Chapter 1: Getting Started

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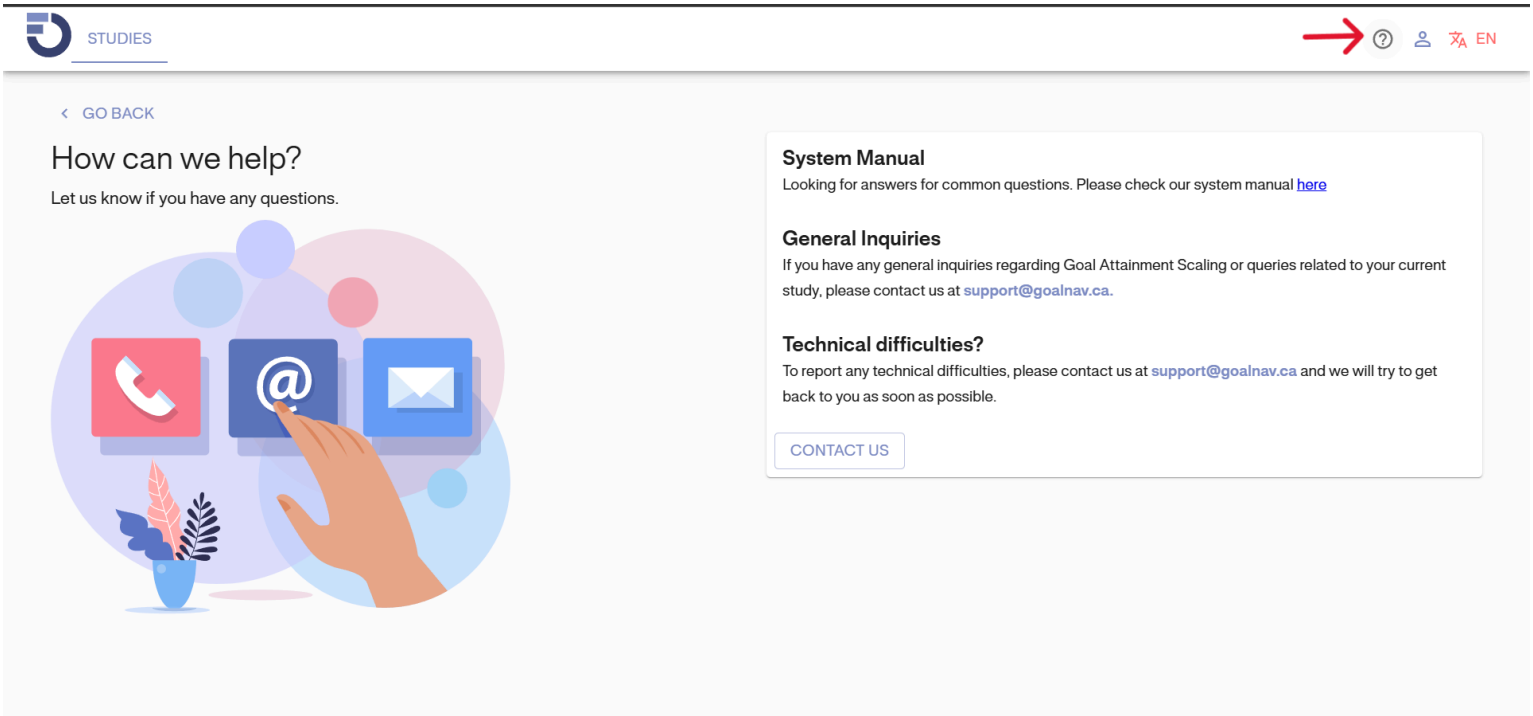
- Help
- Minimum Requirements
- How to Login
- How to Logout

IN THIS CHAPTER

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.



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.

. Please check our system manual here

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

contact us at support@goalnav.ca and we will try to get

Contact Us

Title

Description

UPLOAD IMAGE

Email

CANCEL SEND

IN THIS CHAPTER

1 Minimum Requirements
   a Mobile/Tablet Minimum Specifications
   b Laptop/Desktop Minimum Specifications

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)

IN THIS CHAPTER

1 How to Log In
   a GoalNav® Account Sign-in
   b Common Sign-in Issues

How to Log In

GoalNav® Sign-in and Log-in Instructions

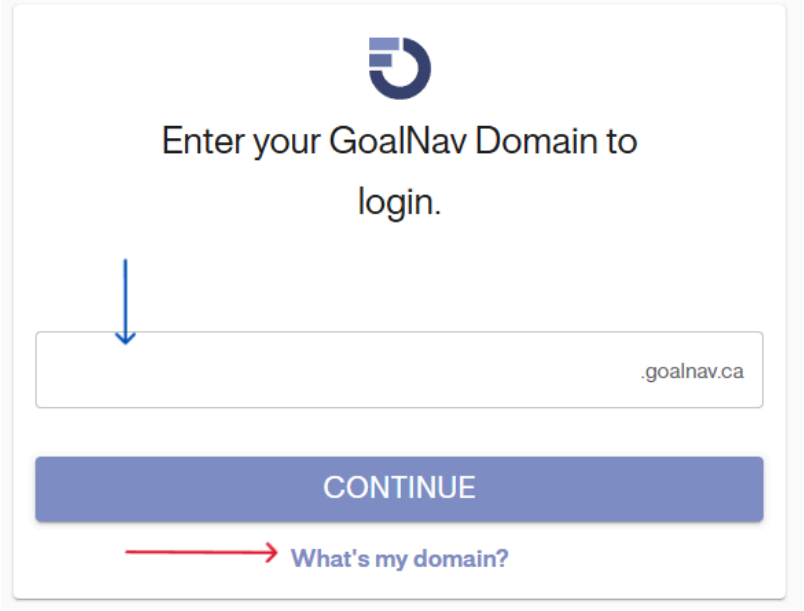
To start using the GoalNav® system, access it through your assigned study domain. It should look similar to this:

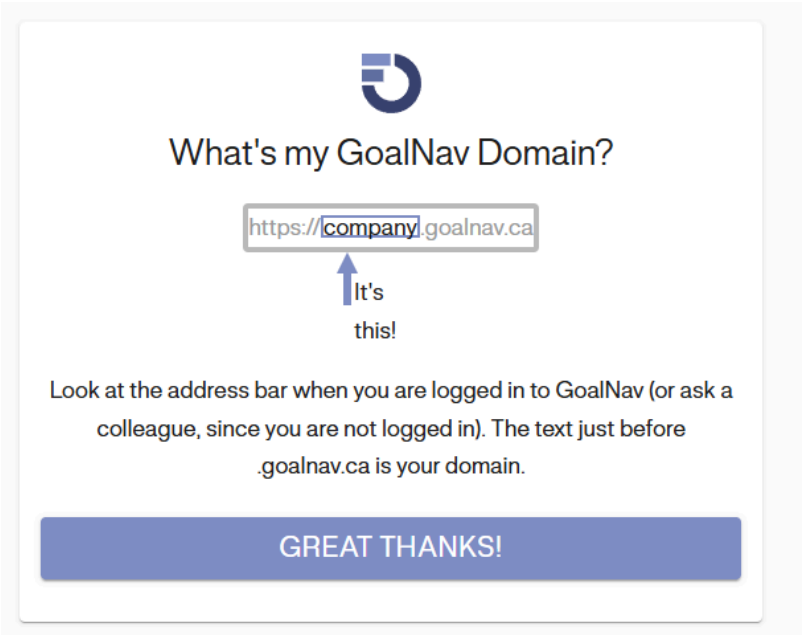
[domain].goalnav.ca

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.





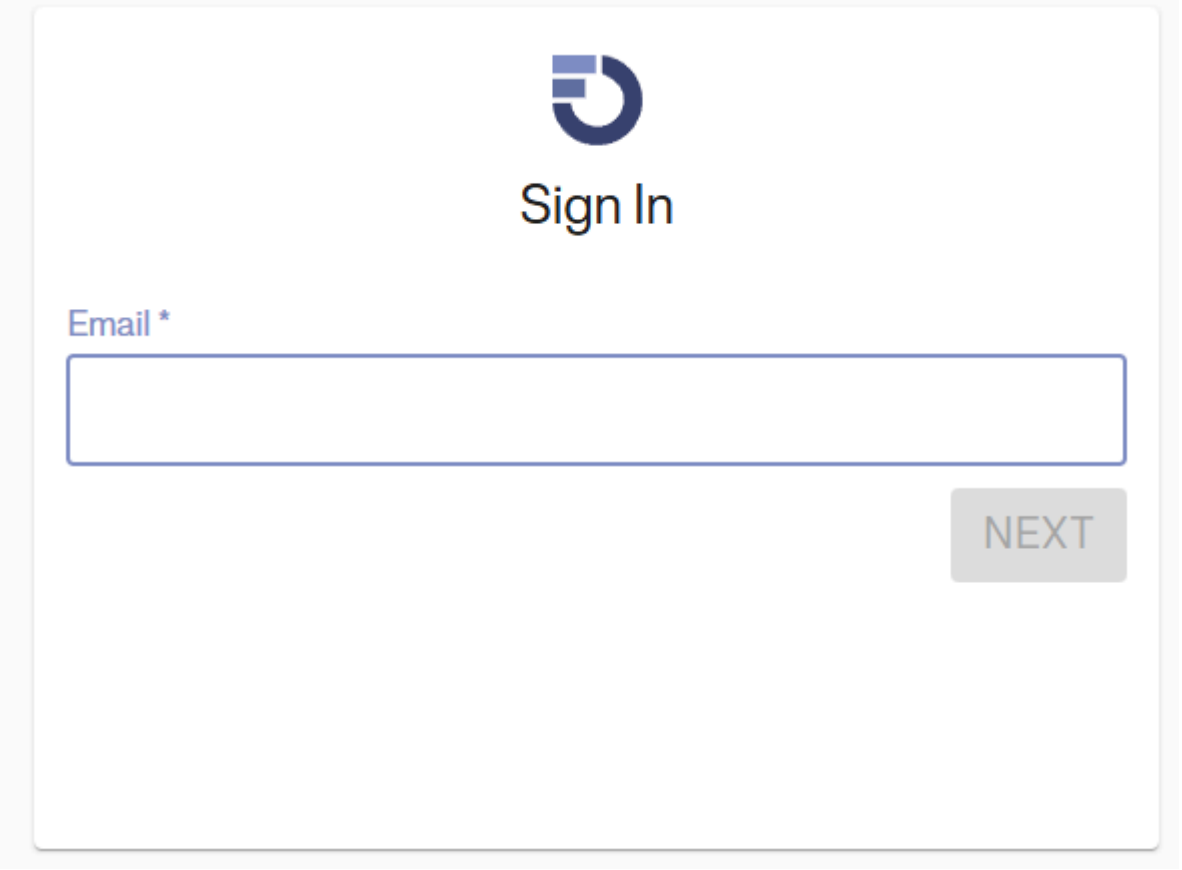
Enter GoalNav domain in the text field, next to ".goalnav.ca"

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.

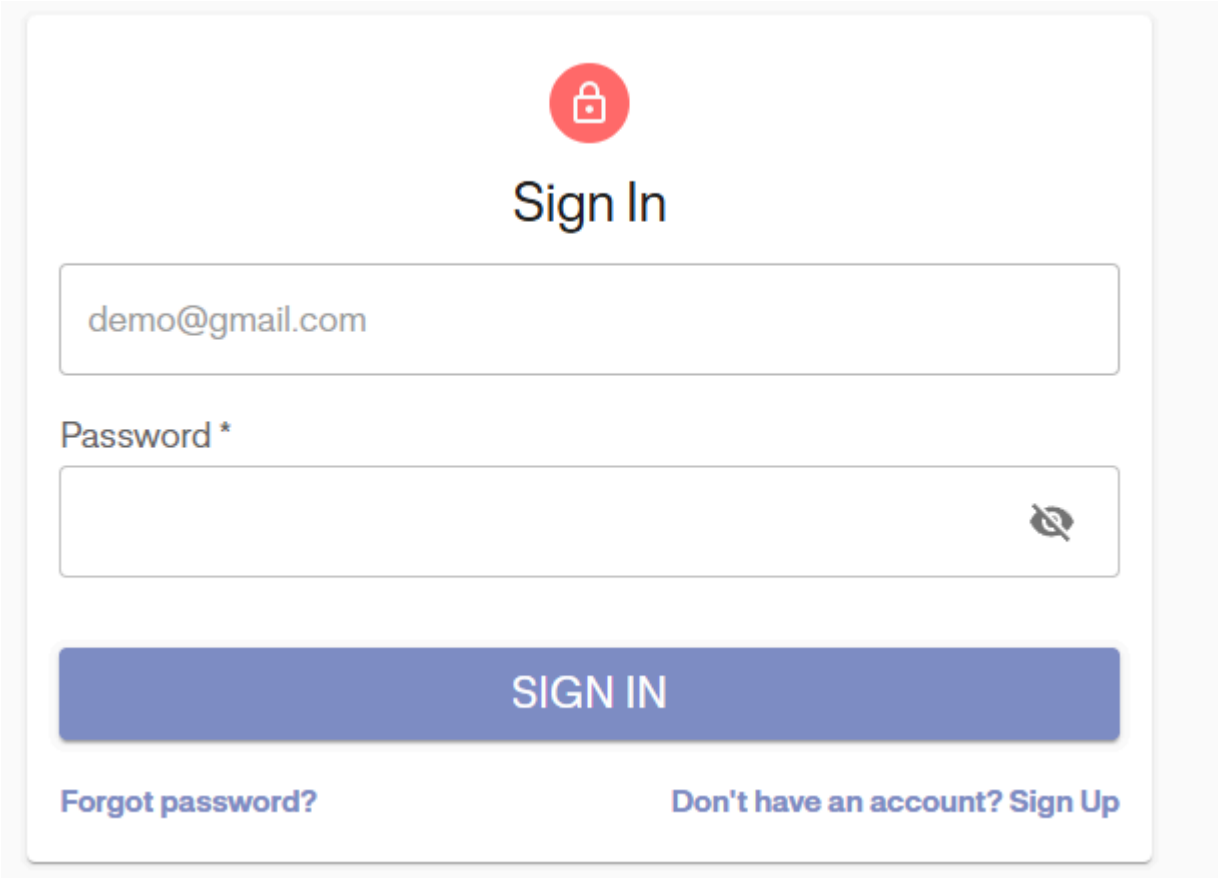
GoalNav® Account Sign-in

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

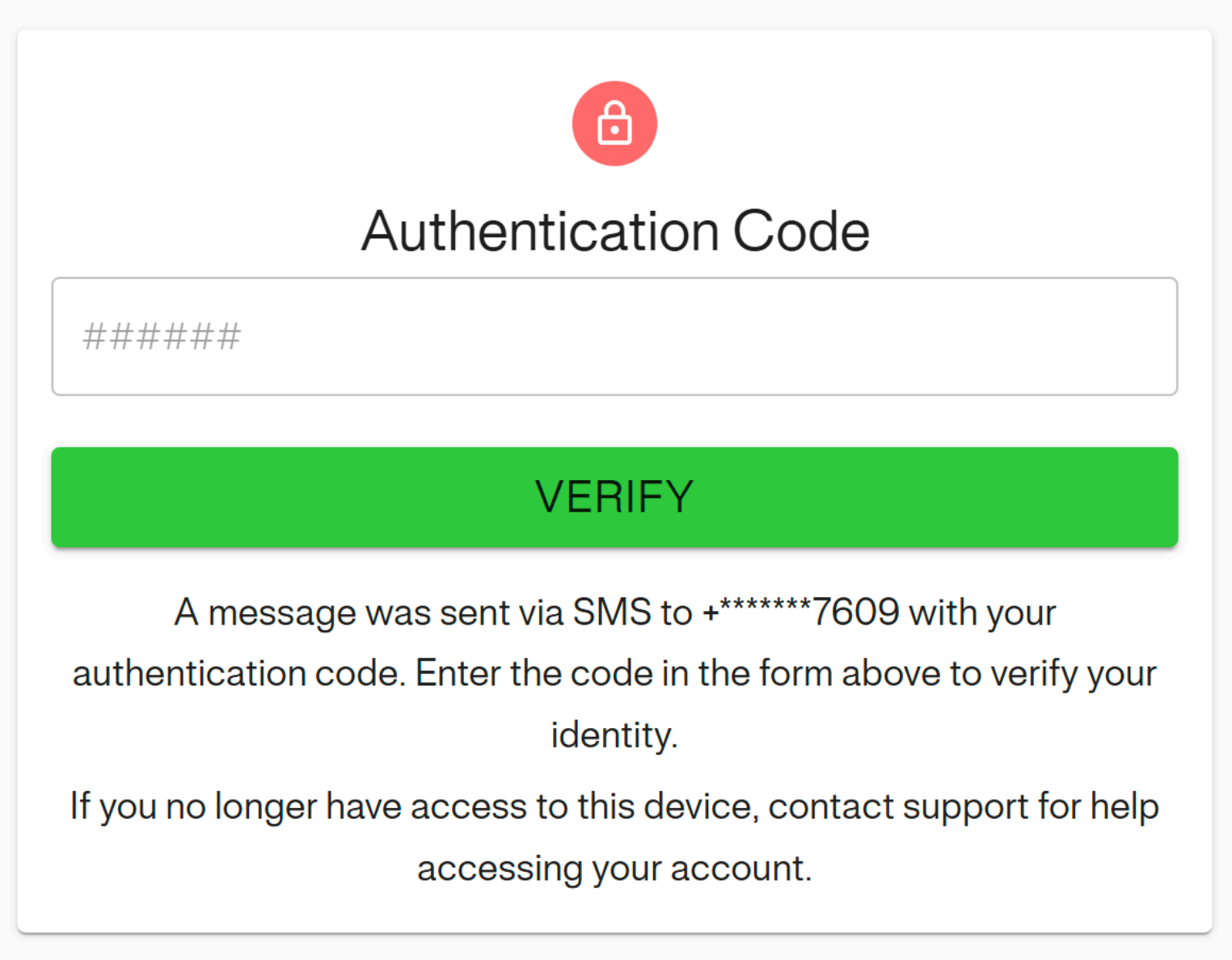


Note: If your organization has chosen to allow signing into GoalNav with a work account via Single Sign On (SSO), after clicking Next on the email prompt you will be redirected to your organization's login page. Login as you normally would with your work account, and you will be redirected back to GoalNav 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".



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



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@goalnav.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@goalnav.ca

IN THIS CHAPTER

1 How to Log Out

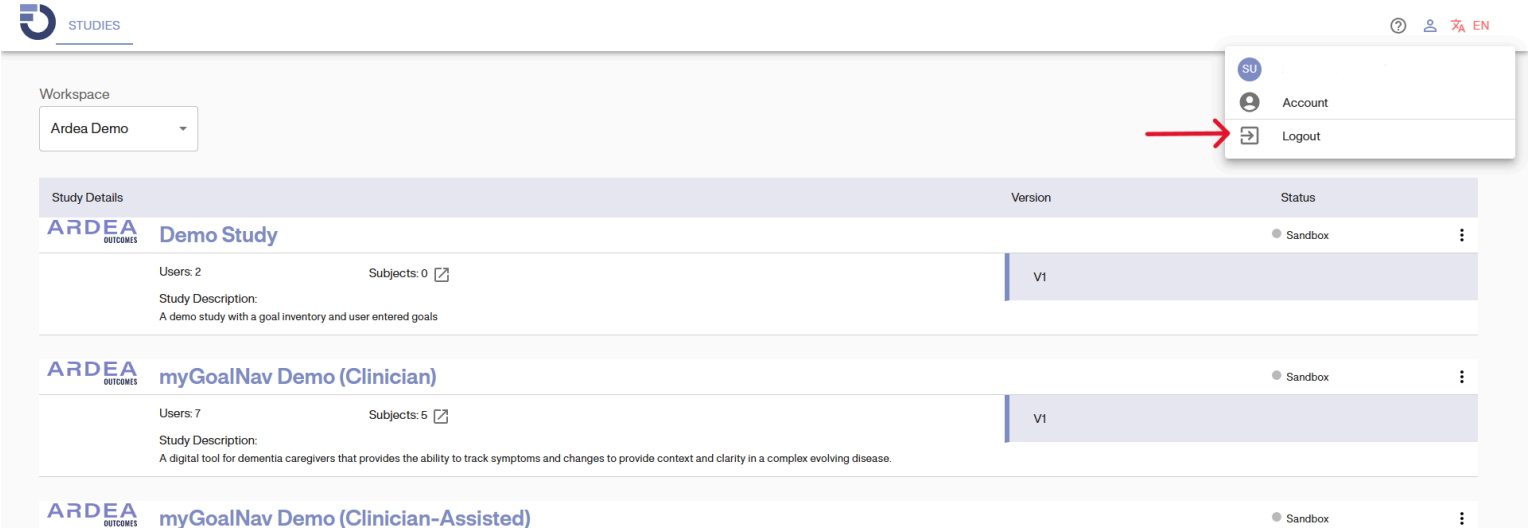
a Log out of the GoalNav® system

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.



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
- User Profile
- Subject Matrix
- Subject Details
- Print Forms
- Goal Reviews

IN THIS CHAPTER

1 Home Screen

a Additional Features

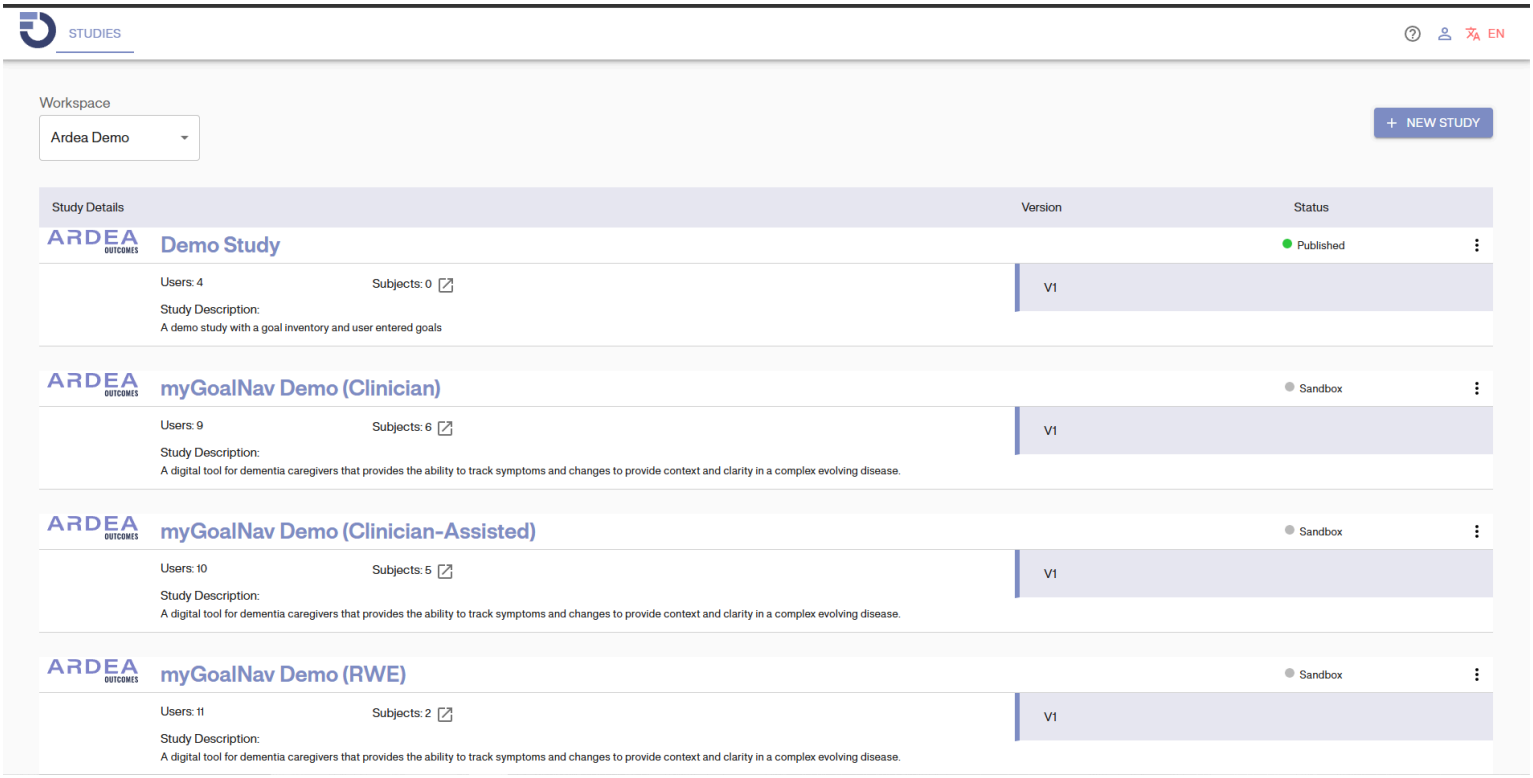
Home Screen

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**)



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)

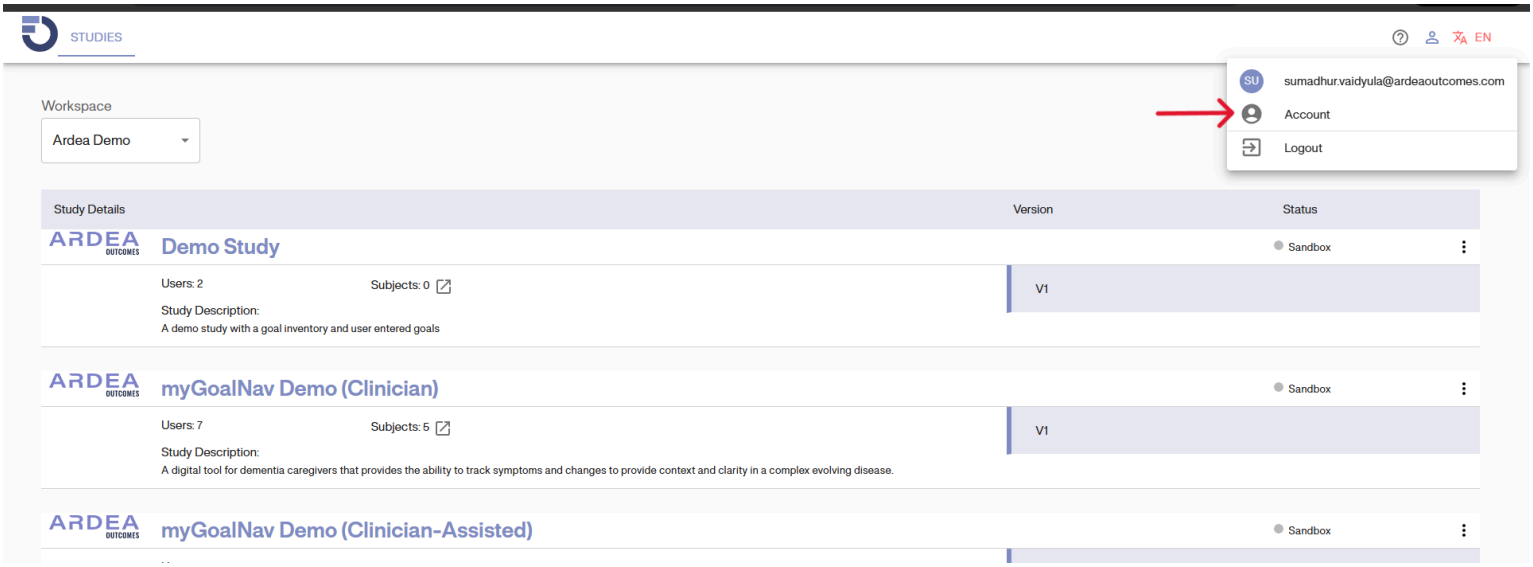
User Profile

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

User Account : User Profile

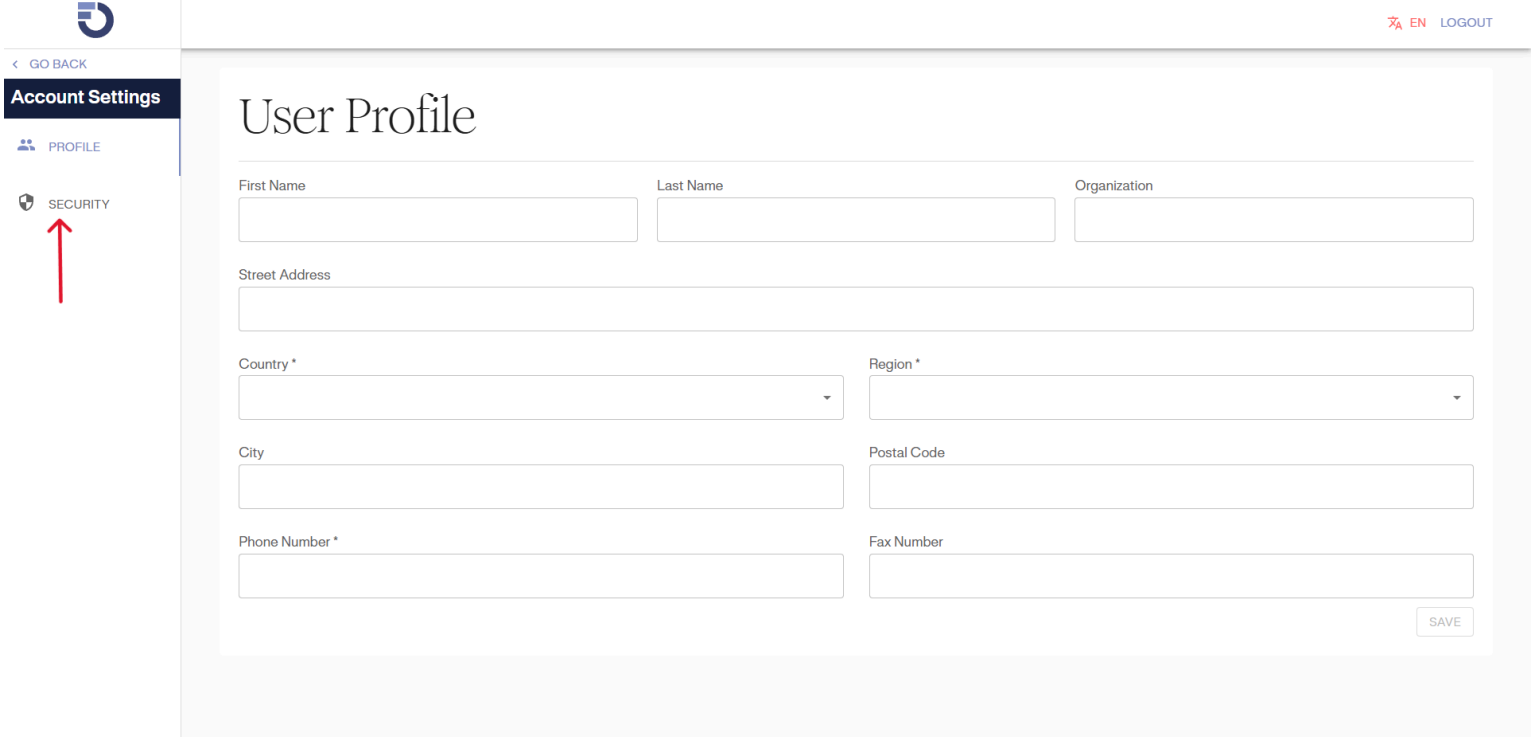
Your user profile page contains all your personal information. You may fill this out at any time. This information is important in case the GoalNav® team must contact the user.

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

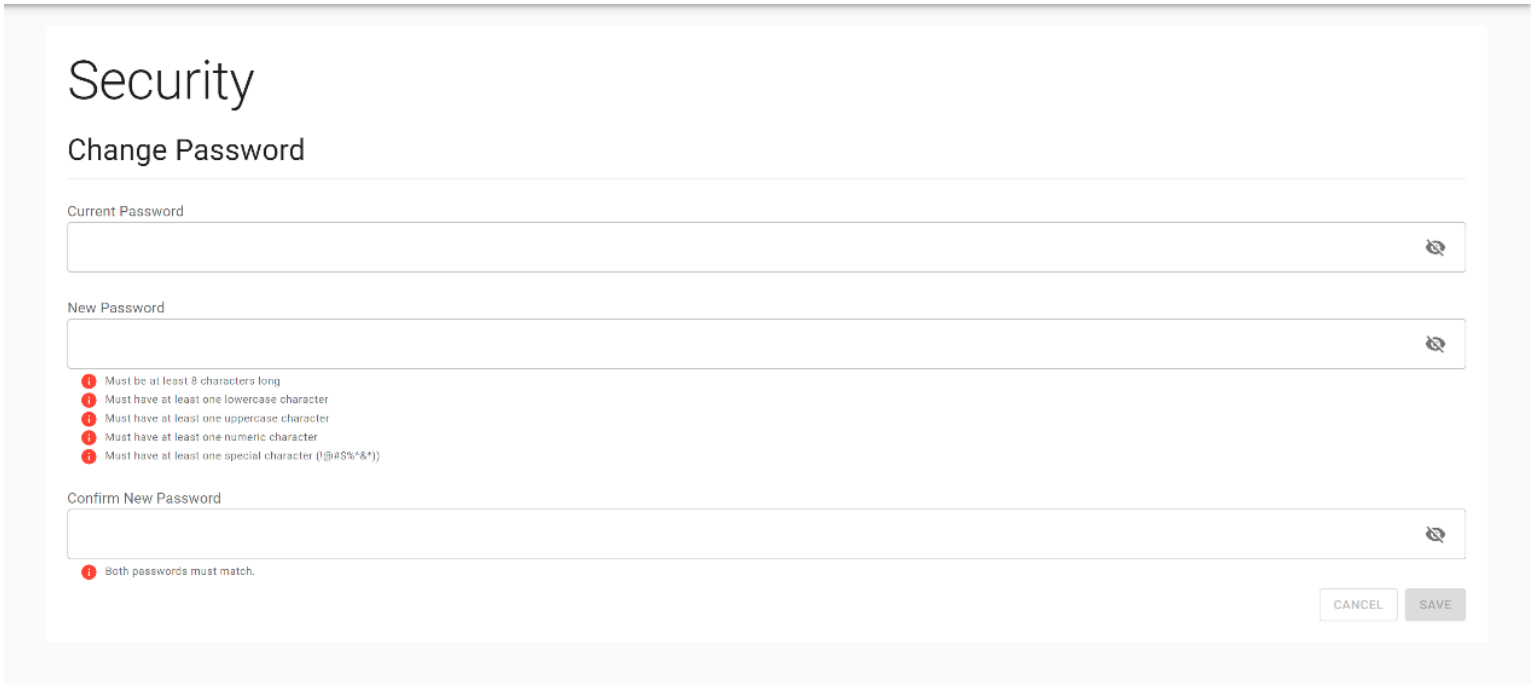


User Account: Security (Change Password)

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



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



IN THIS CHAPTER

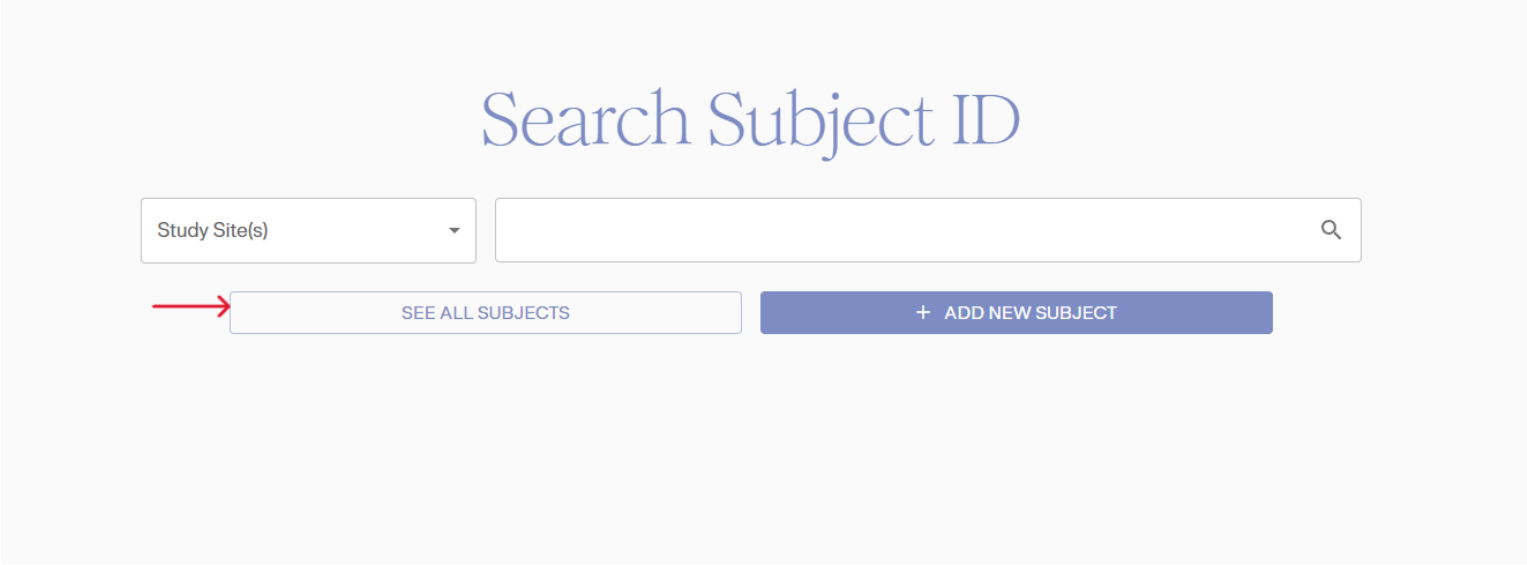
1 Subject Matrix

a Additional Features

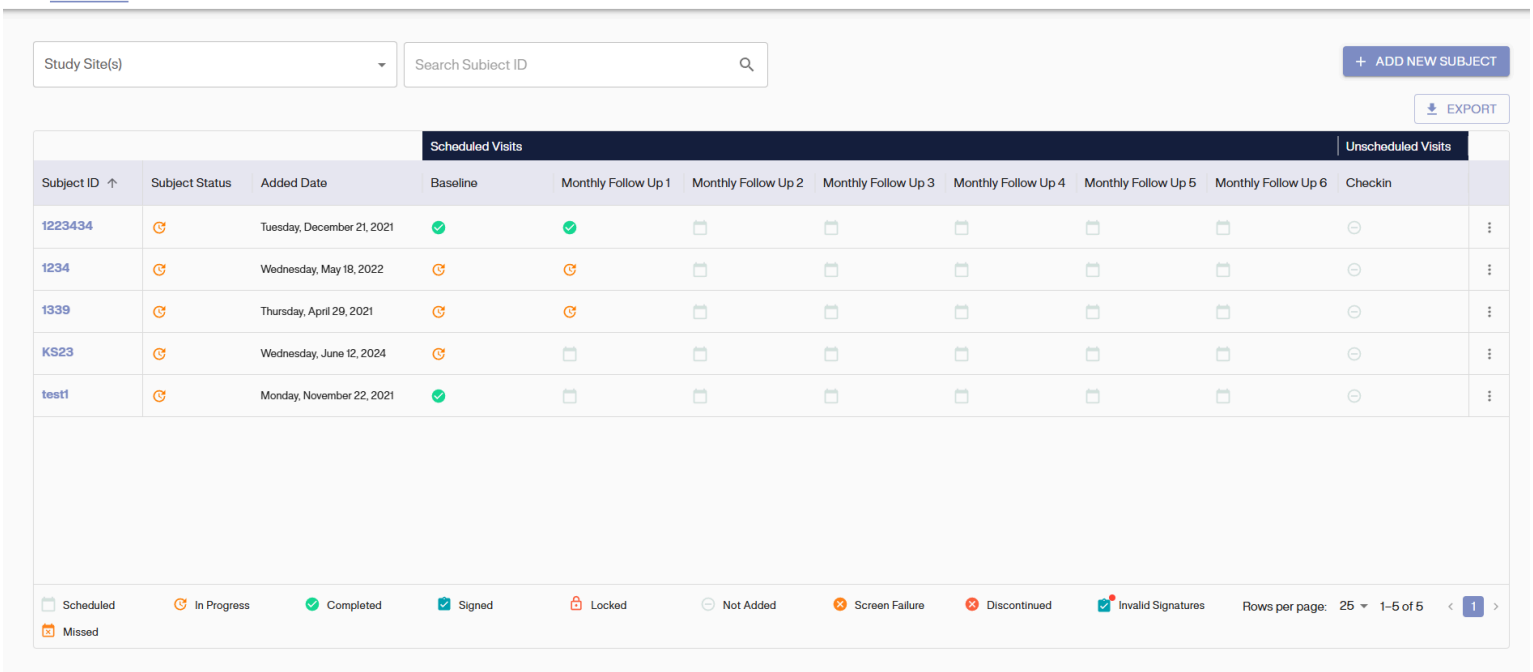
Subject Matrix

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 acess 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.



