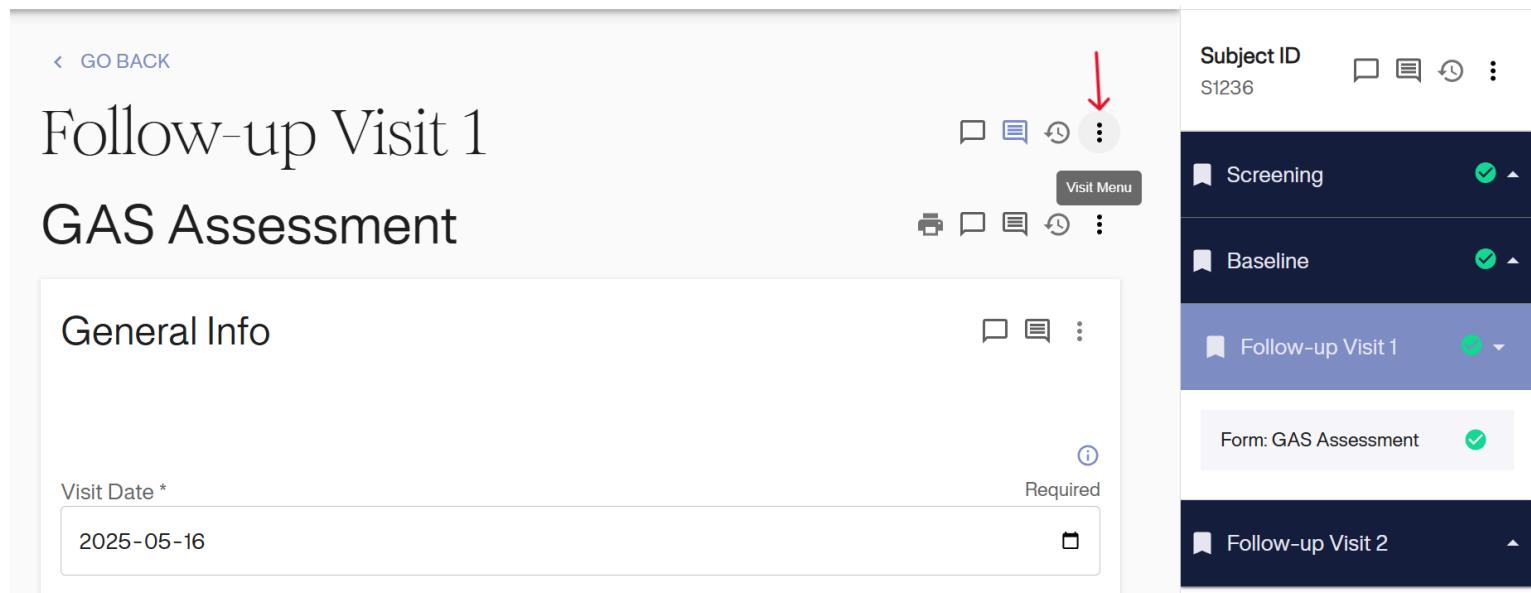
Add Signatures

Once a visit has been completed, you may be required to provide a digital signature, depending on your study requirements.

Signatures at the Subject Level: The PI is generally responsible for signing the subject level if required.

Sign Visit Example:

To sign the visit, click on the 3 dots on the right side of the Goal Attainment Scaling form.



The screenshot shows the GoalNav software interface. On the left, a visit form for 'Follow-up Visit 1 GAS Assessment' is displayed. The form includes sections for 'General Info' and a 'Visit Date' field containing '2025-05-16'. A red arrow points to a 'Visit Menu' icon (three dots) located to the right of the visit form. On the right, the 'Subject ID' study menu is open, showing visit history and form status. The 'Follow-up Visit 1' visit is highlighted in blue, and the 'Form: GAS Assessment' status is marked as 'Required' with a green checkmark.

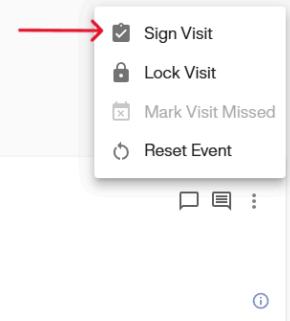
You may note that there are other similar icons present on the page. Those icons represent:

- Signatures at the form level (3 dots above the form visit signature)
- Subject level (3 dots next to the subject ID in the study menu)

All signatures (form, visit, subject) can be done following the same format as outlined below.

Follow-up Visit 1

GAS Assessment

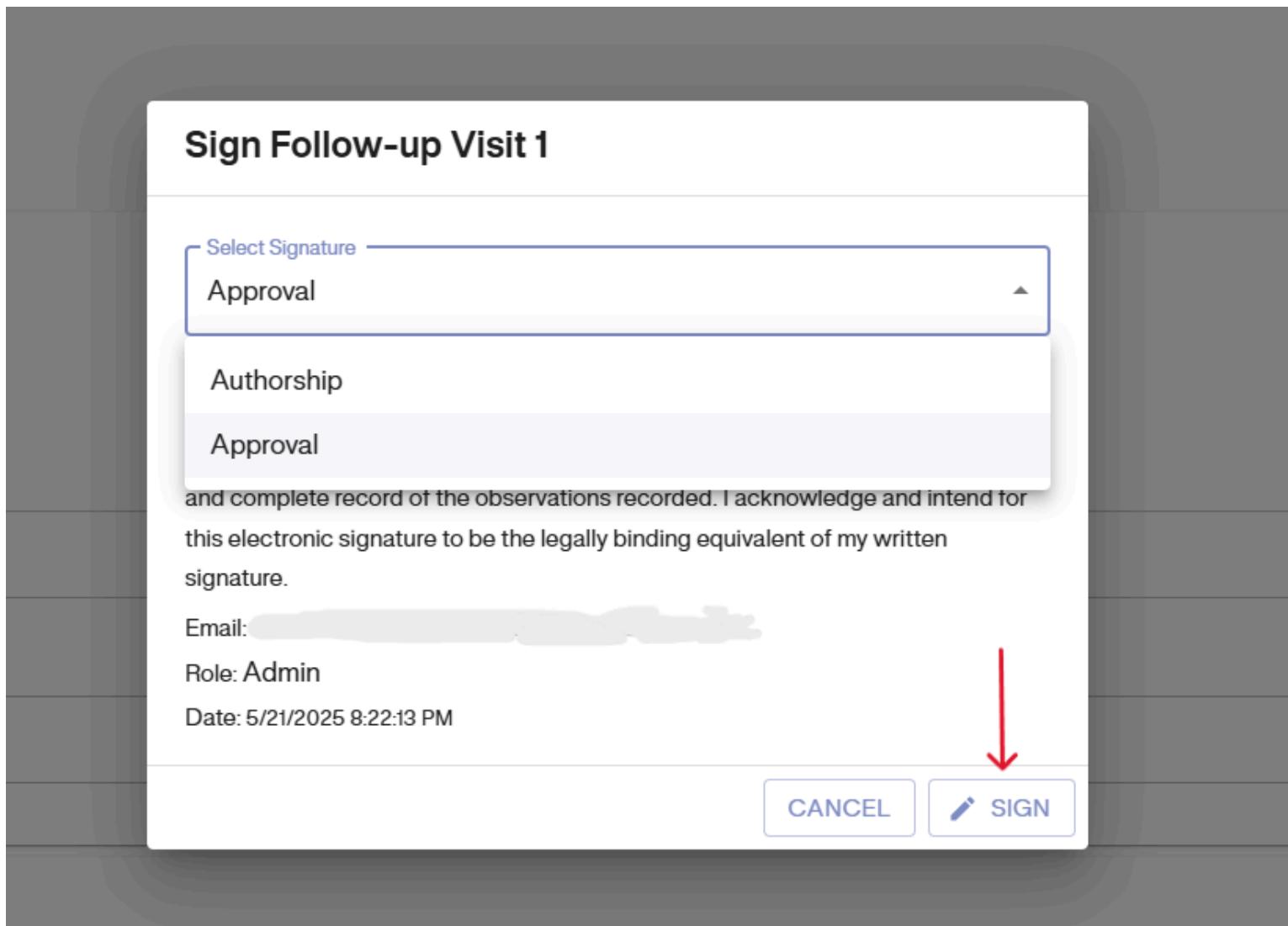


General Info

□ □ :

?

Once you click on 'sign visit', you will be required to re-enter your login information to verify your identity. Once authenticated, you will see a window to select the type of signature Authorship or Approval. Select the relevant option and then click on "Sign" button.



Once the form has been signed, a green pop-up with status 'Signature Added' will appear in the bottom left of the screen and a blue notepad icon will be added right next to the visit name to indicate that the visit has been signed.

Follow-up Visit 1

GAS Assessment



General Info



Visit Date *

Required

2025-05-16



Goal Count

3

Hobbies



Document the participant's current status in relation to the goal area *

Required

Signature added.



In the Subject Details Dashboard, the visit will reflect the signed icon, once they are signed on the visit level as required by the study

Subject: S1236

Back to Subject(s)

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Thursday, May 15, 2025 at 7:38 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:33 PM ADT	✓
Baseline	Tuesday, May 20, 2025 at 8:50 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:41 PM ADT	✓
Follow-up Visit 1	Tuesday, May 20, 2025 at 9:49 PM ADT	✓  	← GAS Assessment	Tuesday, May 20, 2025 at 10:00 PM ADT	✓
Follow-up Visit 2		📅	GAS Assessment		📅
<input type="checkbox"/> Scheduled <input type="checkbox"/> In Progress <input checked="" type="checkbox"/> Completed <input checked="" type="checkbox"/> Signed <input type="checkbox"/> Locked  Invalid Signatures  Missed <input checked="" type="checkbox"/> Source Data Verified					

If you edit the forms, your signature will be invalidated and an invalid signature icon will appear on signature panel. You must resign the form each time you make a change to the data.

Viewing Signatures from Signatures Tab

The signatures page can be accessed by clicking on the 'signatures' tab on the study menu.

Signatures

Subject

Role	User	Signature	Date
------	------	-----------	------

Visits

Role	User	Signature	Date
------	------	-----------	------

Forms

Role	User	Signature	Date
------	------	-----------	------



Subject ID S1235	Screening
	Baseline
	Follow-up Visit 1
	Follow-up Visit 2
	+ Add Visit
	<input checked="" type="checkbox"/> Signatures

On this page, you can see any items that have been signed, as well as individual visits and forms that have been completed and their status.

Your signature will be overwritten if any changes are made to the form. You must re-sign the form every time a change has been made.

Not all studies require signatures on every level. Please refer to CRA for information on what is required for signatures in your study.

Invalid Signatures

There are different consequences for changing data depending on what signatures have been added to the system.

Changes to data at the form level: If any changes are made to the data once a signature has been added to the form, the signature panel for visit will then **become invalidated** (as seen in the screenshot below vs an invalid signature at the visit or subject level as seen in the red below). You are required to re-sign the form once data has been changed if required for your study. The signature panel under forms will then be updated appropriately.

Invalid signatures at the visit or subject level: If any user makes a change to a form within a visit after that visit has been signed all signatures for that visit will be marked as invalid on the signatures tab.

Invalid signatures at the subject level: If any user makes a change to a form, starts a visit, or resets a visit after the subject has been signed, all signatures at the subject level will be marked as invalid on the signatures tab (red panel would then show up at the subject level).

An invalid signature is an indication to the signing user that the data has changed and requires review.

Signatures

Subject

Role	User	Signature	Date
------	------	-----------	------

Visits

Role	User	Signature	Date
Screening			
Baseline			
Follow-up Visit 1			

Admin

louise@verilylife.com

Approval

Wednesday, May 21, 2025 at 8:22 PM ADT



Forms

Role	User	Signature	Date
GAS Assessment(Screening)			
GAS Assessment(Baseline)			
GAS Assessment(Follow-up Visit 1)			

INVALID SIGNATURE: RE-SIGNING A VISIT OR A SUBJECT

A user can re-sign a visit or subject if their current signature has been marked as invalid. Re-signing will update the signature based on the currently entered data and make it valid again.

The signature button will be replaced with “Re-sign visit”.

Follow-up Visit 1

GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

...

Subject ID: S1236

Screening (Valid)

Baseline (Valid)

Follow-up Visit 1 (Valid)

Form: GAS Assessment (Valid)

Follow-up Visit 2

+ Add Visit

Signatures

Chapter 5: Using GoalNav as a Monitor

TABLE OF CONTENTS

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- [Monitor Signatures](#)
- [Manage Queries](#)

IN THIS CHAPTER

- 1 [Data Monitor Guidelines](#)
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 - b [Monitor Source Data Verification \(SDV\) from Subject Details Dashboard](#)
 - c [Monitor SDV from the Data Explorer](#)

DATA MONITOR GUIDELINES

The Data Monitor guidelines provide step-by-step instructions for CRAs monitoring data in GoalNav® which can include reconciliation activities, ensuring SDV signatures by site staff in the Study trial. This section details the necessary actions for data monitors in GoalNav® and outlines the workflow for each task. Data monitoring may include:

- Query Management such as generating query, view query, respond to query and resolve query.
- Monitoring of Source Data Verification (SDV) for the subject.
- Monitoring Signatures.
- Accessing the Data Explorer Dashboard to search for data using a query and perform actions.

Source Data Verification

Overview

Source Data Verification is required only when a paper backup form is used to record visit data, and that data is entered into GoalNav® once the technical issue has been resolved. Not all forms need Source Data Verification.

To check if the form has "Source Data Verified"(SDV), follow the instructions below:

Monitor Source Data Verification (SDV) from Subject Details Dashboard

Click on the Subject ID in the Subject Matrix to access the Subject Details Dashboard.

Scheduled Visits								Unscheduled Visits	
Subject ID ↑	Subject Status	Added Date	Screening	Baseline	Follow-up Visit 1	Follow-up Visit 2	Withdrawal		
S1235	🕒	Wednesday, May 21, 2025	📅	📅	📅	📅	🕒
S1236 ←	🕒	Thursday, May 15, 2025	✓	✓	✓	✓	🕒
S1237	🕒	Tuesday, May 20, 2025	✓	✓	📅	📅	🕒
S1238	🕒	Wednesday, May 21, 2025	📅	📅	📅	📅	🕒

On the Subject Details Dashboard, select the visit name from the navigation menu on the right side.

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Thursday, May 15, 2025 at 7:38 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:33 PM ADT	✓
Baseline	Tuesday, May 20, 2025 at 8:50 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:41 PM ADT	✓
Follow-up Visit 1	Tuesday, May 20, 2025 at 9:49 PM ADT	✓	GAS Assessment	Wednesday, May 21, 2025 at 8:42 PM ADT	✓
Follow-up Visit 2		📅	GAS Assessment		📅

📅 Scheduled 🕒 In Progress ✓ Completed ✓ Signed 🔒 Locked ✗ Invalid Signatures 📅 Missed ⚙️ Source Data Verified

The visit details will be displayed when you click on the visit name. A purple checkmark icon next to the form name indicates that the form has been “Source Data Verified”. If the icon is not present, the form still requires verification.