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.

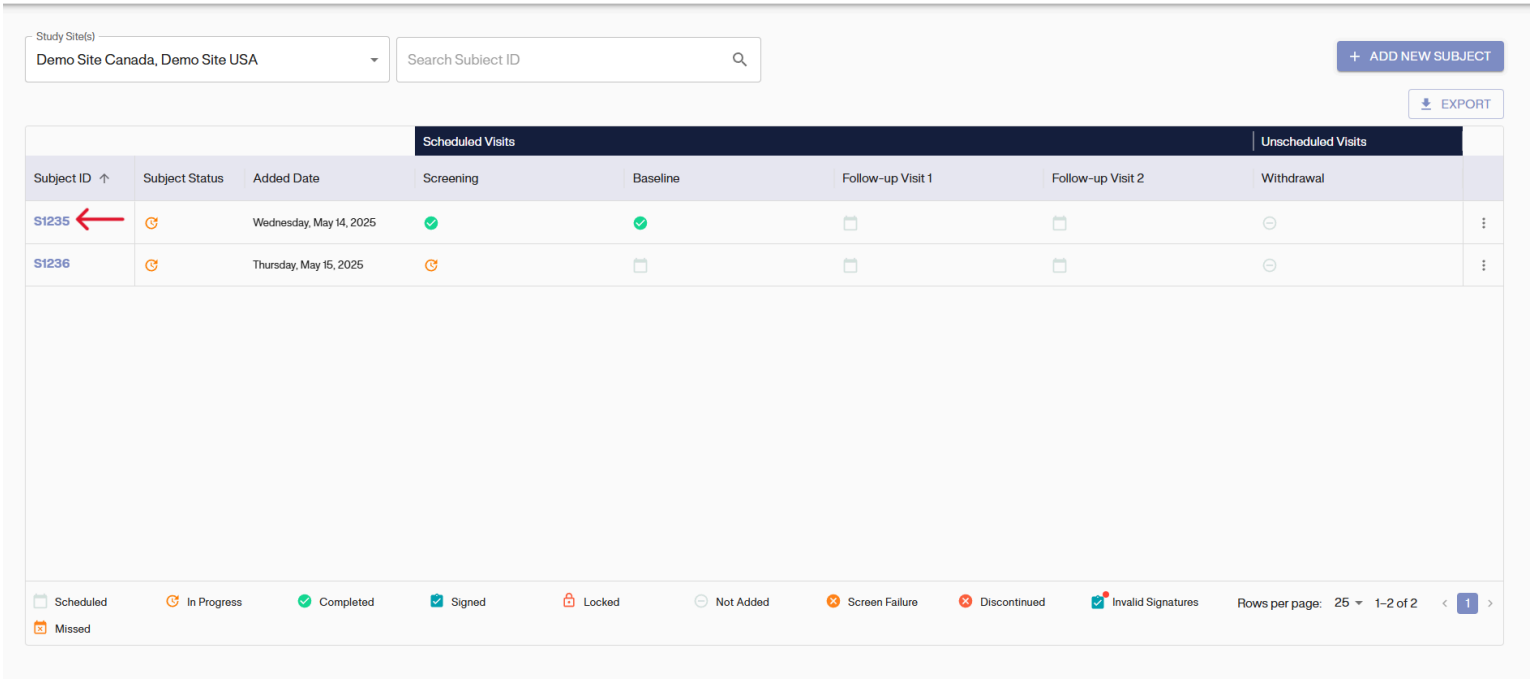
IN THIS CHAPTER

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.

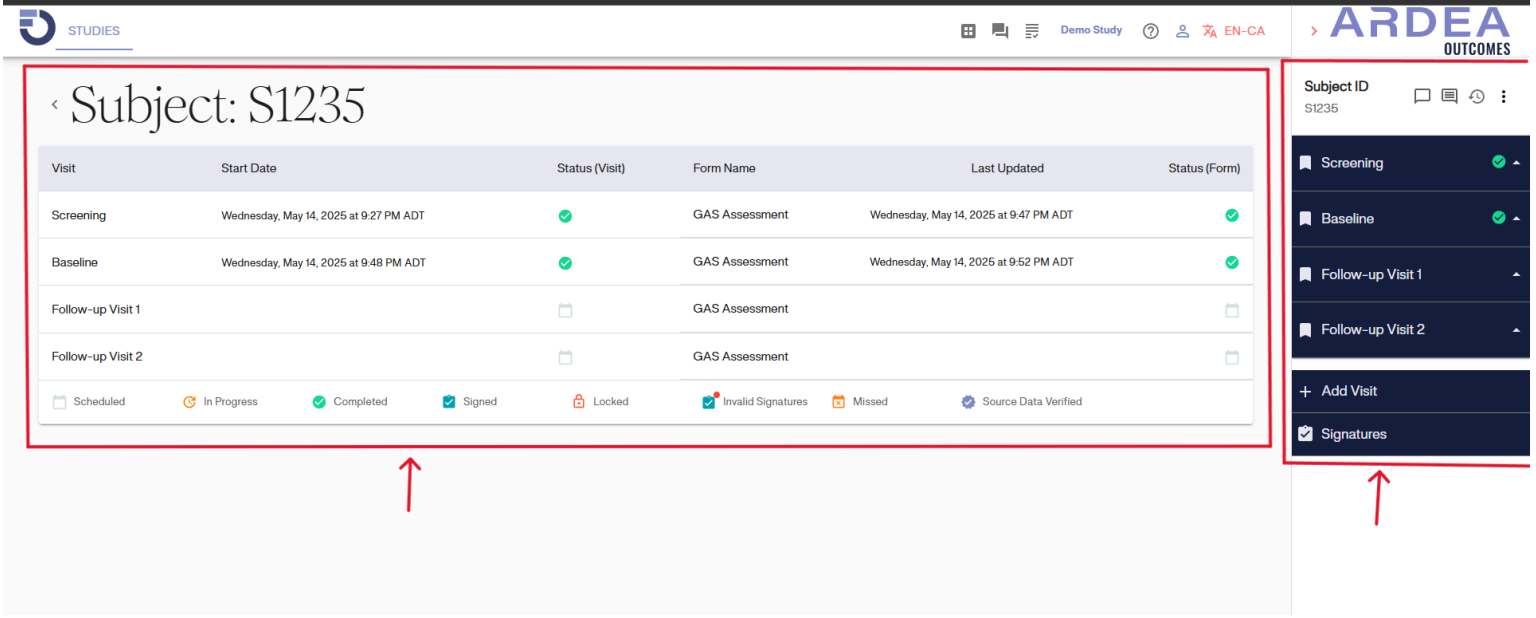


Then, you will be able to view your subject's visits and associated forms.

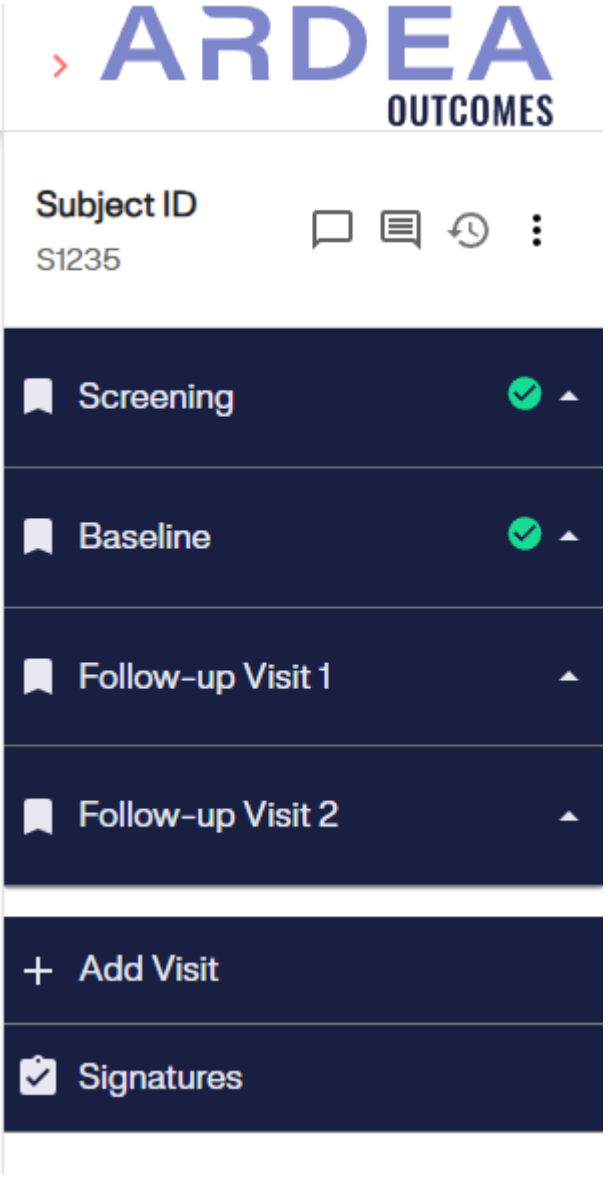
On the **left side of the page**, you will find a table containing:

- 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.



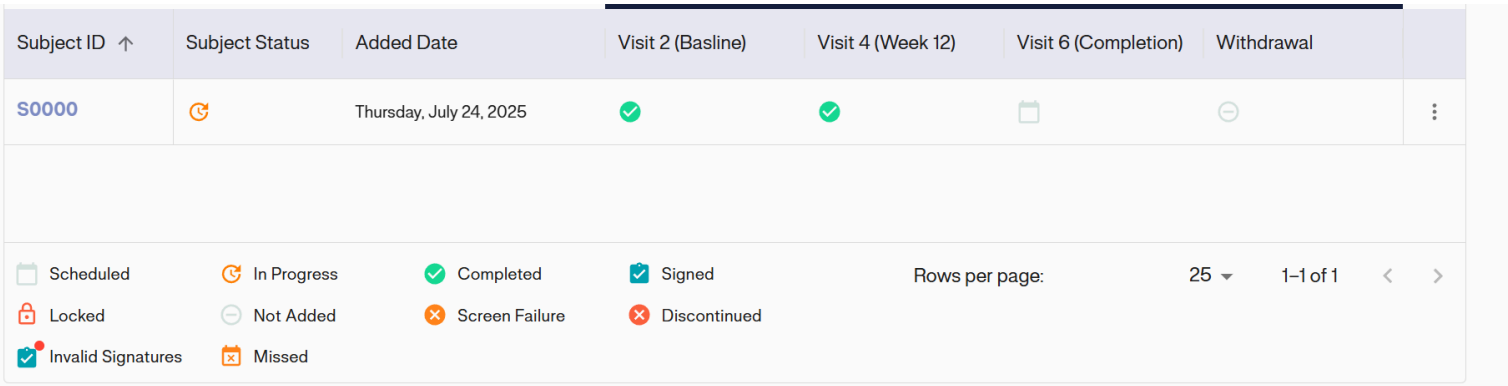
The study menu will remain on every visit page and can be collapsed using the arrow. Icons may appear within the study menu to signify visit statuses.



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.



IN THIS CHAPTER

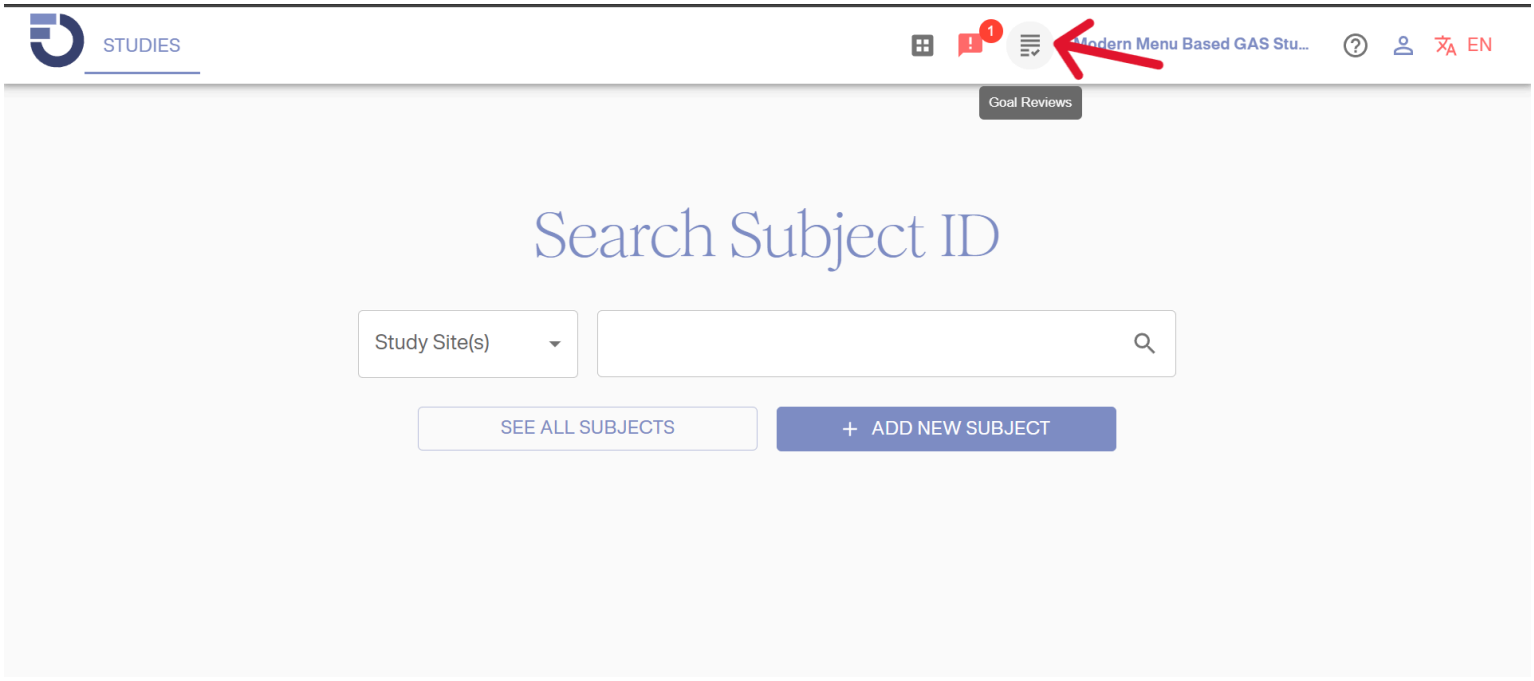
1 Print Forms

Print Forms

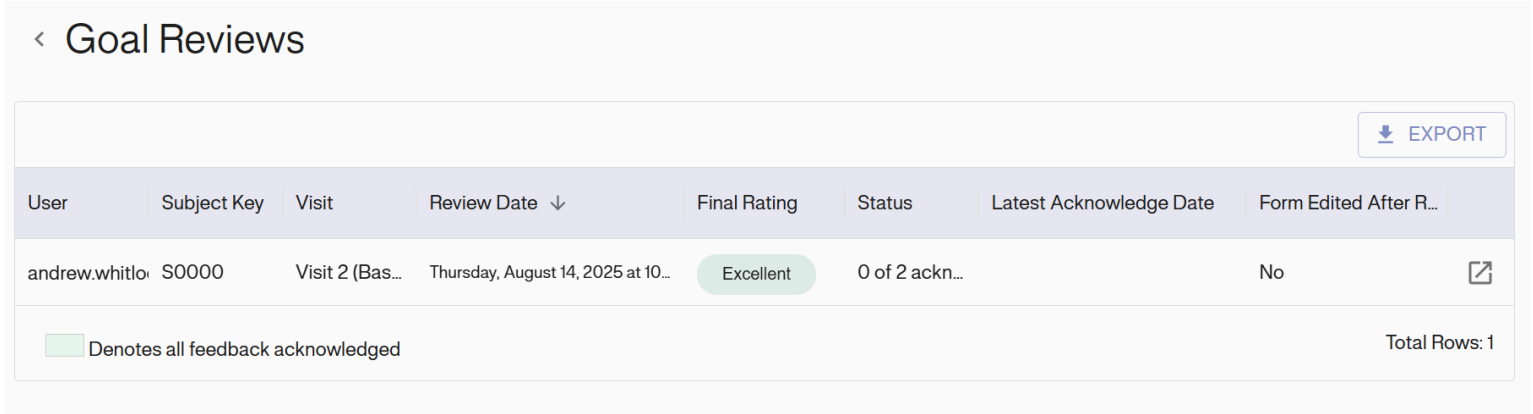
If you need to print the GAS scale form for any reason, first navigate to the GAS form in the appropriate visit. Next, click the 'Print' icon for each page. See example of printing a baseline visit below.

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.



Chapter 3: Using GoalNav as a Data Entry

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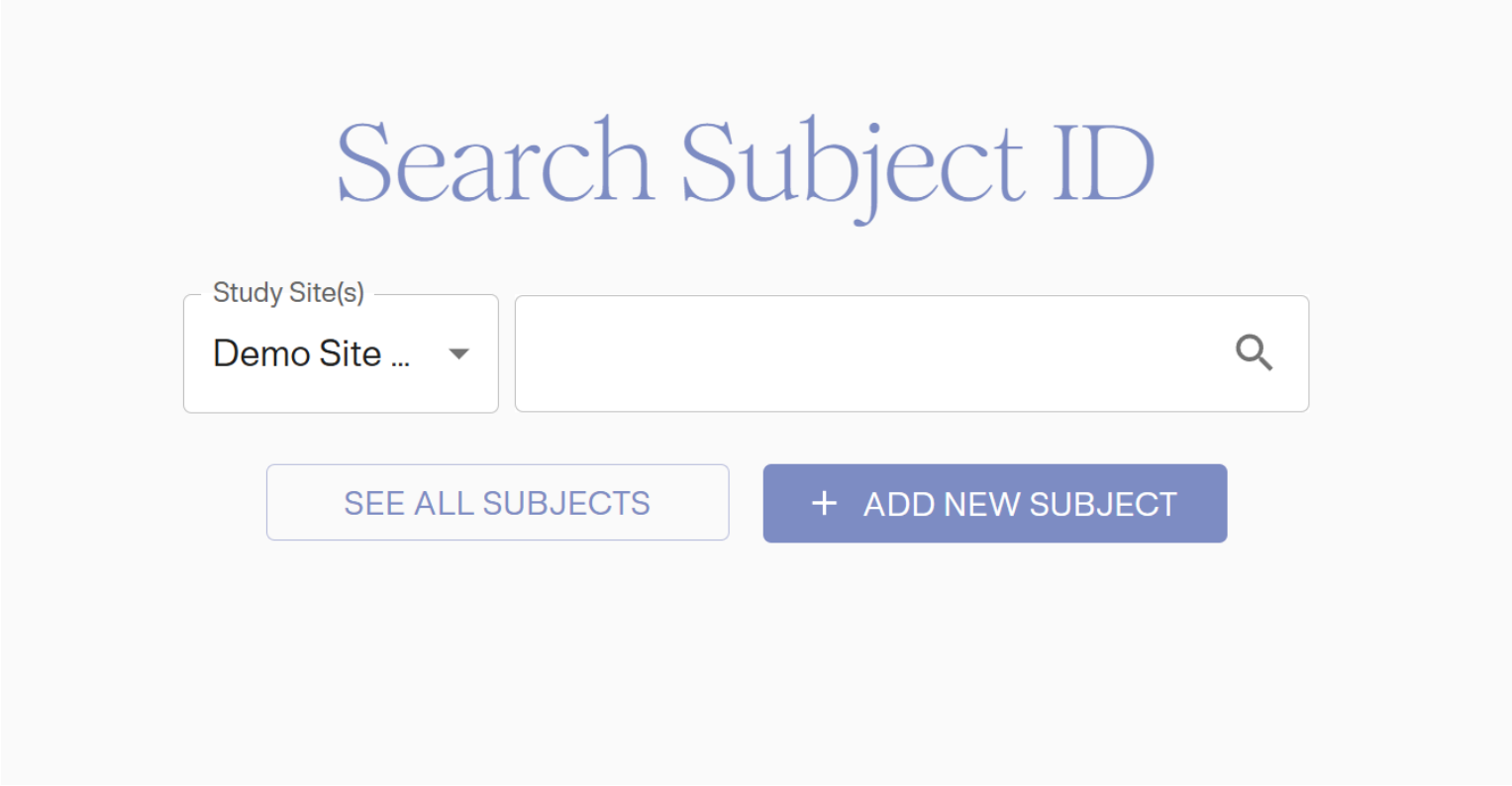
- Add Subjects
- Visits
- Comments
- Changes to Forms
- Missed Visit
- Signatures
- Source Data Verification
- Manage Queries

IN THIS CHAPTER

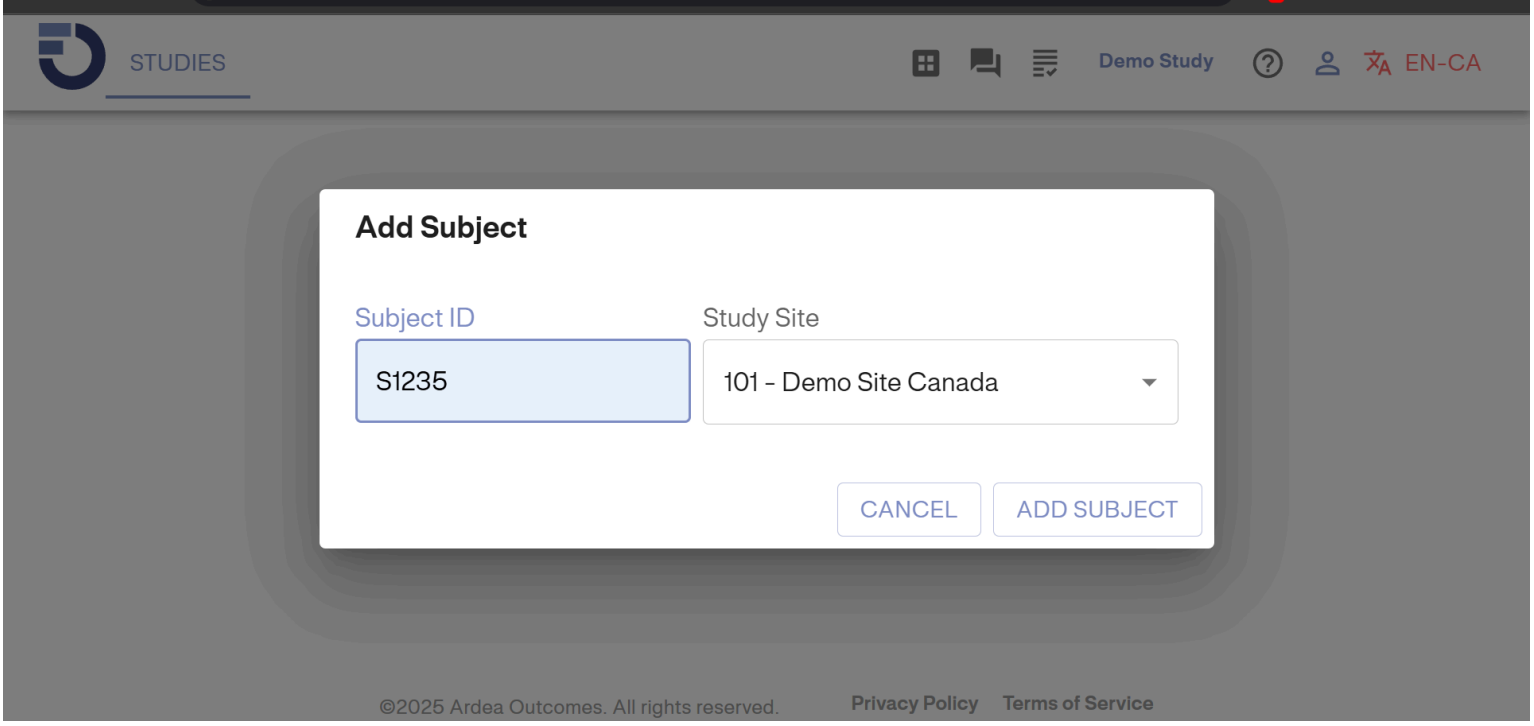
1 Adding Subjects

Adding Subjects

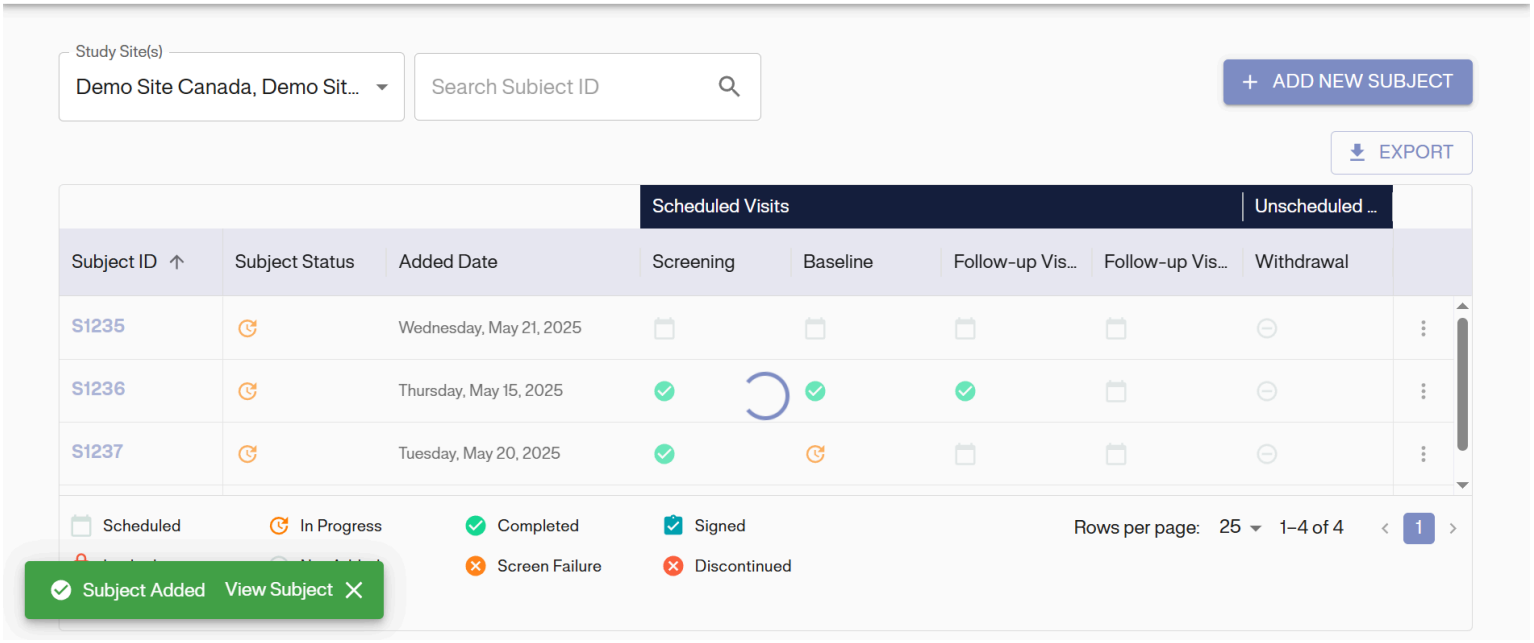
If a subject has not yet been added to the system, you can do so by clicking '+ ADD NEW SUBJECT'.



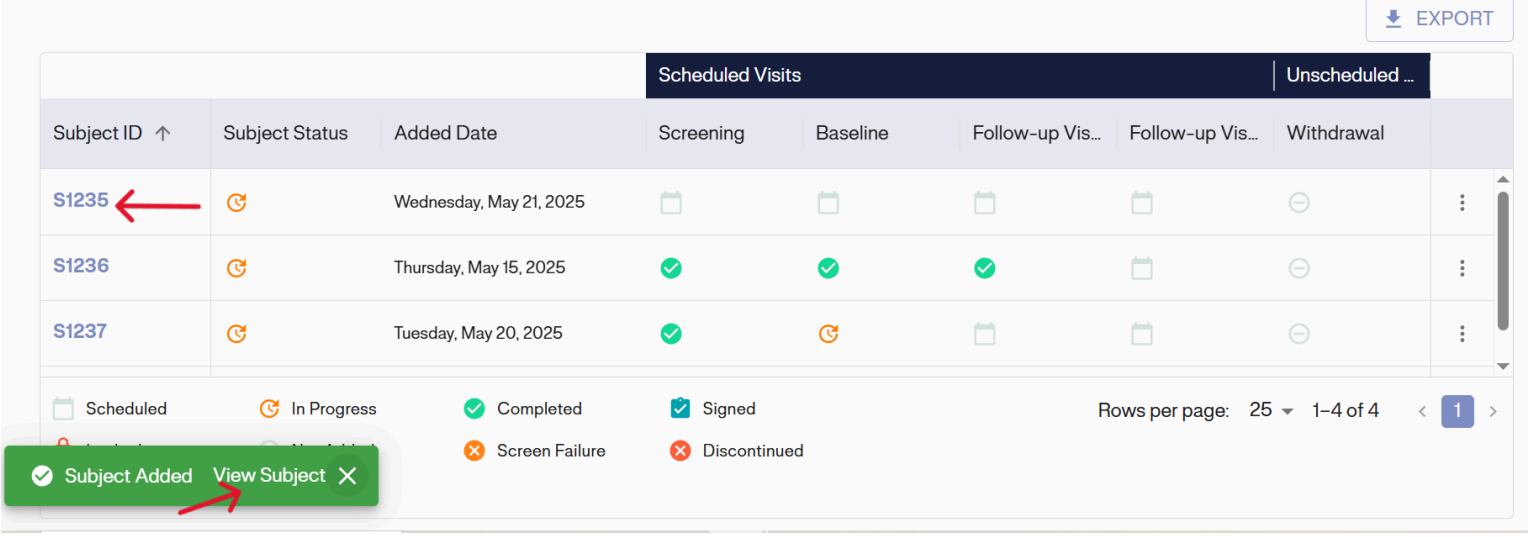
You are required to enter your subject's ID and Study Site. Please double check you are entering the correct subject information before clicking 'ADD SUBJECT'. You will also note the study version if your study has more than one version.



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



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.


EXPORT
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

IN THIS CHAPTER

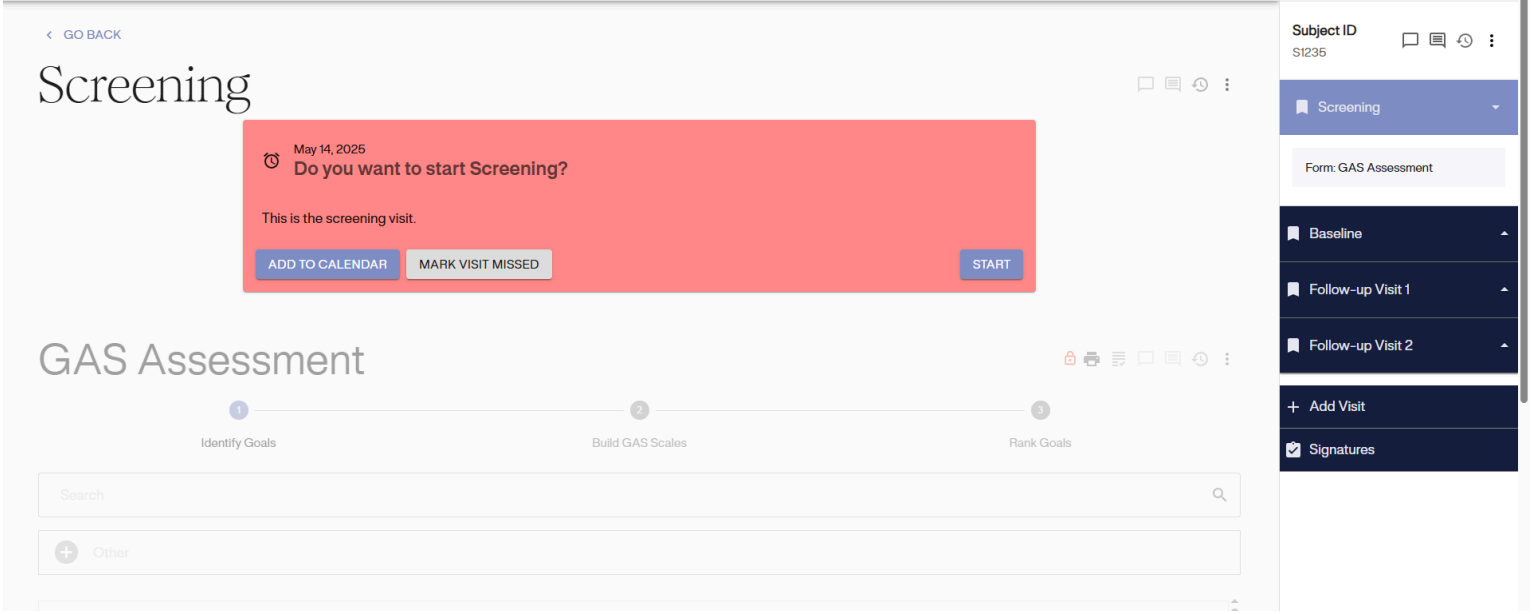
1. Visits
   a. Screening Visit:
   b. Baseline Visit:
   c. Follow-up Visits
   d. Unscheduled Visits
2. Entering Data into Visit Forms
   a. Data Collection visits
   b. Data collection for studies with Separate Screening and Baseline Visit
      a. Screening Visit: GAS Assessment Form Data Entry
         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

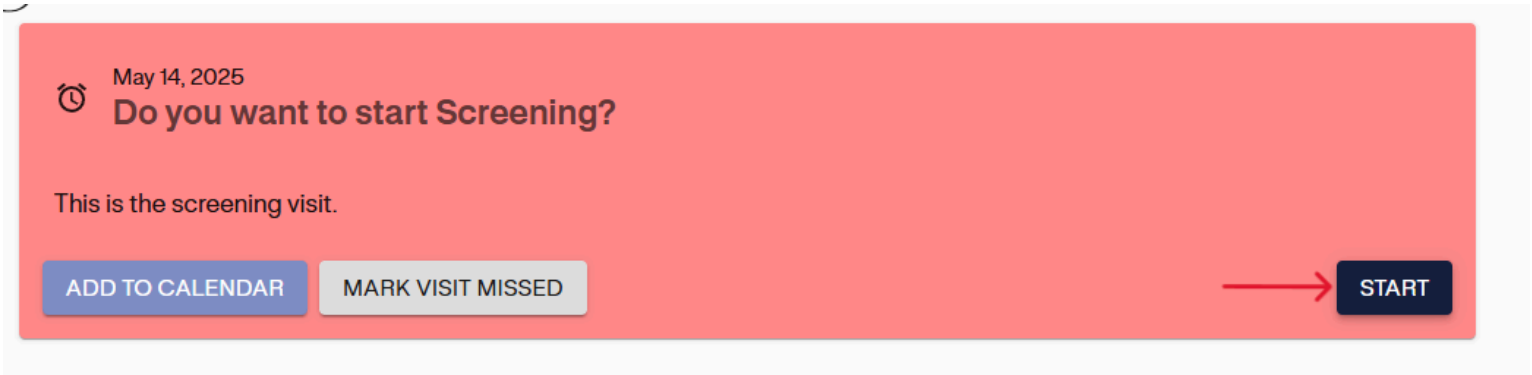
Study visits in GoalNav can be accessed through the study menu on the right side of the subject details page.