GO BACK

Visit 2 (Baseline)

GAS Assessment

Identify Goals Build GAS Scales Rank Goals

Source Data Verified

Monitor SDV from the Data Explorer

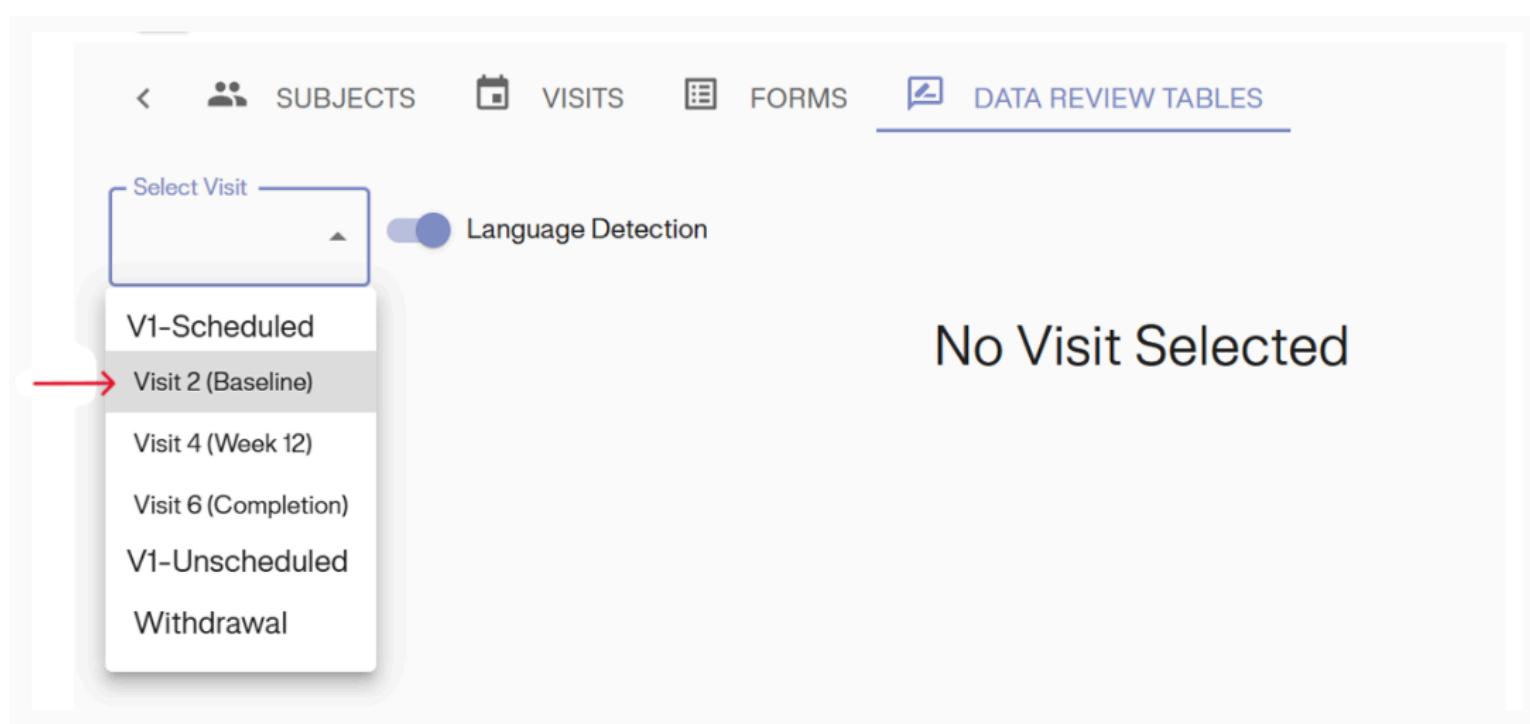
To monitor SDV from Data Explorer, click on the grid icon in the top menu bar on the trial's homepage. The grid icon is visible on all pages except the landing page in the top menu bar.



Study Site(s)
Demo Site Canada, Demo Site USA
Search Subject ID
Open Data Explorer

+ ADD NEW SUBJECT
EXPORT

Open the dropdown menu and select the visits that require monitoring. For example, visit 2 (Baseline) is currently selected.

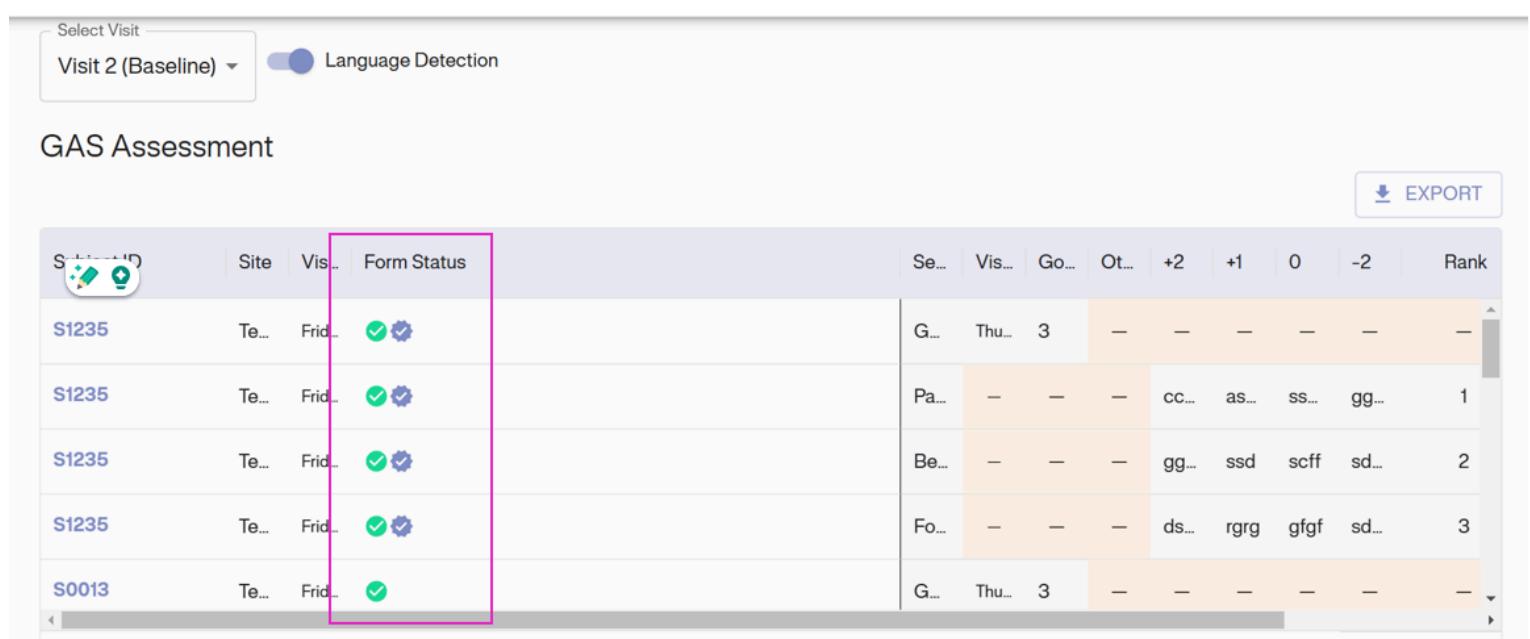


The screenshot shows the 'DATA REVIEW TABLES' tab selected. On the left, a dropdown menu titled 'Select Visit' is open, showing the following options:

- V1-Scheduled
- Visit 2 (Baseline) →
- Visit 4 (Week 12)
- Visit 6 (Completion)
- V1-Unscheduled
- Withdrawal

A blue toggle switch labeled 'Language Detection' is visible to the right of the dropdown. The main area displays the message 'No Visit Selected'.

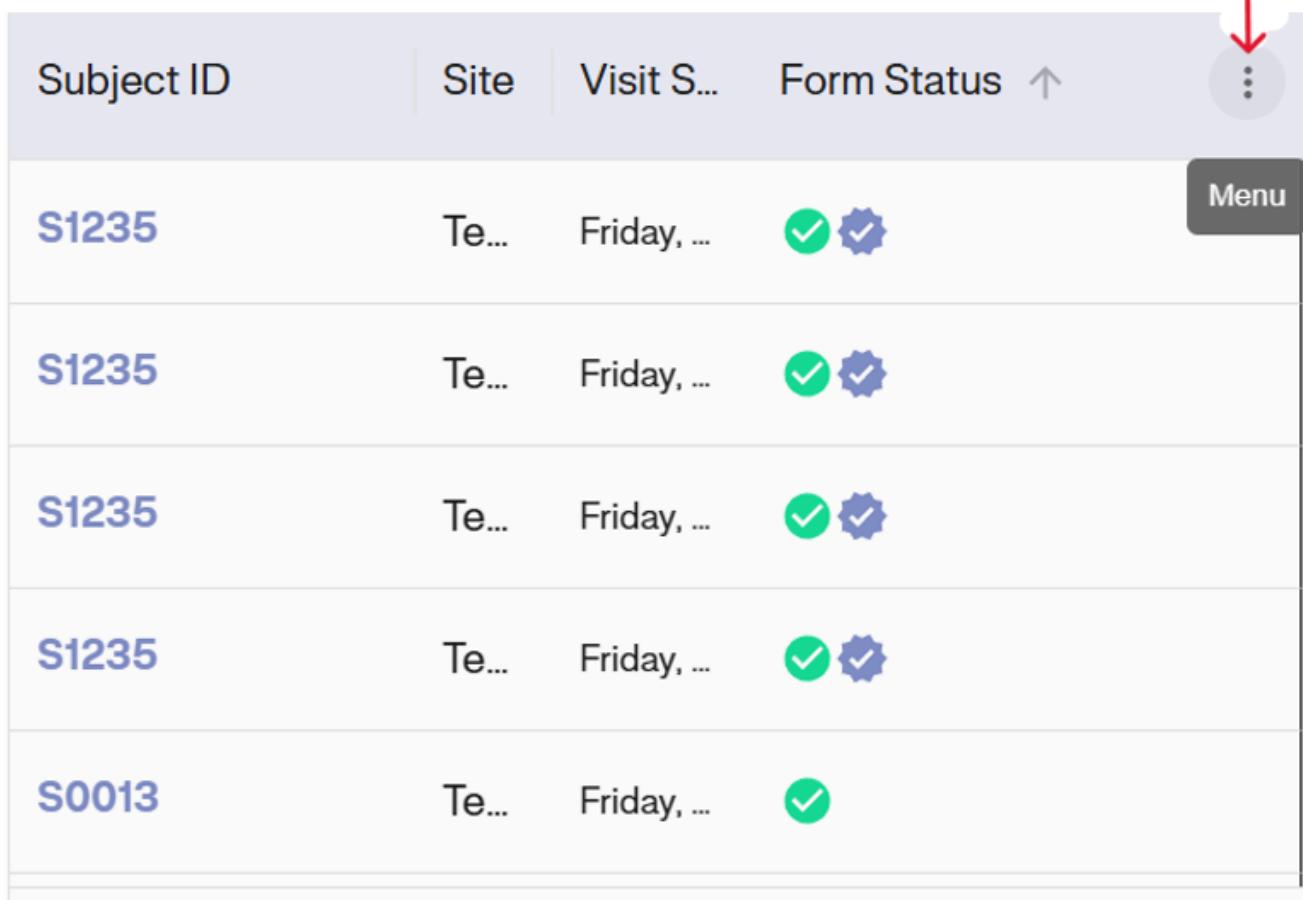
The table features a “Form Status” column that displays the status of all forms for each subject. Forms that are marked as “Source Data Verified” are indicated in the “Form Status” column with a purple checkmark icon. Please note that not all forms are required to be “Source Data Verified”.



The screenshot shows a table with the following columns:

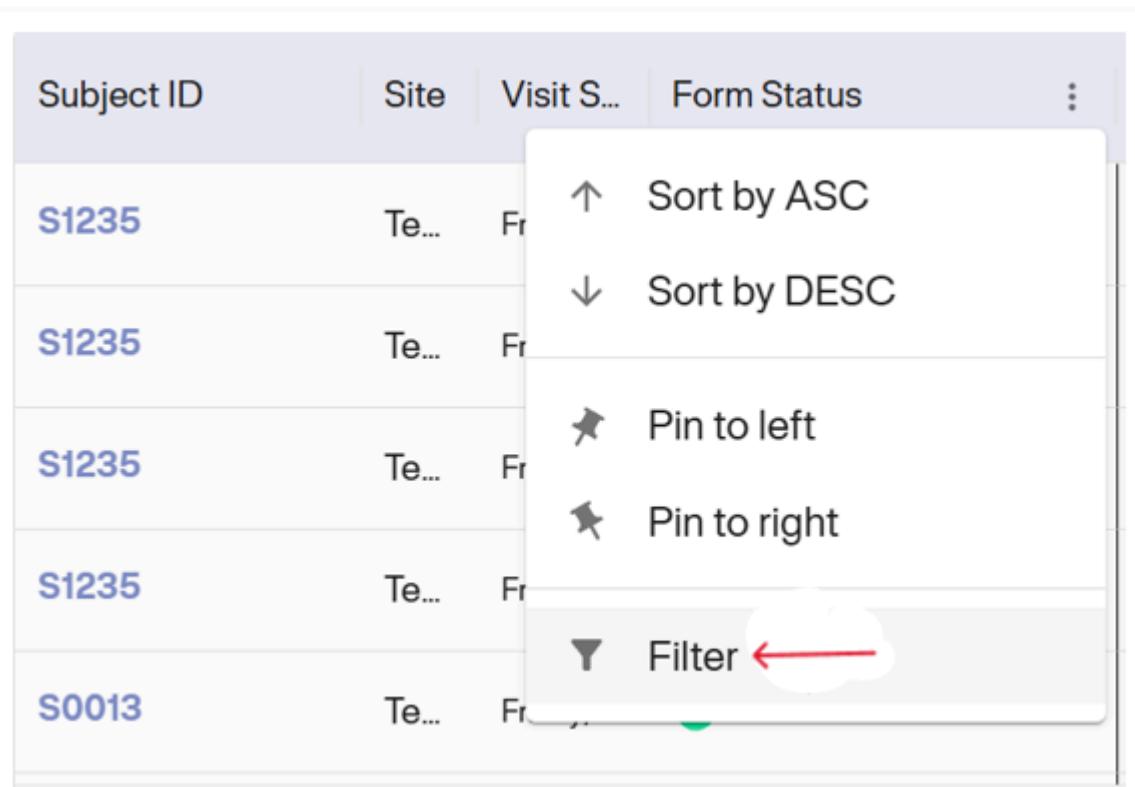
Subject ID	Site	Vis...	Form Status	Se...	Vis...	Go...	Ot...	+2	+1	0	-2	Rank
S1235	Te...	Frid...	✓	G...	Thu...	3	—	—	—	—	—	—
S1235	Te...	Frid...	✓	Pa...	—	—	—	cc...	as...	ss...	gg...	1
S1235	Te...	Frid...	✓	Be...	—	—	—	gg...	ssd...	scff	sd...	2
S1235	Te...	Frid...	✓	Fo...	—	—	—	ds...	rgrg	gf...	sd...	3
S0013	Te...	Frid...	✓	G...	Thu...	3	—	—	—	—	—	—

Instead of scrolling through the rows of data to find forms that are “Source Data Verified (SDV)”, use the filter option for a more efficient search. Click the options menu (the three-dot icon) next to the “Form Status” column to access the filter.



Subject ID	Site	Visit S...	Form Status	↑
S1235	Te...	Friday, ...	 	
S1235	Te...	Friday, ...	 	
S1235	Te...	Friday, ...	 	
S1235	Te...	Friday, ...	 	
S0013	Te...	Friday, ...		

To search for data, click “Filter” and choose the appropriate option from the provided filters.



Subject ID	Site	Visit S...	Form Status	⋮
S1235	Te...	Fr	↑ Sort by ASC	
S1235	Te...	Fr	↓ Sort by DESC	
S1235	Te...	Fr	↗ Pin to left	
S1235	Te...	Fr	↘ Pin to right	
S0013	Te...	Fr	Filter 	

Next, select the appropriate value from the dropdown menu to search for the data.

Subject ID

Site

Visit S...

Form Status

Se...

Vis...

Go...

Ot...

Columns
Form StatusOperator
containsValue

+ ADD FILTER

REMOVE ALL

From the dropdown, select the option “Source Data Verified.”

Subject ID

Site

Visit S...

Form Status

Columns
Form StatusOperator
contains

+ ADD FILTER

Scheduled

Completed

In Progress

Locked

Signed

Invalid Signatures

Source Data Verified

The table now displays only the records whose form “Status” is “Source Data Verified”.

GAS Assessment

EXPORT

Subject ID	Site	Visit St...	Form Status	Se...	Vis...	Go...	Ot...	+2	+1	0	-2	Rank	De...	Last ...	Last M...
S1235	Te...	Friday, N...	✓	G...	Thu...	3	—	—	—	—	—	—	de	sum...	Friday, N...
S1235	Te...	Friday, N...	✓	Pa...	—	—	—	cc...	as...	ss...	gg...	1	de	sum...	Friday, N...
S1235	Te...	Friday, N...	✓	Be...	—	—	—	gg...	ssd	scff	sd...	2	de	sum...	Friday, N...
S1235	Te...	Friday, N...	✓	Fo...	—	—	—	ds...	rgrg	gfjf	sd...	3	de	sum...	Friday, N...

Total Rows: 4 of 27

IN THIS CHAPTER

1 Monitor Signatures

- a Monitor Applied and Missing Signatures
- b Monitor Invalid Signatures

Monitor Signatures

Monitor Applied and Missing Signatures

To monitor a subject's signatures for each visit, navigate to the Subject Details Dashboard. A signed visit will display a blue notepad icon in the Status (Visit) column. Hover over this icon to show the status and the role that added the signature. For example, as shown in the image below, it states "Signed: Data Entry." If a visit does not have a blue notepad icon, it indicates that the visit is missing a signature.

Subject: S0013

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Visit 2 (Baseline)	Friday, November 8, 2024 at 5:33 AM AST		GAS Assessment	Friday, November 8, 2024 at 5:35 AM AST	
Withdrawal (1)	Friday, November 8, 2024 at 5:59 AM AST		GAS Assessment		
Visit 4 (Week 12)	Friday, November 8, 2024 at 5:20 AM AST		GAS Assessment	Friday, November 8, 2024 at 6:03 AM AST	
Visit 6 (Completion)	Friday, November 8, 2024 at 6:02 AM AST		GAS Assessment	Friday, November 8, 2024 at 6:04 AM AST	

Subject ID: S0013

Visit 2 (Baseline)

Withdrawal (1)

Visit 4 (Week 12)

Visit 6 (Completion)

Signatures

Missing signatures

Alternatively, search for signed and unsigned visits using the data explorer. To view signed visits, click the grid icon in the top menu bar.

Select "Visits" from the menu options. Then click on the options icon (three-dot icon) on the "Visit Status" Column



Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status	Signature Rol...	Forms Compl...	Last Modified By	Visit Queries	Other Queries
S1236	101 - Demo Site Ca...	Screening	Scheduled	Thursday, May 15, 2025 at 7:38 PM ADT	✓		1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Baseline	Scheduled	Tuesday, May 20, 2025 at 8:50 PM ADT	✓		1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Follow-up Visit 1	Scheduled	Tuesday, May 20, 2025 at 9:49 PM ADT	✓ ✓	Admin	1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Screening	Scheduled	Tuesday, May 20, 2025 at 9:34 PM ADT	✓		1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Baseline	Scheduled	Wednesday, May 21, 2025 at 11:42 AM ADT	✓		1/1	sumadhur.vaidyula...	-	No

Visit Status Up ⋮ Signature Rol... Forms Compl... Last Modified By Visit Queries Other Queries

↑ Sort by ASC

↓ Sort by DESC

★ Pin to left

★ Pin to right

Filter

From the options, select the filter option and then from the filter options, select the “Signed” option.

Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status
S1237	101 - Demo Site Ca...	Screening	Scheduled	Thursday, May 15, 2025 at 7:38 PM ADT	✓
S1237	101 - Demo Site Ca...	Baseline	Completed	Tuesday, May 20, 2025 at 8:50 PM ADT	✓
S1237	101 - Demo Site Ca...	Follow-up Visit 1	In Progress	Tuesday, May 20, 2025 at 9:49 PM ADT	✓ ✓
S1237	101 - Demo Site Ca...	Baseline	Missed	Tuesday, May 20, 2025 at 9:34 PM ADT	✓
S1237	101 - Demo Site Ca...	Baseline	Locked	Wednesday, May 21, 2025 at 11:42 AM ADT	✓
→ Signed					
Invalid Signatures					

All visits with an applied signature are then displayed on the table.

Subject ID	Site	Visit Name	Visit Type	Visit ...	Visit Status	Signature Roles	Forms Completed	Last Modified By	Visit Queries	Other Queries
S0005	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Tues...		Data Entry	1/1	demo+thrive@goalnav...		No
S0005	TestSite - Test Site	Withdrawal	Common	Frida...		Data Monitor	1/1	demo+thrive@goalnav...	-	No
S0005	TestSite - Test Site	Visit 6 (Completion)	Scheduled	Frida...		Data Entry	1/1	demo+thrive@goalnav...	-	No
S0013	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Frida...		Data Entry	1/1	demo+thrive@goalnav...	-	No
S9999	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Tues...		Admin	1/1	jacob.coyne@ardeaout...	-	Yes

To view all unsigned visits, set the visit status filter condition to “does not contain” and the value to “Signed”

Subject ID

Site

Visit Name

Visit Type

Columns: Visit Status

Operator: does not contain

Value: Signed

+ ADD FILTER

REMOVE ALL

This displays all the visits that are missing signatures.

Subject ID	Site	Visit Name	Visit Type	Visit ...	Visit Status	Signature Roles	Forms Completed	Last Modified By	Visit Queries	Other Queries
S1222	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Tues...			1/1	jacob.coyne@ardeaout...	-	No
S1235	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Frida...			1/1	sumadhur.vaidyula@ar...		No
S0005	TestSite - Test Site	Visit 4 (Week 12)	Scheduled	Frida...			0/1	demo+thrive@goalnav...		No
S0013	TestSite - Test Site	Visit 4 (Week 12)	Scheduled	Frida...			1/1	demo+thrive@goalnav...	-	No
S0013	TestSite - Test Site	Withdrawal	Common	Frida...			0/1	demo+thrive@goalnav...	-	No
S0013	TestSite - Test Site	Visit 6 (Completion)	Scheduled	Frida...			1/1	demo+thrive@goalnav...	-	No
S3001	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Mon...			1/1	jtj@lundbeck.com	-	No
S3001	TestSite - Test Site	Visit 4 (Week 12)	Scheduled	Mon...			0/1	jtj@lundbeck.com	-	No
S2222	TestSite - Test Site	Visit 2 (Baseline)	Scheduled	Mon...			0/1	sumadhur.vaidyula@ar...	-	No

Total Rows: 9 of 14

Monitor Invalid Signatures

To monitor Invalid Signatures, navigate to the “Signatures” option from the subject menu.

Subject: S1236

Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Thursday, May 15, 2025 at 7:38 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:33 PM ADT	✓
Baseline	Tuesday, May 20, 2025 at 8:50 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:41 PM ADT	✓
Follow-up Visit 1	Tuesday, May 20, 2025 at 9:49 PM ADT	✓	GAS Assessment	Wednesday, May 21, 2025 at 8:42 PM ADT	✓
Follow-up Visit 2			GAS Assessment		
 Scheduled In Progress Completed Signed Locked Invalid Signatures Missed Source Data Verified					

Screening
Baseline
Follow-up Visit 1
Follow-up Visit 2

+ Add Visit
 Signatures

All the Signatures(Valid and Invalid) will be displayed on this dashboard.

Signatures

Subject

Role	User	Signature	Date
------	------	-----------	------

Visits

Visit	Role	User	Signature	Date
Visit 2 (Baseline)				
	Data Entry	demo+thrive	Authorship	Friday, November 8, 2024 at 5:13 AM AST
Withdrawal (t)				
	Data Monitor	sumadhur.vaidyula	Approval	Thursday, December 5, 2024 at 12:15 PM AST
Visit 4 (Week 12)				
Visit 6 (Completion)				
	Data Entry	demo+thrive	Approval	Friday, November 8, 2024 at 6:00 AM AST

Forms

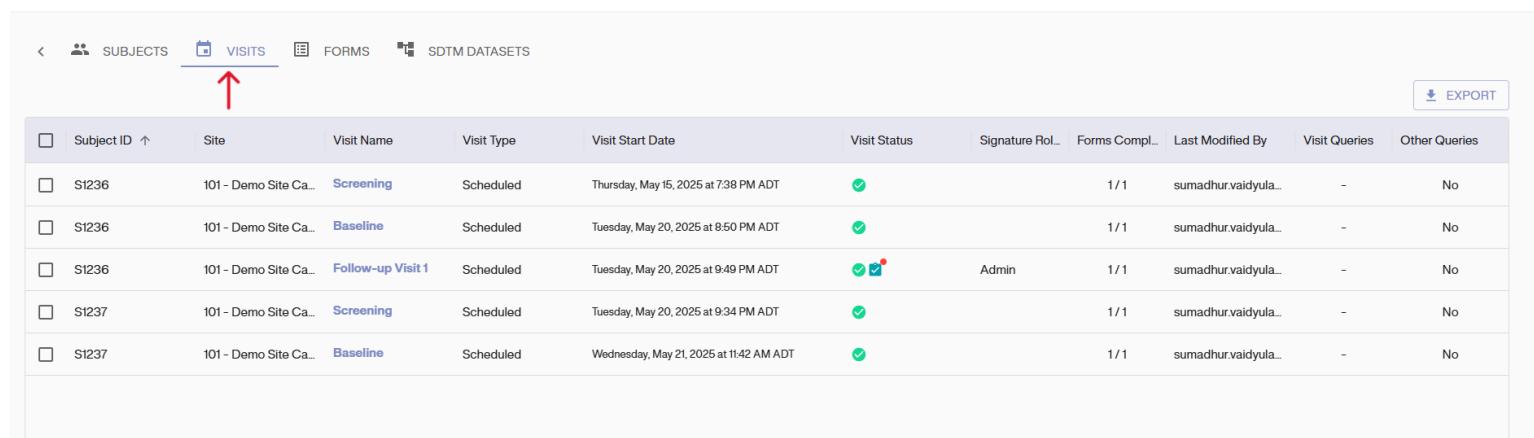
Form	Role	User	Signature	Date
GAS Assessment(Visit 2 (Baseline))				
GAS Assessment(Withdrawal (t))				
GAS Assessment(Visit 6 (Completion))				

To check for invalid signatures, navigate to the Subject Details Dashboard. On the dashboard, an orange dot above the blue notepad icon (which represents the signature) indicates that the signature is invalid. Hover over the icon to view the signature's creator (e.g., Admin in the screenshot) and confirm its status as invalid.

Subject: S1236

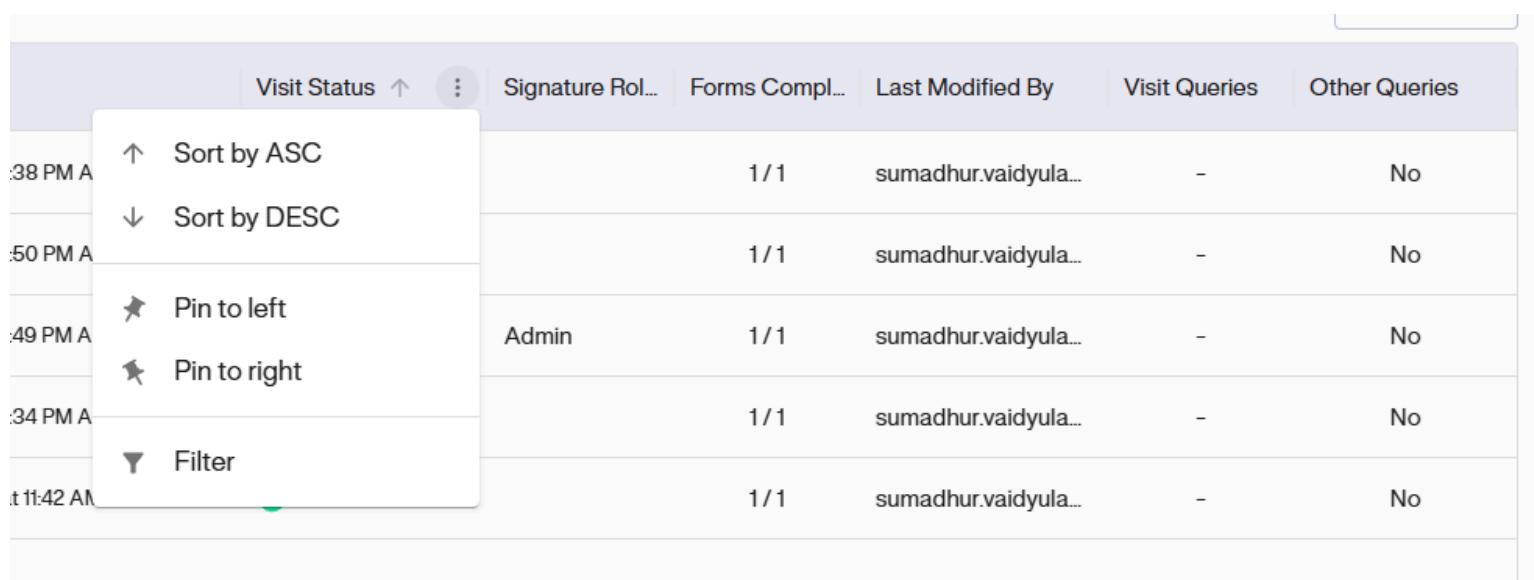
Visit	Start Date	Status (Visit)	Form Name	Last Updated	Status (Form)
Screening	Thursday, May 15, 2025 at 7:38 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:33 PM ADT	✓
Baseline	Tuesday, May 20, 2025 at 8:50 PM ADT	✓	GAS Assessment	Tuesday, May 20, 2025 at 9:41 PM ADT	✓
Follow-up Visit 1	Tuesday, May 20, 2025 at 9:49 PM ADT	✓	GAS Assessment	Wednesday, May 21, 2025 at 8:42 PM ADT	✓
Follow-up Visit 2			GAS Assessment		
 Scheduled In Progress Completed Signed Locked Invalid Signatures Missed Source Data Verified					

To use Data Explorer to check for invalid signatures, click on the grid icon in the top menu bar. The “Visits” option is selected for this demonstration.