Screening Visit:

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

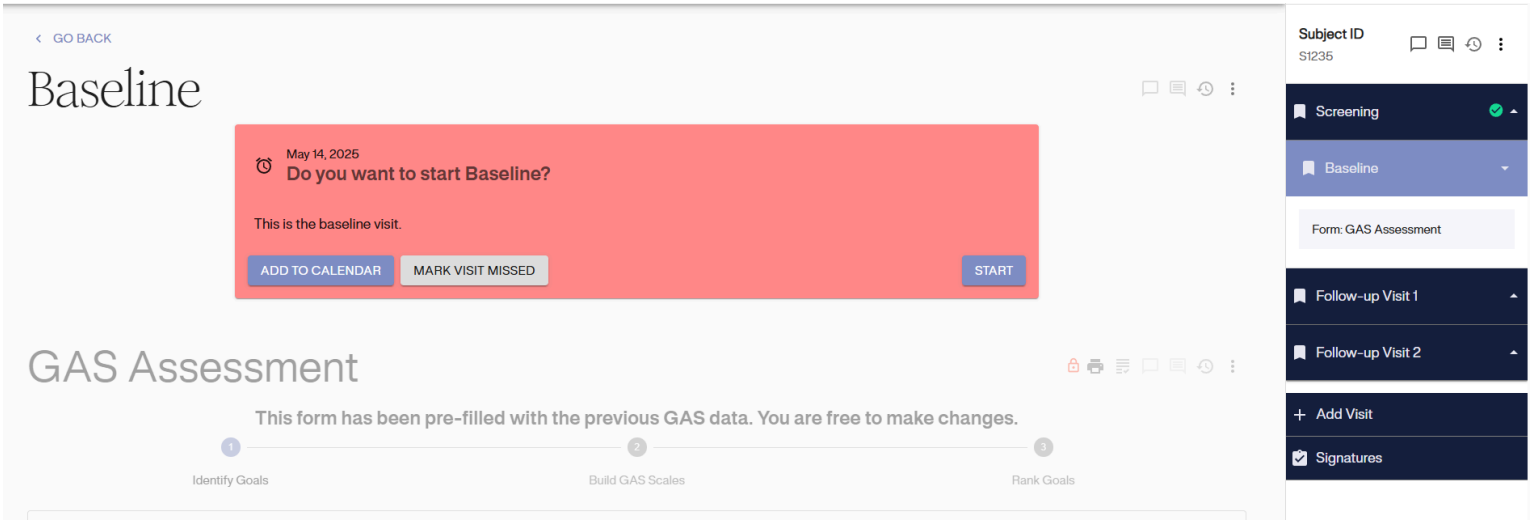


To start the Screening visit, click on the start button on the visit details page.



Baseline Visit:

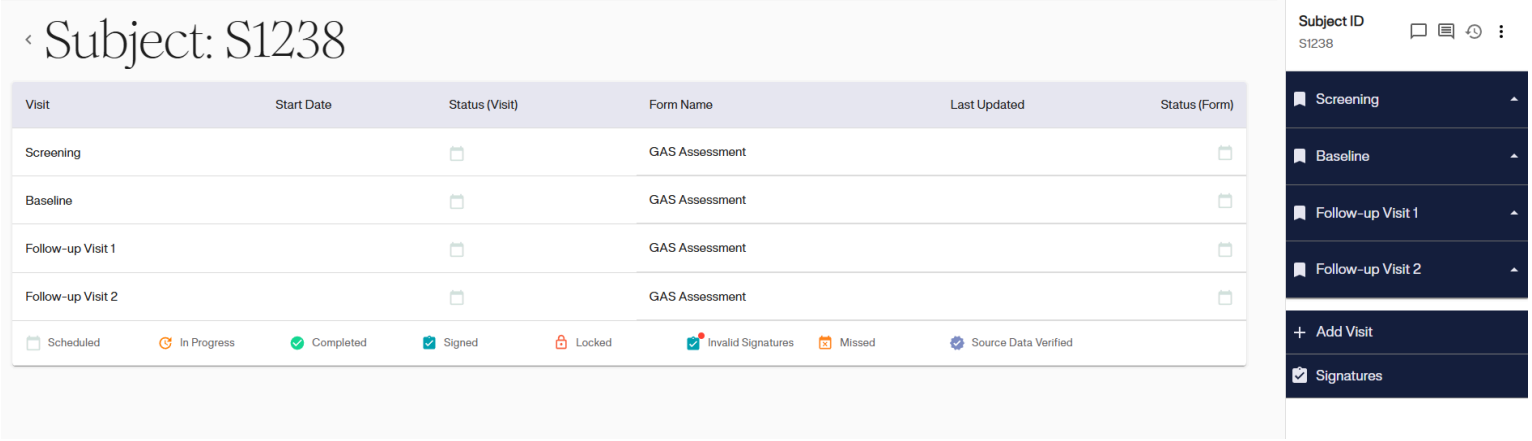
To access the Baseline Visit page, click on the visit labeled “Baseline.”



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

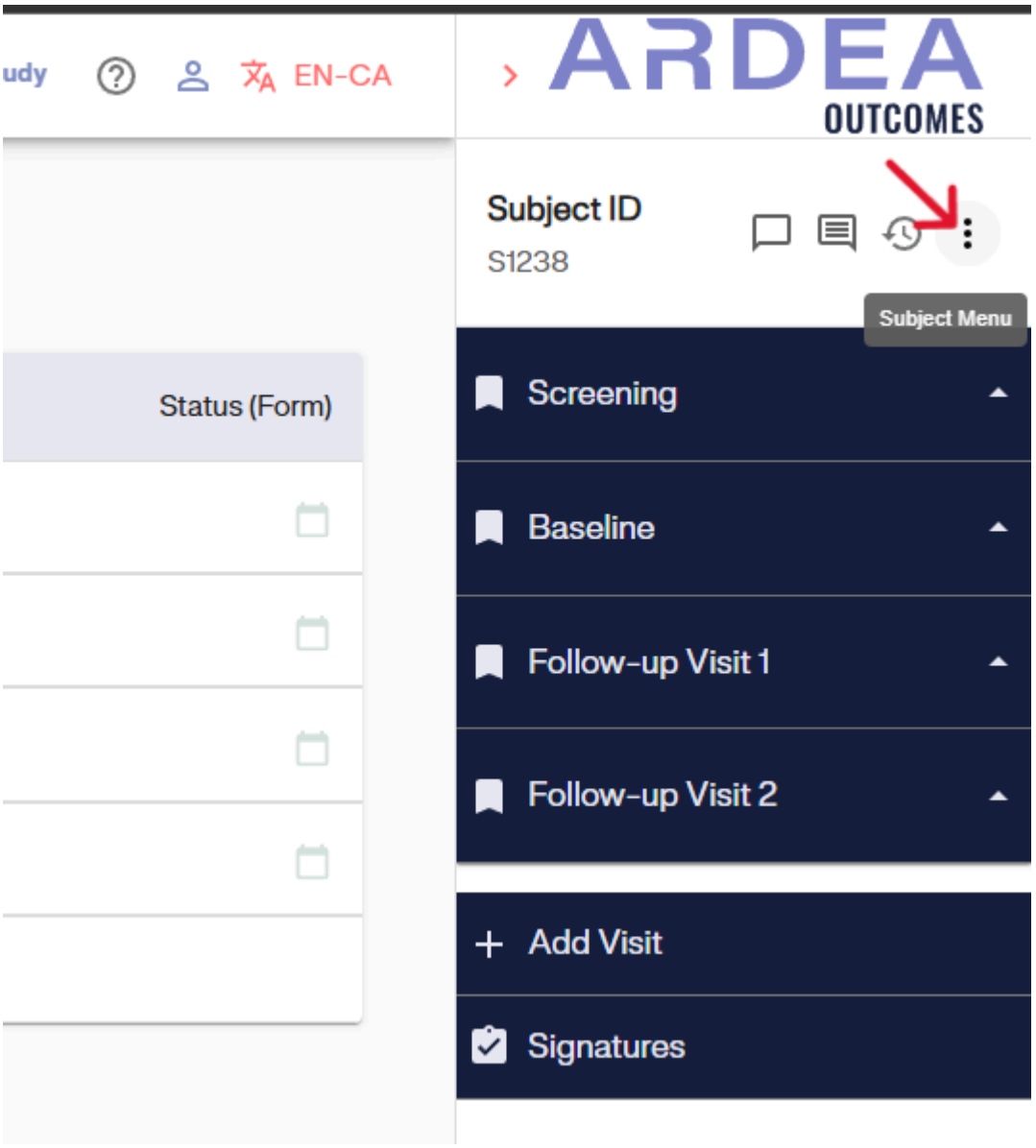
Follow-up Visits

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.

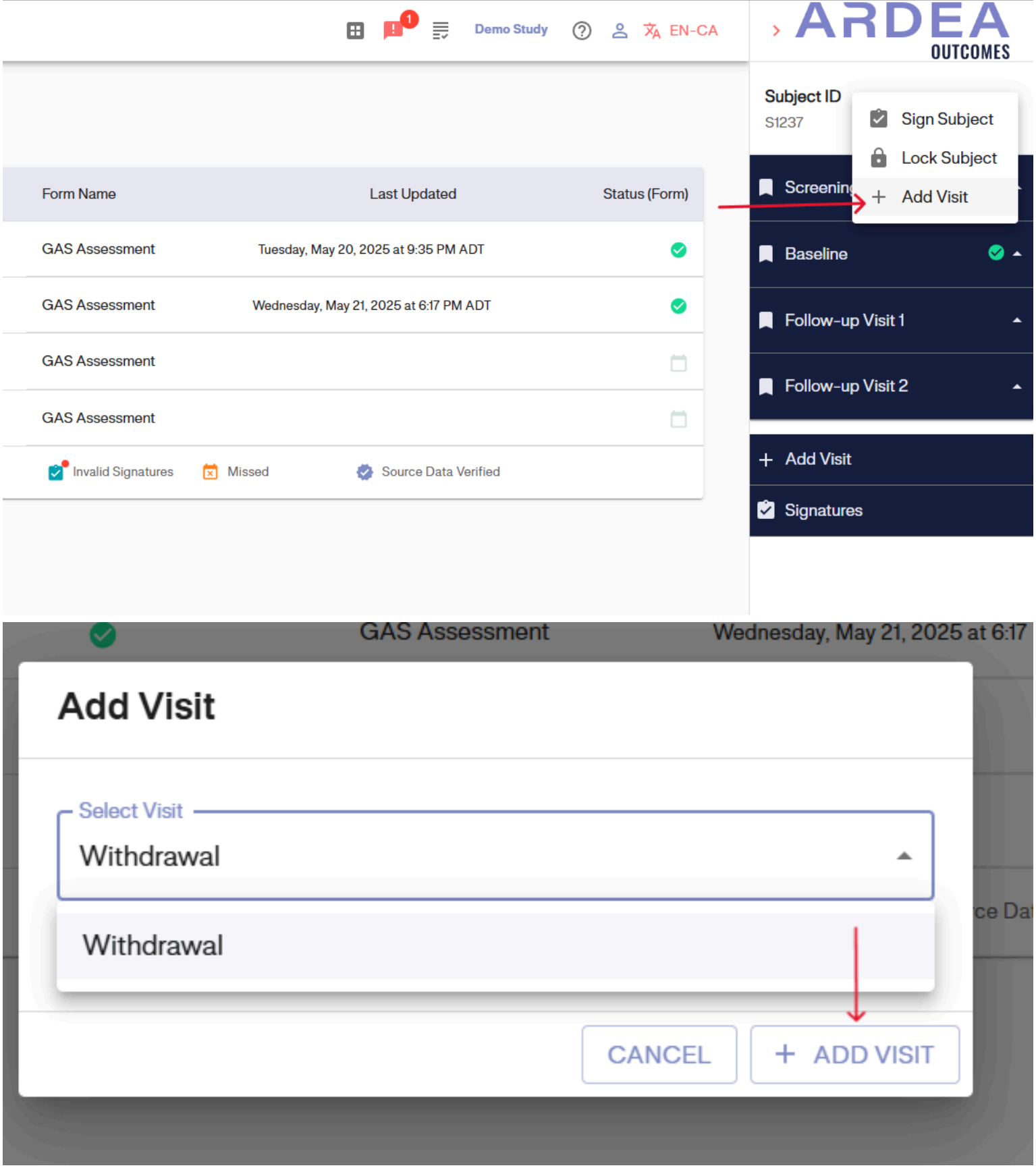


Unscheduled Visits

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'.



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.

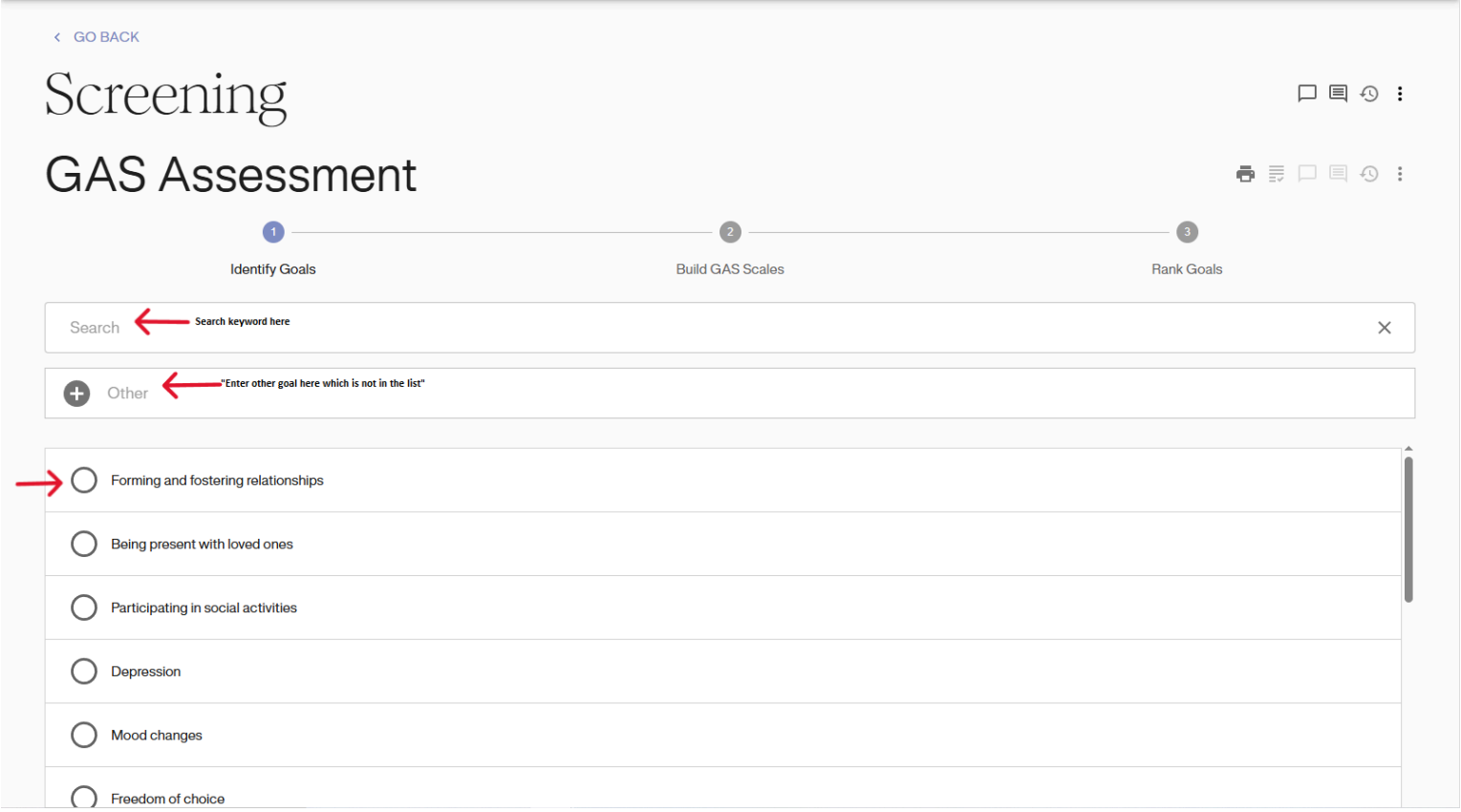
Data collection for studies with Separate Screening and Baseline Visit

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.

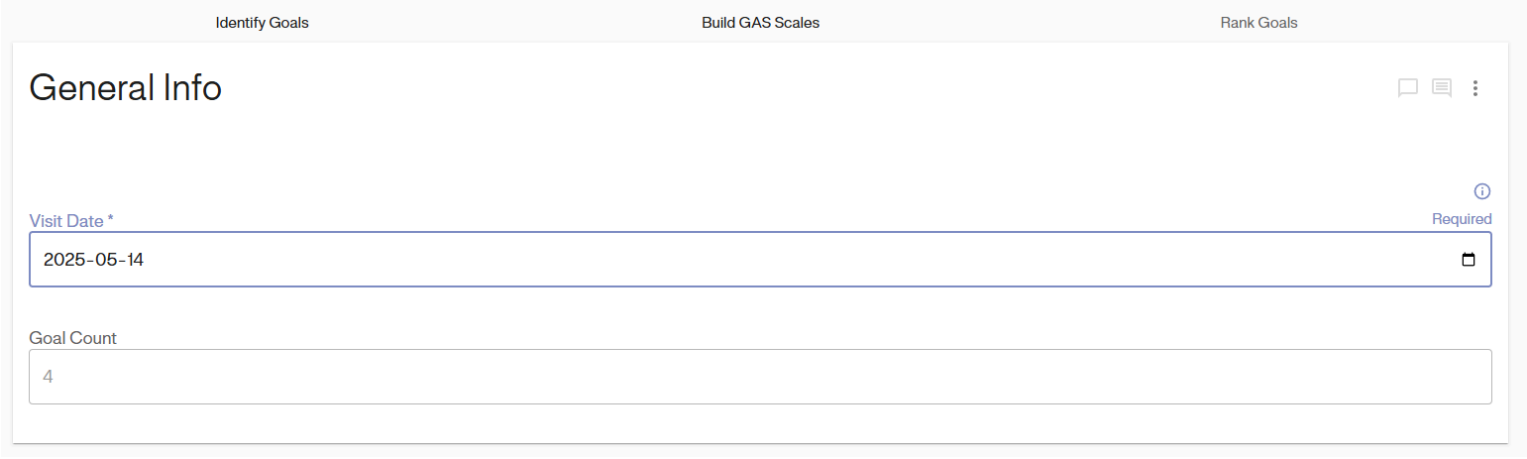
Note: Not all studies include a goal inventory therefore you may only be required to add a custom goal.



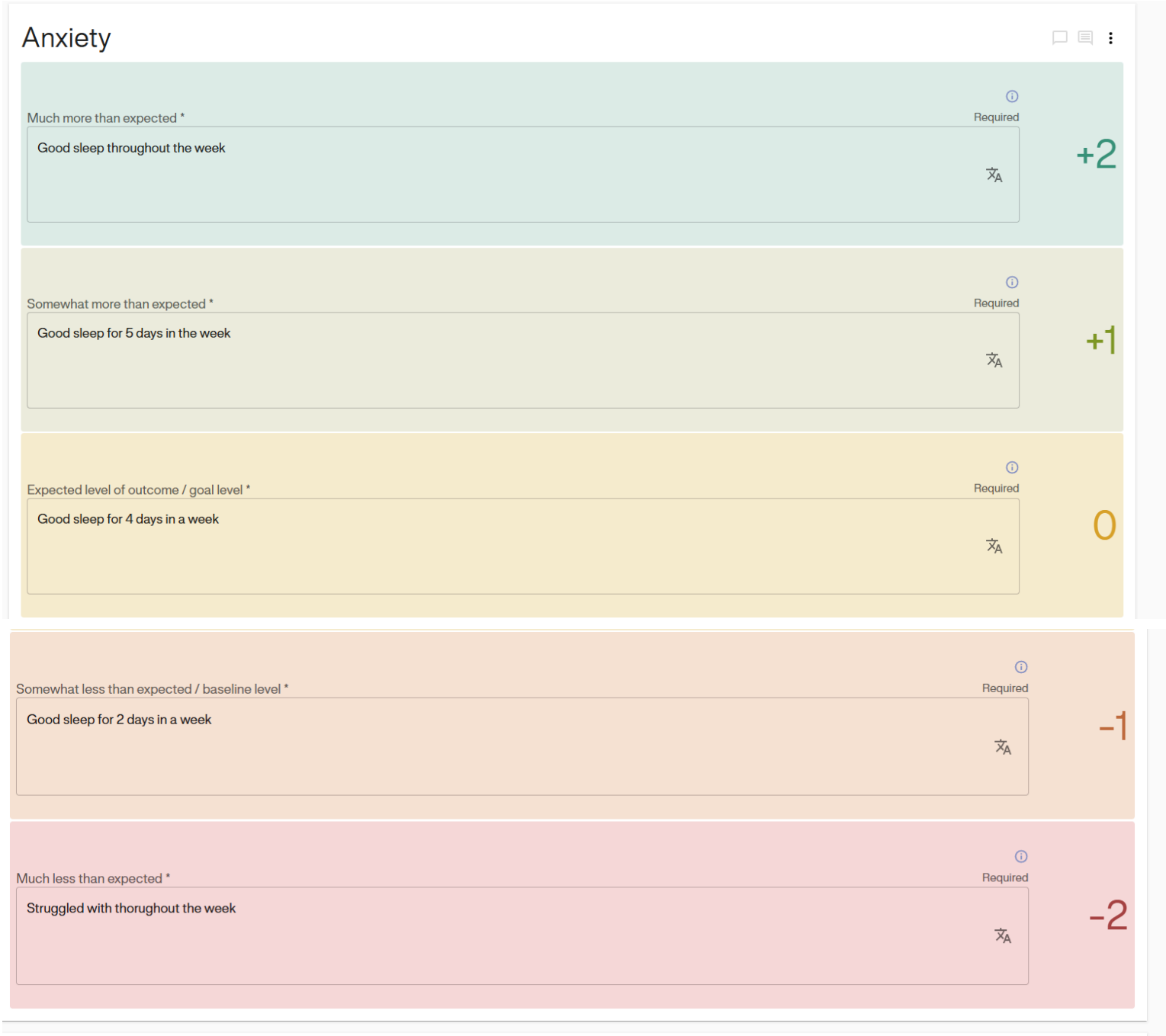
Once the goals are identified, click on Next to move to next step.

Build GAS Scales

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.

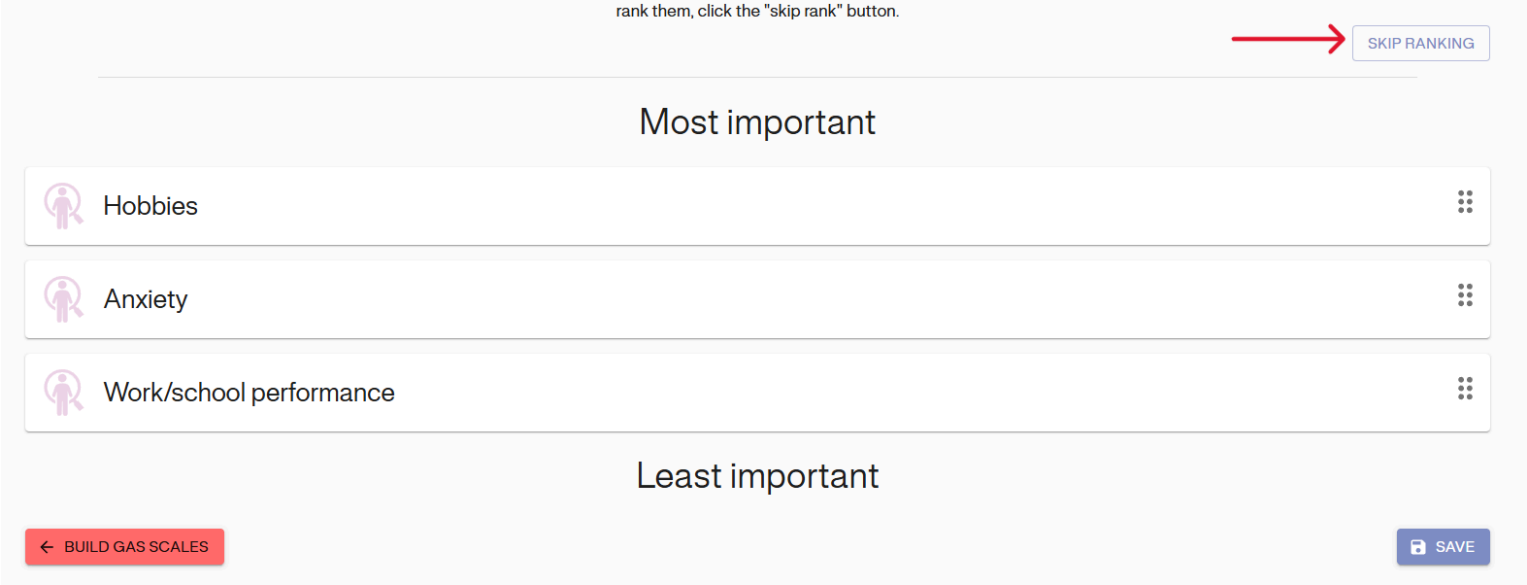


Next, enter the attainment level descriptions in the goal scale for each of the identified goals as shown in the image below. Repeat this process for all the goals selected.

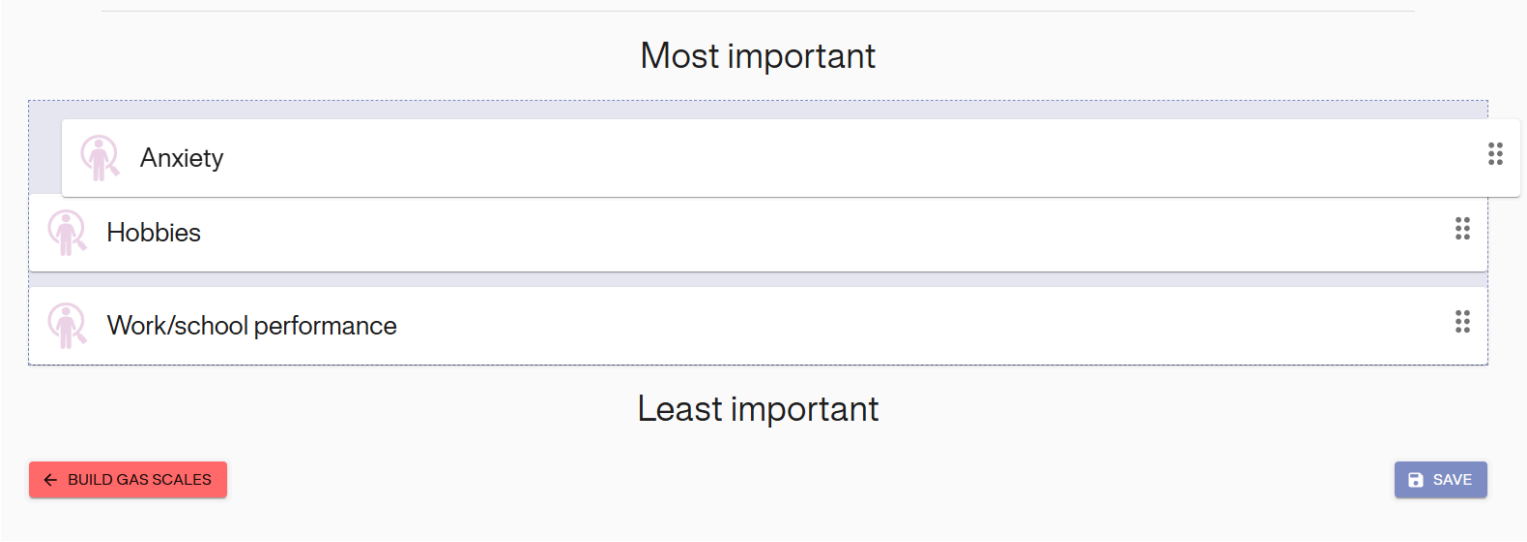


Rank Goals (Optional - Study Dependent)

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



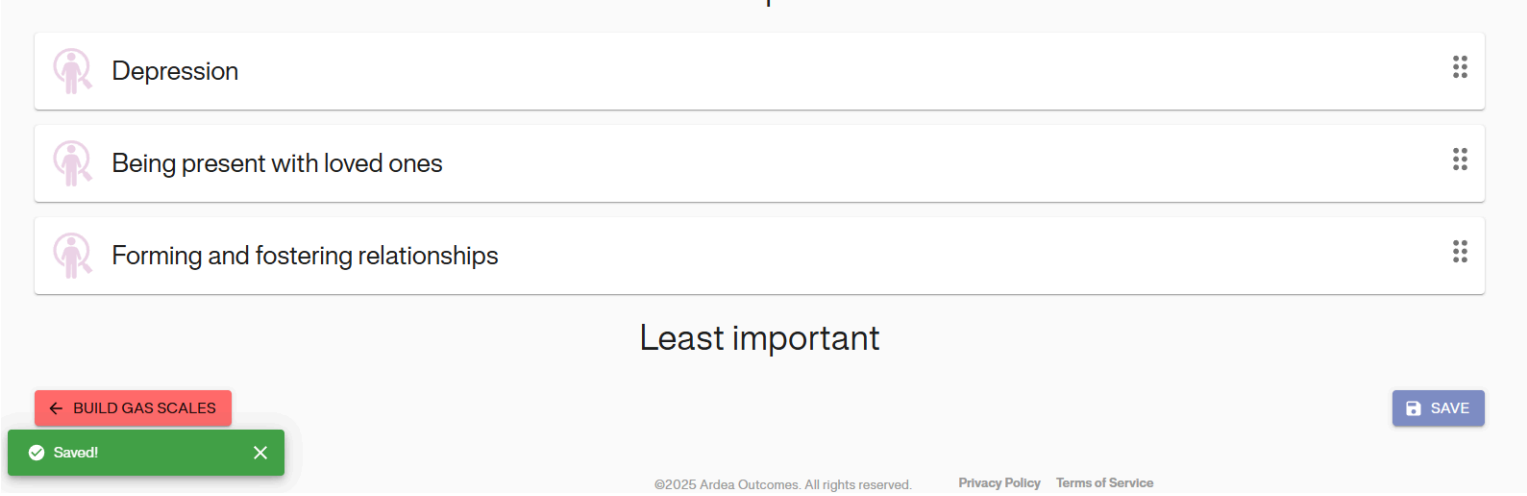
Enter the ranks by dragging and dropping each goal to sort them from Most Important (top) to Least Important (bottom).



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 show below):

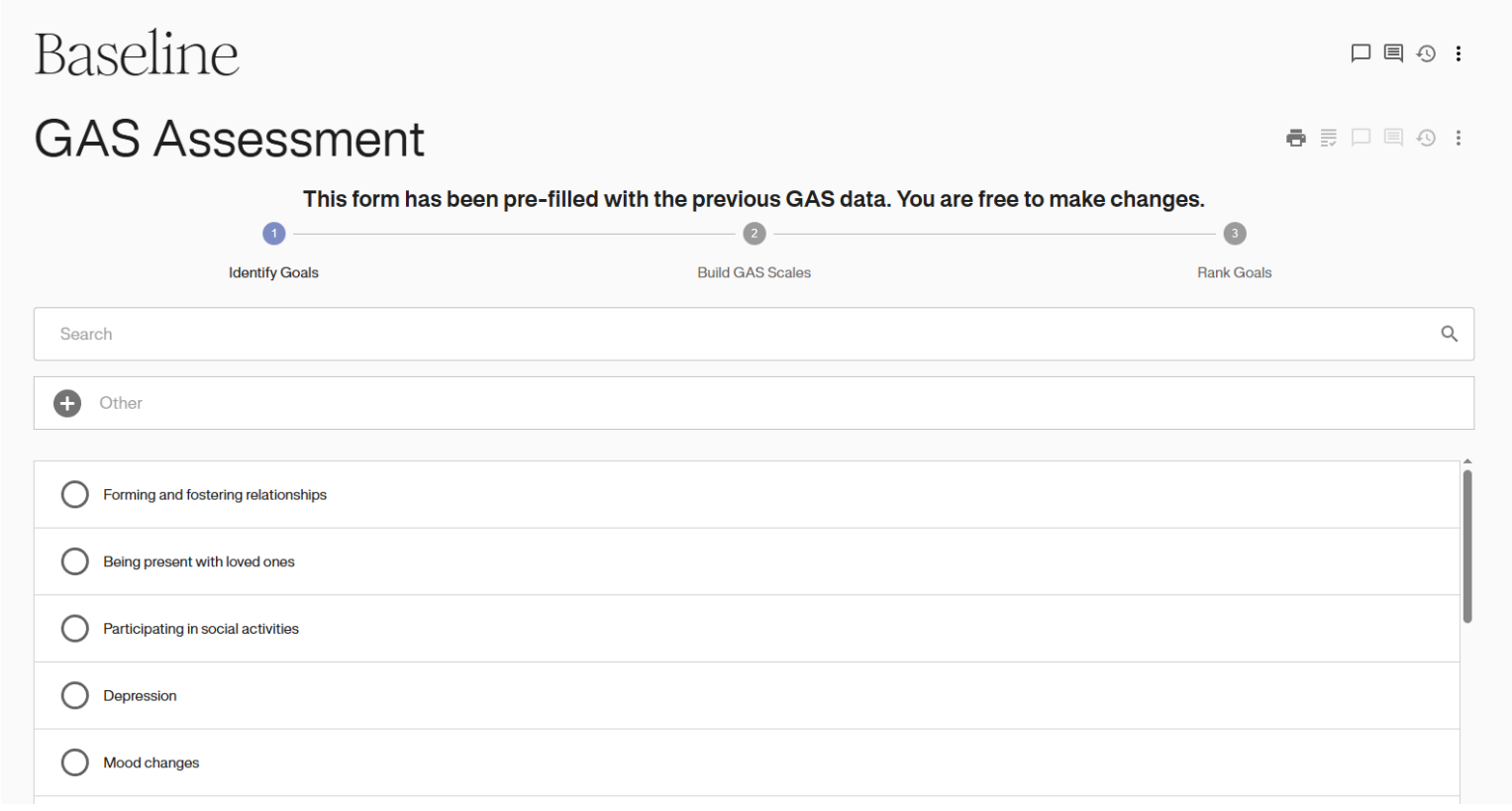


If you have another form to fill out at the visit, navigate to the form in the study menu and follow the same instructions for entering data and saving the form.

BASELINE VISIT

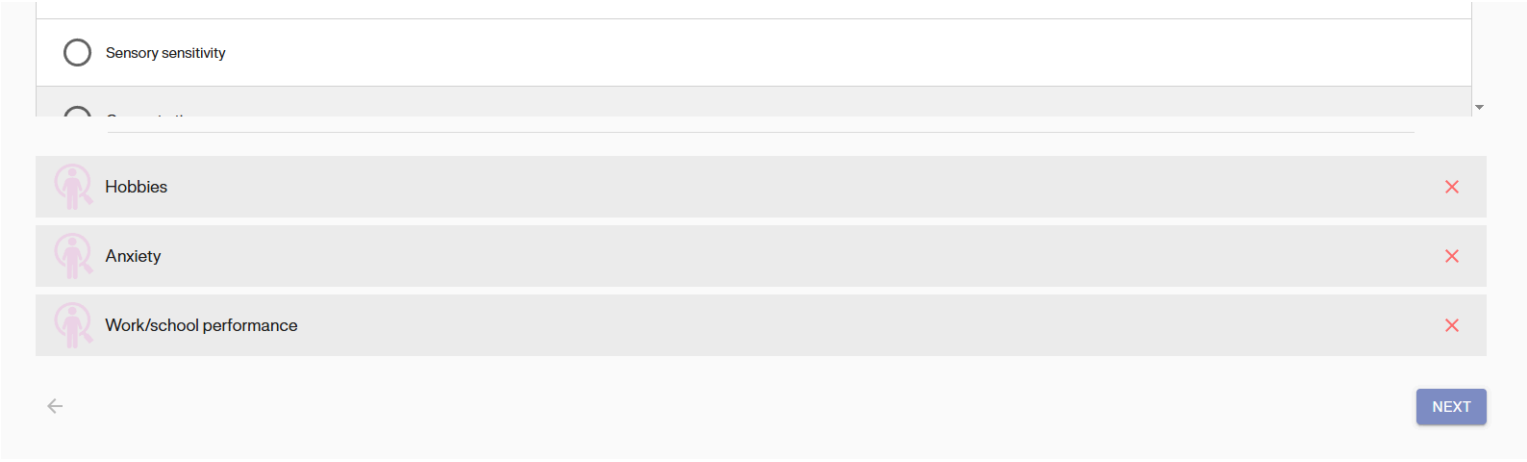
To begin, navigate to the study menu and select the Baseline visit. Then, click on the Start Baseline form.