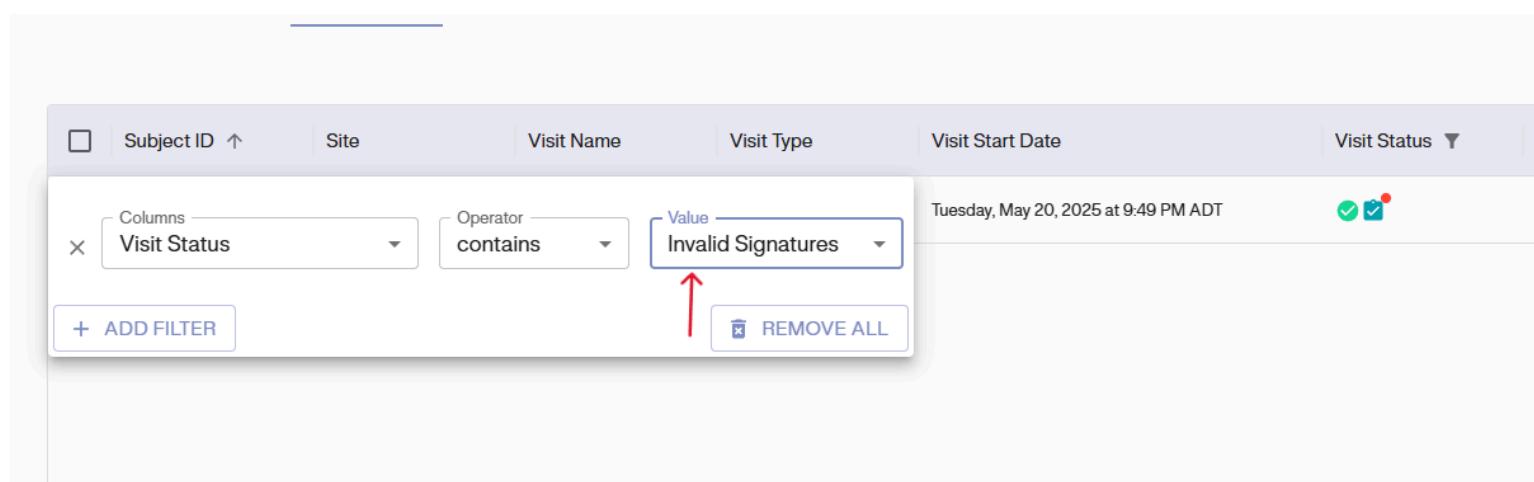
Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status	Signature Rol...	Forms Compl...	Last Modified By	Visit Queries	Other Queries
S1236	101 - Demo Site Ca...	Screening	Scheduled	Thursday, May 15, 2025 at 7:38 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Baseline	Scheduled	Tuesday, May 20, 2025 at 8:50 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Follow-up Visit 1	Scheduled	Tuesday, May 20, 2025 at 9:49 PM ADT		Admin	1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Screening	Scheduled	Tuesday, May 20, 2025 at 9:34 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Baseline	Scheduled	Wednesday, May 21, 2025 at 11:42 AM ADT			1/1	sumadhur.vaidyula...	-	No

Locate the “Visit Status” column in the table, and click on the options icon (three-dot icon).



Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status	Signature Rol...	Forms Compl...	Last Modified By	Visit Queries	Other Queries
S1236	101 - Demo Site Ca...	Screening	Scheduled	Thursday, May 15, 2025 at 7:38 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Baseline	Scheduled	Tuesday, May 20, 2025 at 8:50 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1236	101 - Demo Site Ca...	Follow-up Visit 1	Scheduled	Tuesday, May 20, 2025 at 9:49 PM ADT		Admin	1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Screening	Scheduled	Tuesday, May 20, 2025 at 9:34 PM ADT			1/1	sumadhur.vaidyula...	-	No
S1237	101 - Demo Site Ca...	Baseline	Scheduled	Wednesday, May 21, 2025 at 11:42 AM ADT			1/1	sumadhur.vaidyula...	-	No

Click on “Filter” from the dropdown options and then from the value dropdown list, select “Invalid Signatures”.



Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status
				Tuesday, May 20, 2025 at 9:49 PM ADT	

Filter configuration:

- Columns: Visit Status
- Operator: contains
- Value: Invalid Signatures

Buttons: ADD FILTER, REMOVE ALL

The records with Invalid Signature are displayed on the table

Subject ID	Site	Visit Name	Visit Type	Visit Start Date	Visit Status	Signature Rol...	Forms Compl...	Last Modified By	Visit Queries	Other Queries
St236	101 - Demo Site Ca...	Follow-up Visit 1	Scheduled	Tuesday, May 20, 2025 at 9:49 PM ADT	 	Admin	1 / 1	sumadhur.vaidyula...	-	No

IN THIS CHAPTER

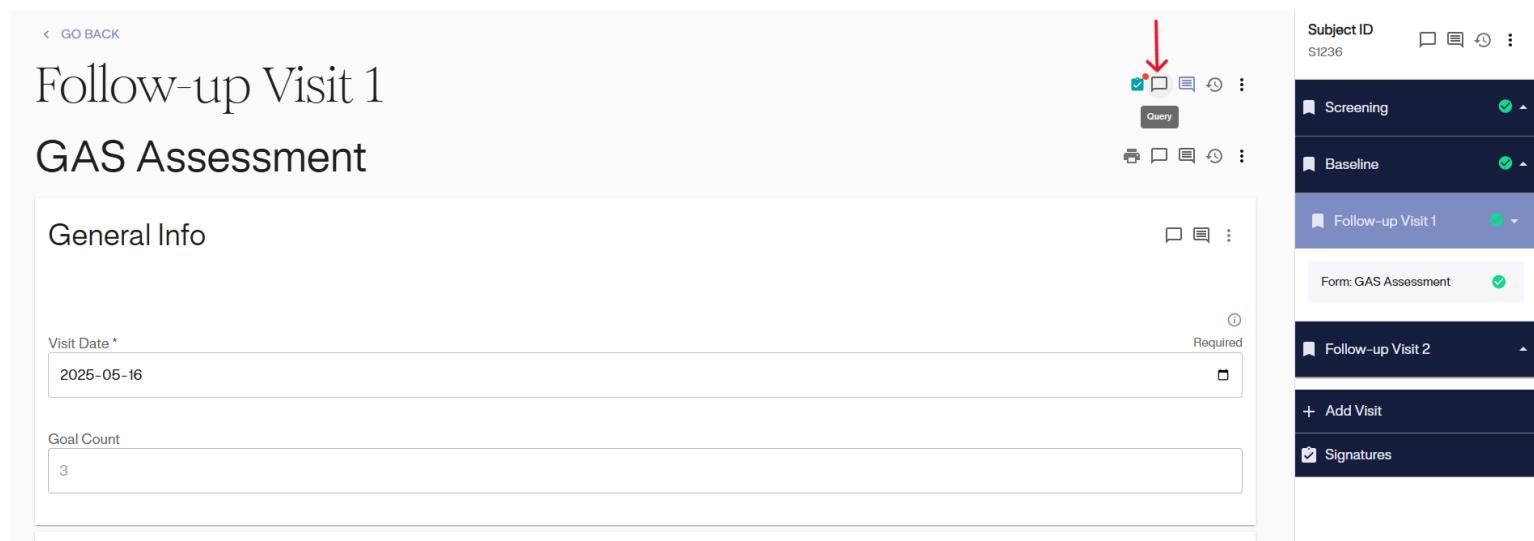
1 Managing Queries

- a Create a GoalNav® Query
- b View All GoalNav® Queries
- c Respond to GoalNav® Queries
- d Close Queries

Managing Queries

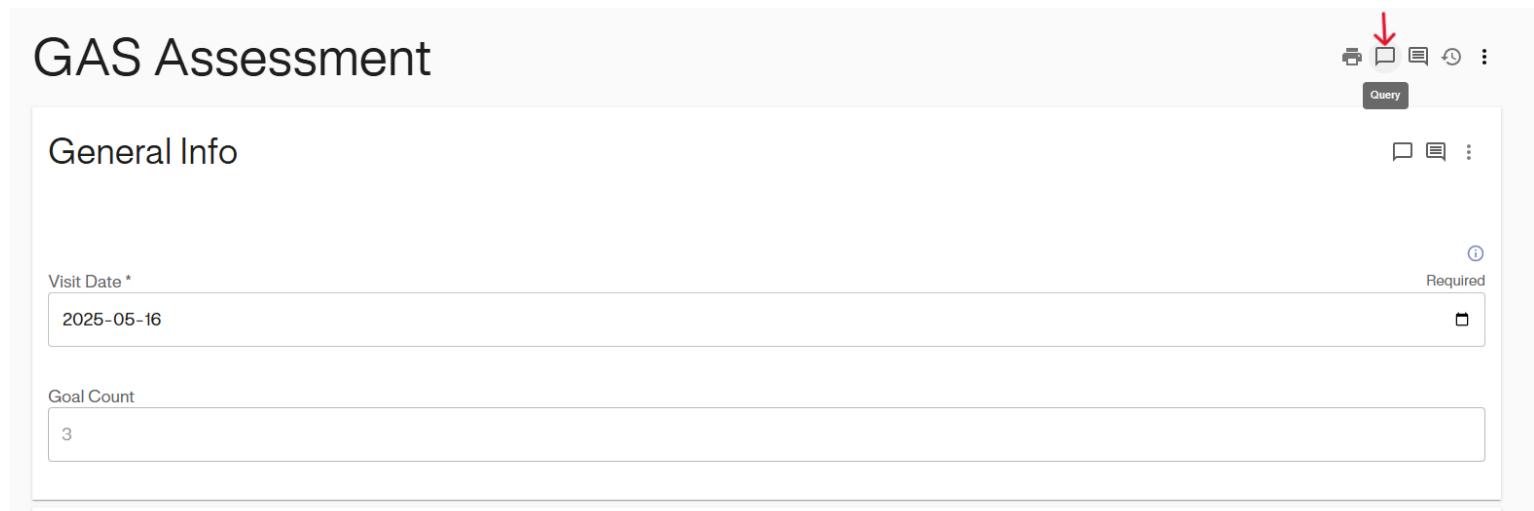
Create a GoalNav® Query

To create a new GoalNav® query on the visit level, click on the blank dialogue box icon right next to the name of the visit.



The screenshot shows the 'Follow-up Visit 1 GAS Assessment' page. On the right, a sidebar displays visit history and a list of forms. The 'Follow-up Visit 1' visit is highlighted. A red arrow points to the 'Query' icon (a blank dialogue box) next to the visit name. The sidebar also shows 'Subject ID: SI236' and a list of forms: 'Screening', 'Baseline', 'Follow-up Visit 1' (selected), 'Form: GAS Assessment', 'Follow-up Visit 2', '+ Add Visit', and 'Signatures'.

To create a new GoalNav® query on the form level, click on the blank dialogue box icon right next to the name of the form.



The screenshot shows the 'GAS Assessment' page. On the right, a sidebar displays visit history and a list of forms. The 'GAS Assessment' form is highlighted. A red arrow points to the 'Query' icon (a blank dialogue box) next to the form name. The sidebar also shows 'Subject ID: SI236' and a list of forms: 'Screening', 'Baseline', 'Follow-up Visit 1', 'Form: GAS Assessment' (selected), 'Follow-up Visit 2', '+ Add Visit', and 'Signatures'.

To create a new GoalNav® query on the section level, click on the blank dialogue box icon at the top of the form section.

General Info

Visit Date * Required

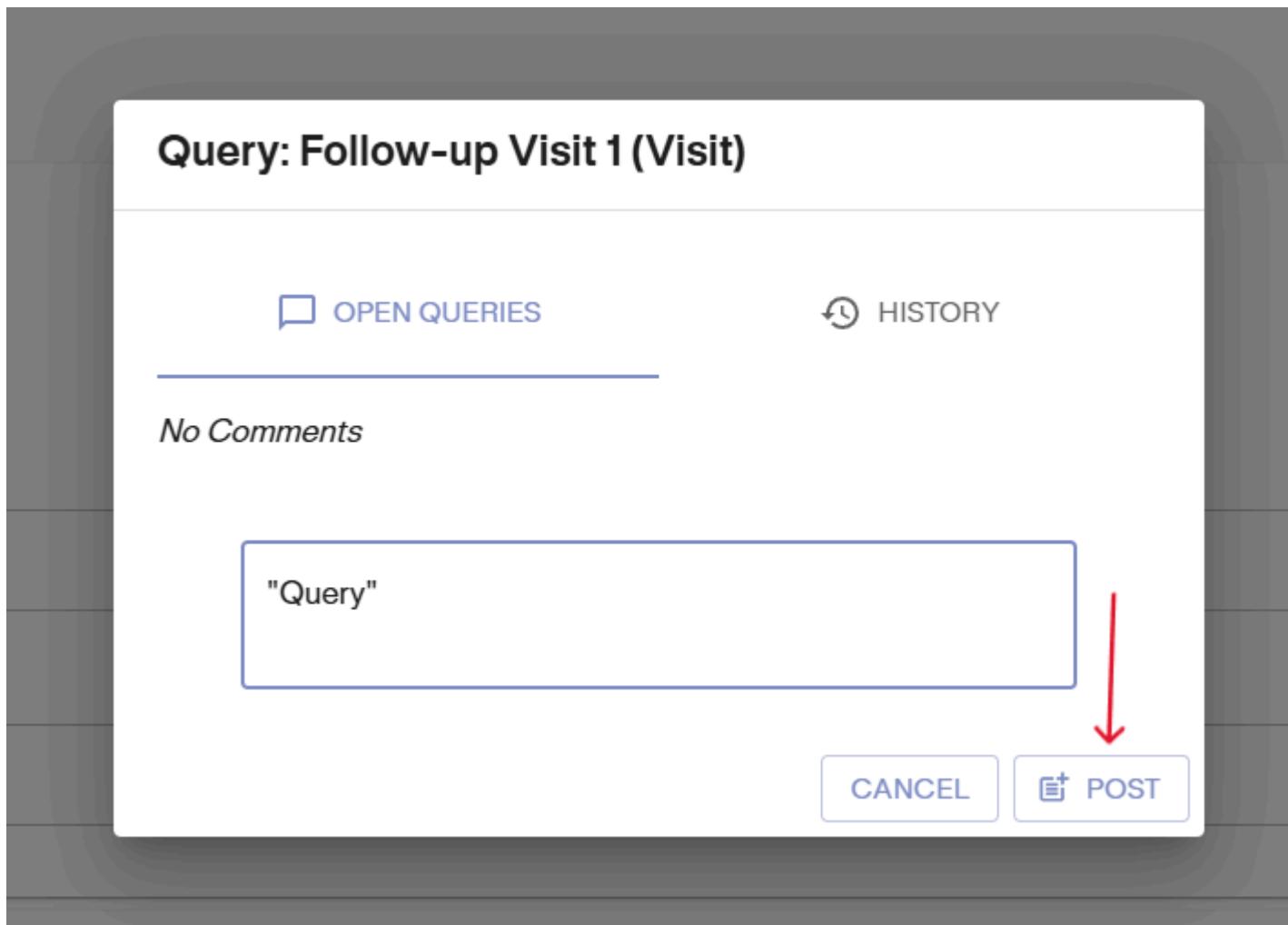
2025-05-16

Goal Count

3

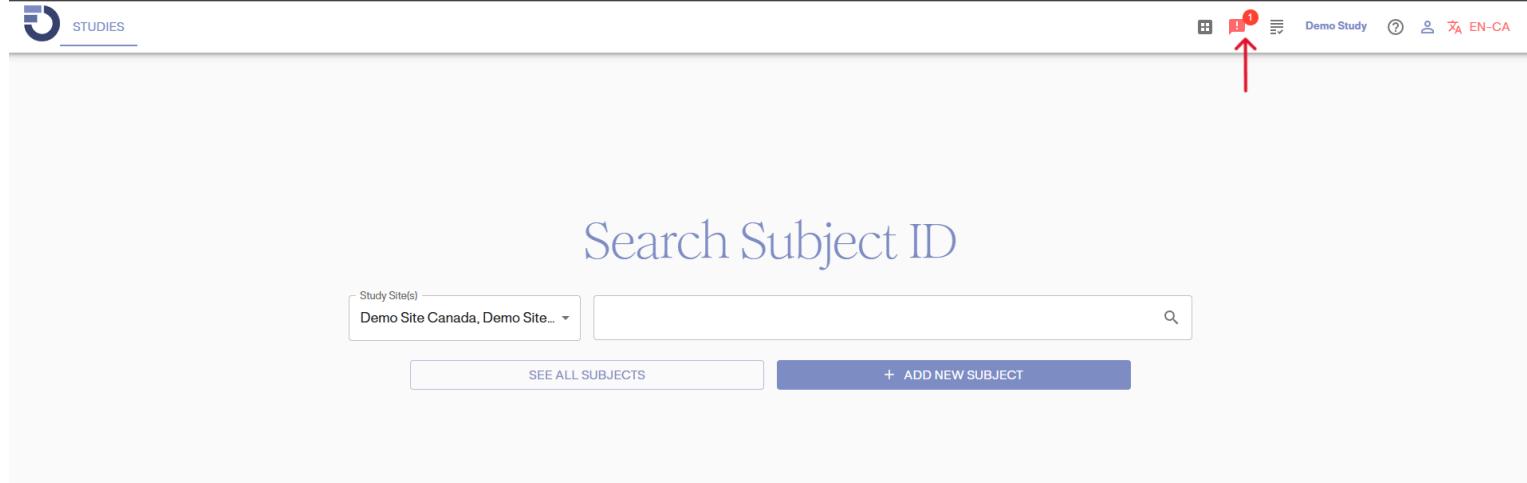
Query

Click the icon to open a pop-up window. Here, start a new query thread in GoalNav® for the selected subject and visit. In the text box, enter the query. Then, click the “Post” button to submit it. When a new query is posted, the author of the visit will be notified.