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.



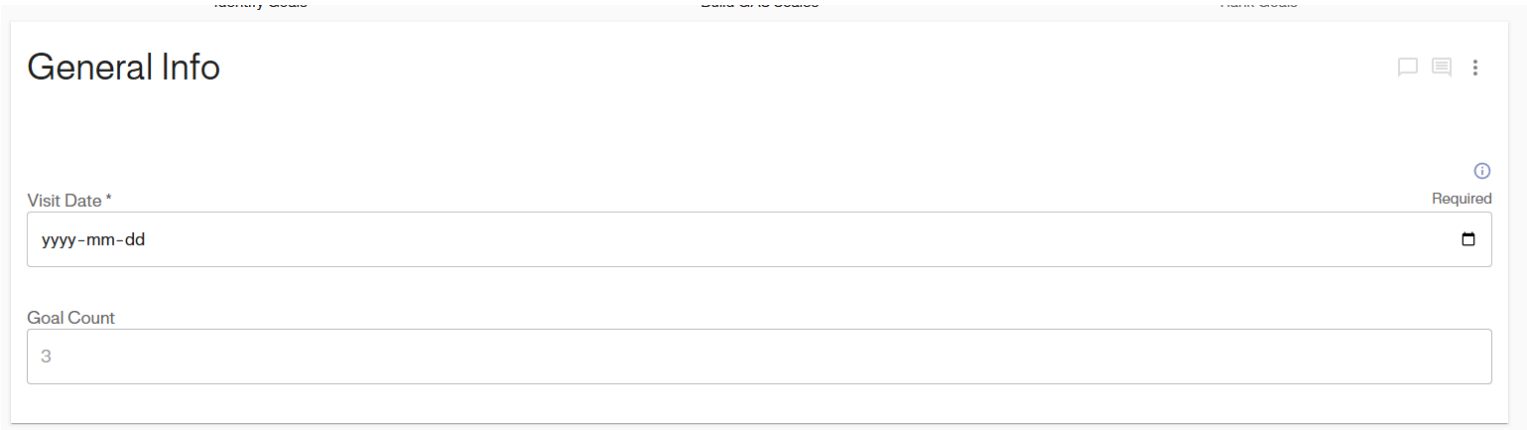
Identify Goals

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.

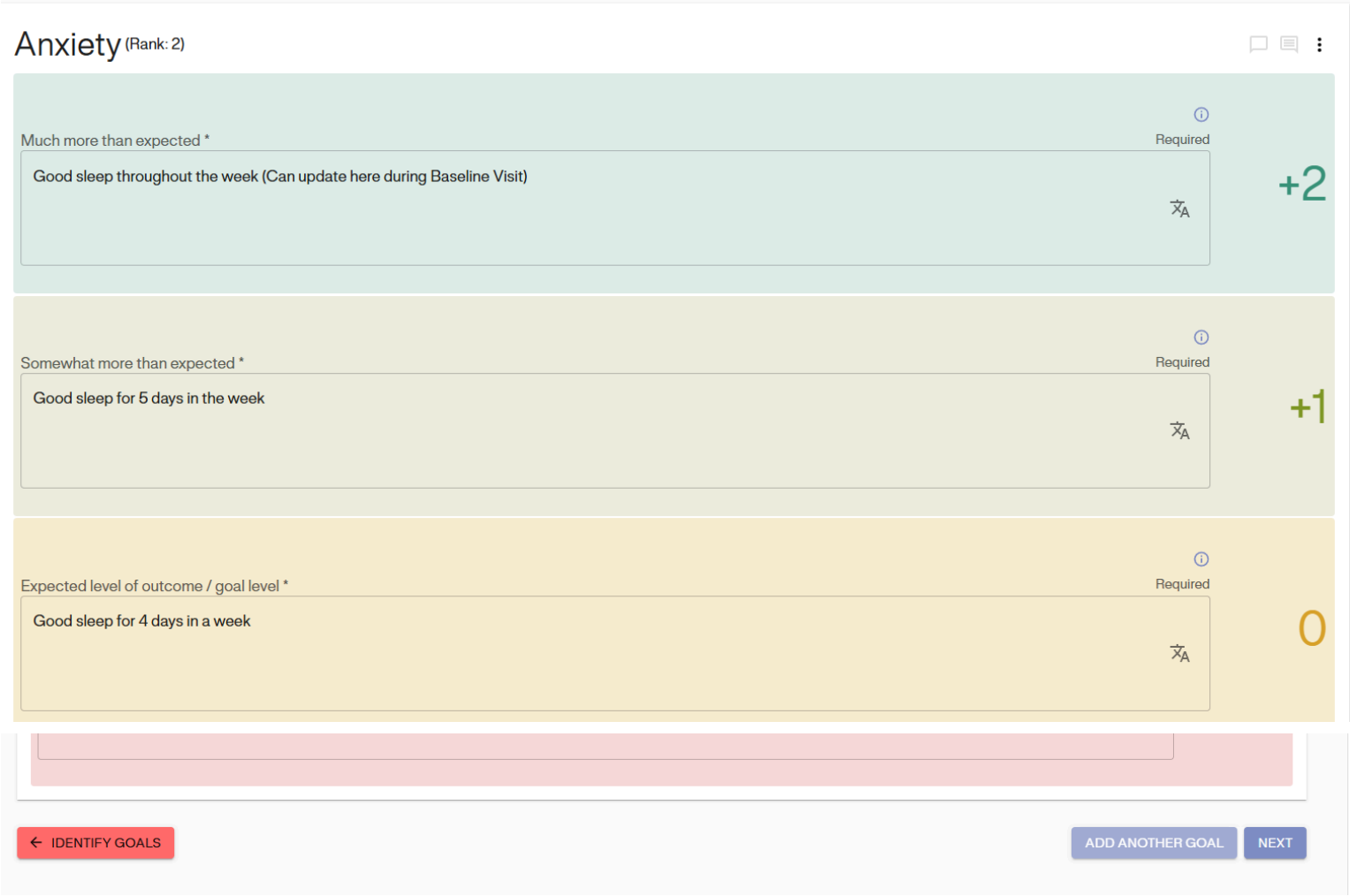


Build GAS Scales

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.

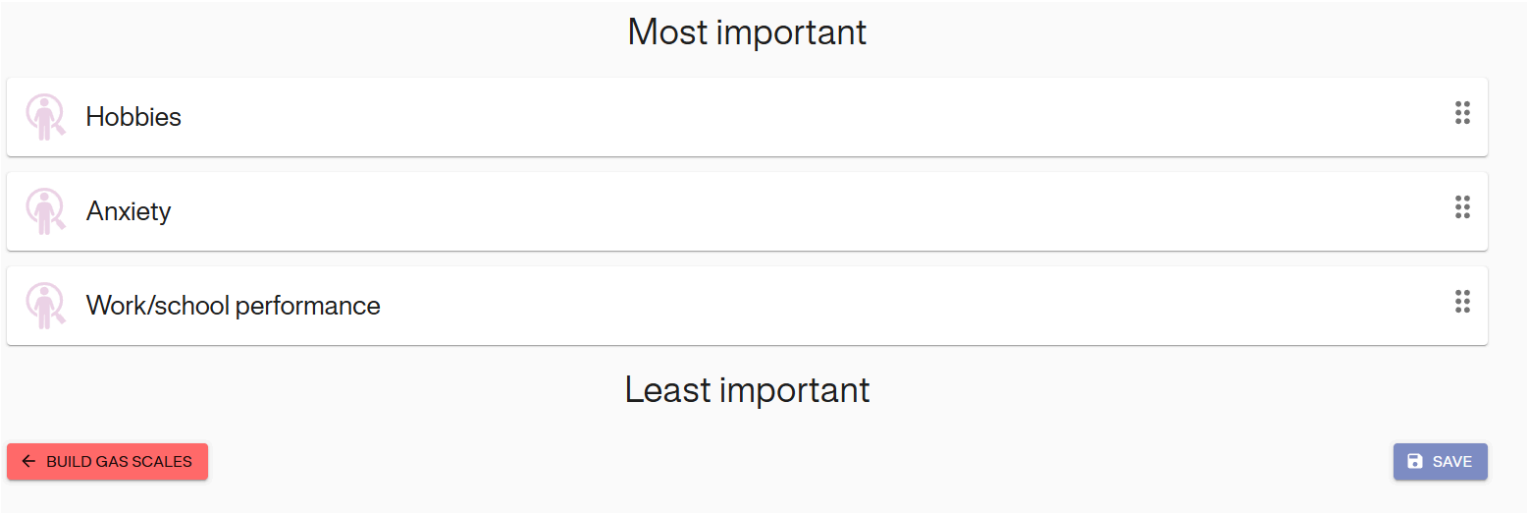


First, scroll down to find the goal scales and the pre-filled attainment levels. Review these items, and if necessary, you can make modifications during the baseline visit as well. Ensure you complete the data entry for any newly added goals during this visit. Once you have finished all the goal scales,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



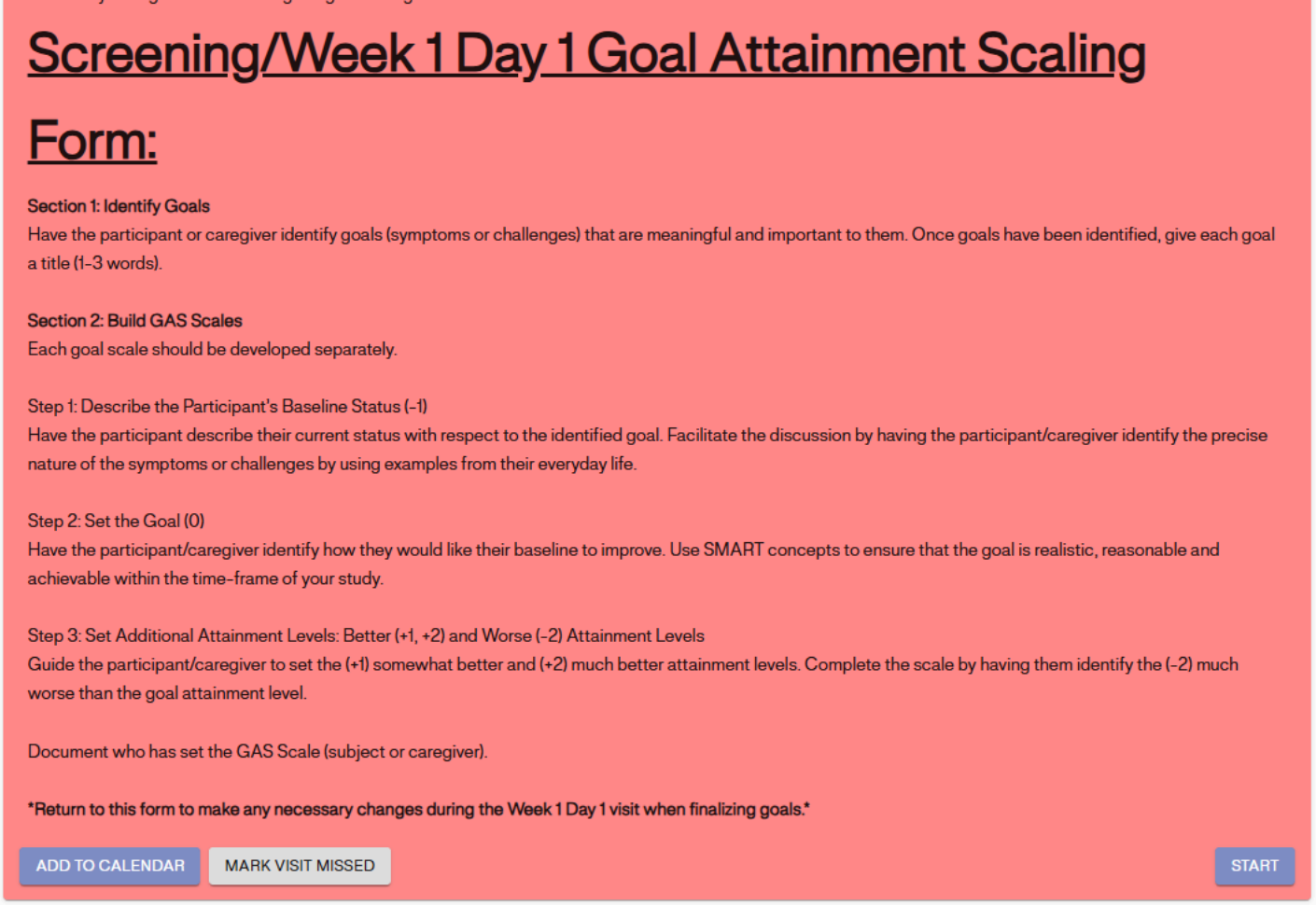
Rank Goals

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.



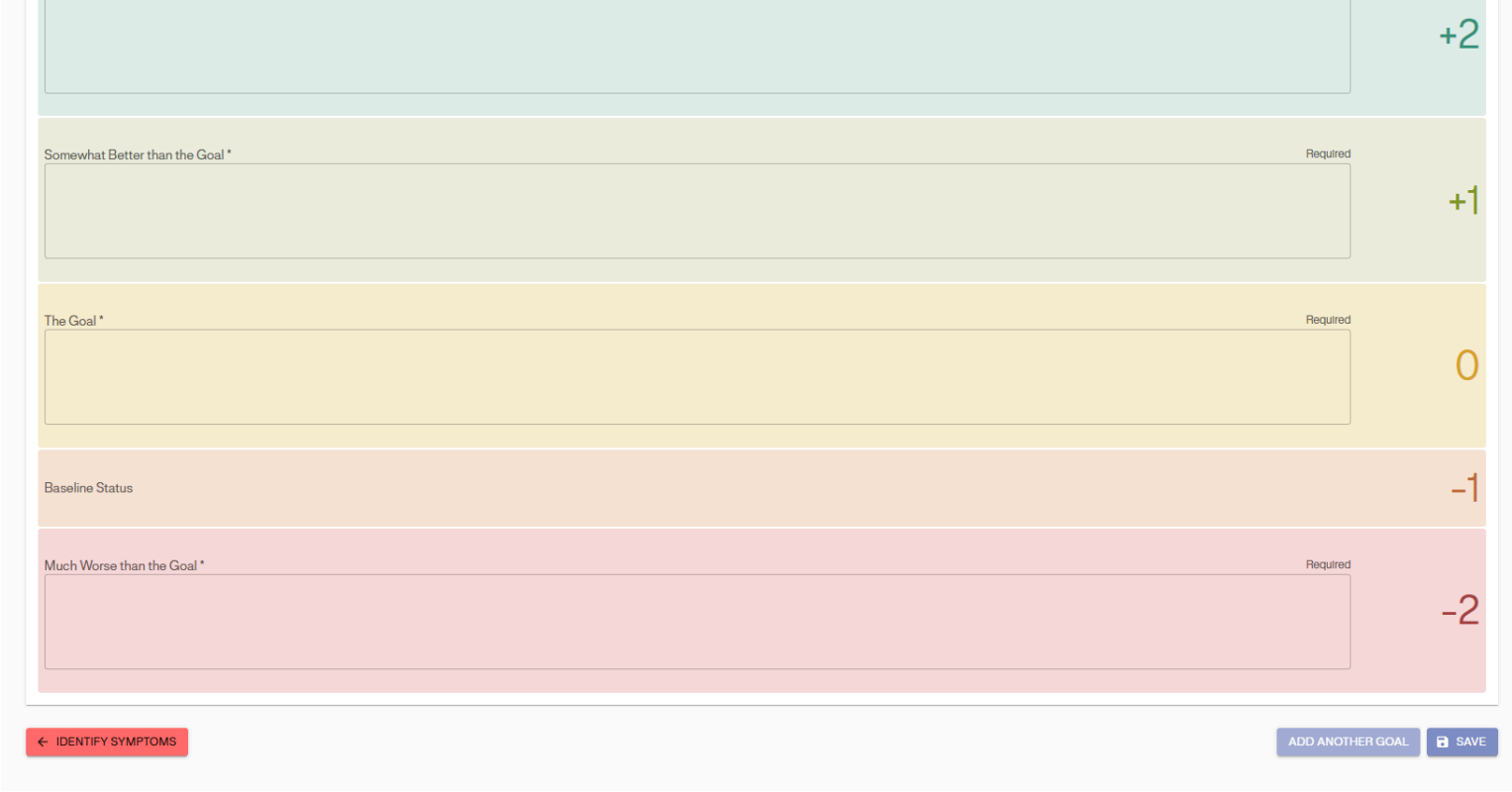
Data collection for studies with a combined Screening/ Baseline visit.

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.



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.

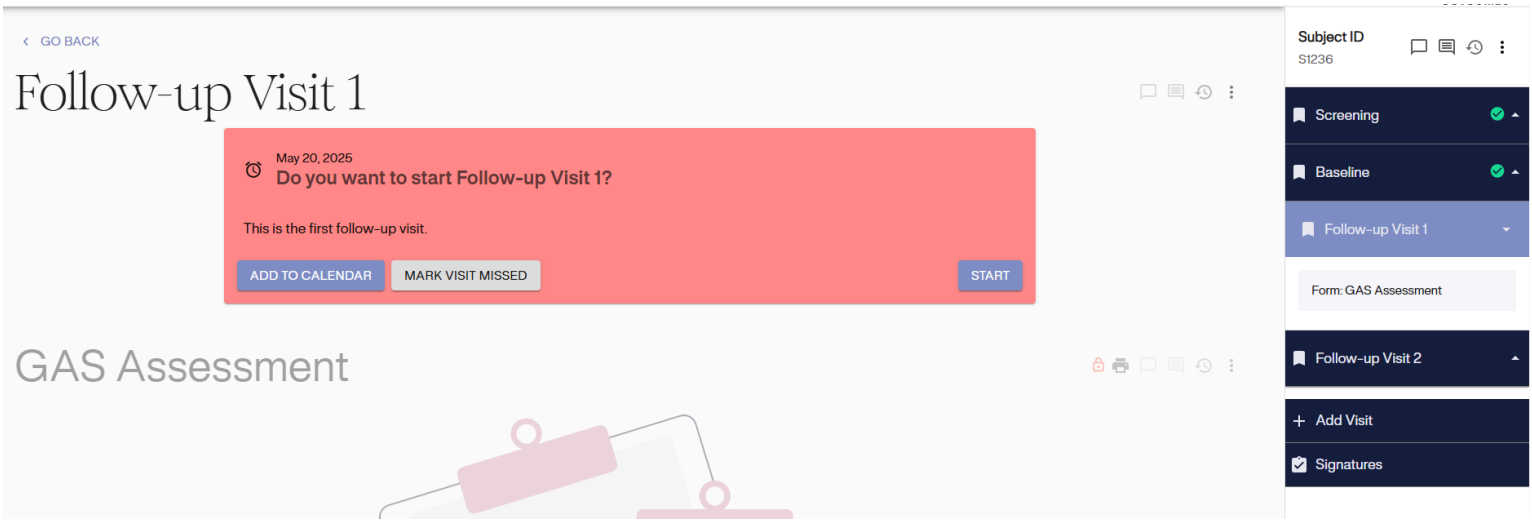
Note: The data collected in Baseline form and the text fields may appear differently based on the configuration of study.



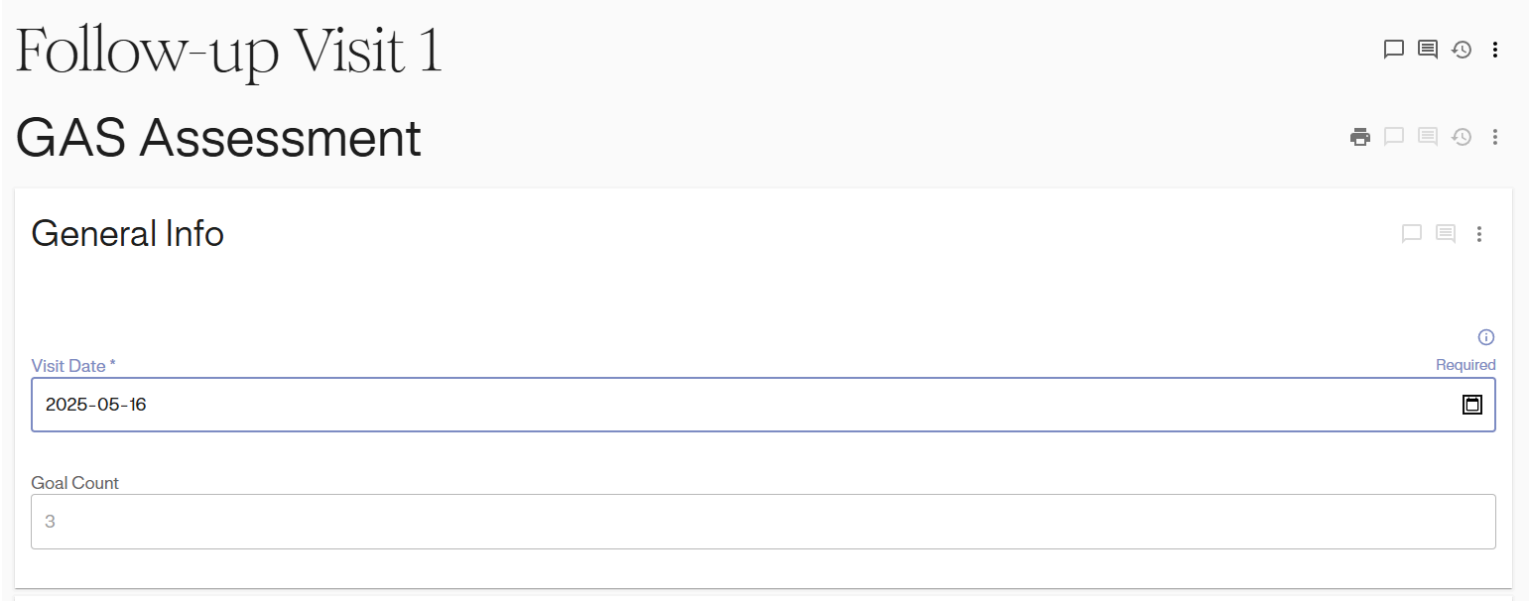
Follow-up Visits

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.



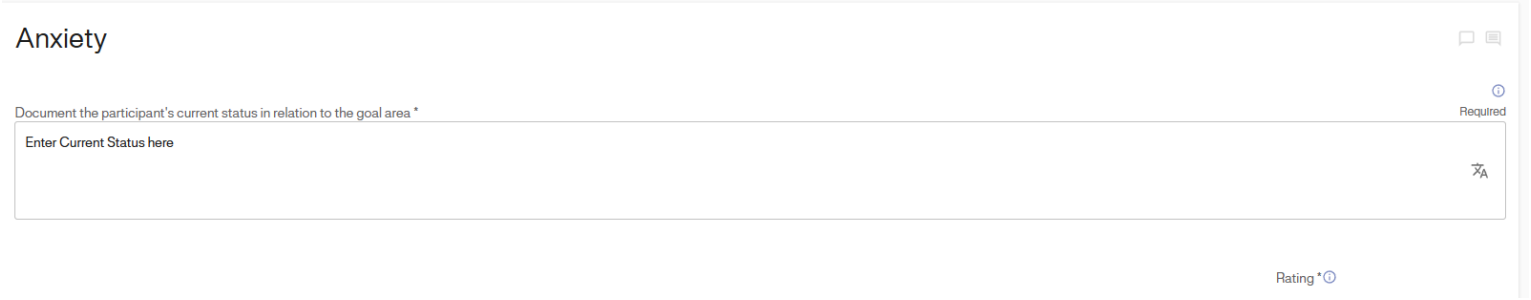
Enter the date of Follow-up Visit.



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.



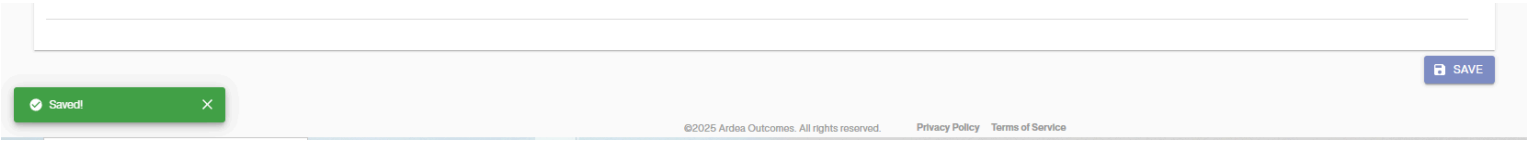
SUBJECT AND GAS INTERVIEWER RATING

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.)

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.

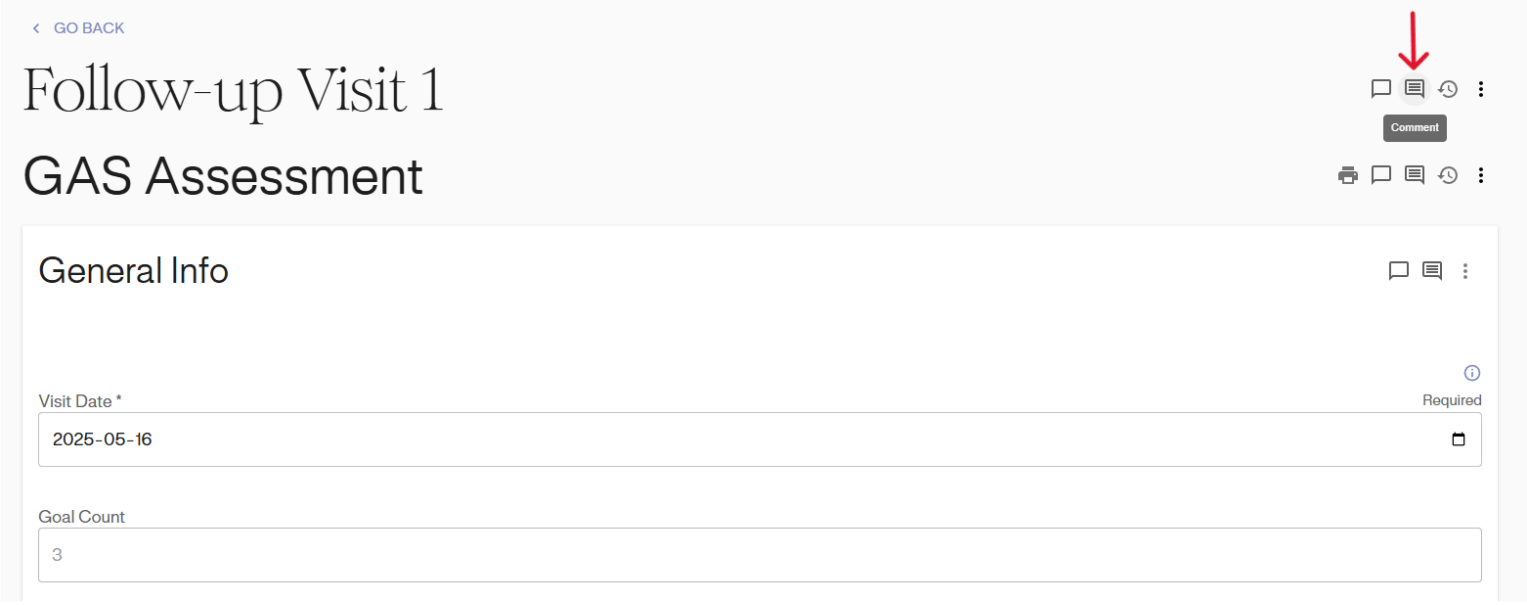


IN THIS CHAPTER

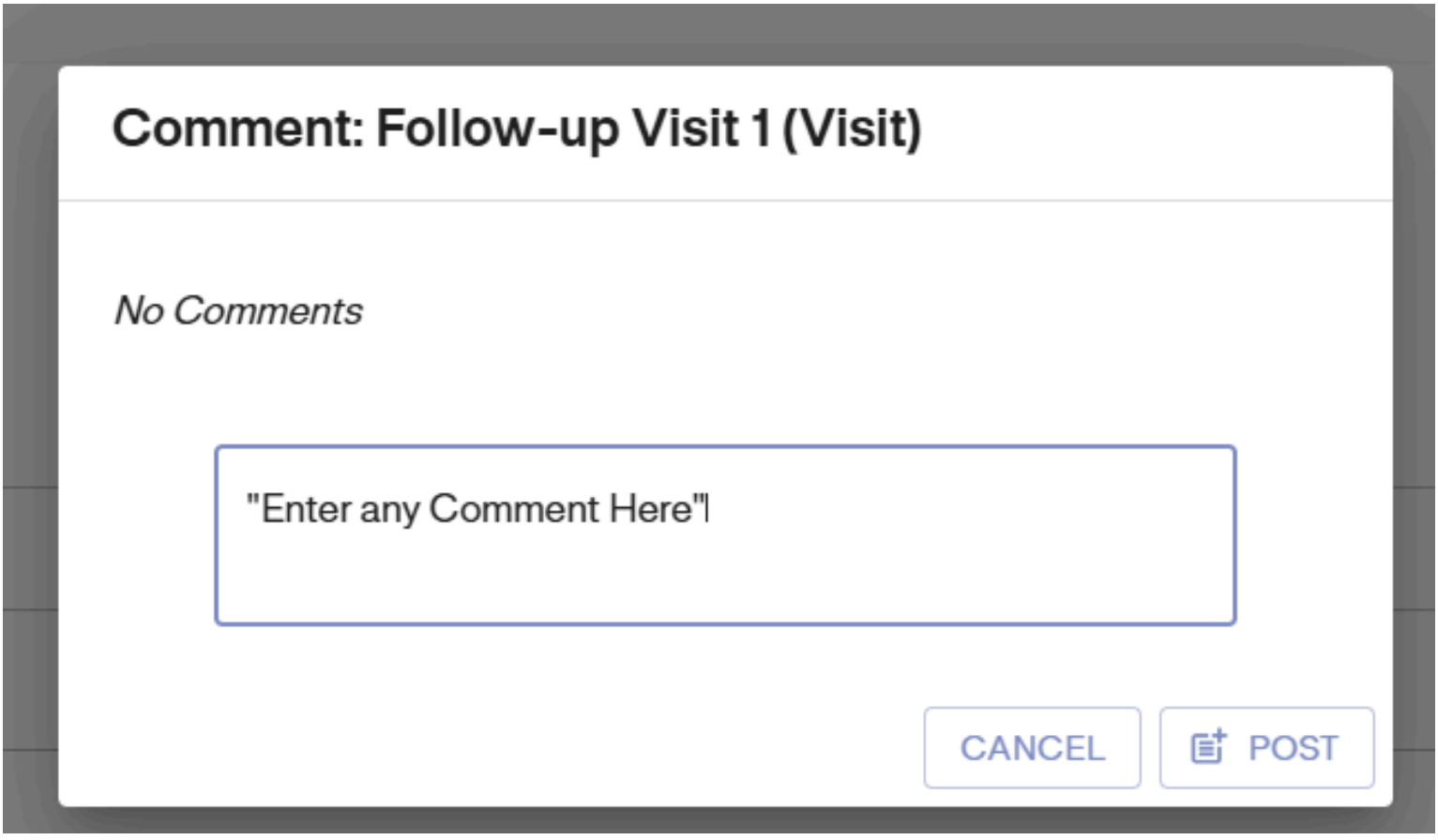
1 Comments

Comments

You can leave a comment by clicking the Comments icon.

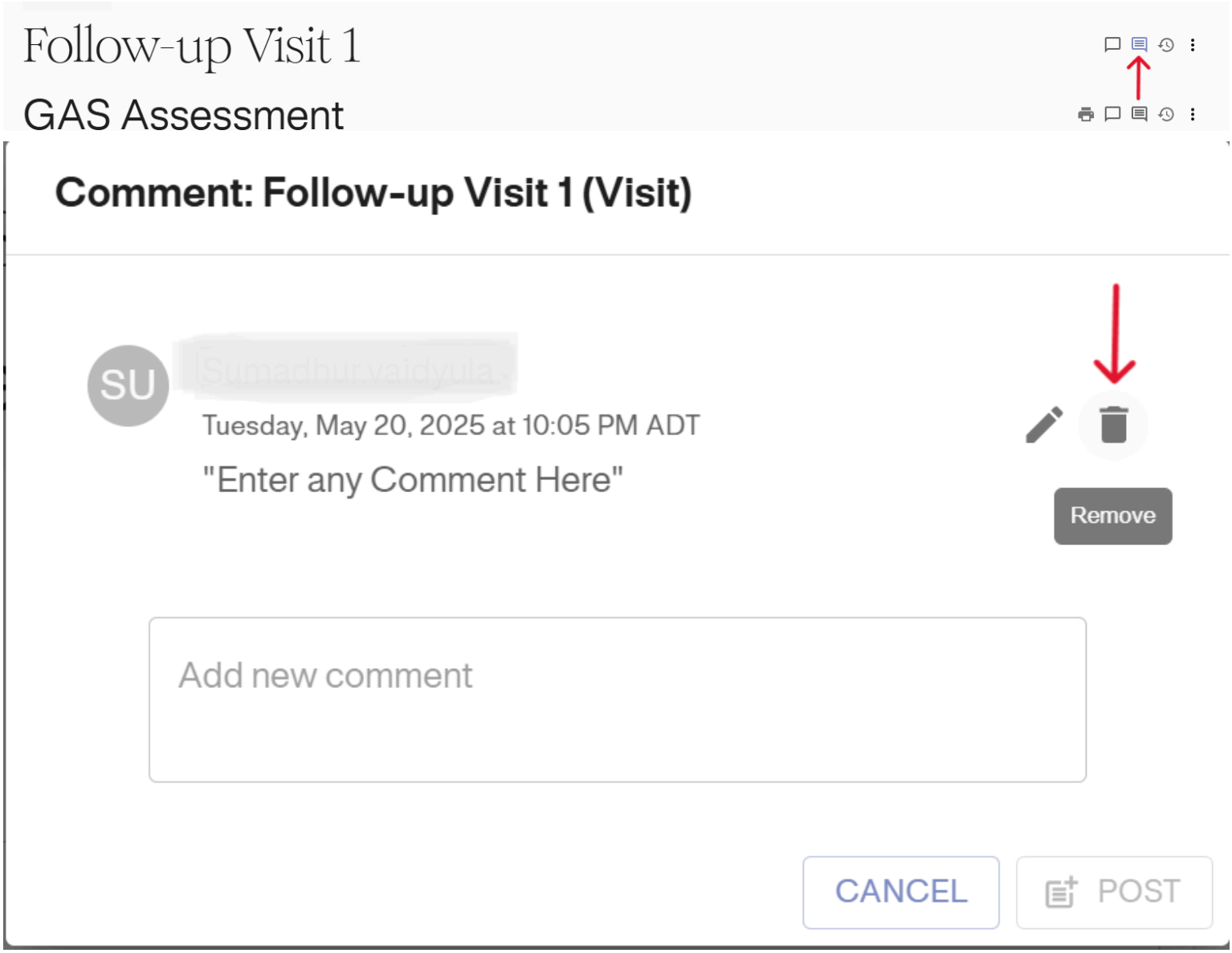


A pop up window will appear with a text box to enter comment.



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.

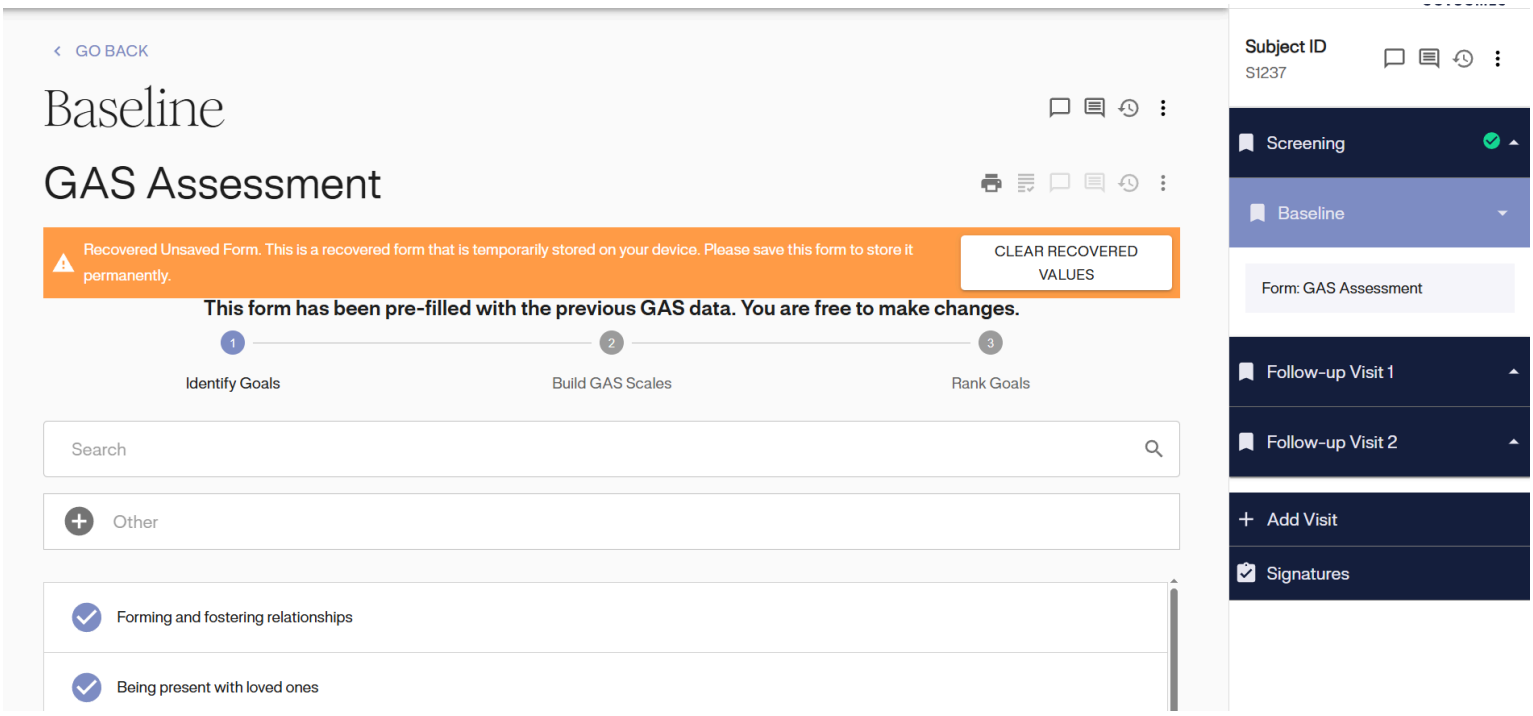


IN THIS CHAPTER

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.