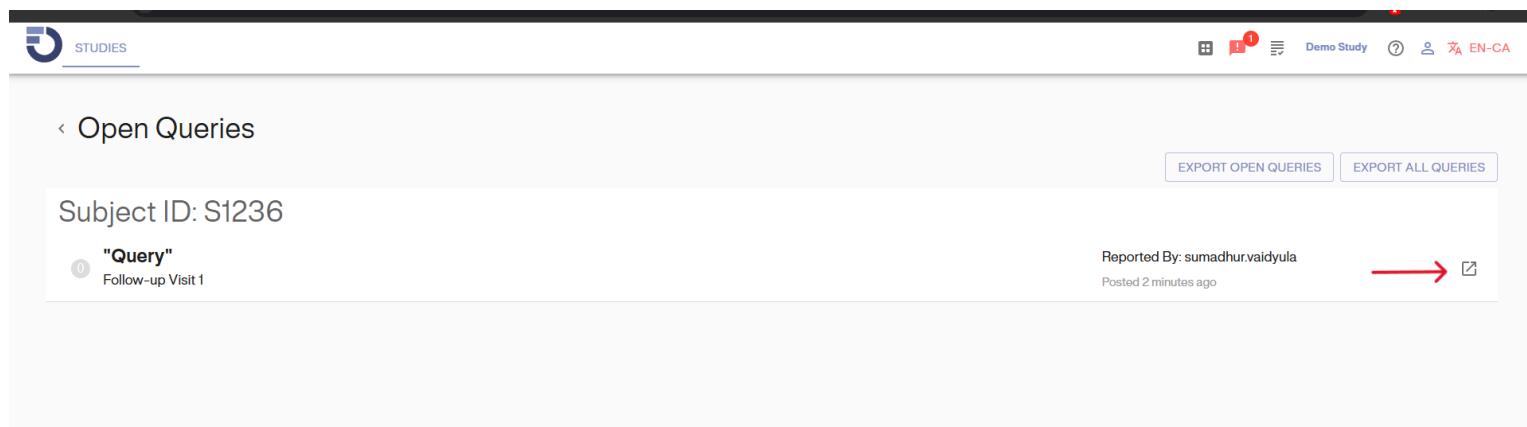


[View All GoalNav® Queries](#)

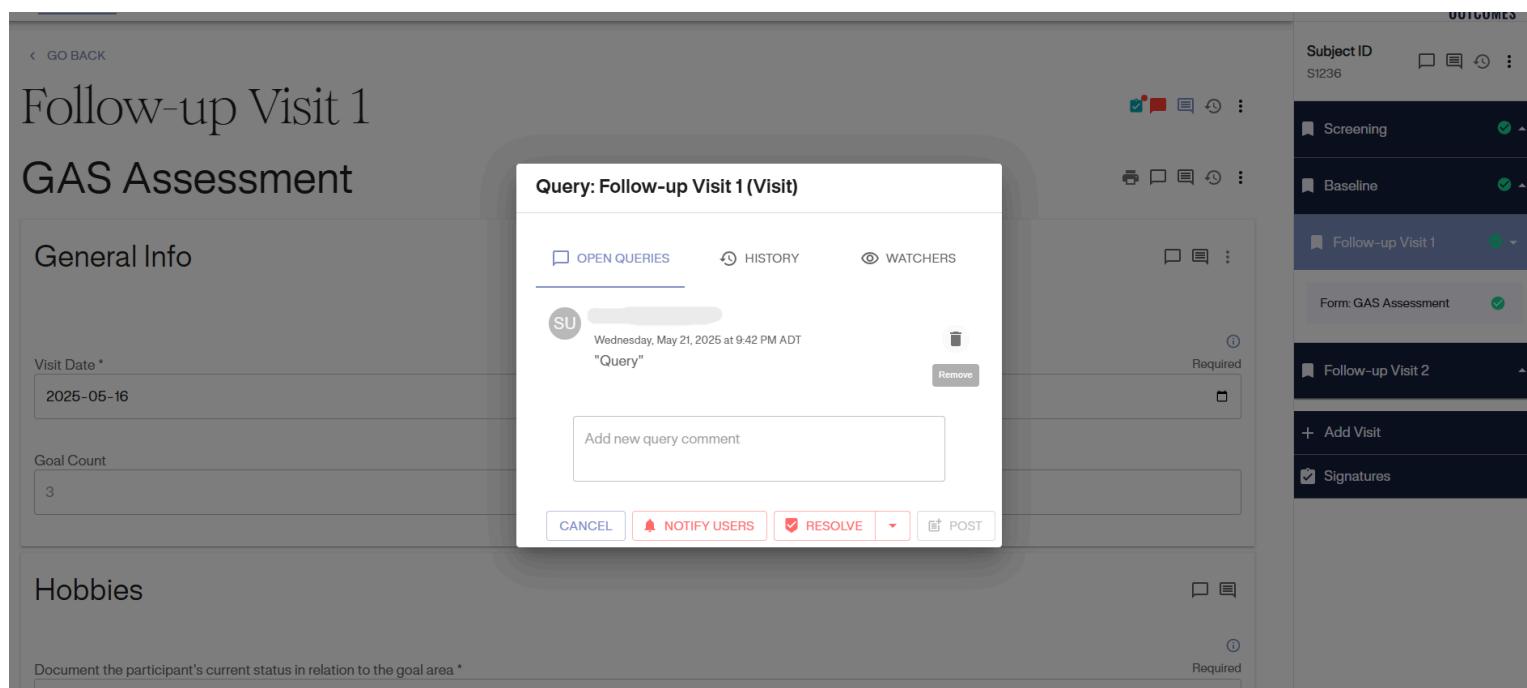
To view all open queries in GoalNav®, click the dialogue icon, which will be highlighted in red when unresolved queries are present within the study.



Click on the dialogue icon button, as shown in the image above, to display all open queries on the page, as highlighted in the image below. Click the link icon (the arrow icon) on the right-hand side of each query, to be directed to that specific query thread. For example, the first query is selected for viewing in this case.

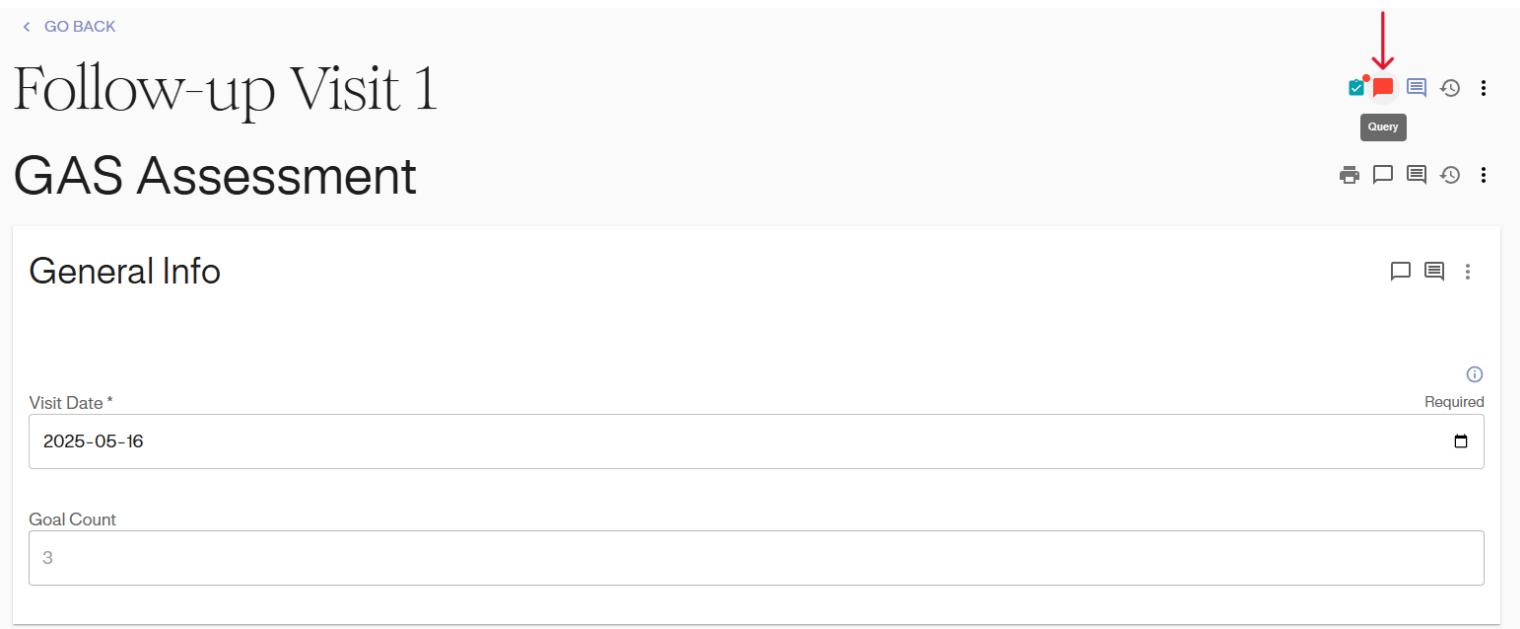


Click the link icon to open a pop-up window to display the visit, form, or form section where the query was created, including the entire query thread.



Respond to GoalNav® Queries

To respond to a query thread in GoalNav®, first navigate to any visit that has an open query. Alternatively, click the dialogue icon in the top bar and select the appropriate query thread to access the Query page. To view the query, click on the red dialogue box icon. Please be aware that a red dialogue icon next to the visit name, form name, or form section name indicates there is an active query for that visit.



GO BACK

Follow-up Visit 1

GAS Assessment

General Info

Visit Date * Required

2025-05-16

Goal Count

3

Query

Print

Print

Print

Print

Click on the red dialogue icon to open a pop-up window that displays the active query thread. In the text box, enter the answer to the query. Click on “Post” to post the response. Posting a response will notify the author of the data and any users who have previously responded/participated in the query thread.

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



"Answer to Query"

CANCEL

 NOTIFY USERS

 RESOLVE



 POST



Close Queries

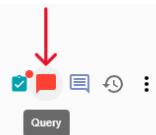
Once an answer to a query is accepted and validated, click the "Resolve" button to close the query. Once "Resolve" is selected, the resolved query will disappear. Note: The Data Monitors should only close queries they created themselves or those that have been resolved. They should not close any unanswered queries. To close a query, follow the instructions below:

Click on the Query Icon on the visit details page.

[GO BACK](#)

Follow-up Visit 1

GAS Assessment



General Info

Visit Date *

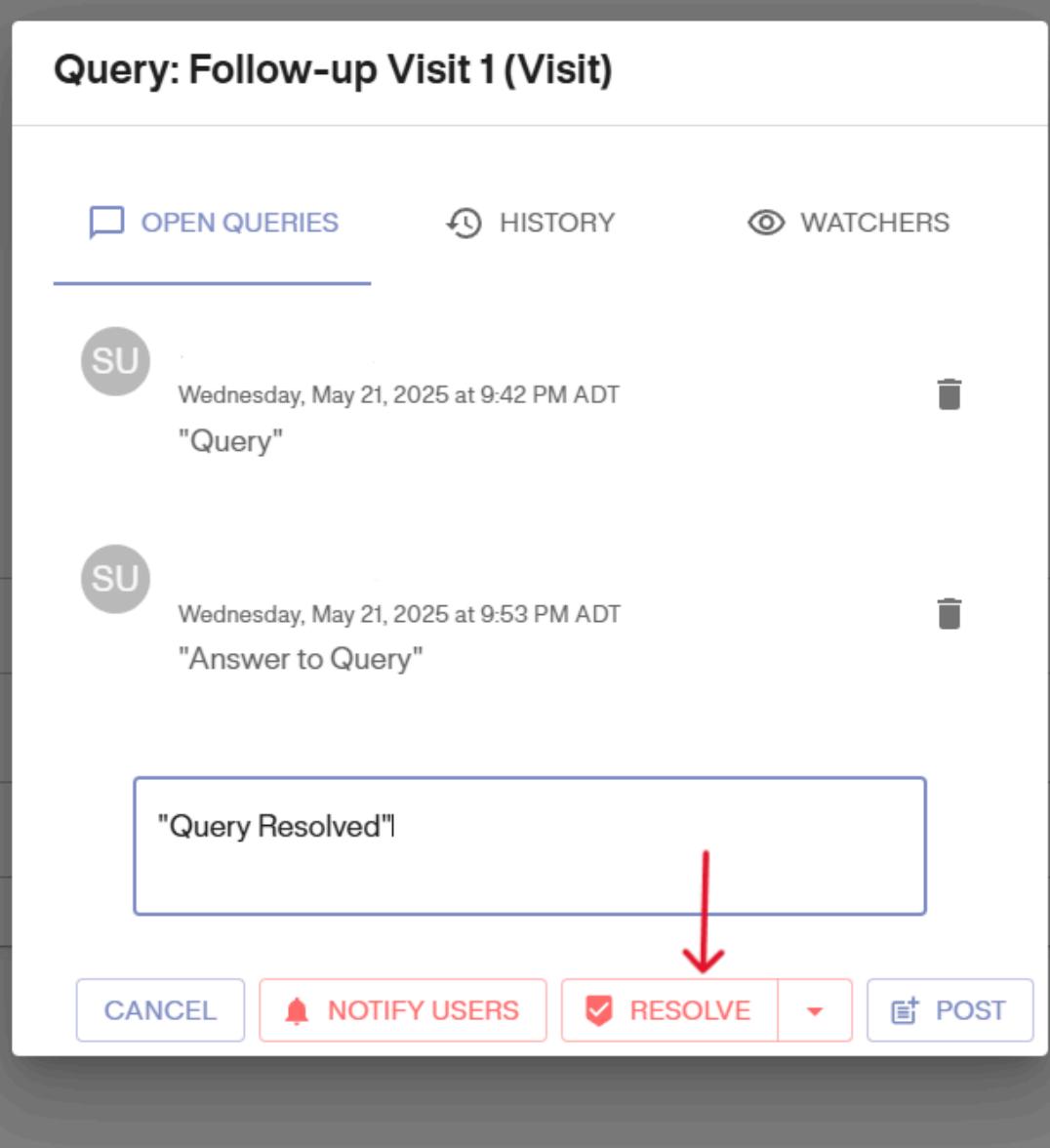
2025-05-16

 Required

Goal Count

3

This opens the existing query thread with the initial query and subsequent replies. Click on the “Resolve” button to close the query. A query can also be closed without a resolution. To do so, click the arrow icon next to the “Resolve” button. This opens a dropdown menu with an option labeled “Unresolvable.” Click on this option to close the query with an “Unresolvable” status.