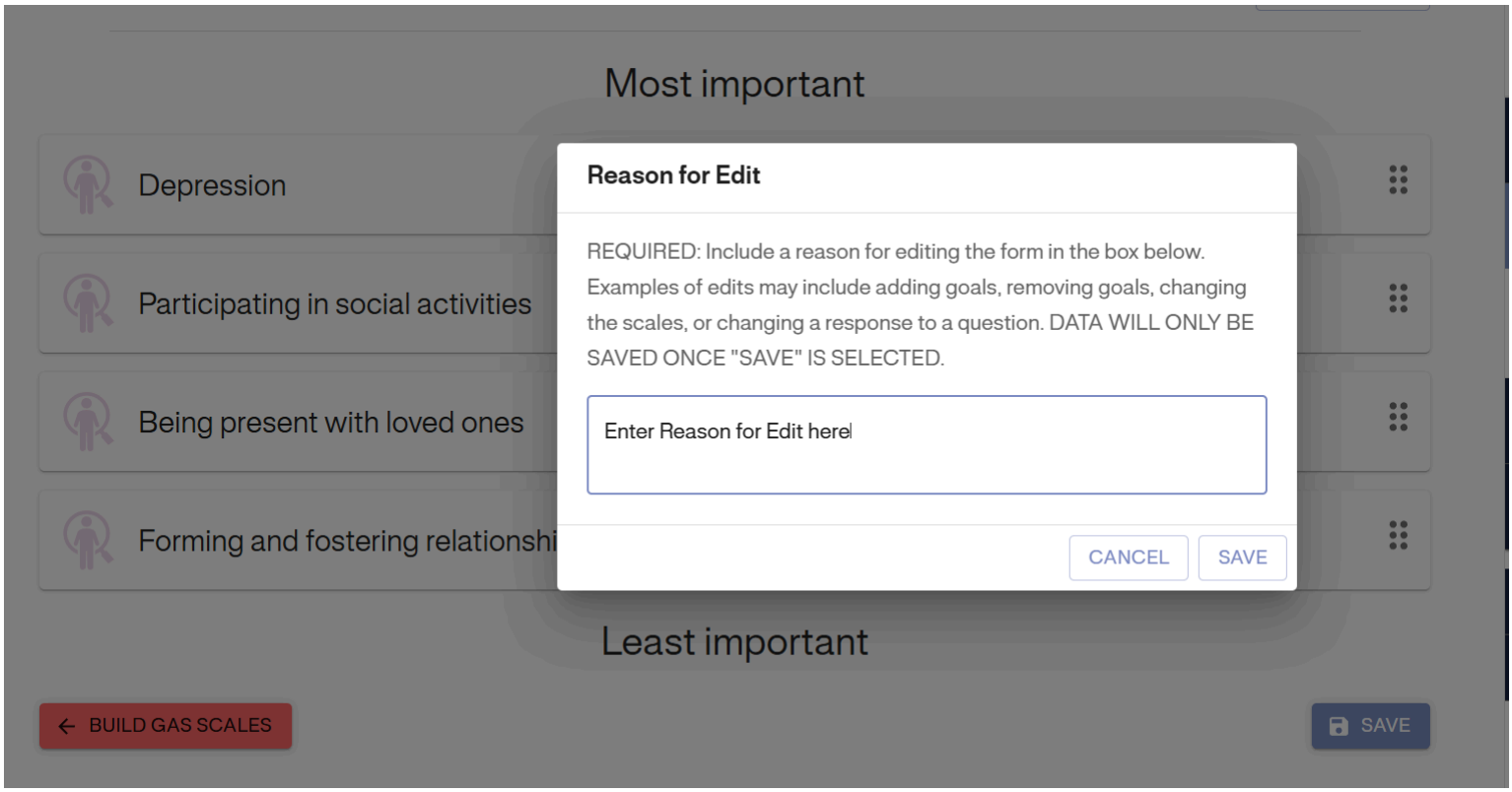


It is important to remember that data should only be changed in the following circumstances:

- 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.



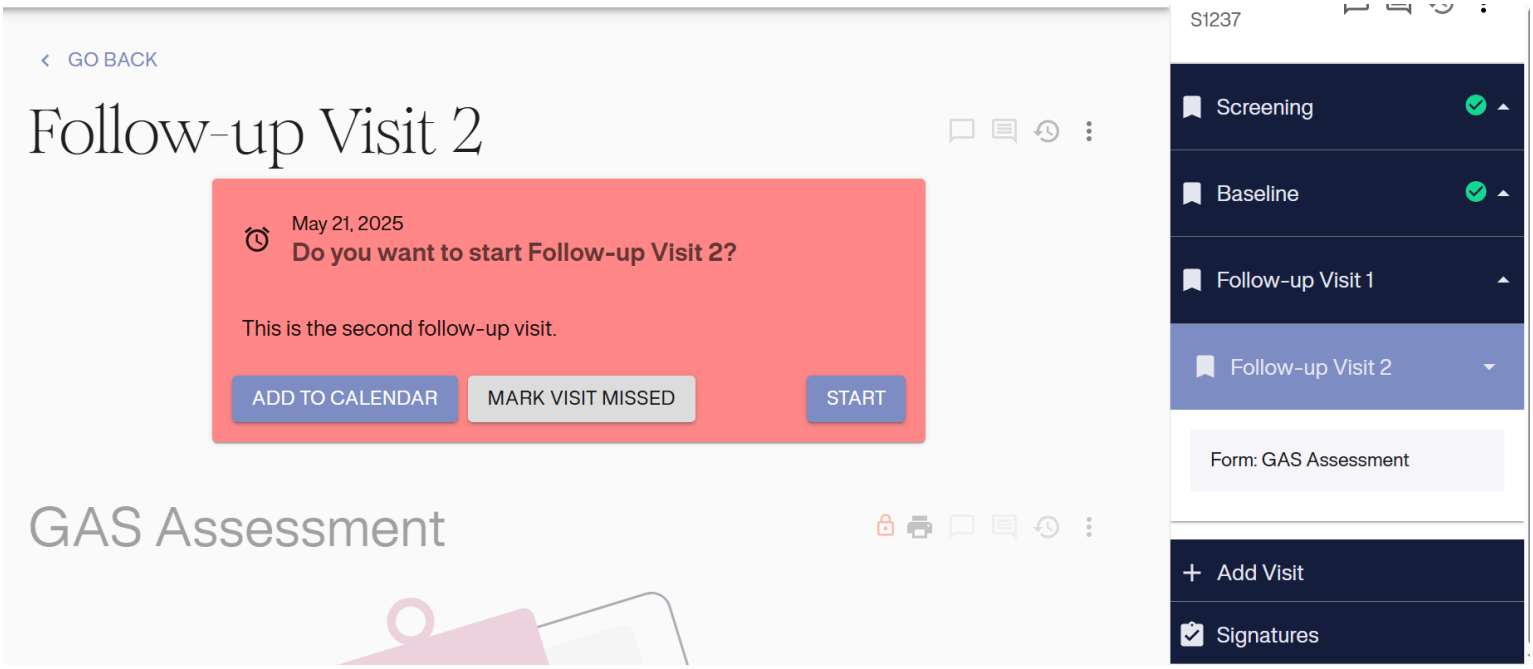
REMEMBER: Re-signing the data is required by all those responsible at their designated level each time changes are made. **Re-signing the data is required by all those responsible at their designated level each time changes are made.**

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 know).



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

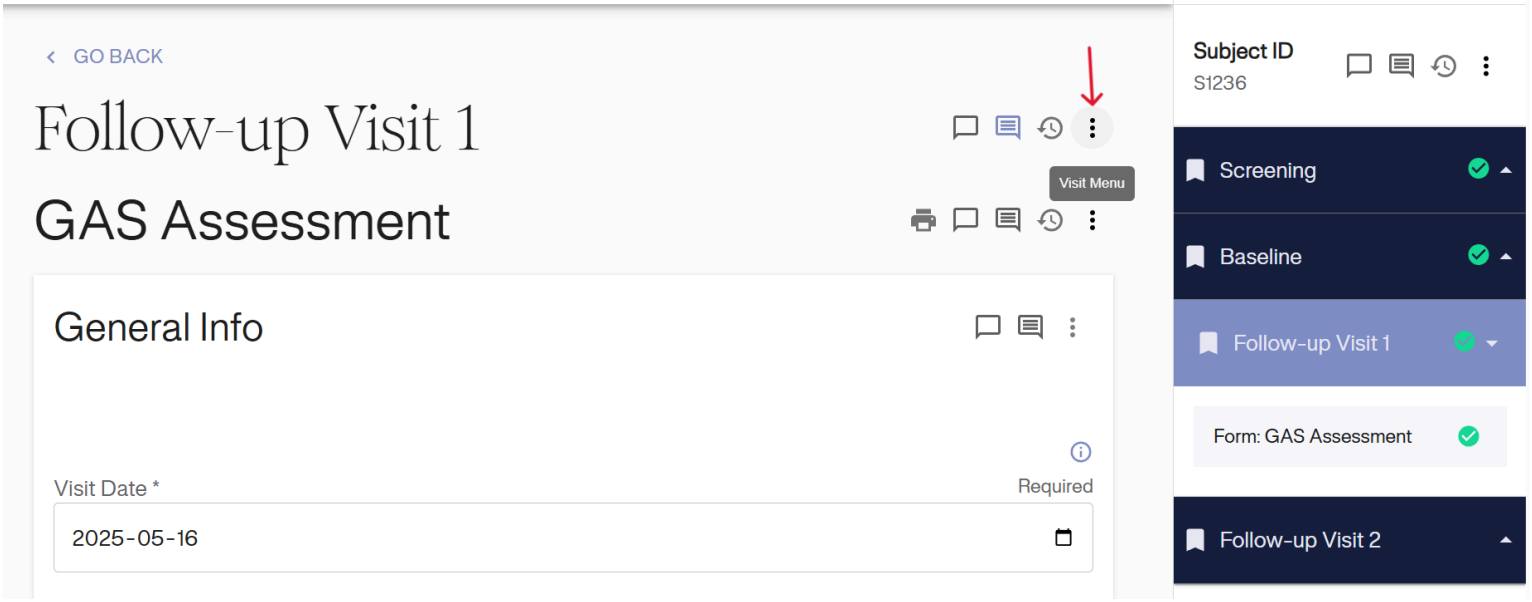
Add Signatures

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.

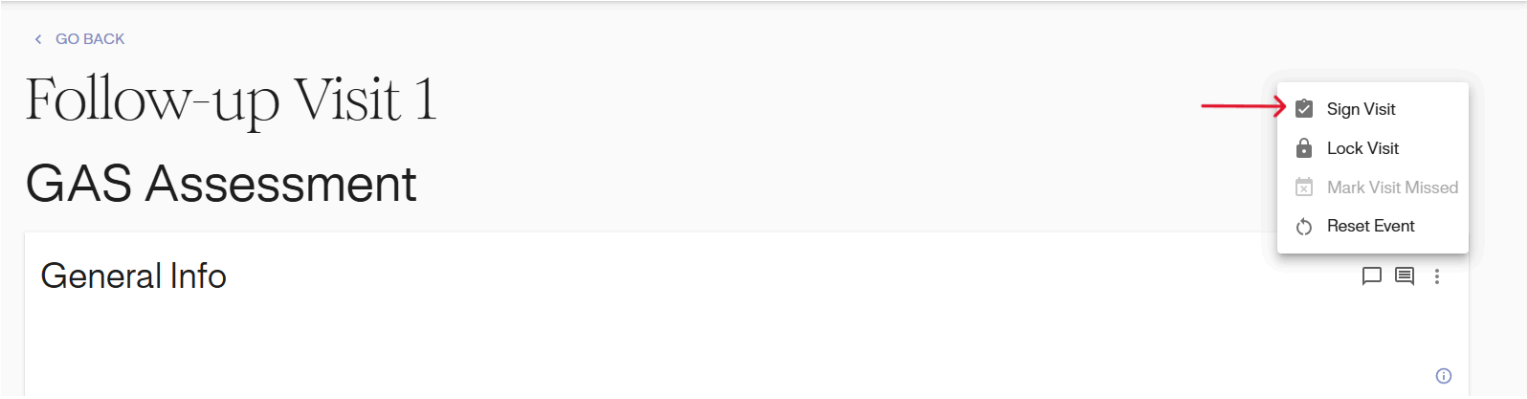


You may note that there are other similar icons present on the page. Those icons represent:

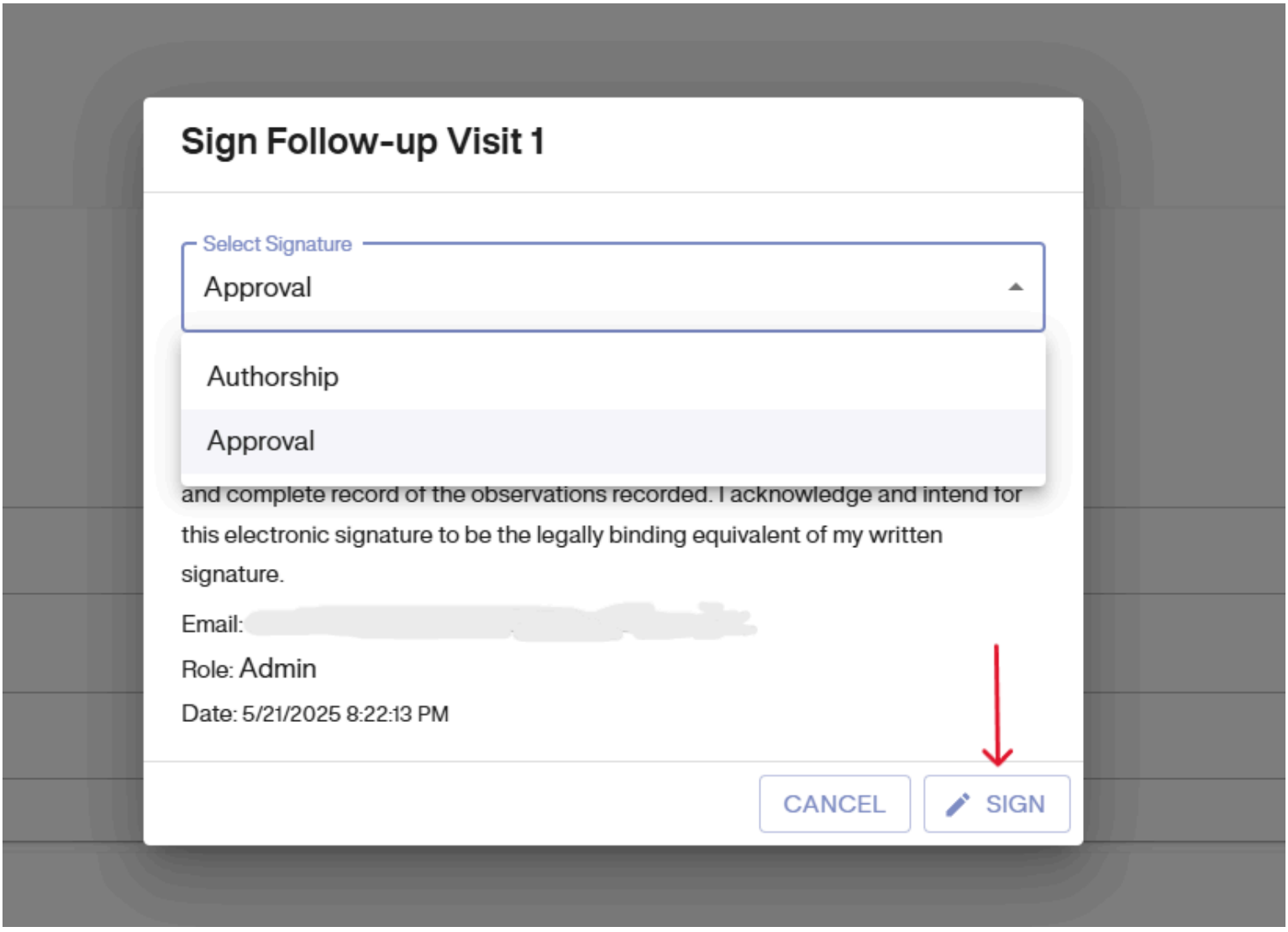
- Signatures at the form level (3 dots above the form visit signature)

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

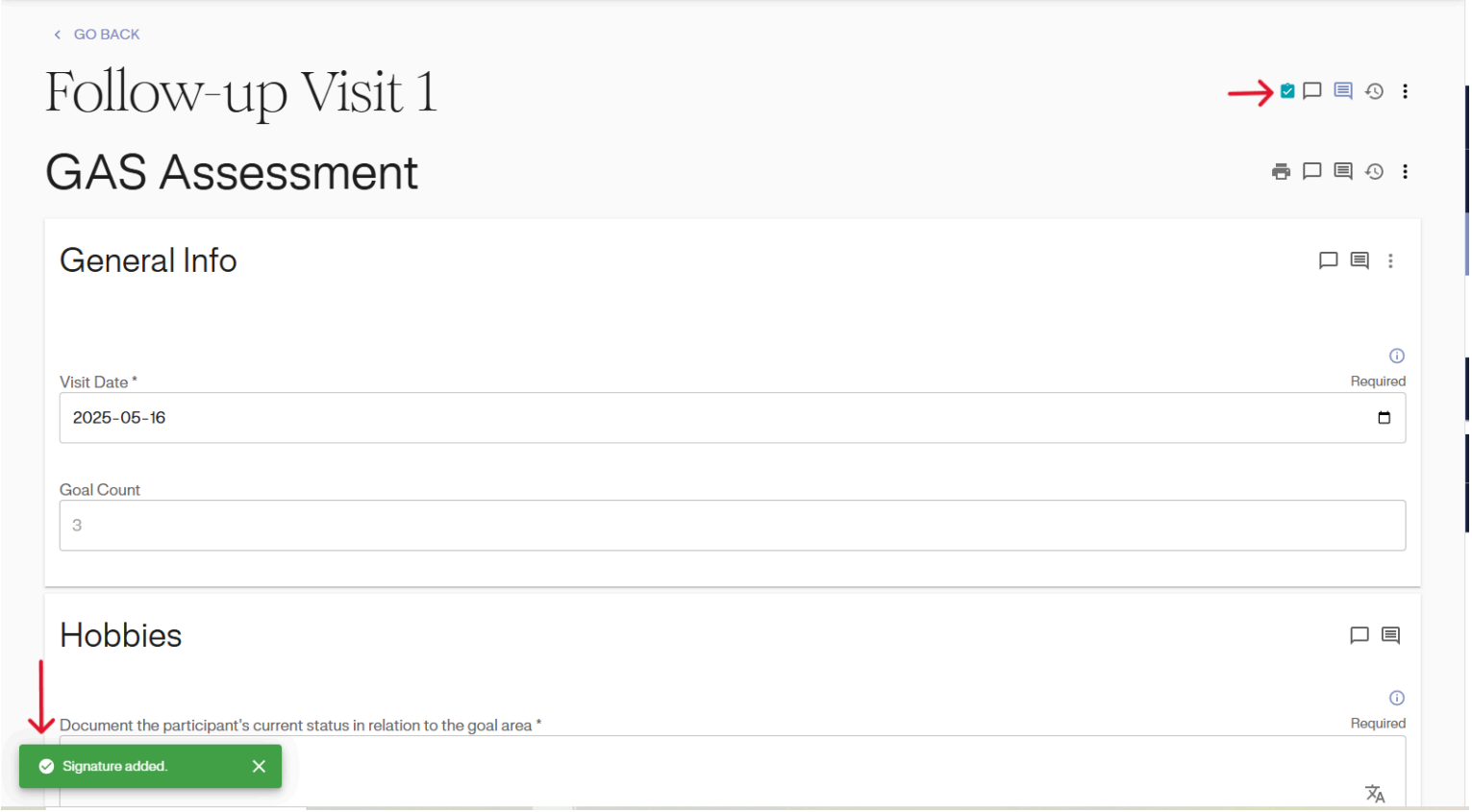
All signatures (form, visit, subject) can be done following the same format as outlined below.



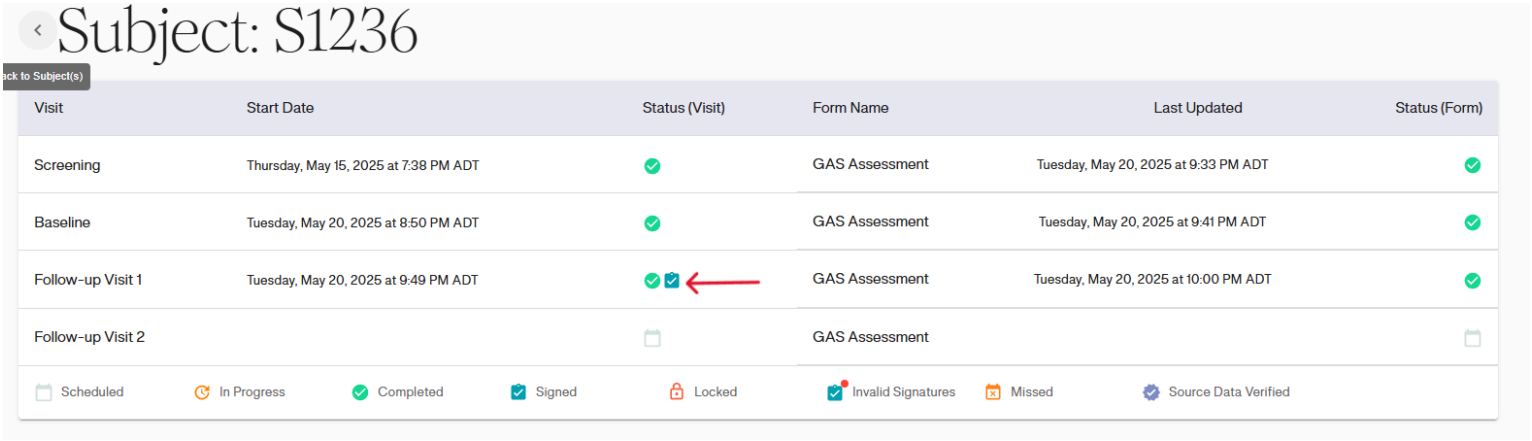
Once you click on 'sign visit', you will be required to re-enter your login information to verify your identity. Once authenticated, you will see a window to select the type of signature Authorship or Approval. Select the relevant option and then click on "Sign" button.



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.



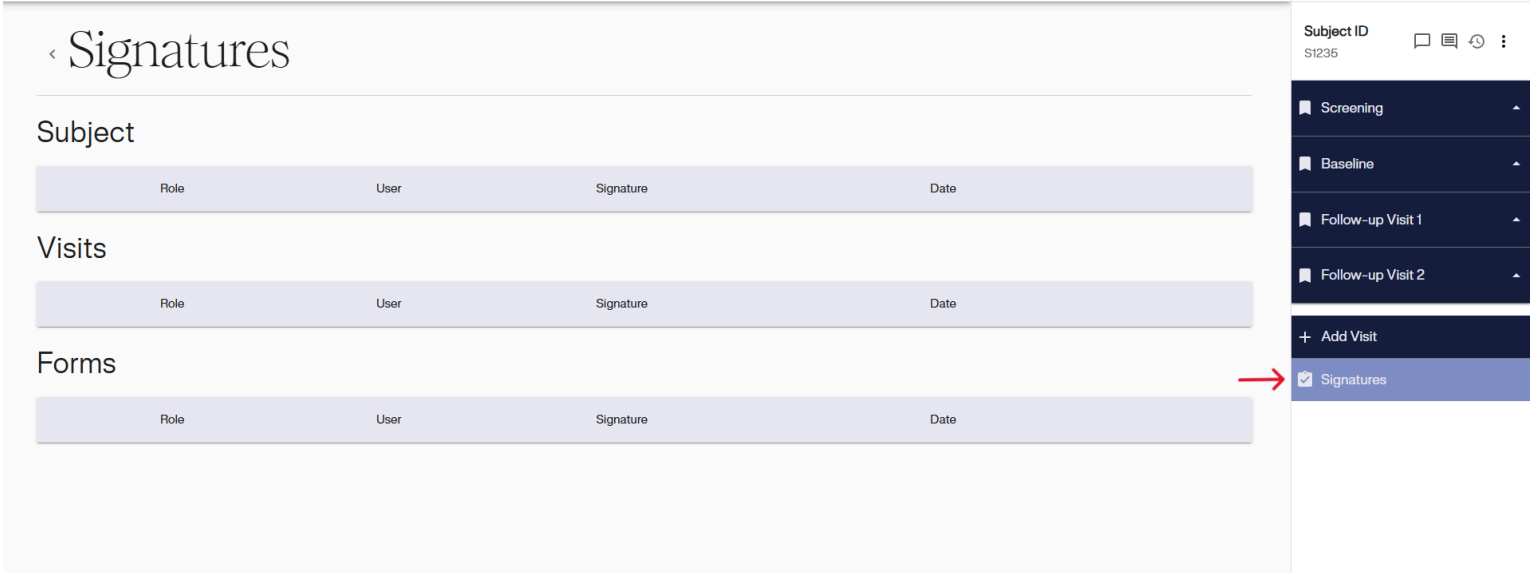
In the Subject Details Dashboard, the visit will reflect the signed icon, once they are signed on the visit level as required by the study



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.



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

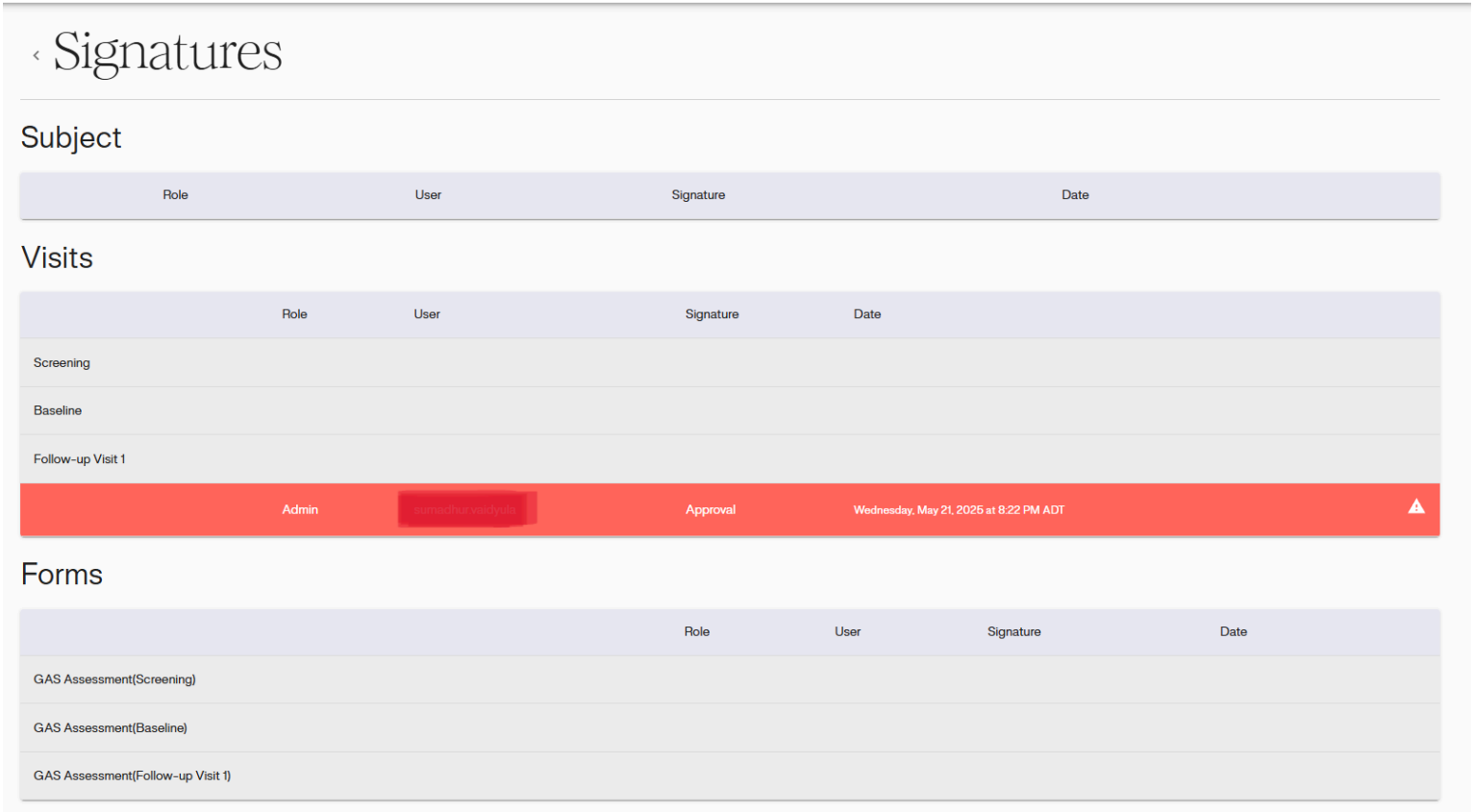
There are different consequences for changing data depending on what signatures have been added to the system.

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).

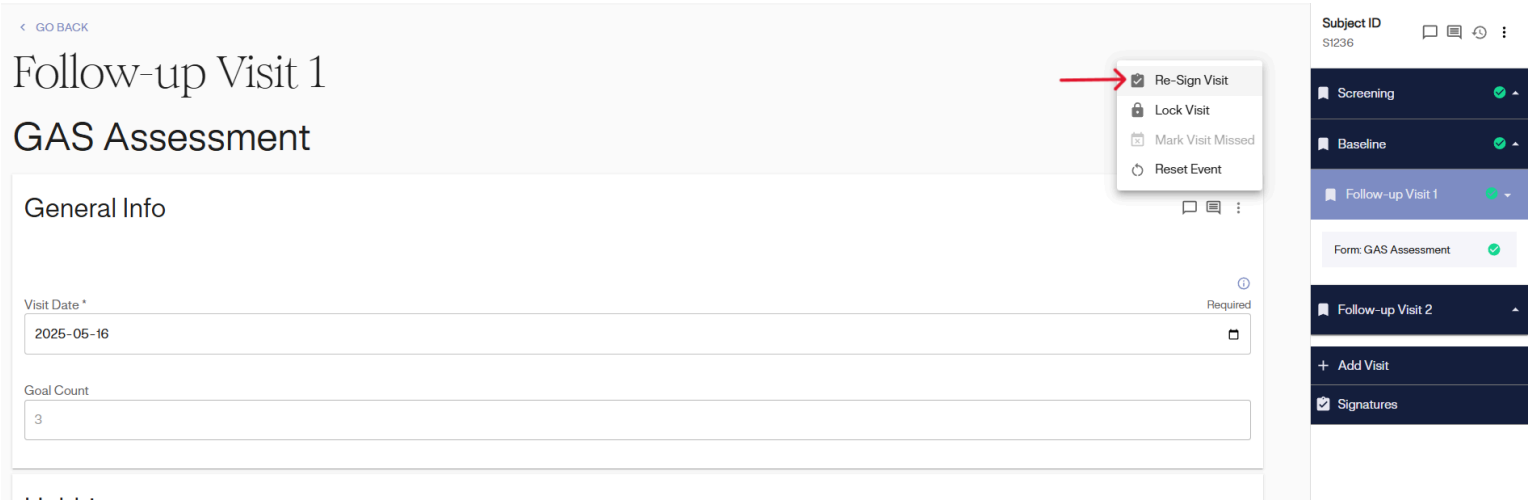
An invalid signature is an indication to the signing user that the data has changed and requires review.



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”.



IN THIS CHAPTER

1 Source Data Verification

Source Data Verification

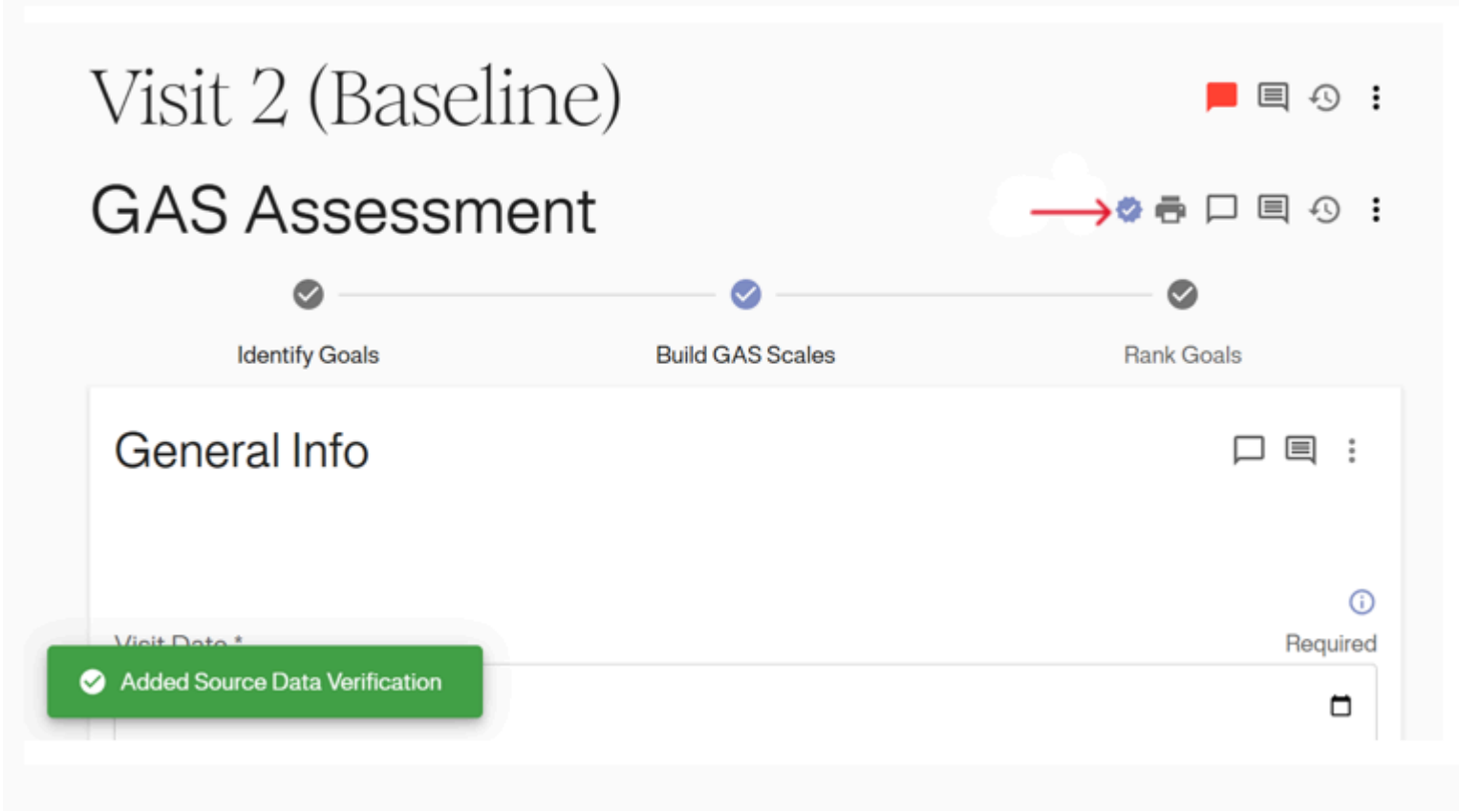
NOTE: This section only applies for those studies that allow source data verification to be completed by the sites alternate GAS interviewer.