Closing query with an unresolvable status:

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



SU

Wednesday, May 21, 2025 at 9:53 PM ADT

"Answer to Query"



 CANCEL

 NOTIFY USERS

 RESOLVE



 POST

Unresolvable

Chapter 6: Using GoalNav as a Data Manager

TABLE OF CONTENTS

- [Reviewing and Managing Data](#)
- [Manage Queries](#)

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1 [Reviewing and Managing Data](#)a [Data Explorers](#)a [Overview](#)b [View Data](#)c [Export Data](#)b [Data Locking](#)

Reviewing and Managing Data

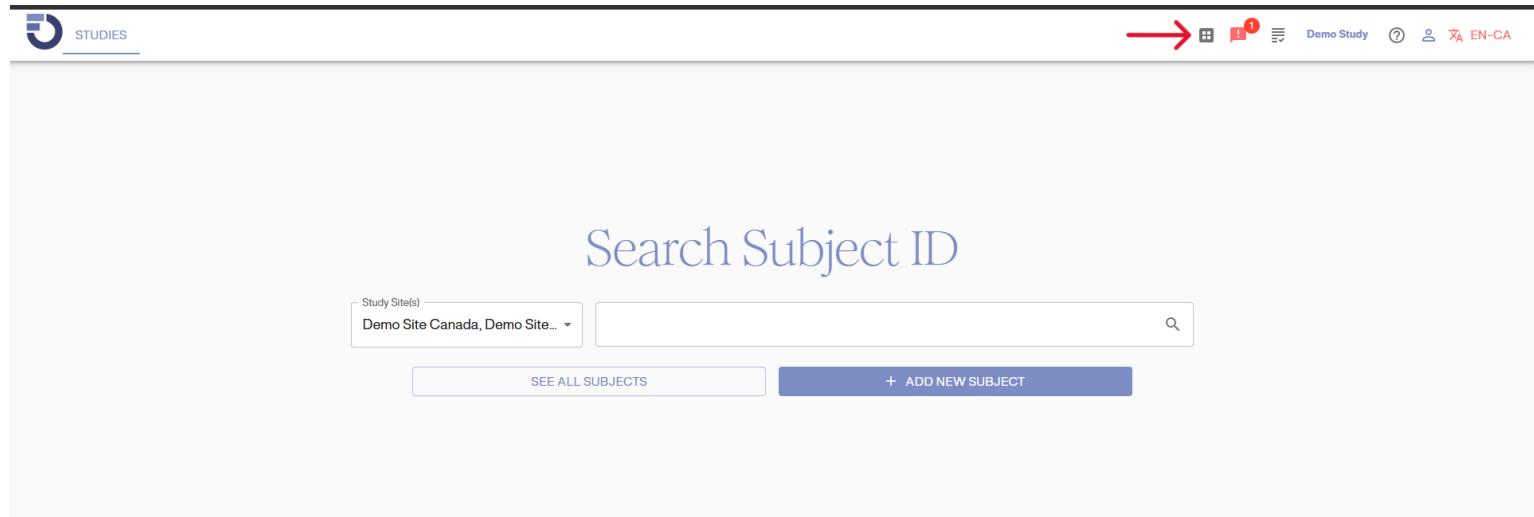
Data Explorers

OVERVIEW

The data explorer section in GoalNav® enables users to search for records efficiently using queries and apply specific filters for data retrieval. Instructions to access the data explorer are provided below.

VIEW DATA

On the Trial homepage, click the grid icon in the menu bar to access the data explorer.



The screenshot shows the GoalNav Trial homepage. At the top, there is a navigation bar with icons for 'STUDIES', 'Grid' (highlighted with a red arrow), 'Demographic', 'Demographic', 'Demographic', 'Demographic', 'Demographic', 'Demographic', 'EN-CA'. Below the navigation bar, the main content area has a title 'Search Subject ID'. It includes a dropdown menu 'Study Site(s)' with 'Demo Site Canada, Demo Site...' selected, a search input field with a magnifying glass icon, and a 'SEE ALL SUBJECTS' button. At the bottom of the search area is a blue button with '+ ADD NEW SUBJECT'.

Click the grid button to open the data explorer dashboard, as shown in the image below. This dashboard displays records for Subjects and Visits and data review tables that show records based on the selected visit. For example, the table below shows the records related to "Subjects".

[EXPORT](#)

	Subject	Site	Added By	Last Modified Date	Last Modified By	Subject	Signature	Visits Count	Unscheduled	Open Qu...
<input type="checkbox"/>	S0005	TestSite - ...	demo+thrive@g...	Friday, November 8, 2024 at...	demo+thrive@g...			3 / 3	1	1
<input type="checkbox"/>	S0013	TestSite - ...	demo+thrive@g...	Friday, November 8, 2024 at...	demo+thrive@g...			3 / 3	1	0
<input type="checkbox"/>	S1222	TestSite - ...	aaqib.shehzad@...	Thursday, November 7, 202...	aaqib.shehzad@...			1 / 3	0	0
<input type="checkbox"/>	S1235	TestSite - ...	sumadhur.vaidyu...	Friday, November 8, 2024 at...	sumadhur.vaidyu...			1 / 3	0	1
<input type="checkbox"/>	S2222	TestSite - ...	sumadhur.vaidyu...	Sunday, November 24, 2024...	sumadhur.vaidyu...			1 / 3	0	0

Total Rows: 8

Visits Record:

[EXPORT](#)

	Subject	Site	Visit Name	Visit Type	Visit Start Date	Visit Status	Signature	Forms ...	Last Modif...	Visit Q...	Other Q...
<input type="checkbox"/>	S0005	TestSite - ...	Visit 2 (B...)	Scheduled	Friday, November 8, 2024 at ...			Data ...	1 / 1	demo+thri...	-
<input type="checkbox"/>	S0005	TestSite - ...	Withdraw...	Common	Friday, November 8, 2024 at ...			Data ...	1 / 1	demo+thri...	-
<input type="checkbox"/>	S0005	TestSite - ...	Visit 6 (C...)	Scheduled	Friday, November 8, 2024 at ...			Data ...	1 / 1	demo+thri...	-
<input type="checkbox"/>	S0005	TestSite - ...	Visit 4 (W...)	Scheduled	Friday, November 8, 2024 at ...			Data ...	0 / 1	demo+thri...	
<input type="checkbox"/>	S0013	TestSite - ...	Visit 4 (W...)	Scheduled	Friday, November 8, 2024 at ...			Data ...	1 / 1	demo+thri...	-

Total Rows: 14

Forms Record:

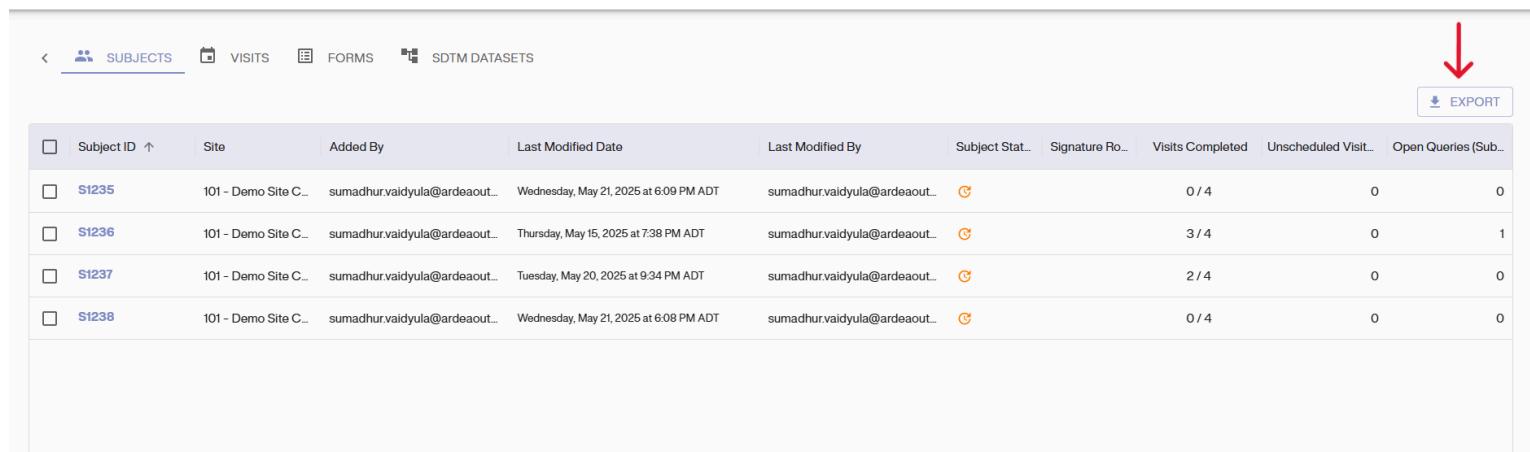
[EXPORT](#)

	Subject	Site	Visit ...	Visit ...	Visit Start Date	Visit ...	Vis...	Form Na...	Form...	For...	Last Modif...	Last Modified ...	Form...	Visit ...	Item ...
<input type="checkbox"/>	S0005	Test...	Visit...	Sch...	Friday, Novemb...			Data ...	GAS As...		demo+th...	Friday, Novemb...	-	-	No
<input type="checkbox"/>	S0005	Test...	With...	Co...	Friday, Novemb...			GAS As...			jacob.co...	Tuesday, Novem...	-	-	No
<input type="checkbox"/>	S0005	Test...	Visit...	Sch...	Friday, Novemb...			Data ...	GAS As...		demo+th...	Friday, Novemb...	-	-	No
<input type="checkbox"/>	S0013	Test...	Visit...	Sch...	Friday, Novemb...			GAS As...			demo+th...	Friday, Novemb...	-	-	No
<input type="checkbox"/>	S0013	Test...	Visit...	Sch...	Friday, Novemb...			Data ...	GAS As...		demo+th...	Friday, Novemb...	-	-	No

Total Rows: 10

EXPORT DATA

Each record table (Subject, Forms, Visit, Data Review Table) has an “Export” button located at the top right corner of the page. This button generates a CSV file of the records and downloads it to your device.

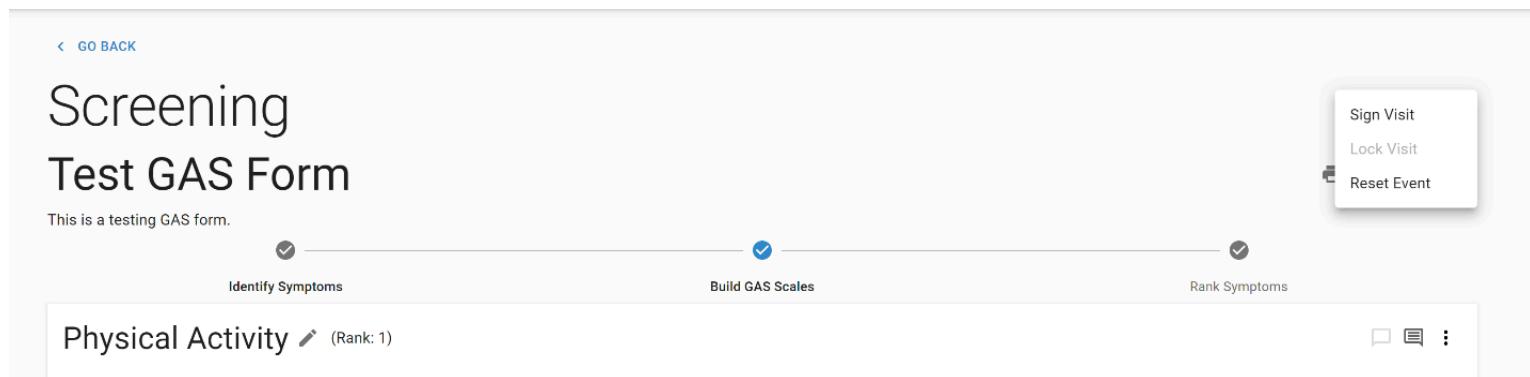


A screenshot of a web-based application showing a table of subjects. The table has columns for Subject ID, Site, Added By, Last Modified Date, Last Modified By, Subject Status, Signature Req'd, Visits Completed, Unscheduled Visit..., and Open Queries (Sub...). There are four rows of data. At the top of the table, there are navigation links: SUBJECTS, VISITS, FORMS, and SDTM DATASETS. On the far right, there is an 'EXPORT' button with a downward arrow icon, which is highlighted with a red arrow pointing to it.

<input type="checkbox"/> Subject ID ↑	Site	Added By	Last Modified Date	Last Modified By	Subject Stat...	Signature Re...	Visits Completed	Unscheduled Visit...	Open Queries (Sub...
<input type="checkbox"/> SI235	101 - Demo Site C...	sumadhur.vaidyula@ardeaout...	Wednesday, May 21, 2025 at 6:09 PM ADT	sumadhur.vaidyula@ardeaout...	🕒		0 / 4	0	0
<input type="checkbox"/> SI236	101 - Demo Site C...	sumadhur.vaidyula@ardeaout...	Thursday, May 15, 2025 at 7:38 PM ADT	sumadhur.vaidyula@ardeaout...	🕒		3 / 4	0	1
<input type="checkbox"/> SI237	101 - Demo Site C...	sumadhur.vaidyula@ardeaout...	Tuesday, May 20, 2025 at 9:34 PM ADT	sumadhur.vaidyula@ardeaout...	🕒		2 / 4	0	0
<input type="checkbox"/> SI238	101 - Demo Site C...	sumadhur.vaidyula@ardeaout...	Wednesday, May 21, 2025 at 6:08 PM ADT	sumadhur.vaidyula@ardeaout...	🕒		0 / 4	0	0

Data Locking

Data locking may occur during your study depending on data management requirements. The locking of the data is primarily completed by the studies data management teams and is not a feature for data entry personnel. If you have data entry access, you will see the lock option is unavailable. See example of unavailable locked visit option below:



A screenshot of a web-based application showing a 'Screening Test GAS Form'. The page title is 'Screening Test GAS Form'. Below the title, it says 'This is a testing GAS form.' There are three horizontal buttons: 'Identify Symptoms' (checked), 'Build GAS Scales' (checked), and 'Rank Symptoms' (checked). On the right side, there is a vertical menu with three options: 'Sign Visit', 'Lock Visit', and 'Reset Event'. The 'Lock Visit' option is highlighted with a red box. Below the buttons, there is a section for 'Physical Activity' with a rank of 1. At the bottom right, there are three small icons: a square, a circle, and a triangle.