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
Required
Added Source Data Verification

IN THIS CHAPTER

1 Managing Queries

a Create a GoalNav® Query

b View All GoalNav® Queries

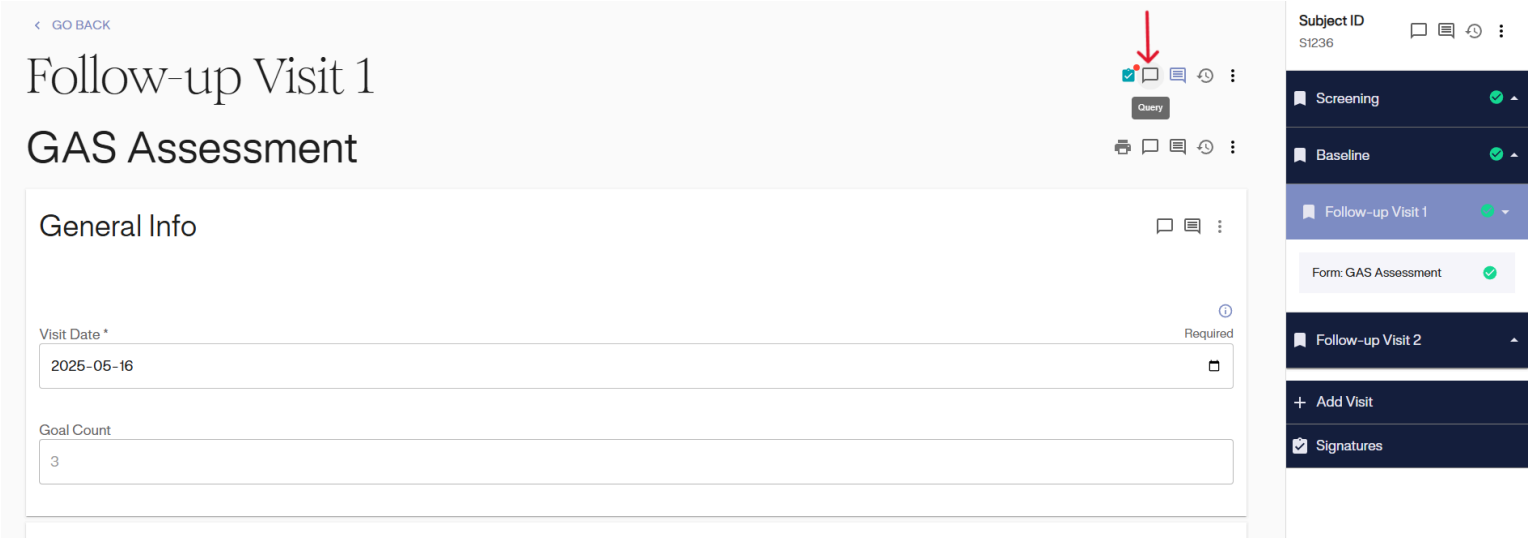
c Respond to GoalNav® Queries

d Close Queries

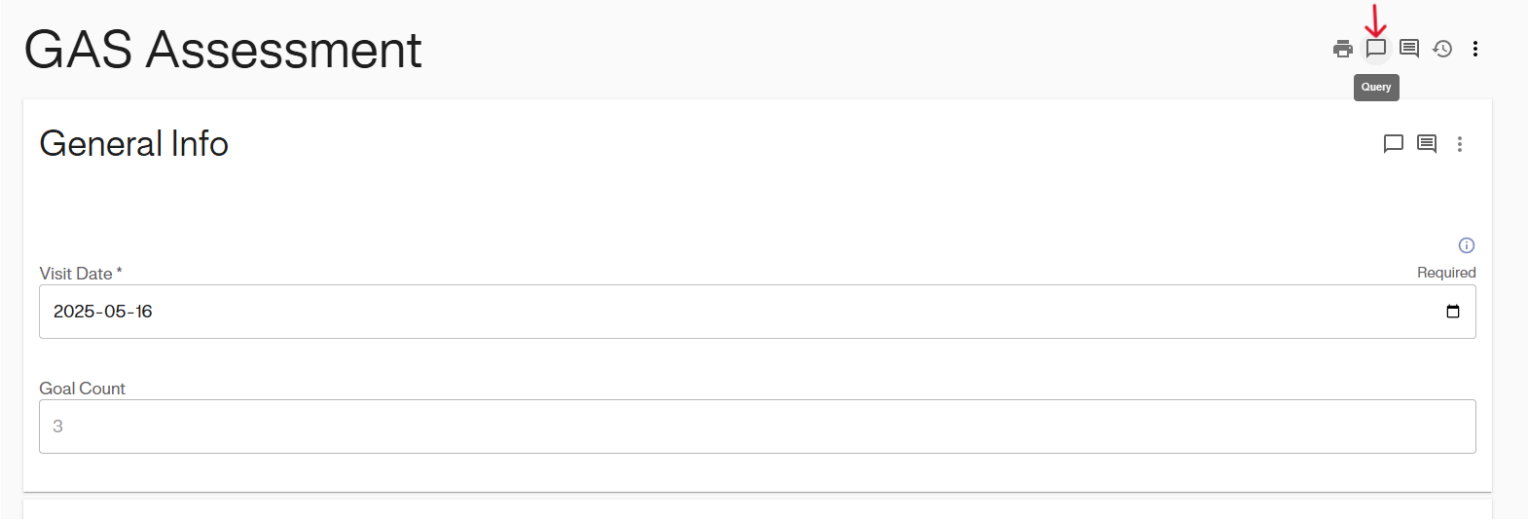
Managing Queries

Create a GoalNav® Query

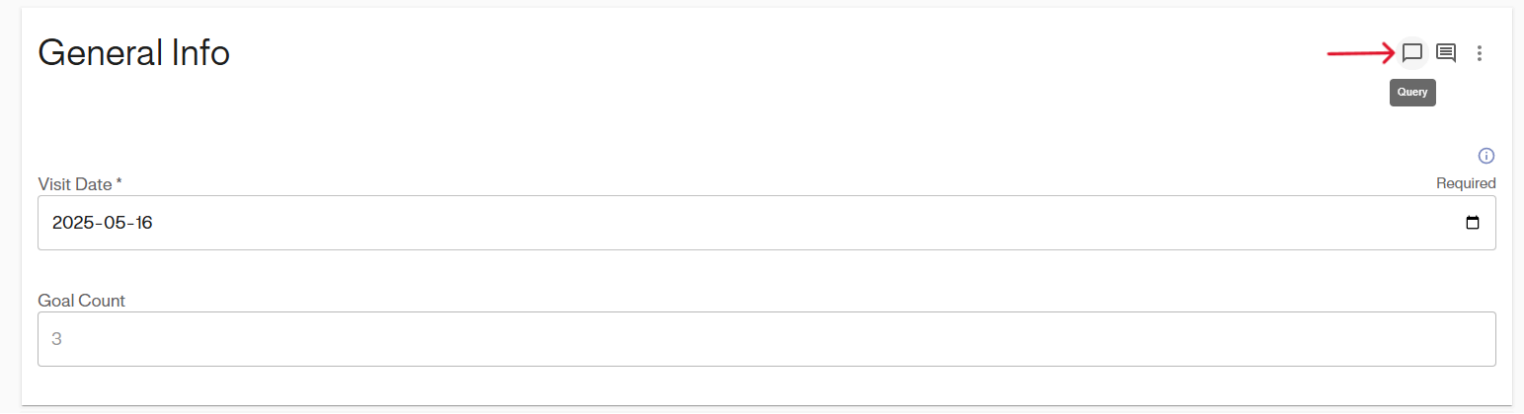
To create a new GoalNav® query on the visit level, click on the blank dialogue box icon right next to the name of the visit.



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.



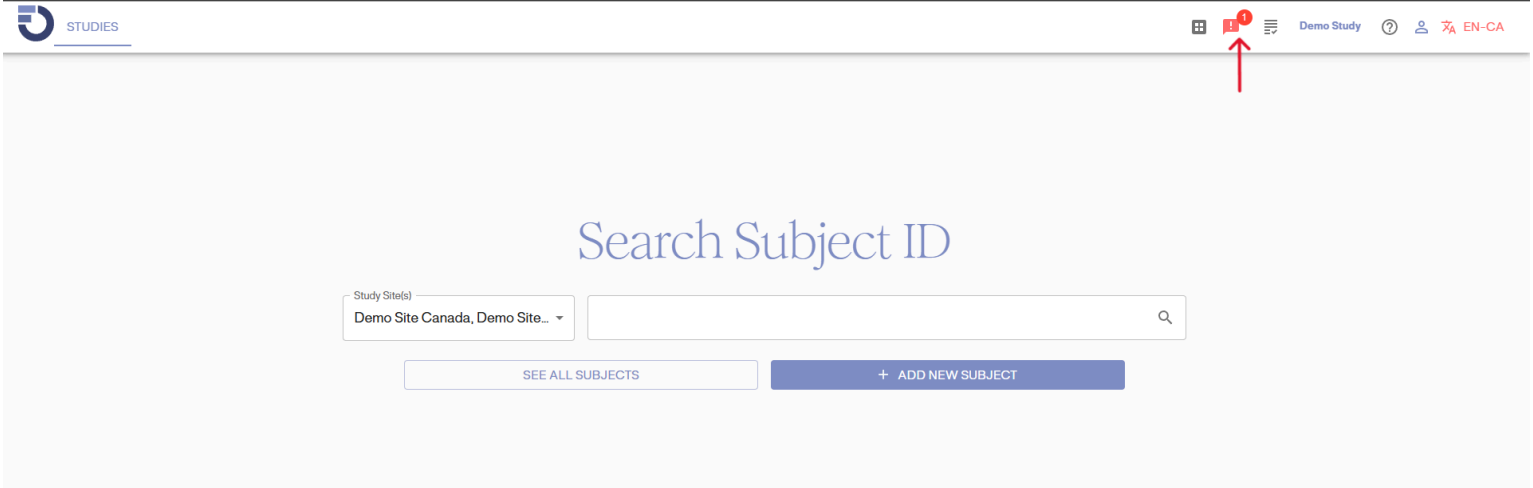
To create a new GoalNav® query on the section level, click on the blank dialogue box icon at the top of the form section.



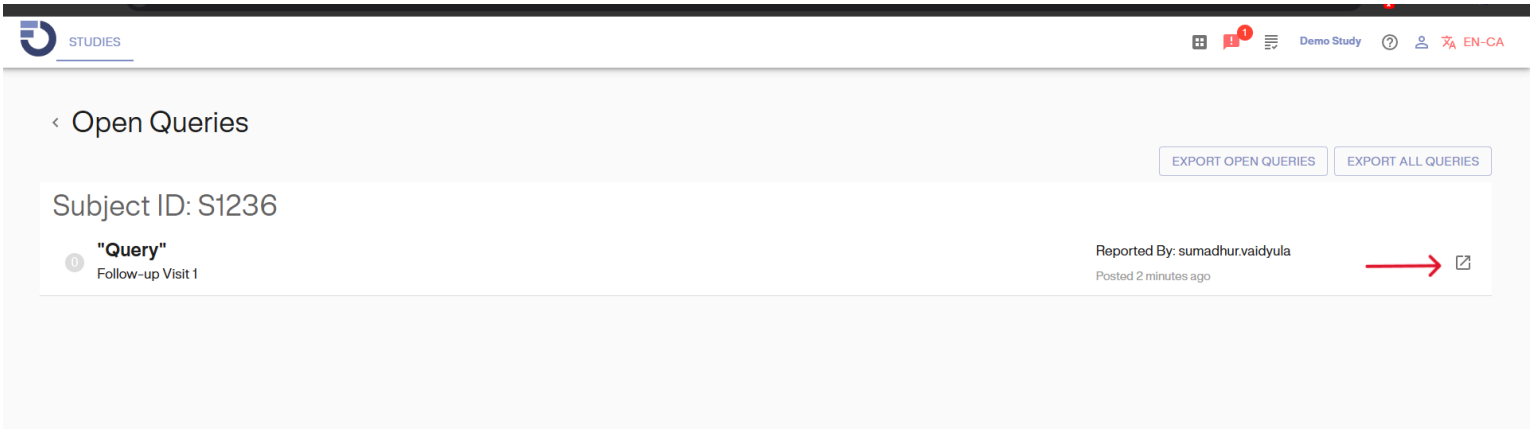
Click the icon to open a pop-up window. Here, start a new query thread in GoalNav® for the selected subject and visit. In the text box, enter the query. Then, click the “Post” button to submit it. When a new query is posted, the author of the visit will be notified.

View All GoalNav® Queries

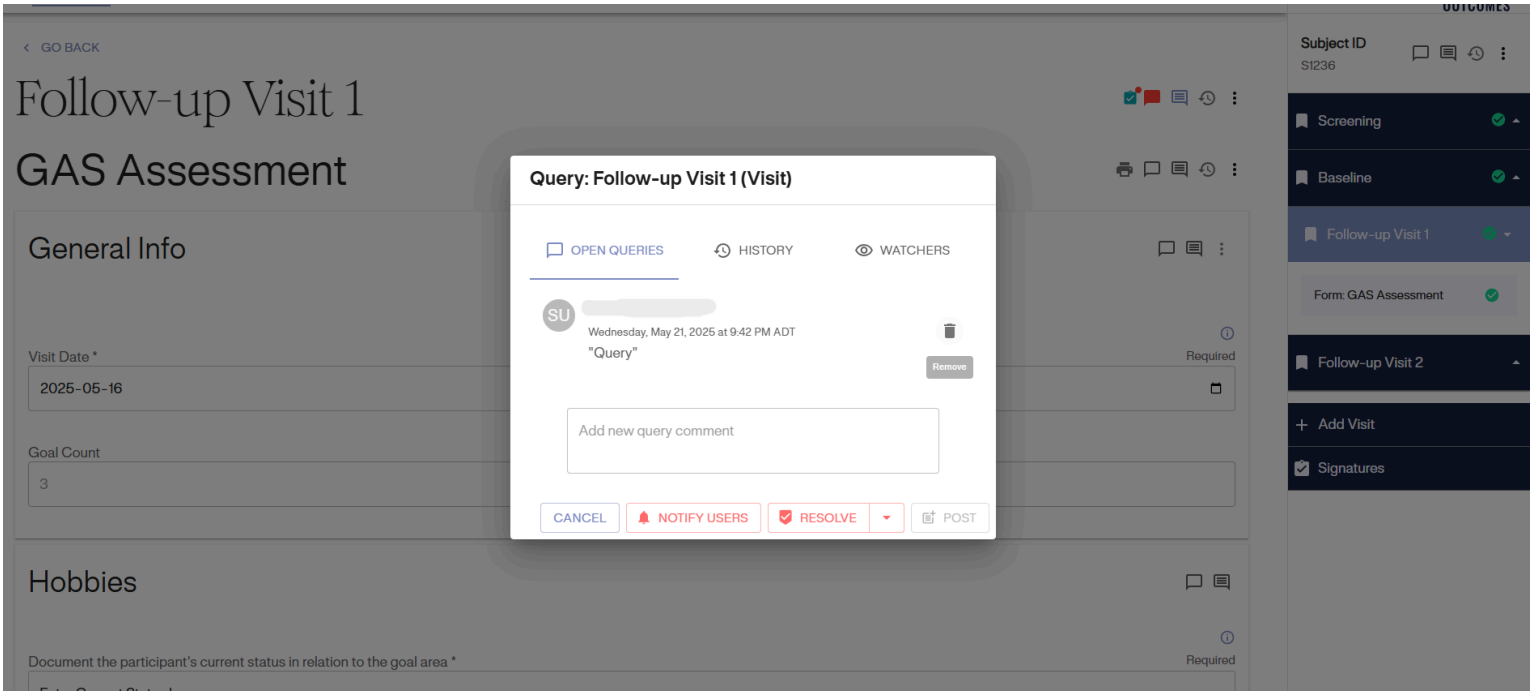
To view all open queries in GoalNav®, click the dialogue icon, which will be highlighted in red when unresolved queries are present within the study.



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.

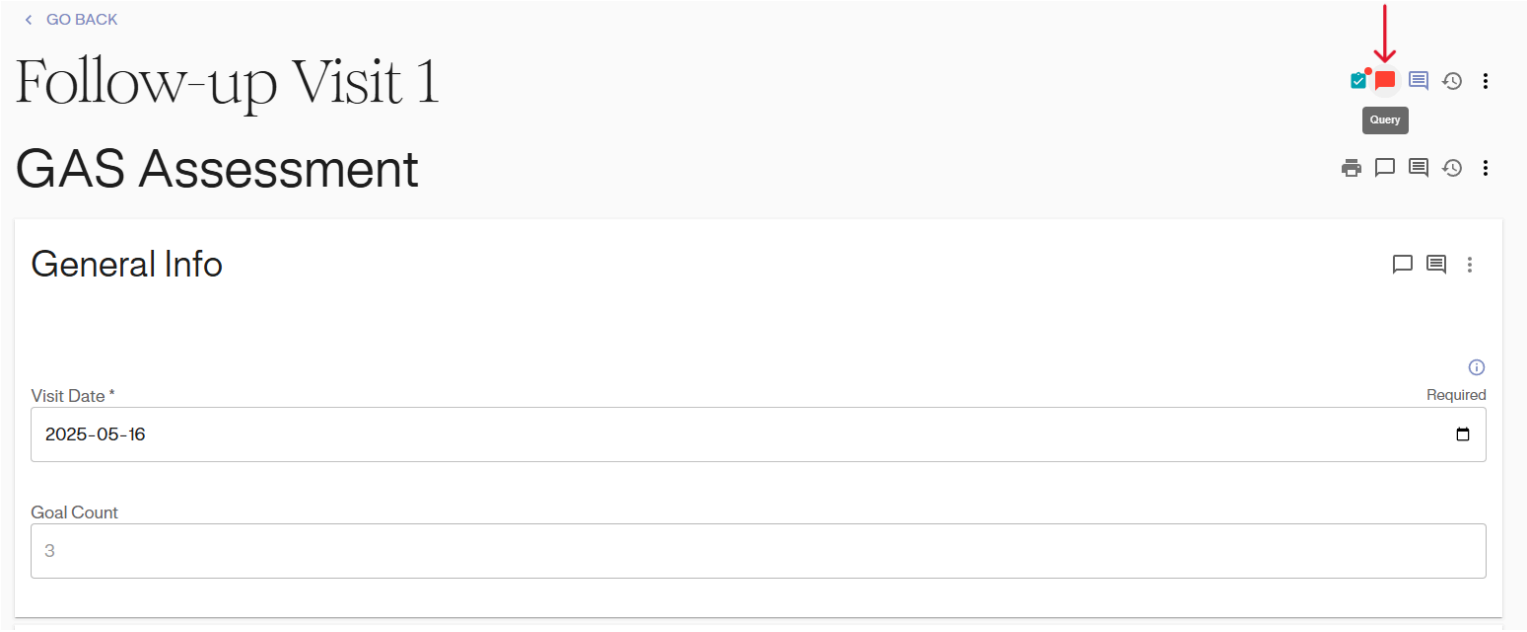


Click the link icon to open a pop-up window to display the visit, form, or form section where the query was created, including the entire query thread.

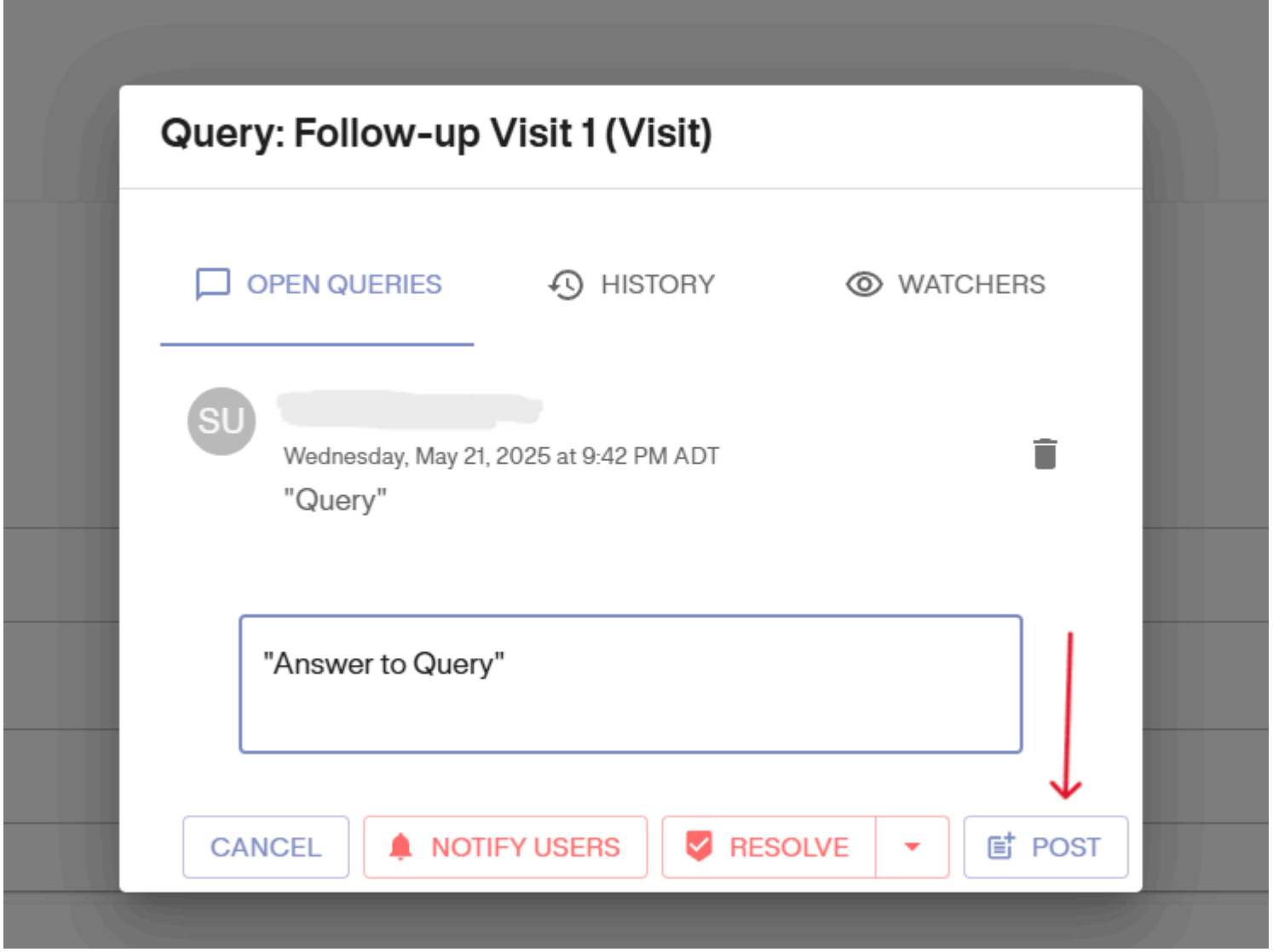


Respond to GoalNav® Queries

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.



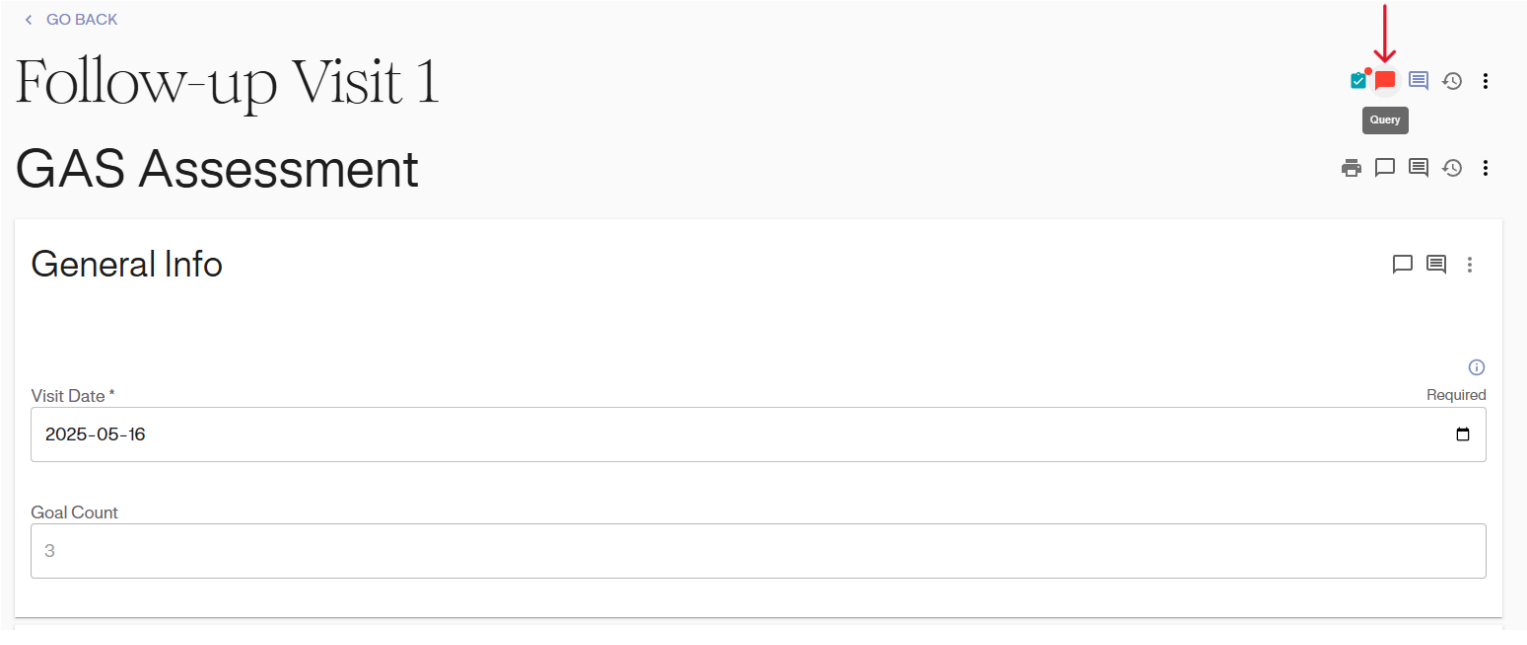
Click on the red dialogue icon to open a pop-up window that displays the active query thread. In the text box, enter the answer to the query. Click on “Post” to post the response. Posting a response will notify the author of the data and any users who have previously responded/participated in the query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



Close Queries

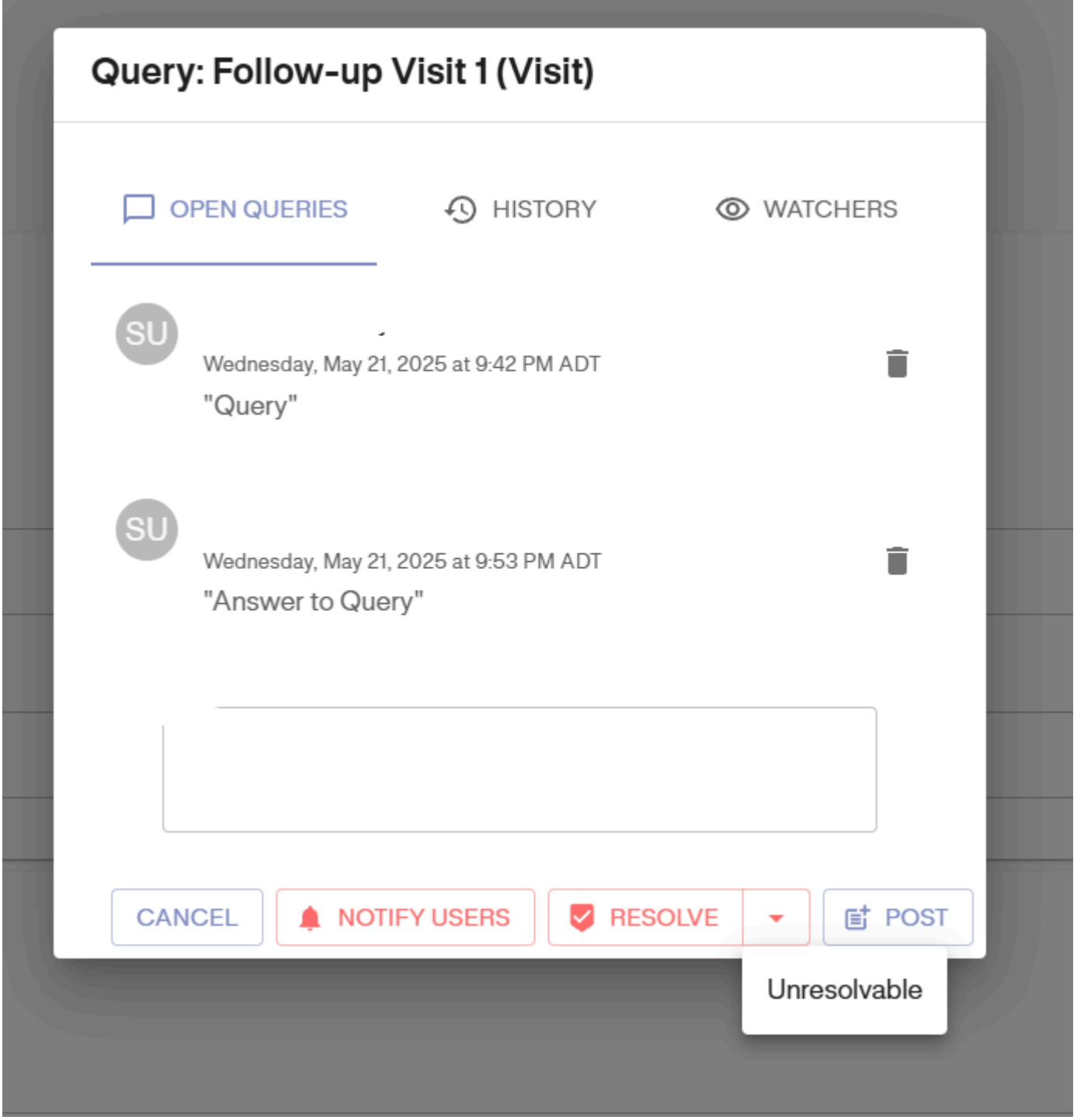
Once an answer to a query is accepted and validated, click the “Resolve” button to close the query. Once “Resolve” is selected, the resolved query will disappear. Note: The Data Monitors should only close queries they created themselves or those that have been resolved. They should not close any unanswered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

Click on the Query Icon on the visit details page.



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

TABLE OF CONTENTS

- Signing Records

IN THIS CHAPTER

1 Signature Records
   a Add Signatures
   b Viewing Signatures from Signatures Tab
   c Invalid Signatures
      a Invalid Signature: Re-signing a Visit or a Subject

Signature Records

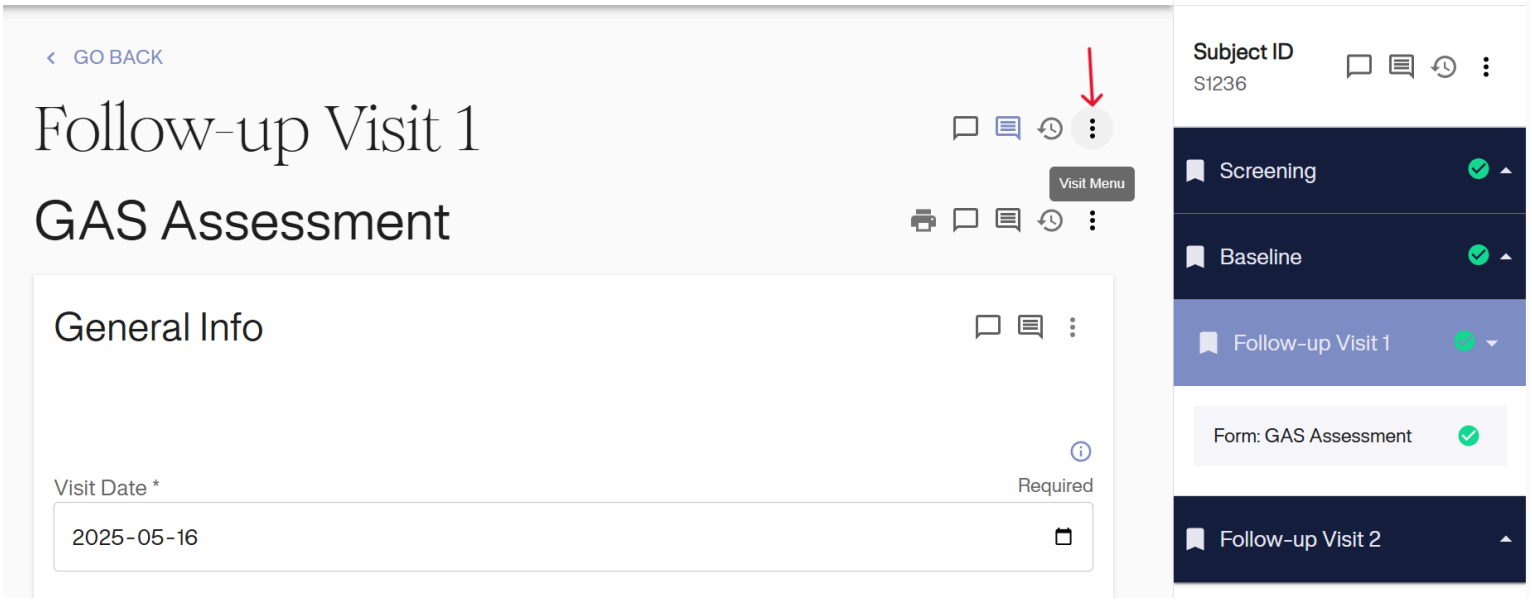
Add Signatures

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:

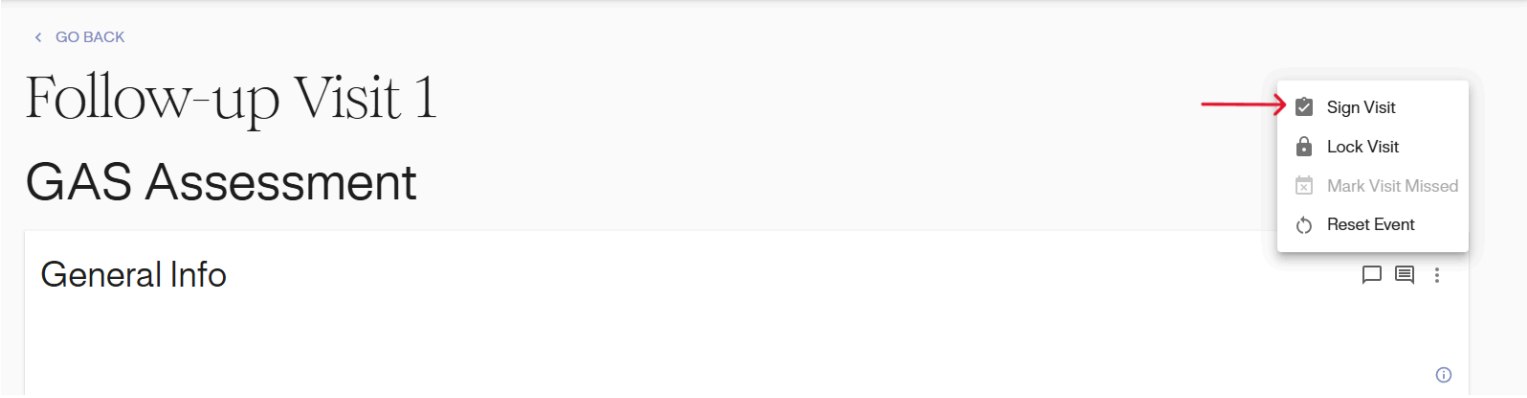
To sign the visit, click on the 3 dots on the right side of the Goal Attainment Scaling form.



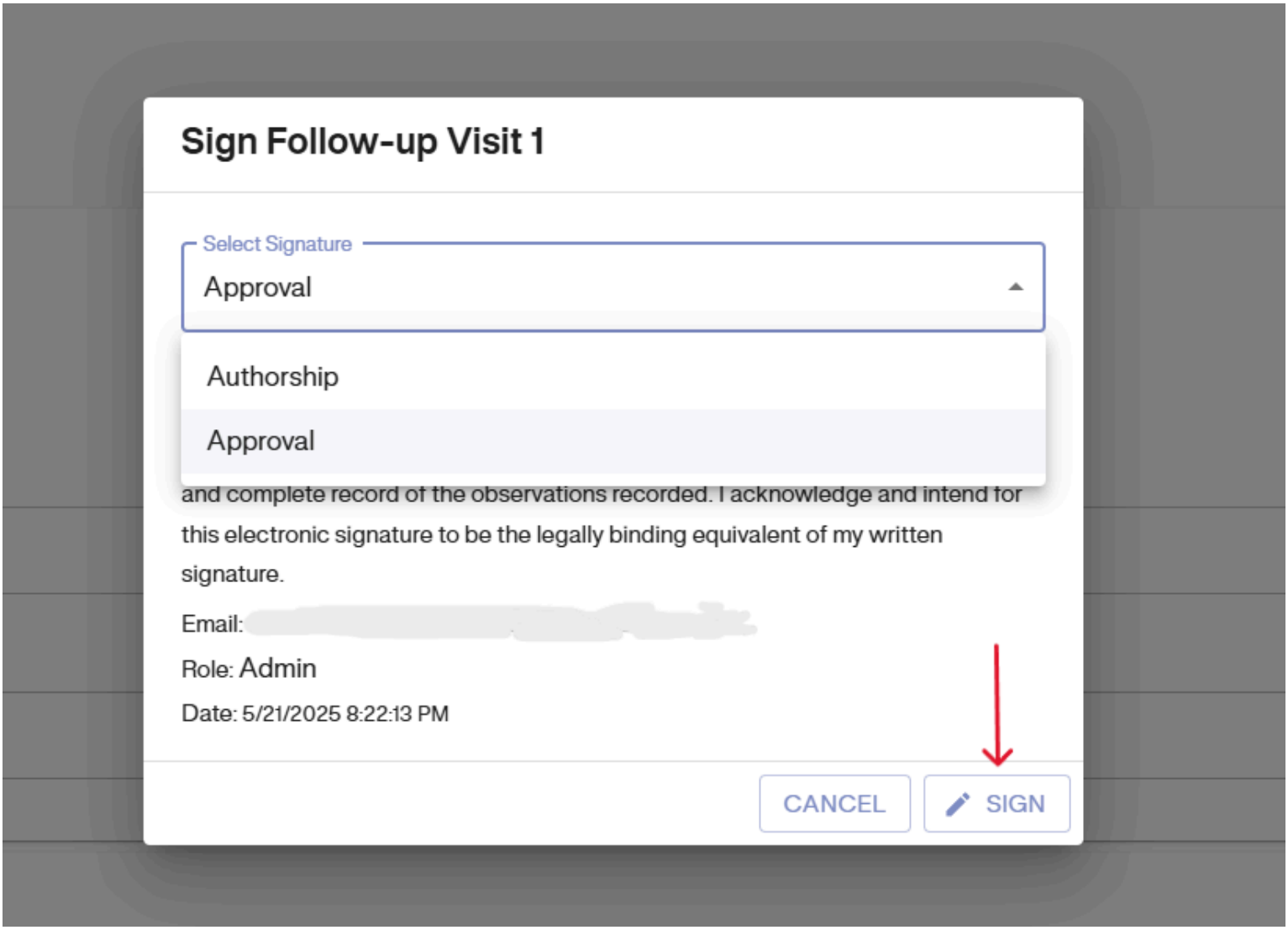
You may note that there are other similar icons present on the page. Those icons represent:

- 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)

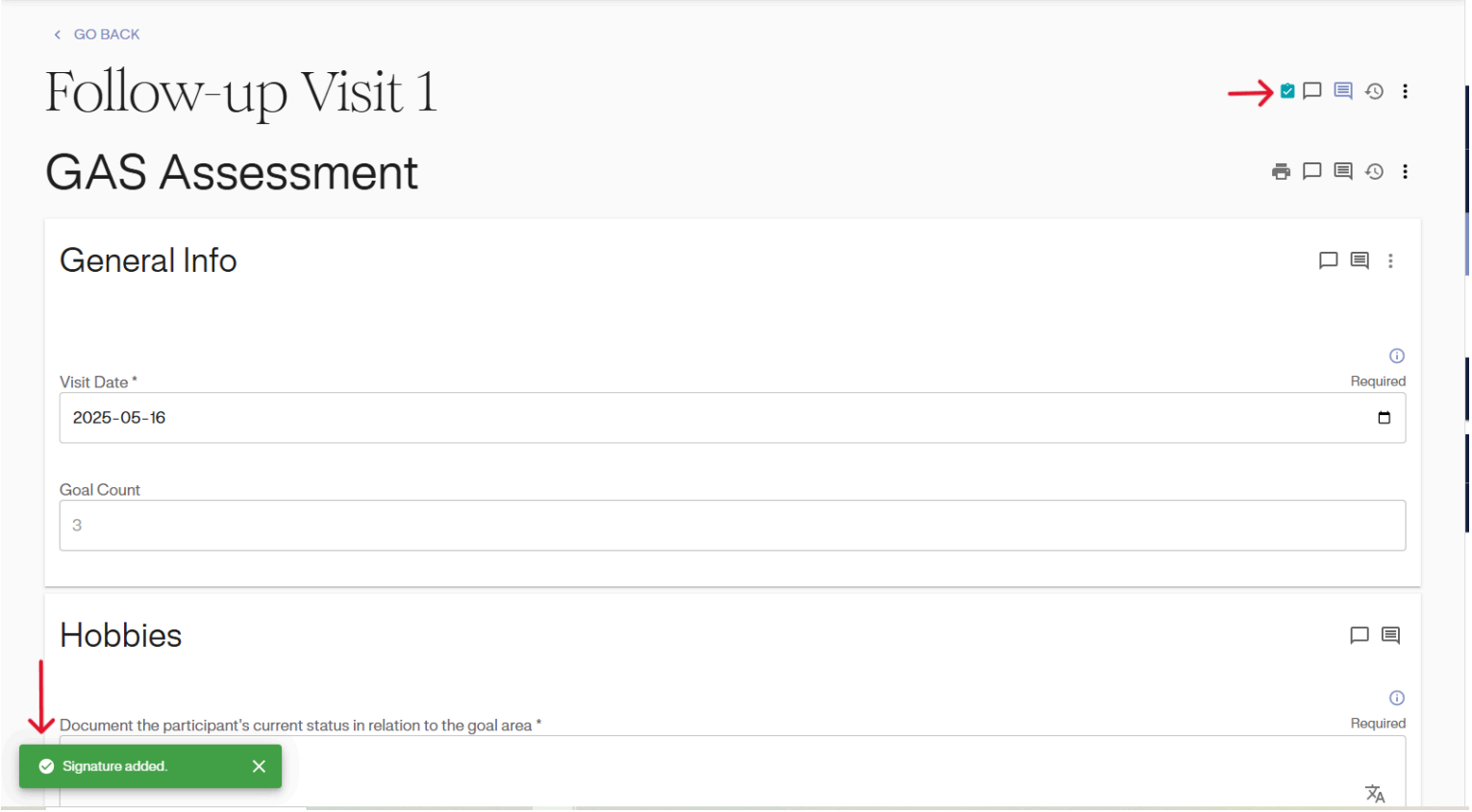
All signatures (form, visit, subject) can be done following the same format as outlined below.



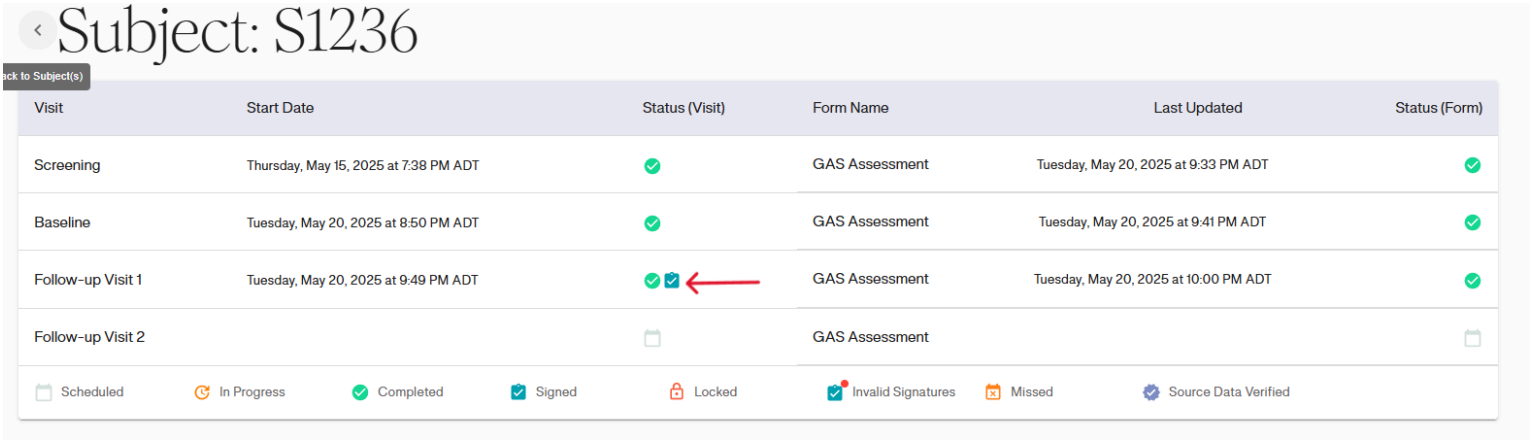
Once you click on 'sign visit', you will be required to re-enter your login information to verify your identity. Once authenticated, you will see a window to select the type of signature Authorship or Approval. Select the relevant option and then click on "Sign" button.



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.



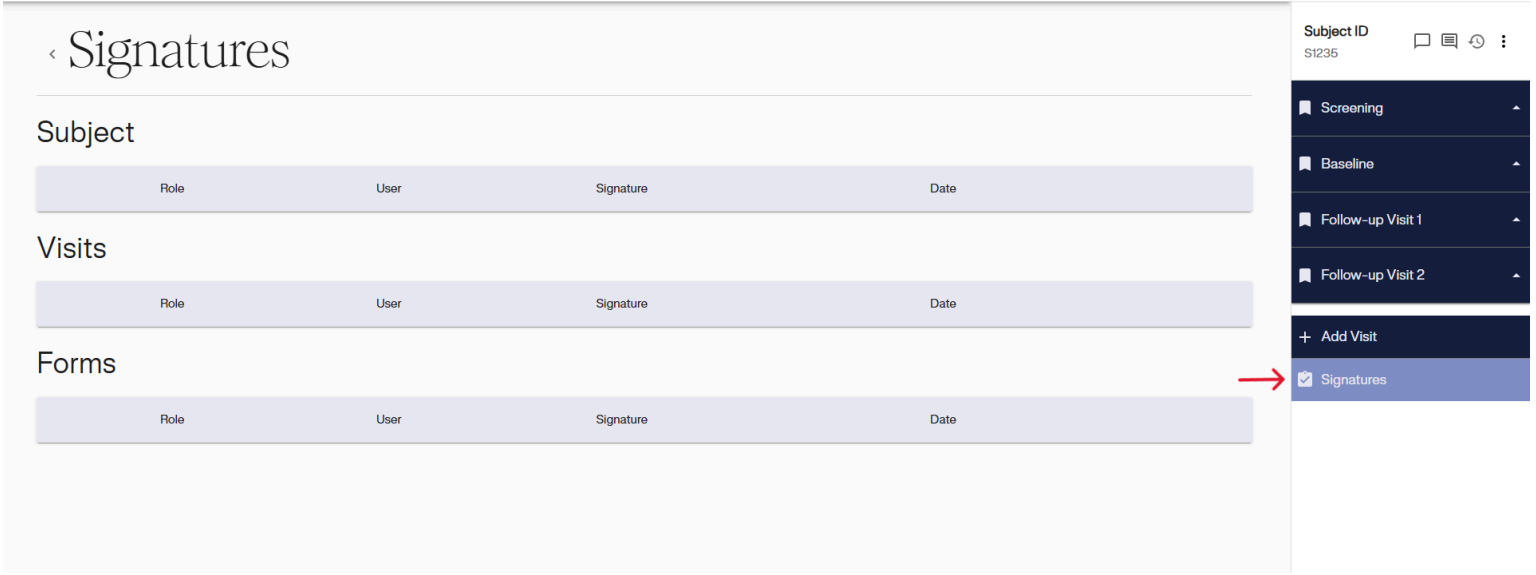
In the Subject Details Dashboard, the visit will reflect the signed icon, once they are signed on the visit level as required by the study



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.



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

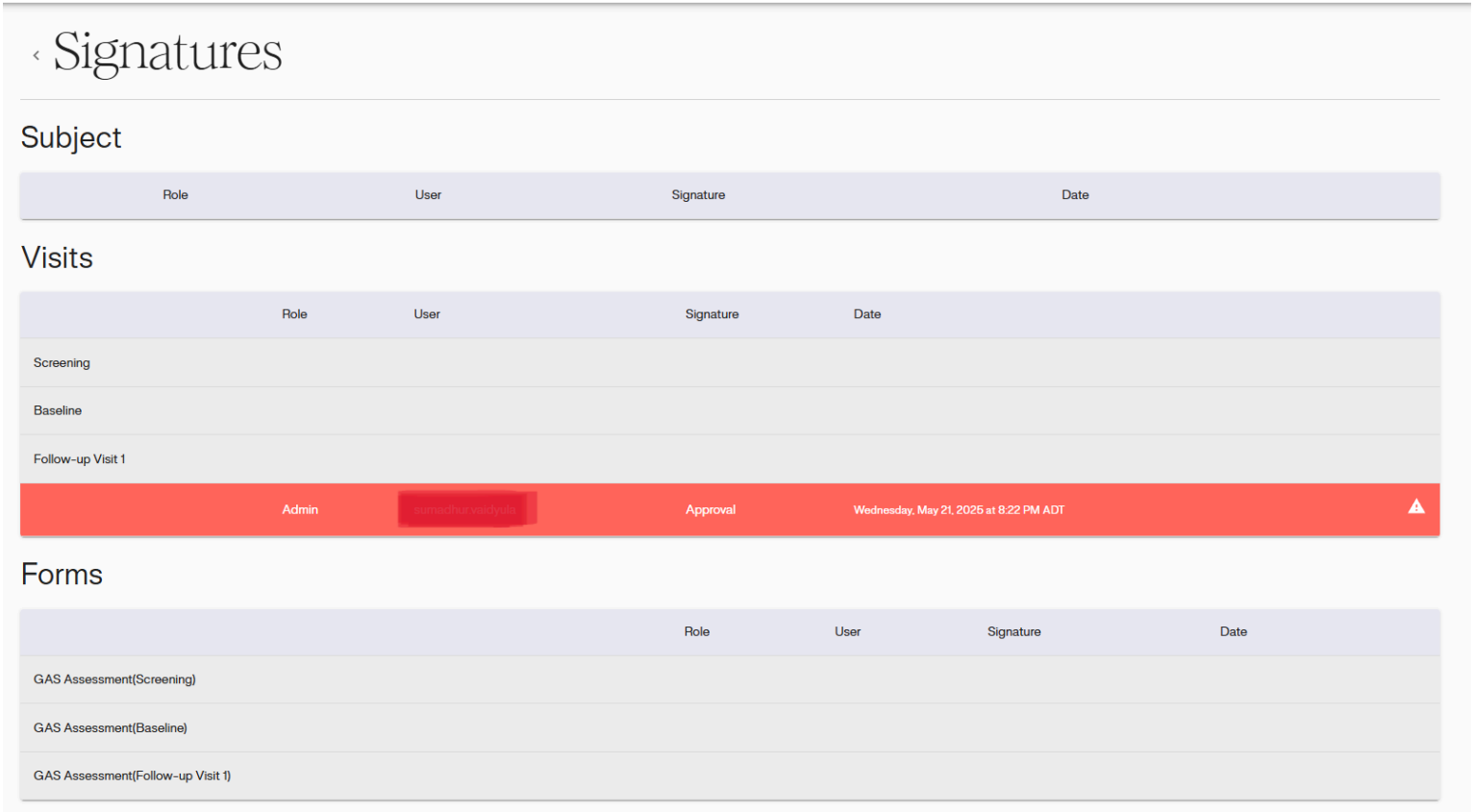
There are different consequences for changing data depending on what signatures have been added to the system.

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).

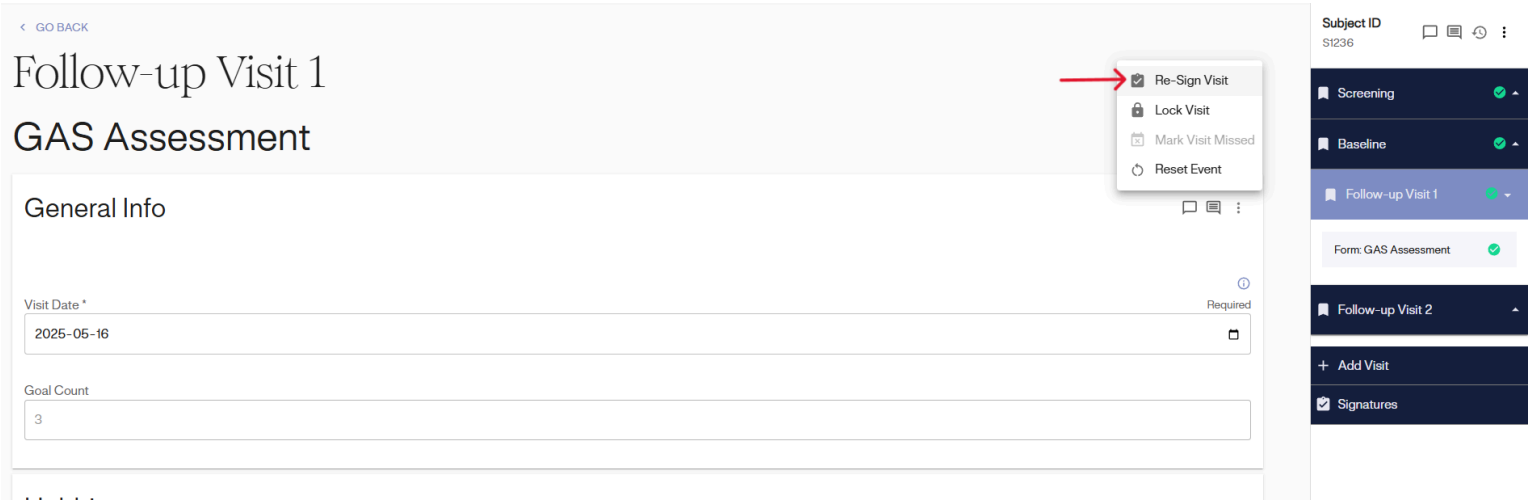
An invalid signature is an indication to the signing user that the data has changed and requires review.



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”.



Chapter 5: Using GoalNav as a Monitor

TABLE OF CONTENTS

- Source Data Verification
- Monitor Signatures
- Manage Queries

IN THIS CHAPTER

1 Data Monitor Guidelines
2 Source Data Verification
   a Overview
   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

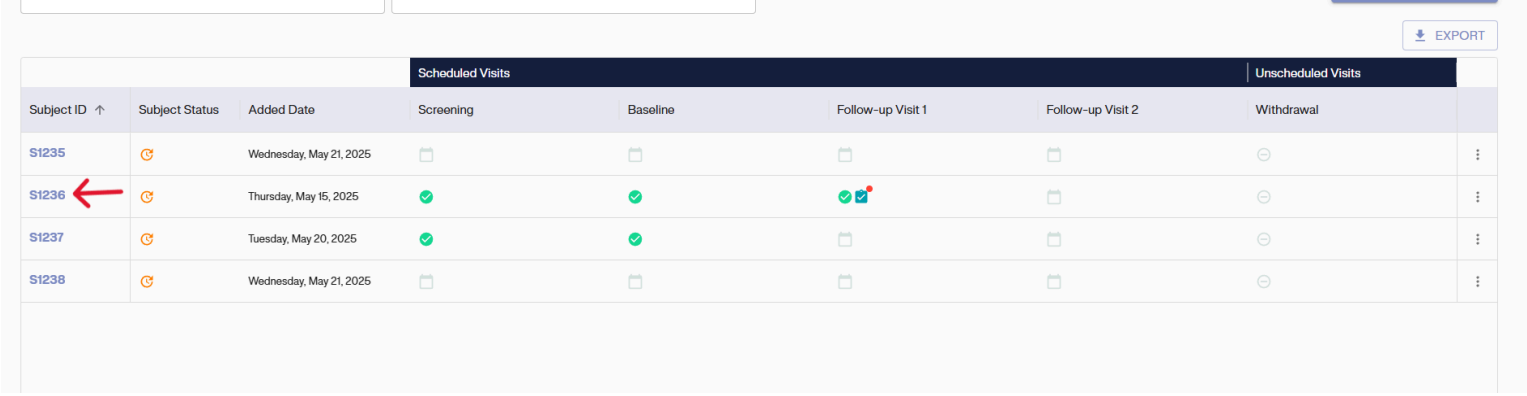
Overview

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.

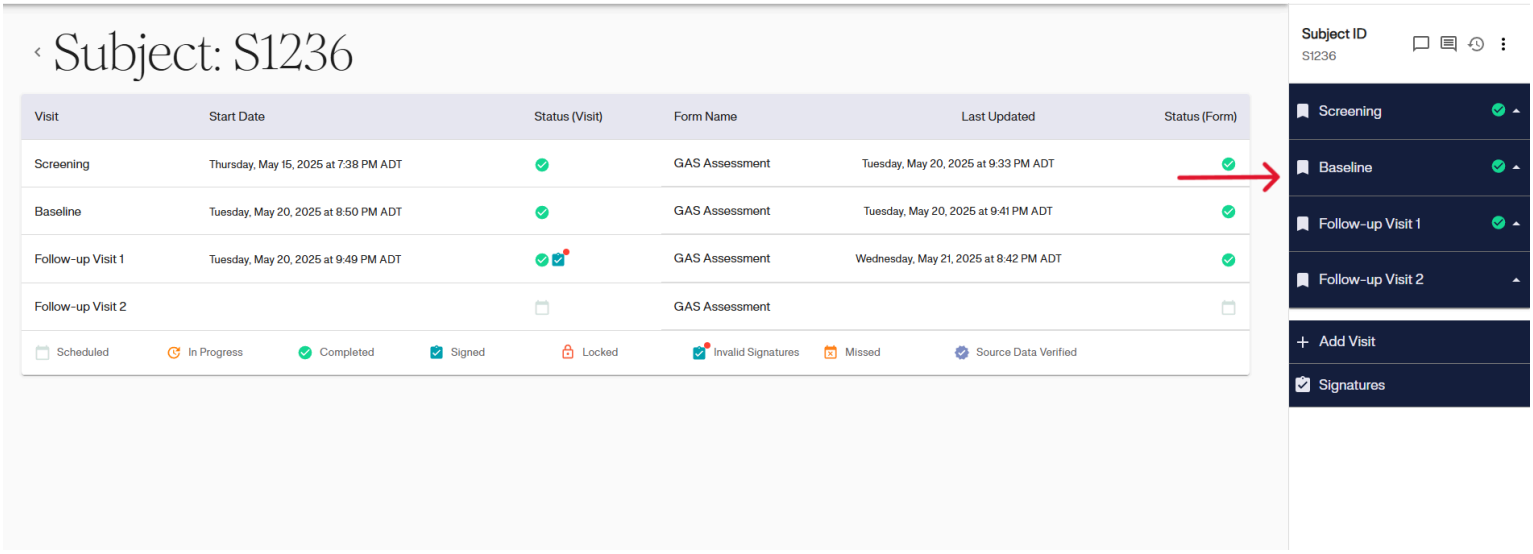
To check if the form has "Source Data Verified"(SDV), follow the instructions below:

Monitor Source Data Verification (SDV) from Subject Details Dashboard

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



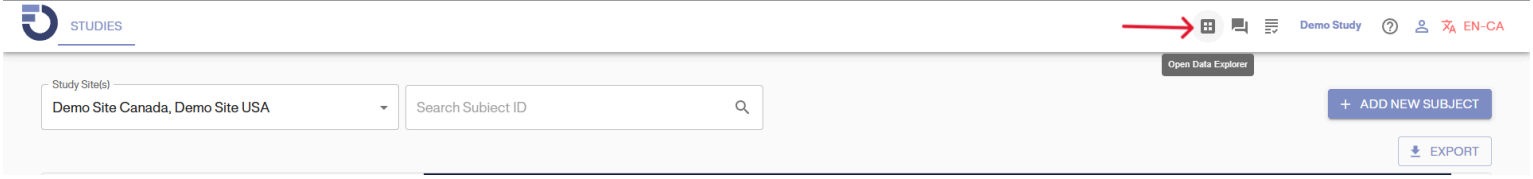
On the Subject Details Dashboard, select the visit name from the navigation menu on the right side.



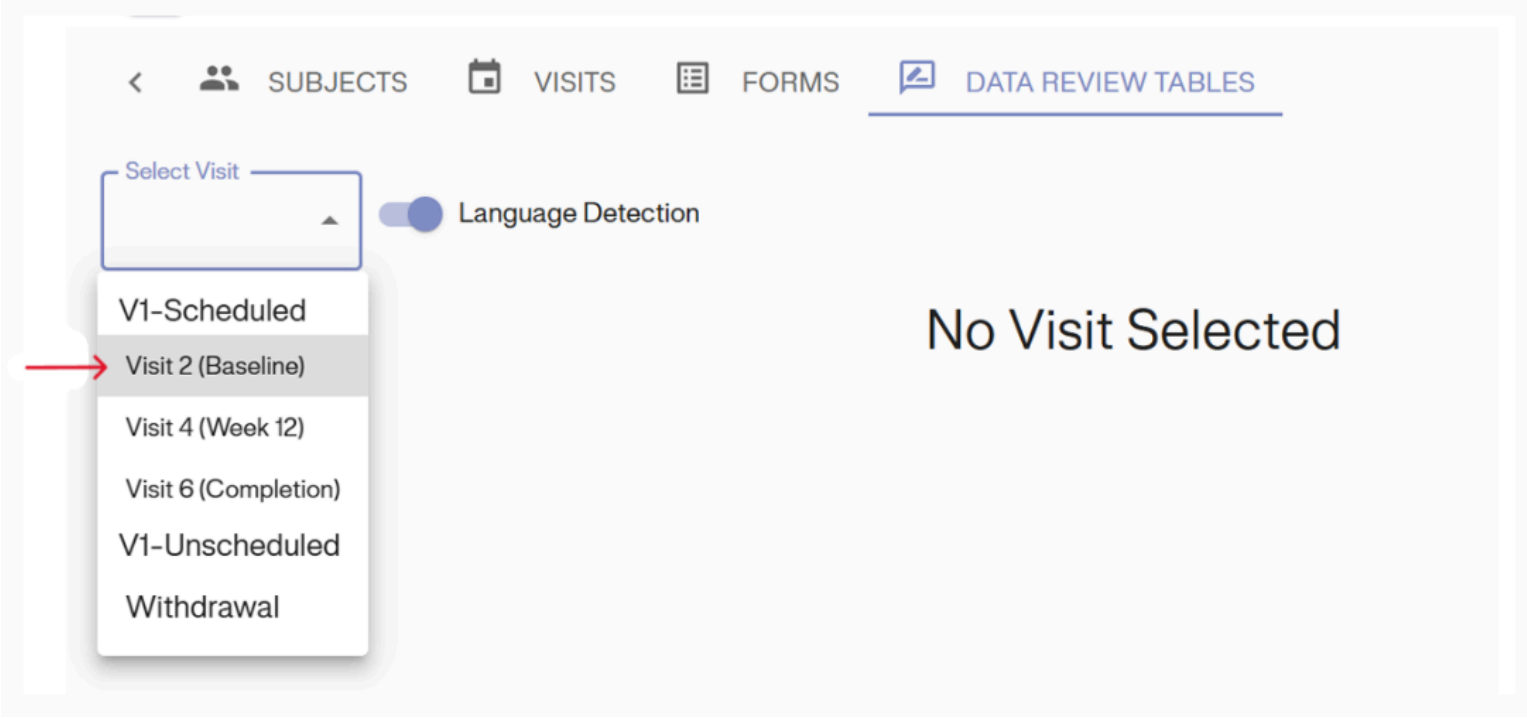
The visit details will be displayed when you click on the visit name. A purple checkmark icon next to the form name indicates that the form has been "Source Data Verified". If the icon is not present, the form still requires verification.

Monitor SDV from the Data Explorer

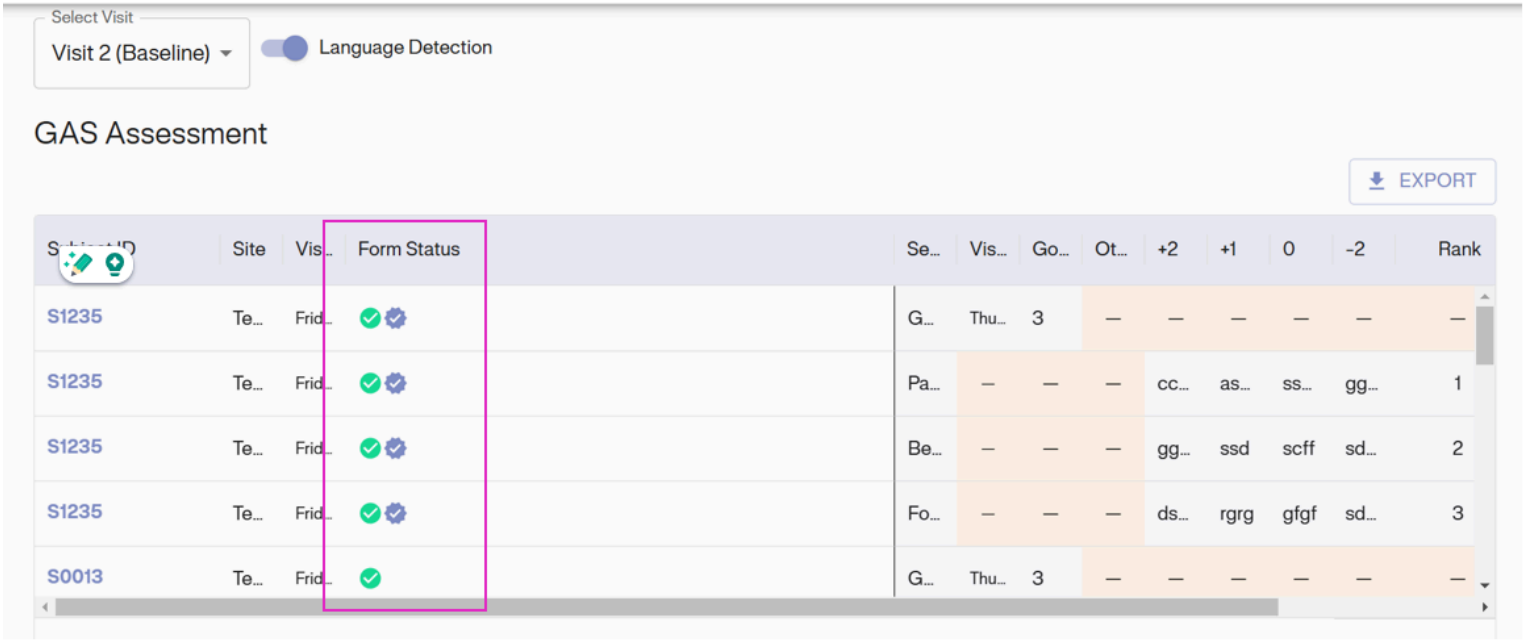
To monitor SDV from Data Explorer, click on the grid icon in the top menu bar on the trial's homepage. The grid icon is visible on all pages except the landing page in the top menu bar.



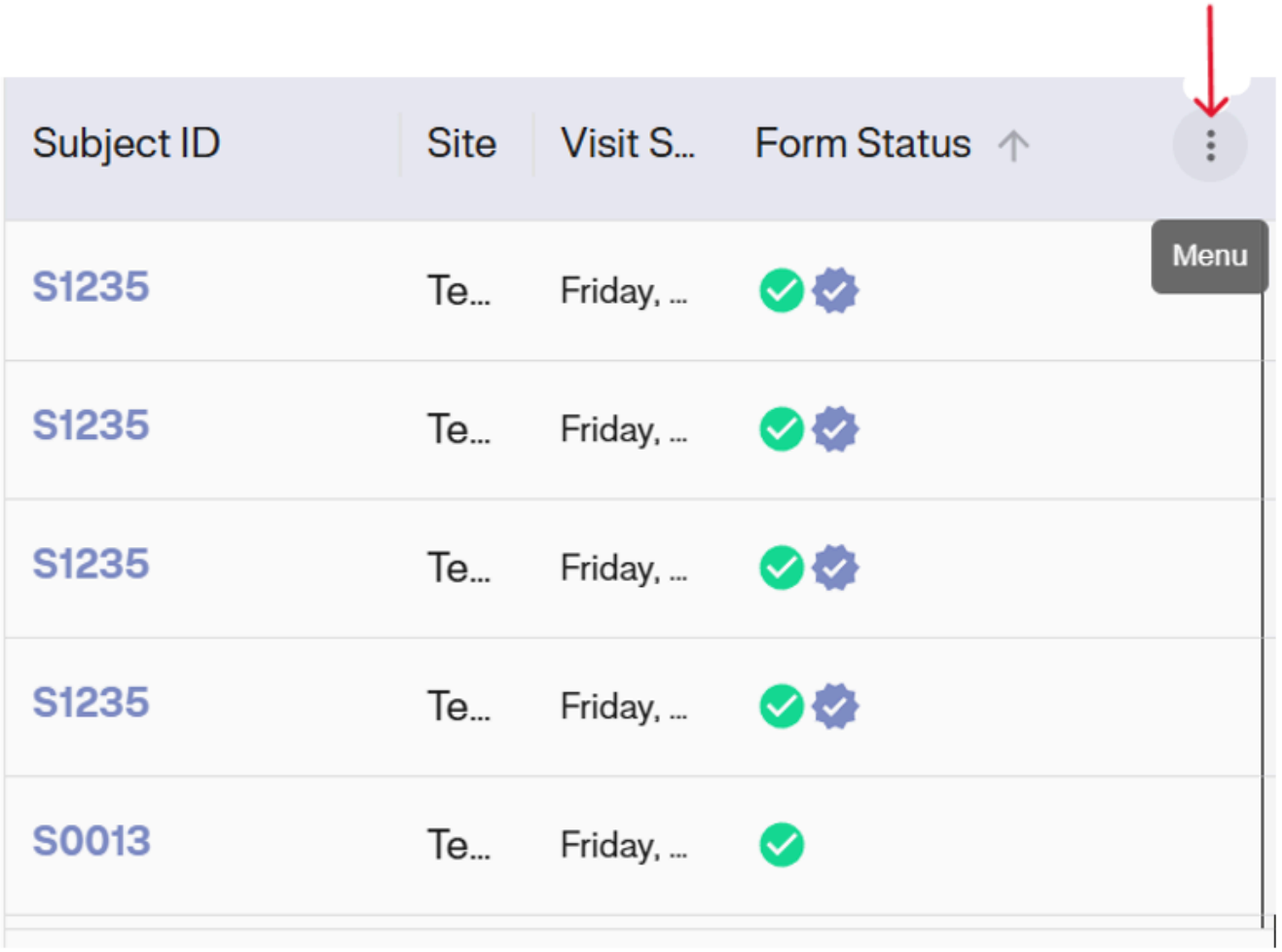
Open the dropdown menu and select the visits that require monitoring. For example, visit 2 (Baseline) is currently selected.



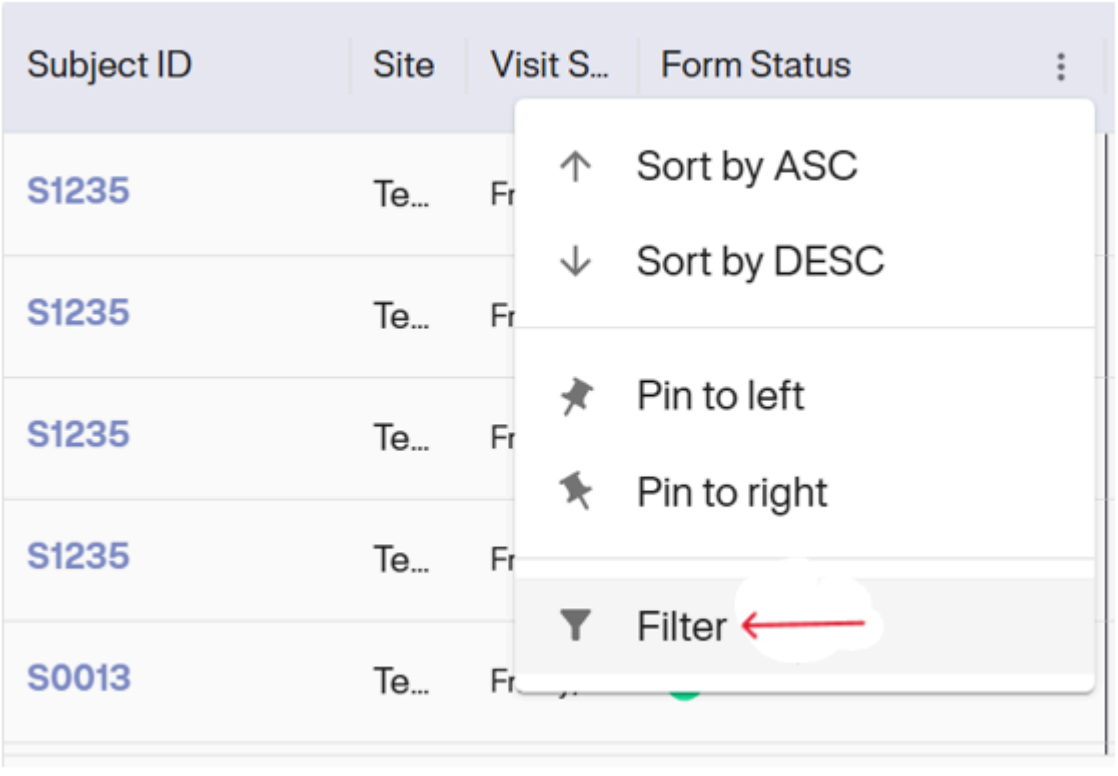
The table features a “Form Status” column that displays the status of all forms for each subject. Forms that are marked as “Source Data Verified” are indicated in the “Form Status” column with a purple checkmark icon. Please note that not all forms are required to be “Source Data Verified”.