It is important to note that once data has been locked (regardless of the level), a special request must be made to the GoalNav® support and/or data management team to unlock the data for a data entry personnel to make any changes unless the changes being made are in response to a query. This may be missing data from the visit or an error when entering data. Whether data will be unlocked for site requested changes or not remains on a case-by-case basis. If the change you are making is in response to a query and the visit is locked, email your study specific email for support.

In general, you will note data locking occurs at the VISIT LEVEL. However, depending on the study, the form level or subject level may also get locked. An example of locking at the visit level is demonstrated below:

A Locked Screening Visit Example:

Follow-up Visit 1

GAS Assessment

General Info

Visit Date *

2025-05-16

Required

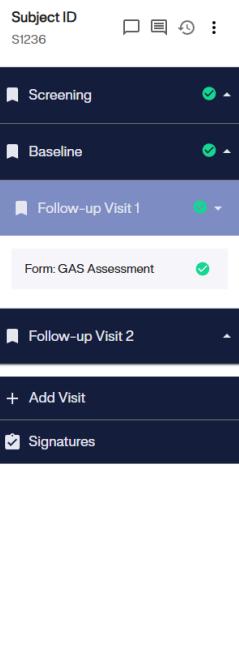
Goal Count

3

Hobbies

Document the participant's current status in relation to the goal area *

Required



IN THIS CHAPTER

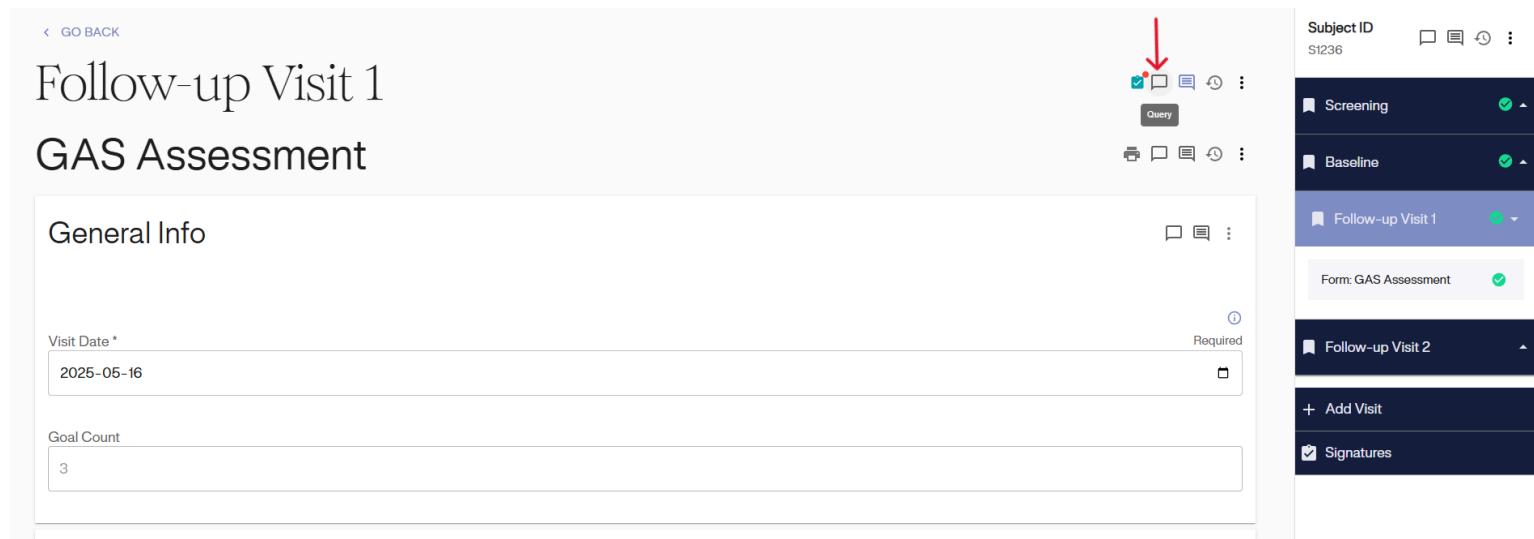
1 Managing Queries

- a Create a GoalNav® Query
- b View All GoalNav® Queries
- c Respond to GoalNav® Queries
- d Close Queries

Managing Queries

Create a GoalNav® Query

To create a new GoalNav® query on the visit level, click on the blank dialogue box icon right next to the name of the visit.



Follow-up Visit 1
GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

Subject ID: SI236

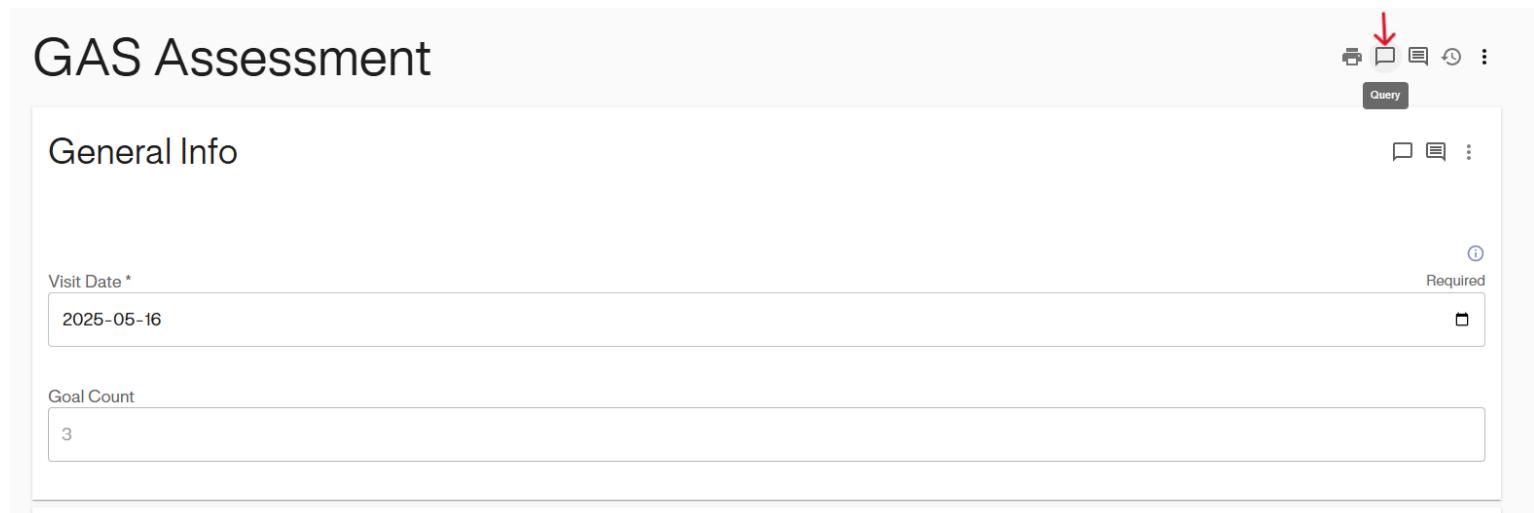
Screening, Baseline, Follow-up Visit 1 (highlighted in blue)

Form: GAS Assessment

Follow-up Visit 2

+ Add Visit, Signatures

To create a new GoalNav® query on the form level, click on the blank dialogue box icon right next to the name of the form.



GAS Assessment

General Info

Visit Date * 2025-05-16

Goal Count 3

To create a new GoalNav® query on the section level, click on the blank dialogue box icon at the top of the form section.

General Info

Visit Date * Required

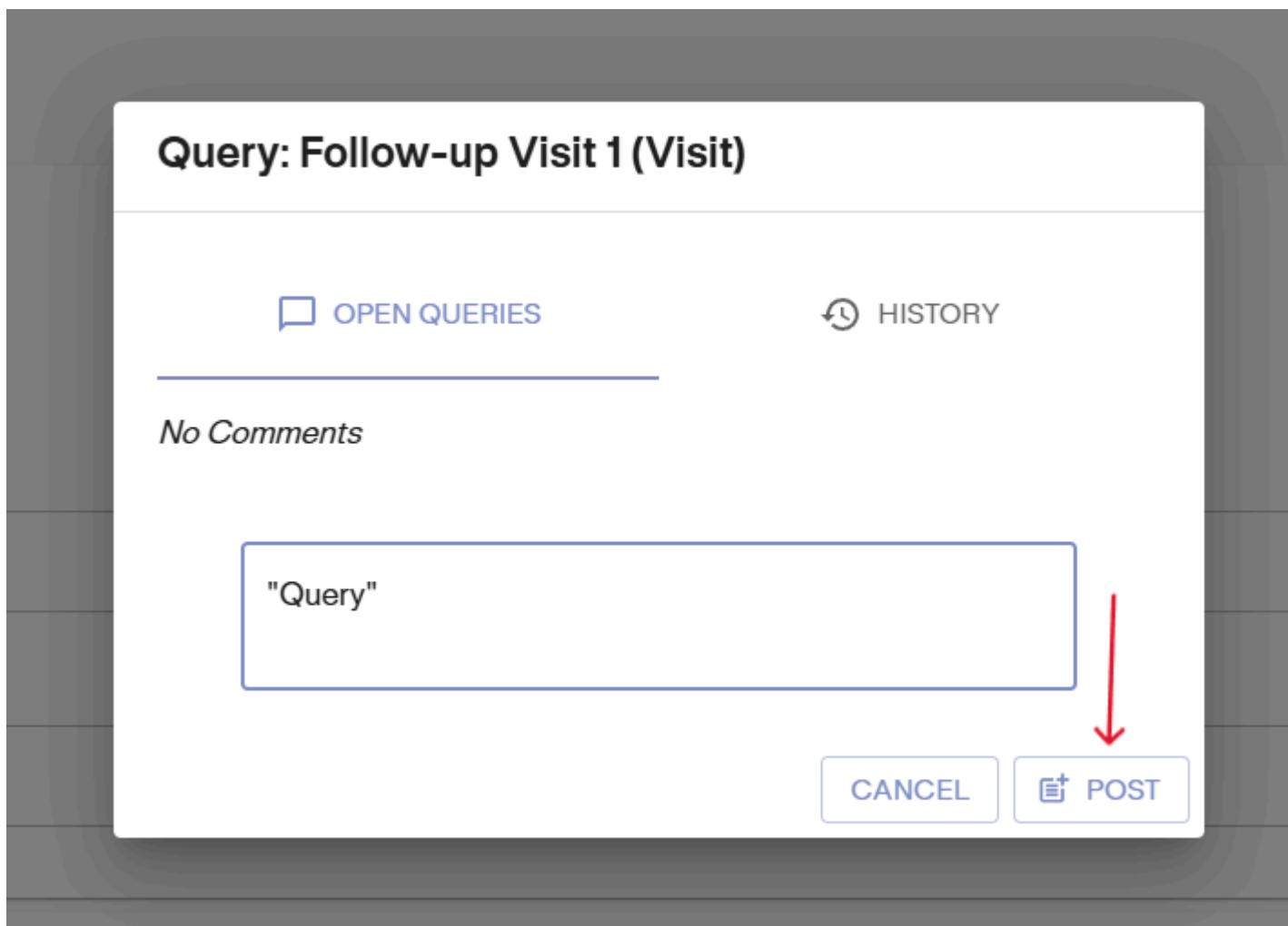
2025-05-16

Goal Count

3

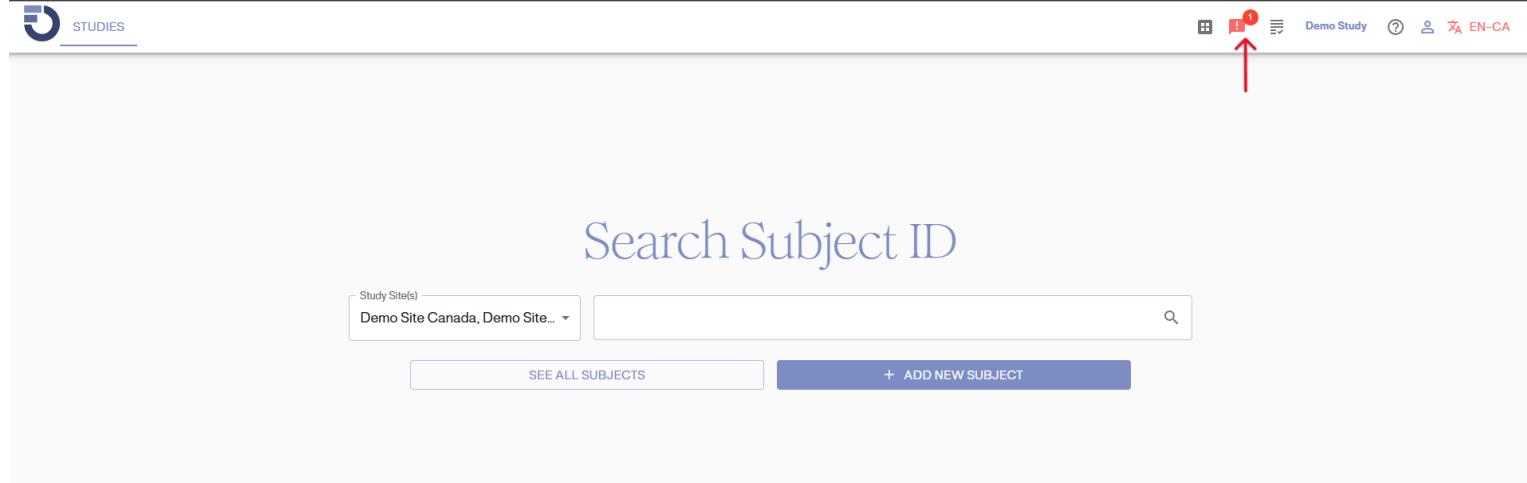
Query

Click the icon to open a pop-up window. Here, start a new query thread in GoalNav® for the selected subject and visit. In the text box, enter the query. Then, click the “Post” button to submit it. When a new query is posted, the author of the visit will be notified.

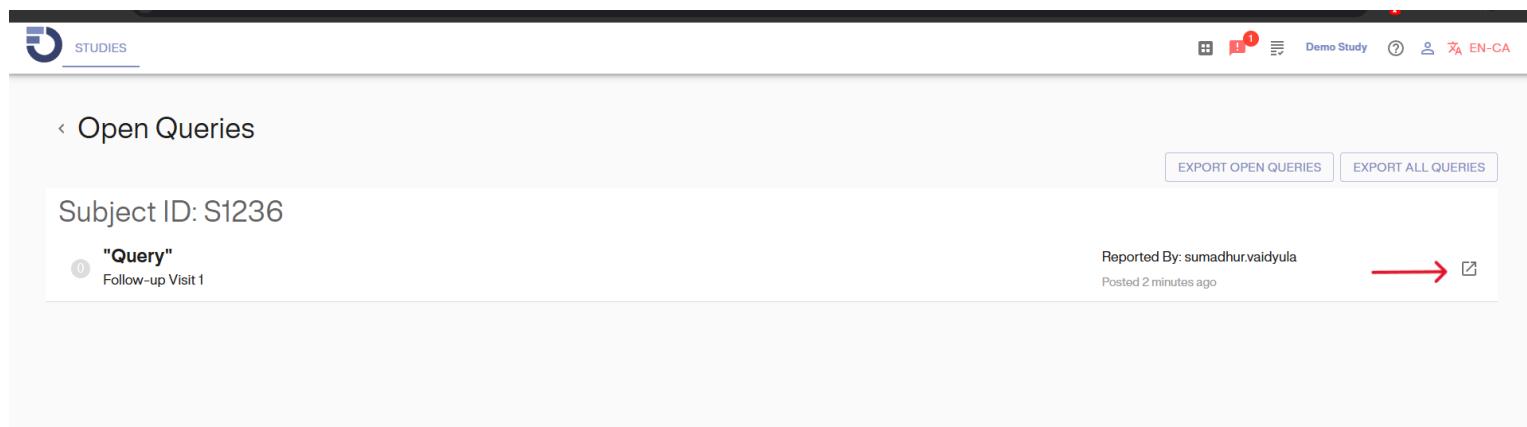


[View All GoalNav® Queries](#)

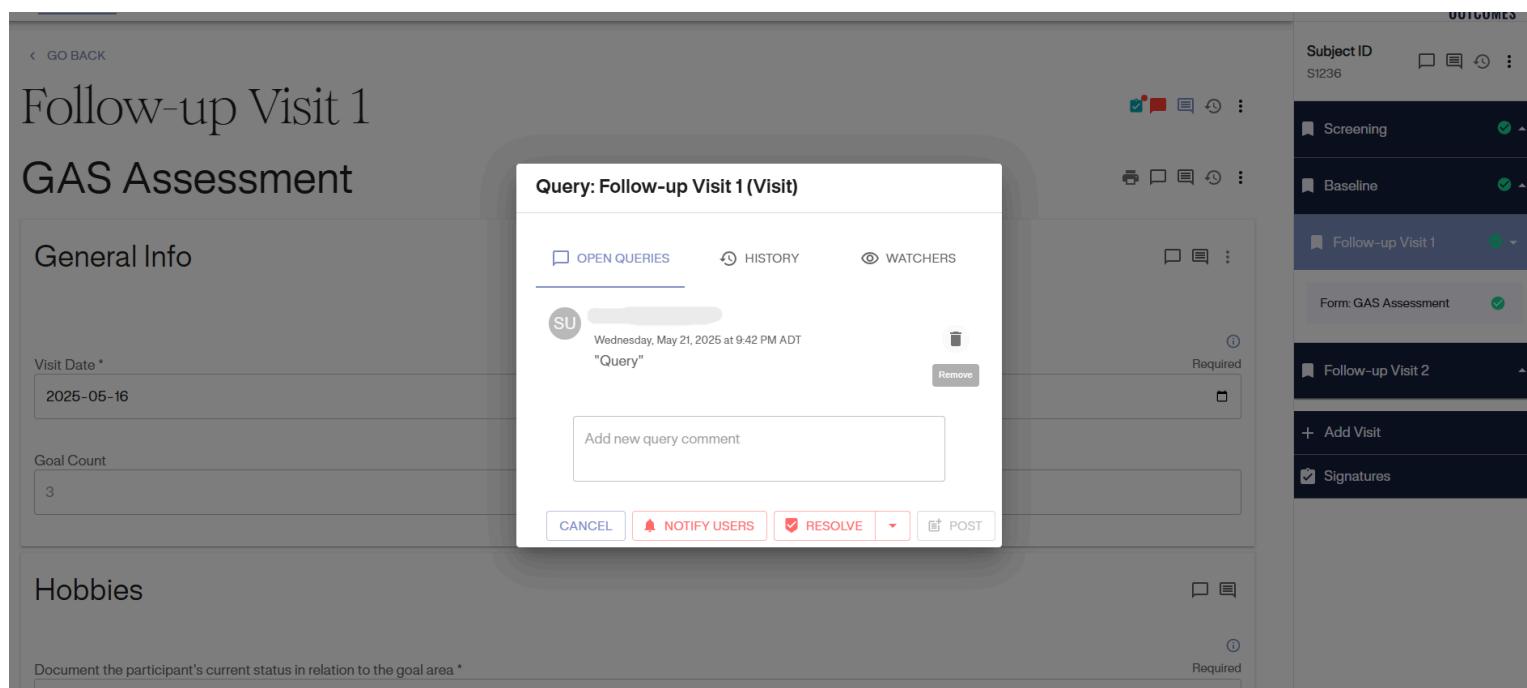
To view all open queries in GoalNav®, click the dialogue icon, which will be highlighted in red when unresolved queries are present within the study.



Click on the dialogue icon button, as shown in the image above, to display all open queries on the page, as highlighted in the image below. Click the link icon (the arrow icon) on the right-hand side of each query, to be directed to that specific query thread. For example, the first query is selected for viewing in this case.

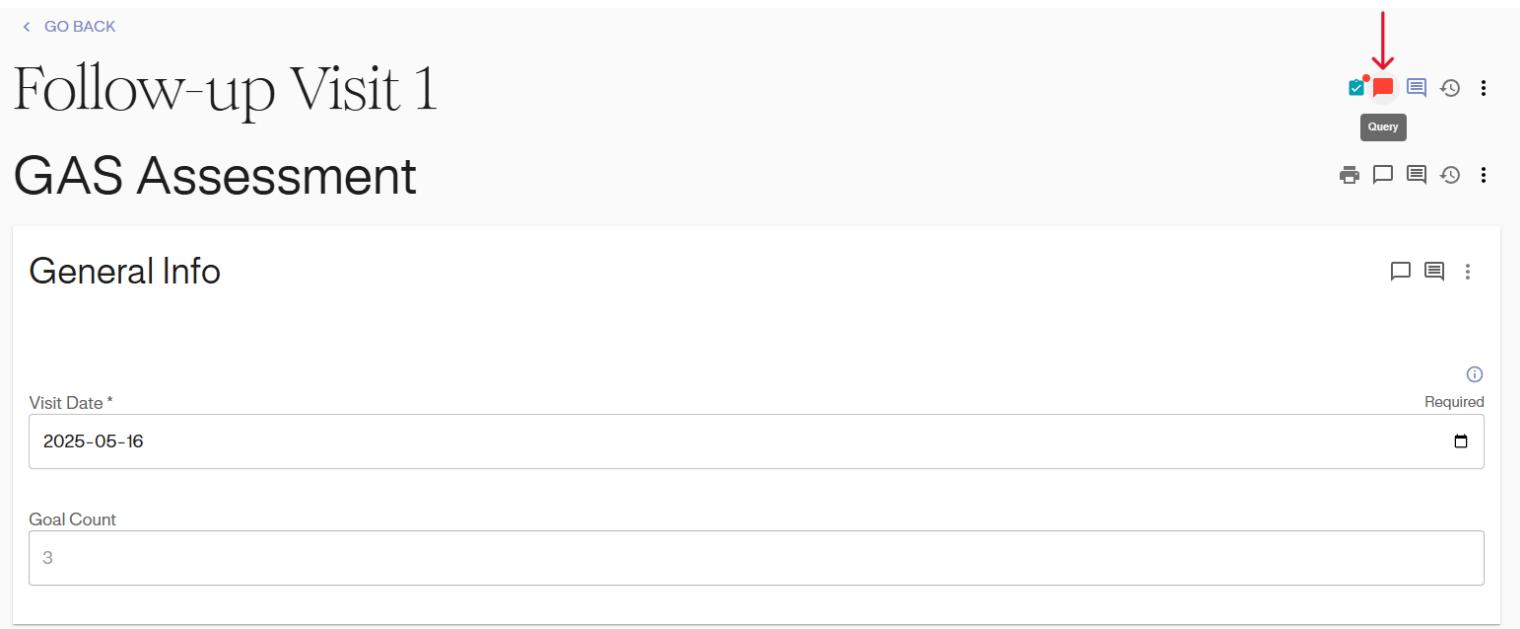


Click the link icon to open a pop-up window to display the visit, form, or form section where the query was created, including the entire query thread.



Respond to GoalNav® Queries

To respond to a query thread in GoalNav®, first navigate to any visit that has an open query. Alternatively, click the dialogue icon in the top bar and select the appropriate query thread to access the Query page. To view the query, click on the red dialogue box icon. Please be aware that a red dialogue icon next to the visit name, form name, or form section name indicates there is an active query for that visit.



GO BACK

Follow-up Visit 1

GAS Assessment

General Info

Visit Date * Required

2025-05-16

Goal Count

3

Query

Print

Print

Print

Print

Click on the red dialogue icon to open a pop-up window that displays the active query thread. In the text box, enter the answer to the query. Click on “Post” to post the response. Posting a response will notify the author of the data and any users who have previously responded/participated in the query thread.

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



"Answer to Query"

CANCEL

 NOTIFY USERS

 RESOLVE



 POST



Close Queries

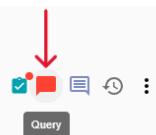
Once an answer to a query is accepted and validated, click the "Resolve" button to close the query. Once "Resolve" is selected, the resolved query will disappear. Note: The Data Monitors should only close queries they created themselves or those that have been resolved. They should not close any unanswered queries. To close a query, follow the instructions below:

Click on the Query Icon on the visit details page.

[GO BACK](#)

Follow-up Visit 1

GAS Assessment



General Info

Visit Date *

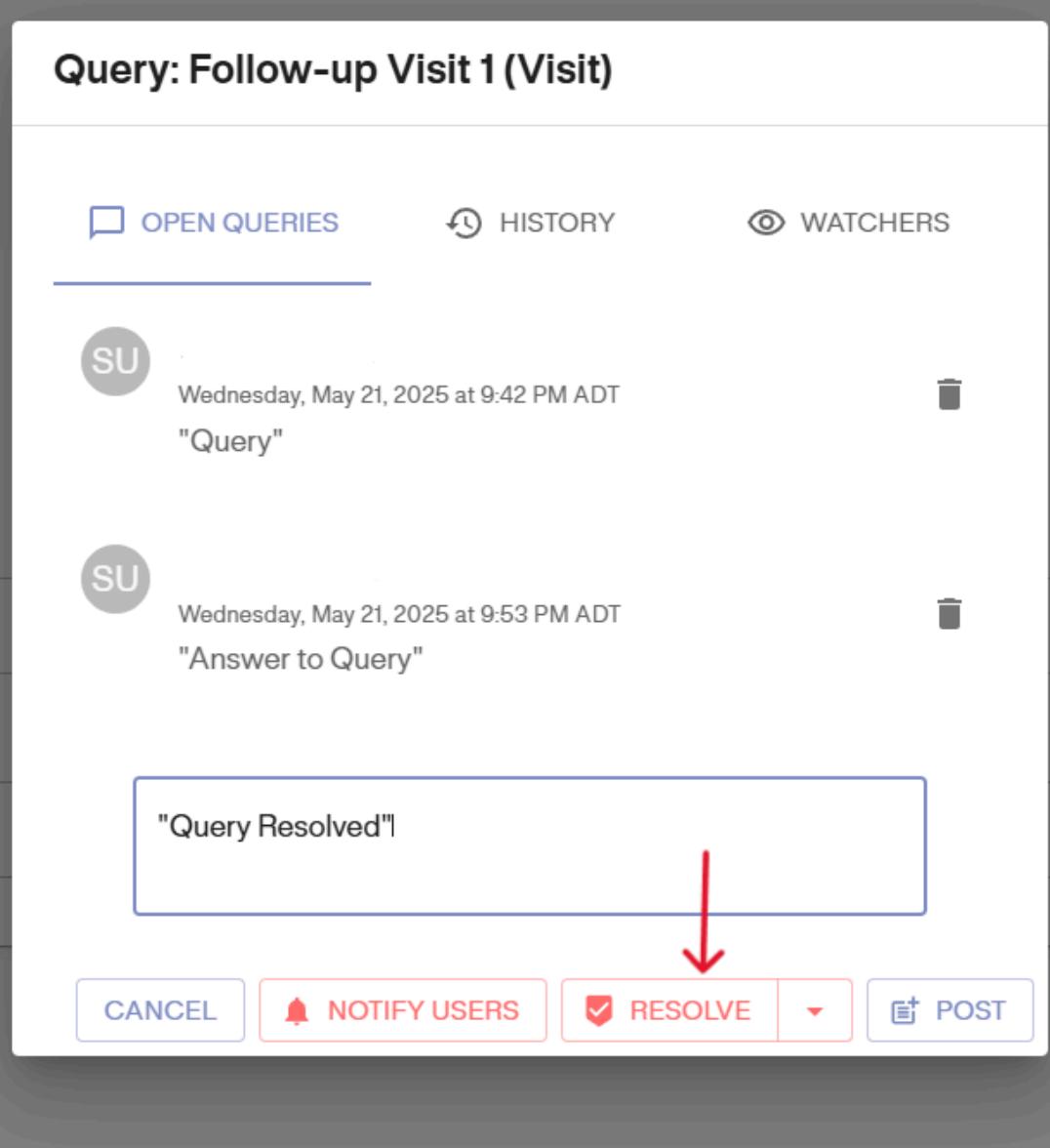
2025-05-16

 Required

Goal Count

3

This opens the existing query thread with the initial query and subsequent replies. Click on the “Resolve” button to close the query. A query can also be closed without a resolution. To do so, click the arrow icon next to the “Resolve” button. This opens a dropdown menu with an option labeled “Unresolvable.” Click on this option to close the query with an “Unresolvable” status.



Closing query with an unresolvable status:

Query: Follow-up Visit 1 (Visit)

 OPEN QUERIES

 HISTORY

 WATCHERS

SU

Wednesday, May 21, 2025 at 9:42 PM ADT

"Query"



SU

Wednesday, May 21, 2025 at 9:53 PM ADT

"Answer to Query"



 CANCEL

 NOTIFY USERS

 RESOLVE



 POST

Unresolvable

GoalNav – Release Notes

Version 2025R2.3 (Latest)

NEW FEATURE

- GN-1770 – Carry forward item translations on form edit when content for an item has not changed.

Version 2025R2.2

BUG FIXES

- GN-1753 – Fixed issue preventing relocation of a Subject from the Subject Matrix.
- GN-1755 – Corrected formatting in system-generated query emails.

NEW FEATURES

- OpenAPI/Intruder Integration (GN-1653).

Form Autolocking:

- Added new study feature for enabling automatic form locking (GN-1691).
- Introduced a three-state provisional lock flag in the form data model (GN-1692)
- Updated UI to support provisional locking (GN-1693)
- Added scheduled job to automatically apply provisional locks (GN-1694)

Translations Management:

- New Table and model for storing translated text data (GN-1719)
- Introduced new permission for managing translations (GN-1720)
- Added new Translations view for managing source data (GN-1721)
- Upload workflow for adding translation data (GN-1722)
- Audit view to track who and when translations were added (GN-1723)
- Updated DisplayQuestion to prefer uploaded translations over machine translation (GN-1724)

Goal Reviews and Reporting:

- Goal review Export now available (GN-1751)
- Unpublished final goal reviews can now be edited by any user (GN-1752)

- Added option to exclude screen failures in GAS enrollment report (GN-1717)

Previous Revisions of System Manual to be downloaded from here.

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