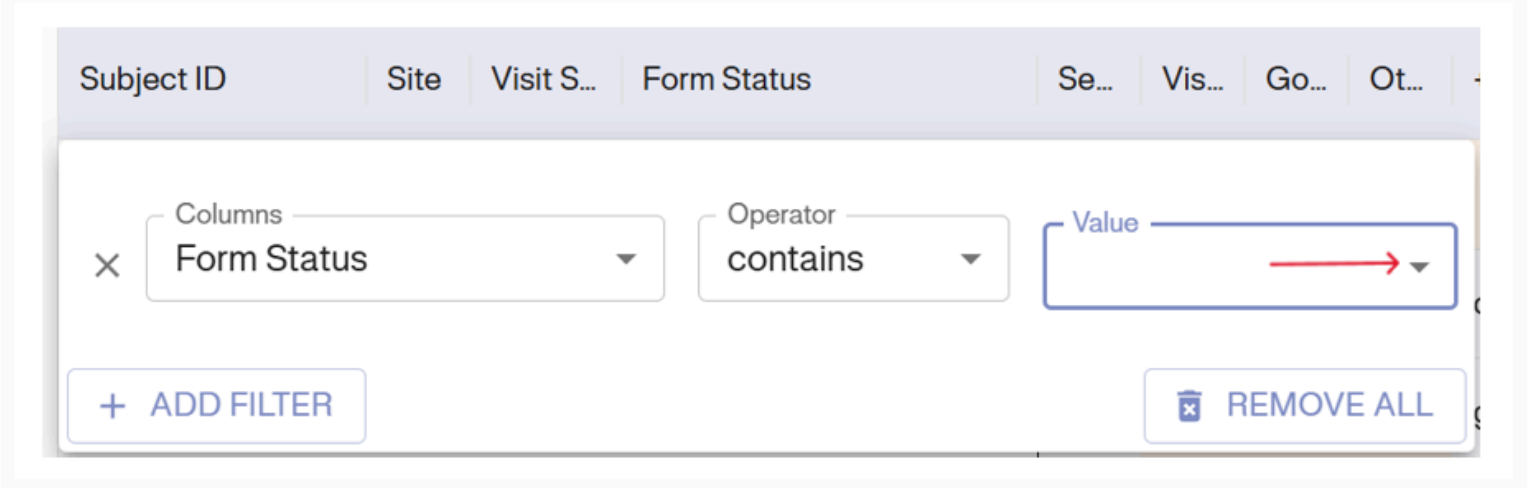
Instead of scrolling through the rows of data to find forms that are “Source Data Verified (SDV)”, use the filter option for a more efficient search. Click the options menu (the three-dot icon) next to the “Form Status” column to access the filter.



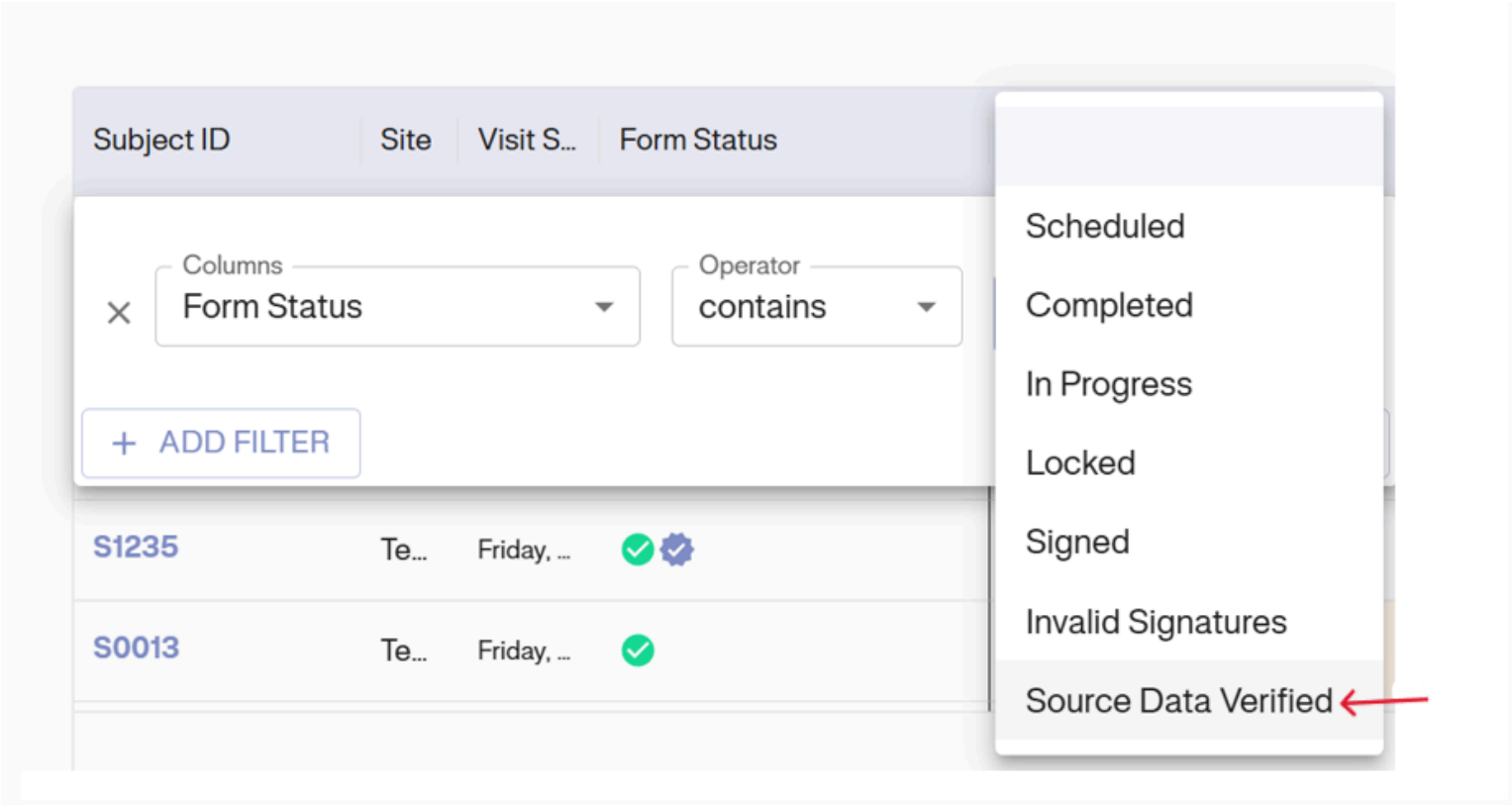
To search for data, click “Filter” and choose the appropriate option from the provided filters.



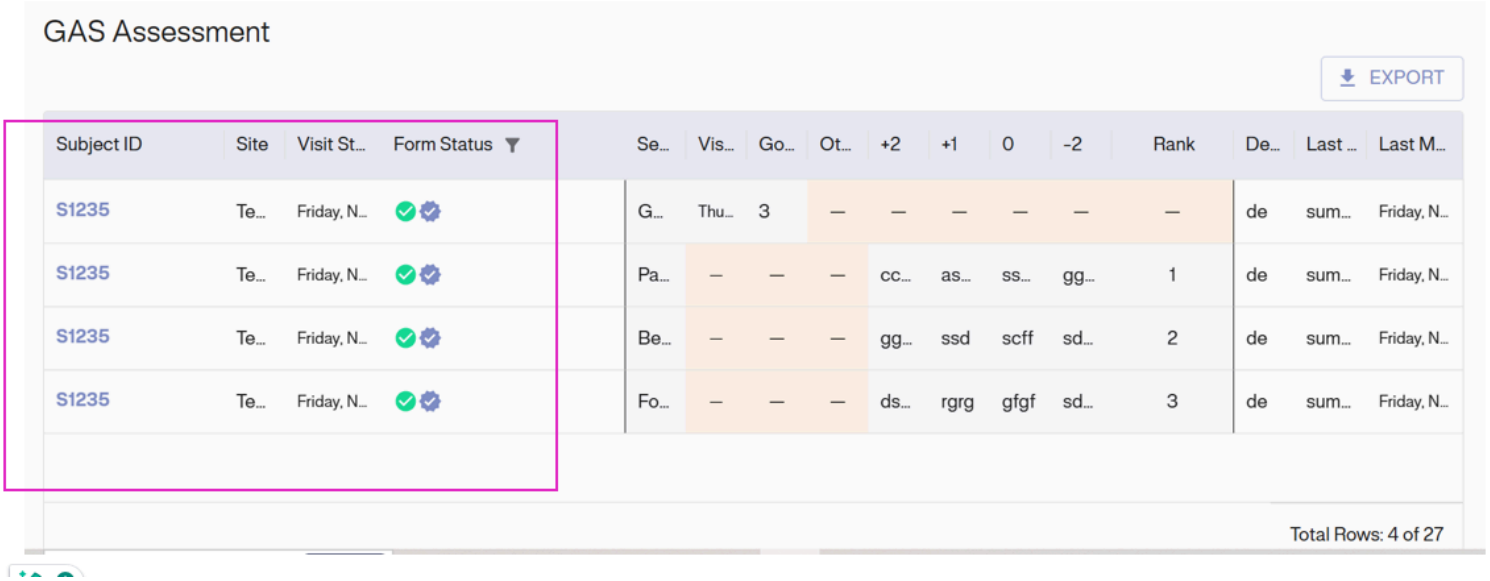
Next, select the appropriate value from the dropdown menu to search for the data.



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



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



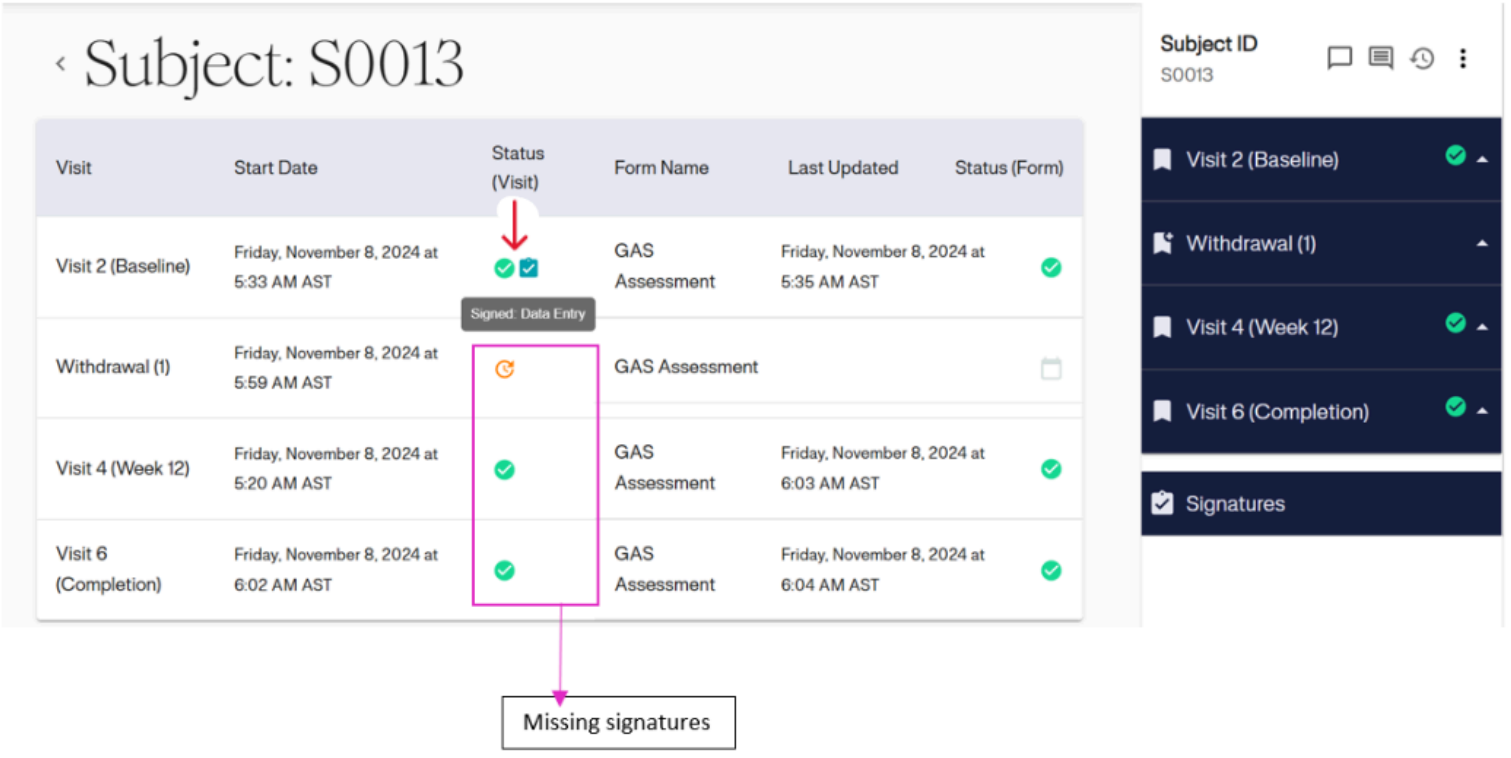
IN THIS CHAPTER

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

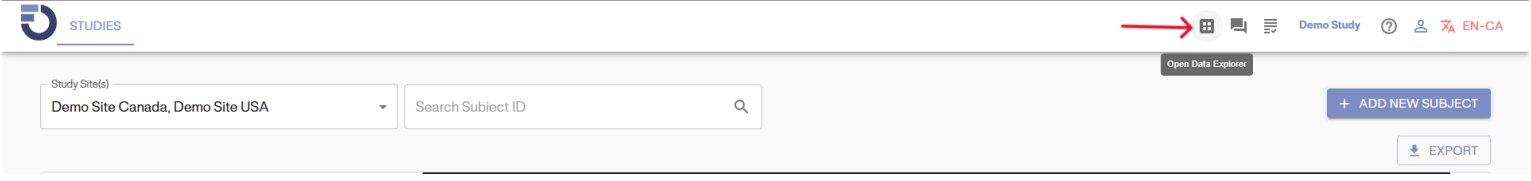
Monitor Signatures

Monitor Applied and Missing Signatures

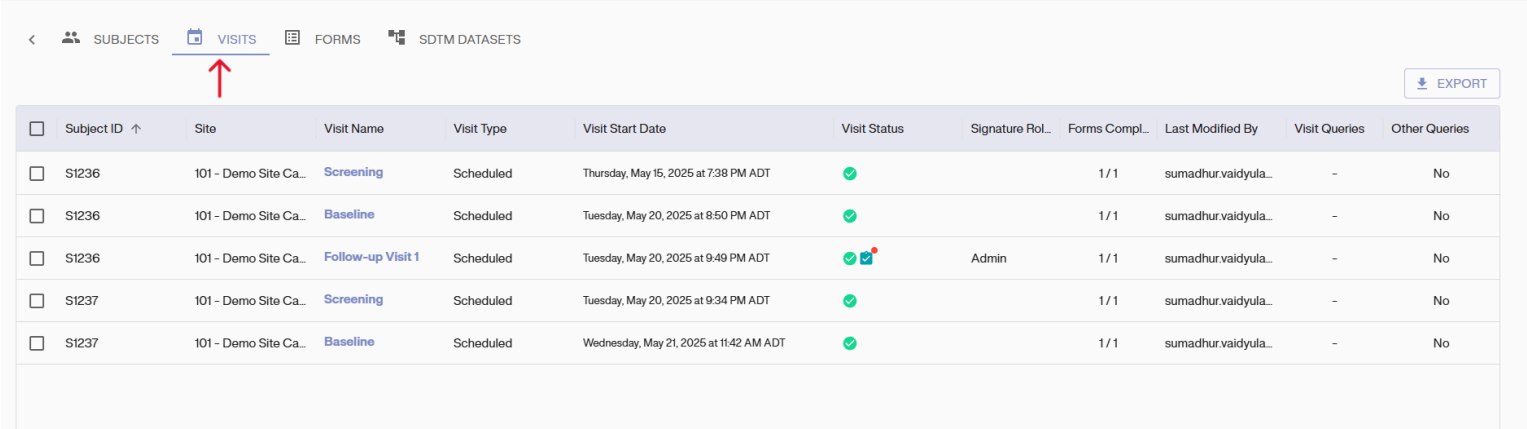
To monitor a subject's signatures for each visit, navigate to the Subject Details Dashboard. A signed visit will display a blue notepad icon in the Status (Visit) column. Hover over this icon to show the status and the role that added the signature. For example, as shown in the image below, it states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

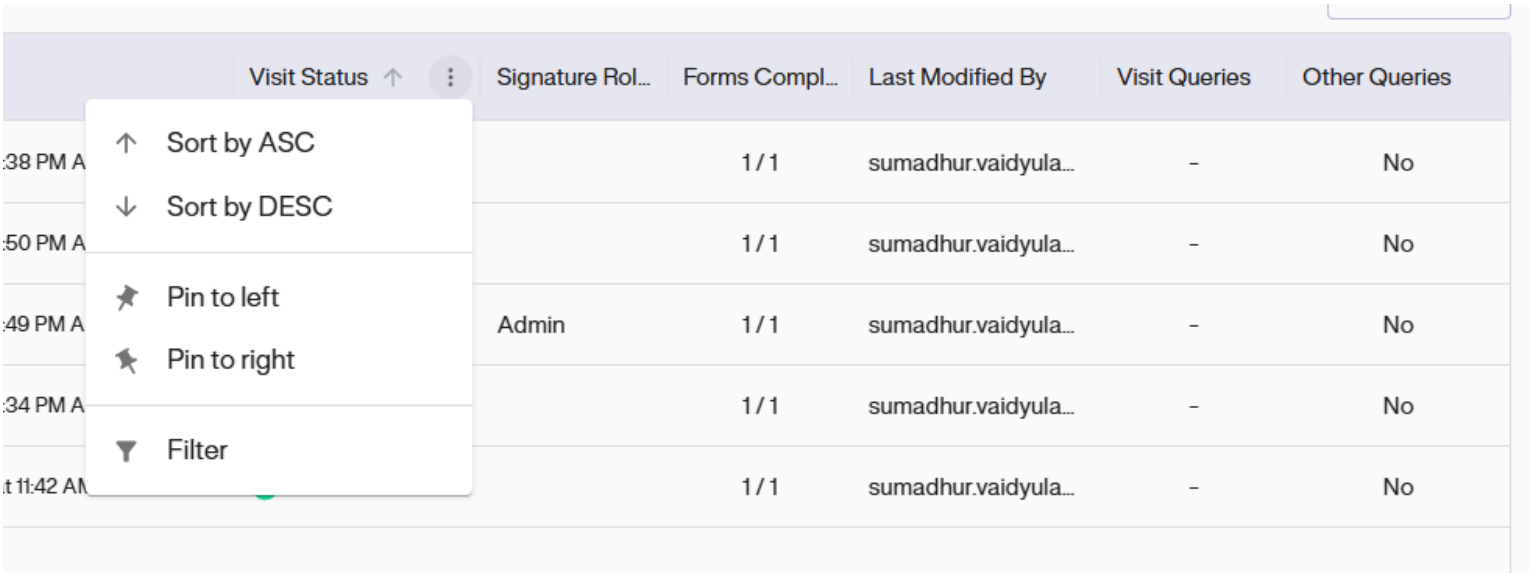


Alternatively, search for signed and unsigned visits using the data explorer. To view signed visits, click the grid icon in the top menu bar.

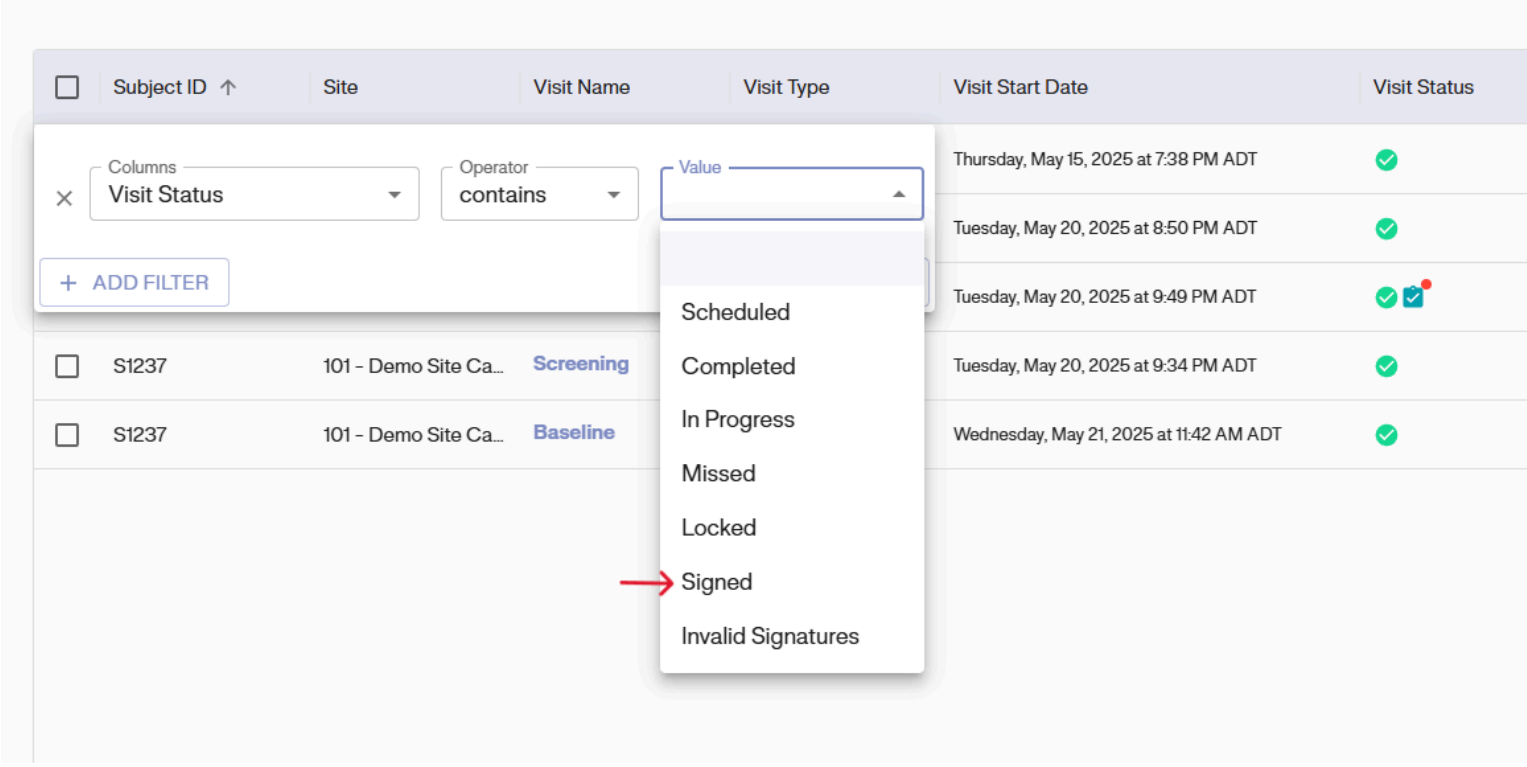


Select "Visits" from the menu options. Then click on the options icon (three-dot icon) on the "Visit Status" Column

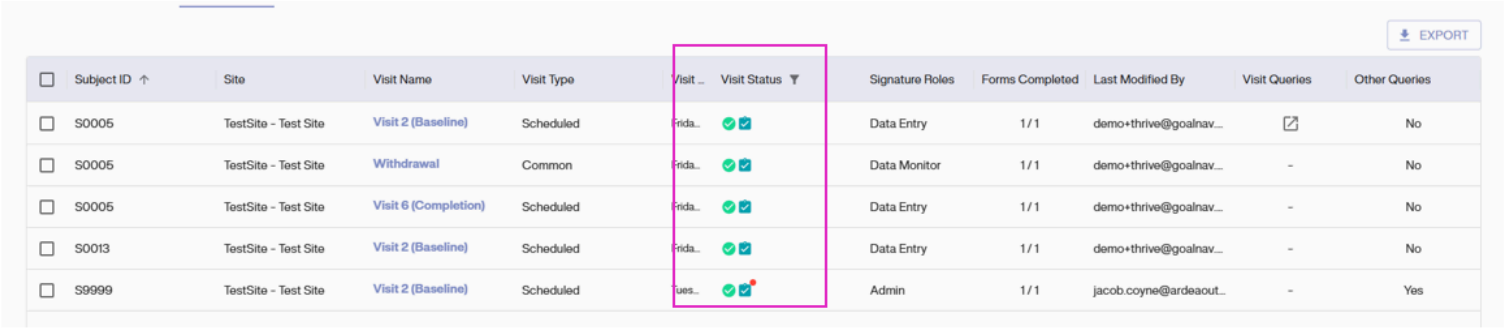




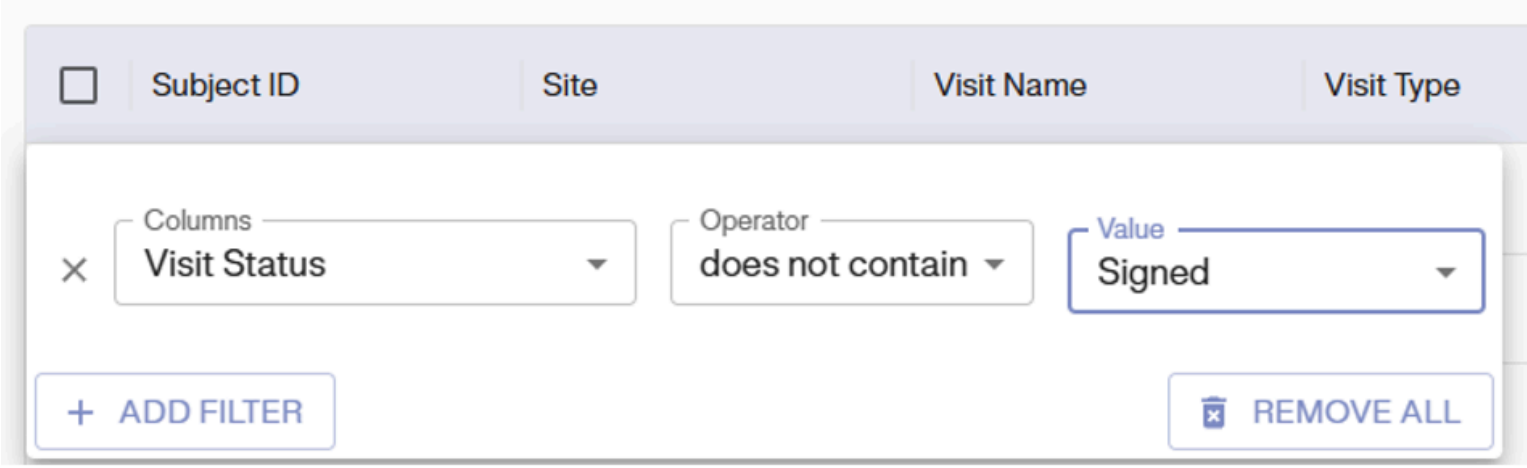
From the options, select the filter option and then from the filter options, select the “Signed” option.\



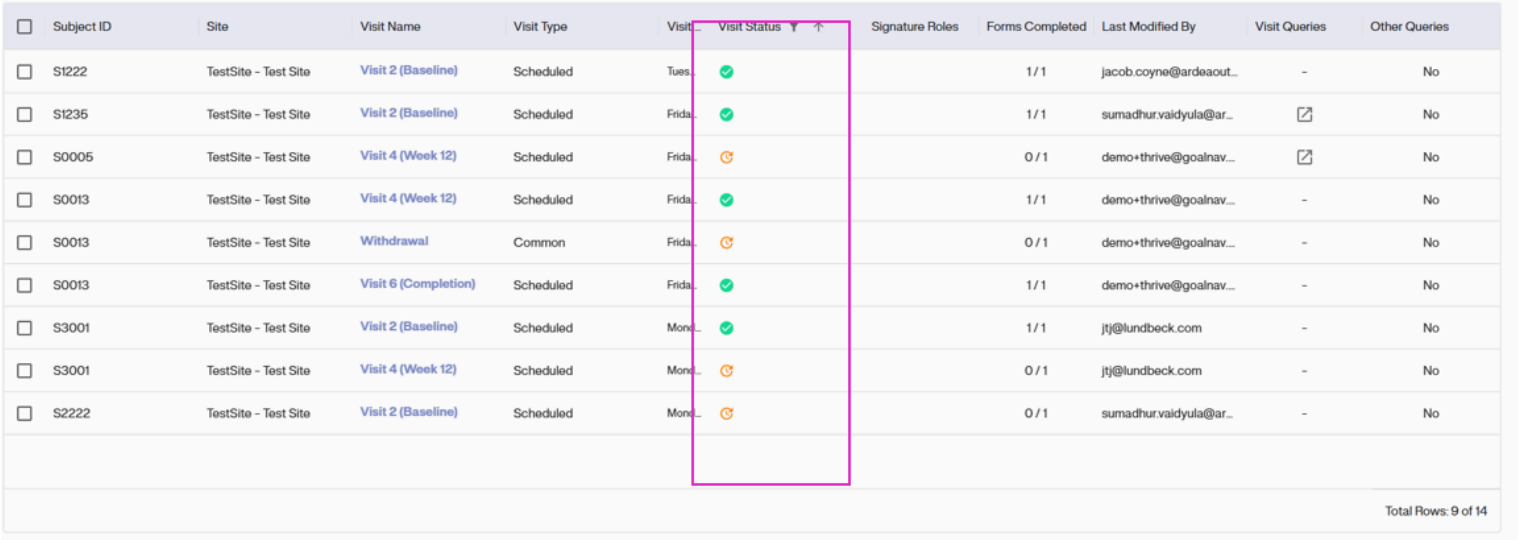
All visits with an applied signature are then displayed on the table.



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

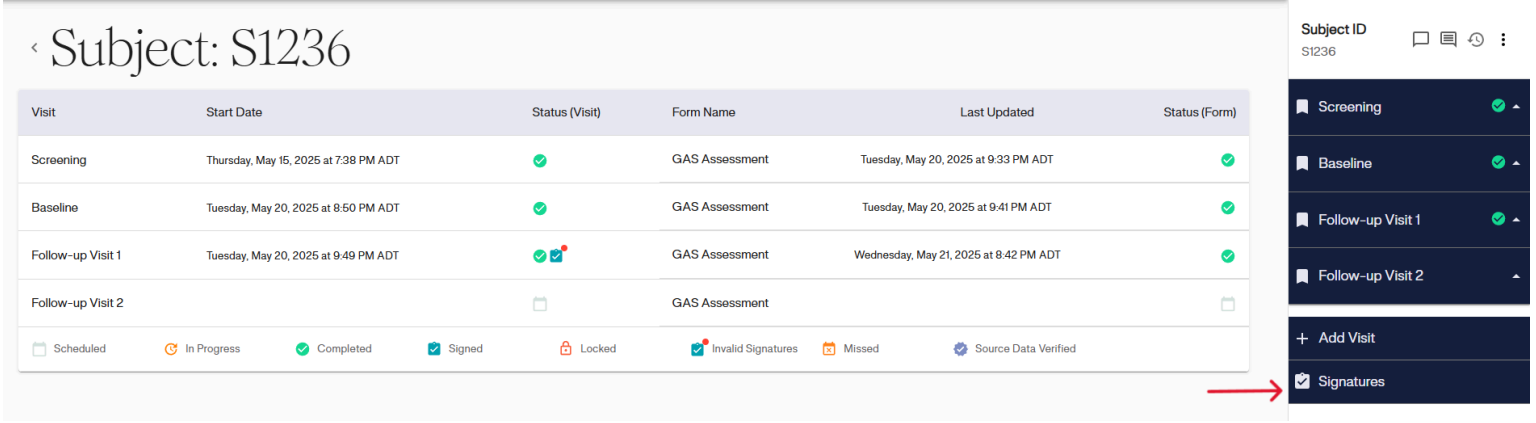


This displays all the visits that are missing signatures.

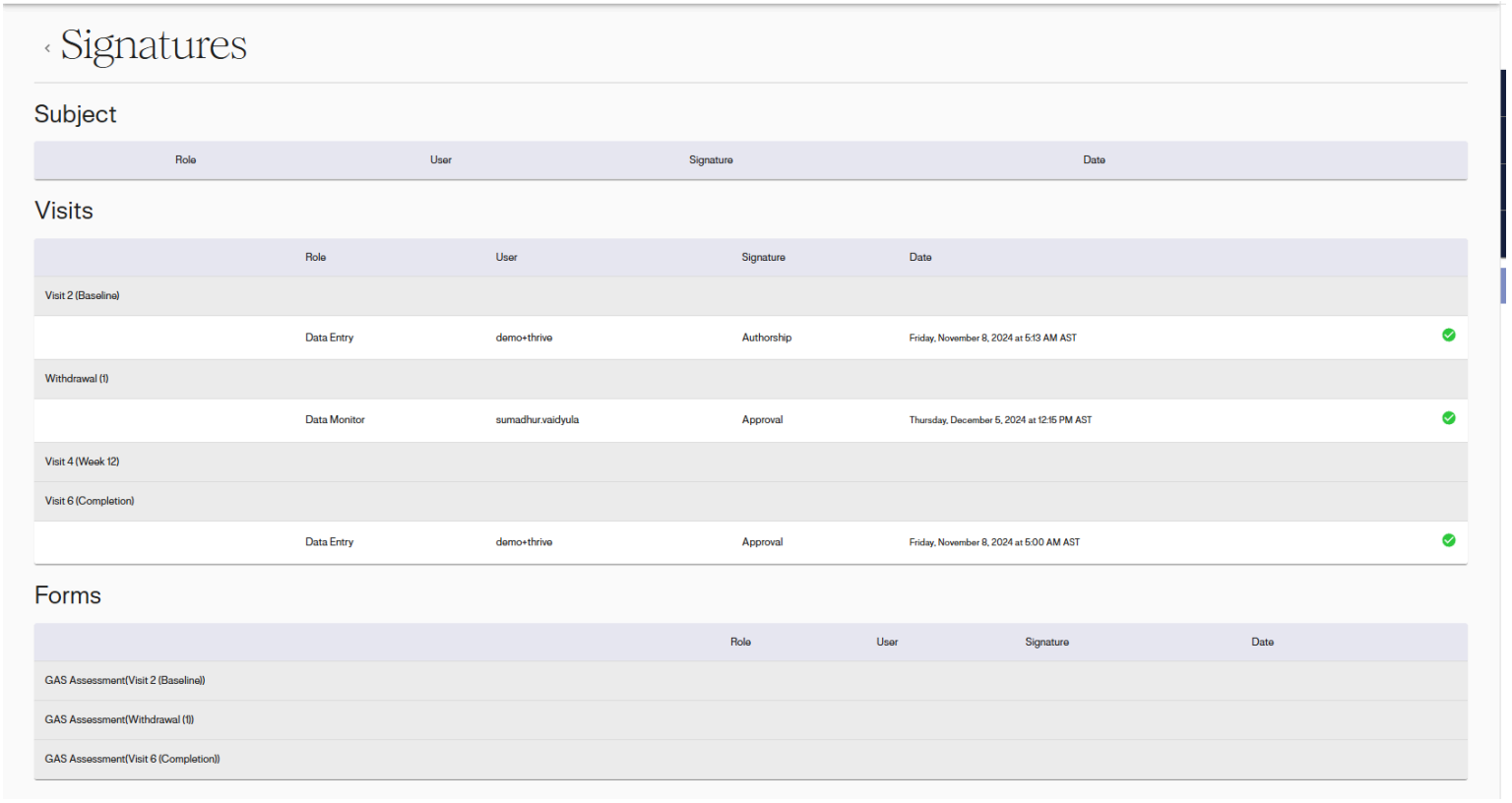


Monitor Invalid Signatures

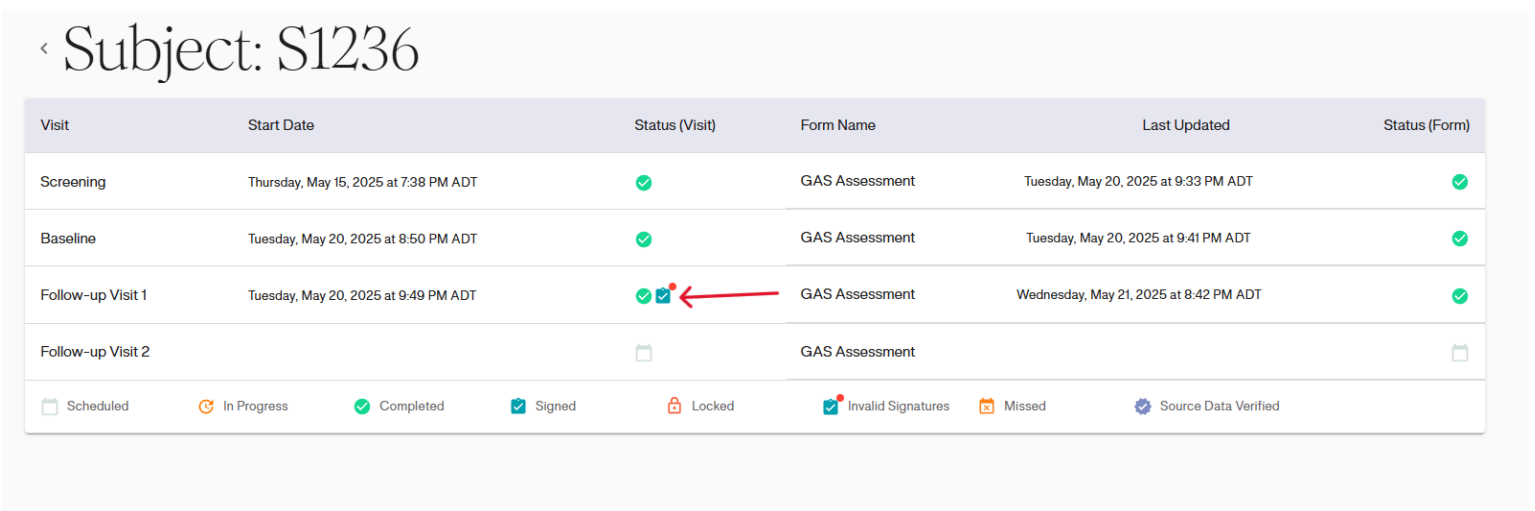
To monitor Invalid Signatures,navigate to the “Signatures” option from the subject menu.



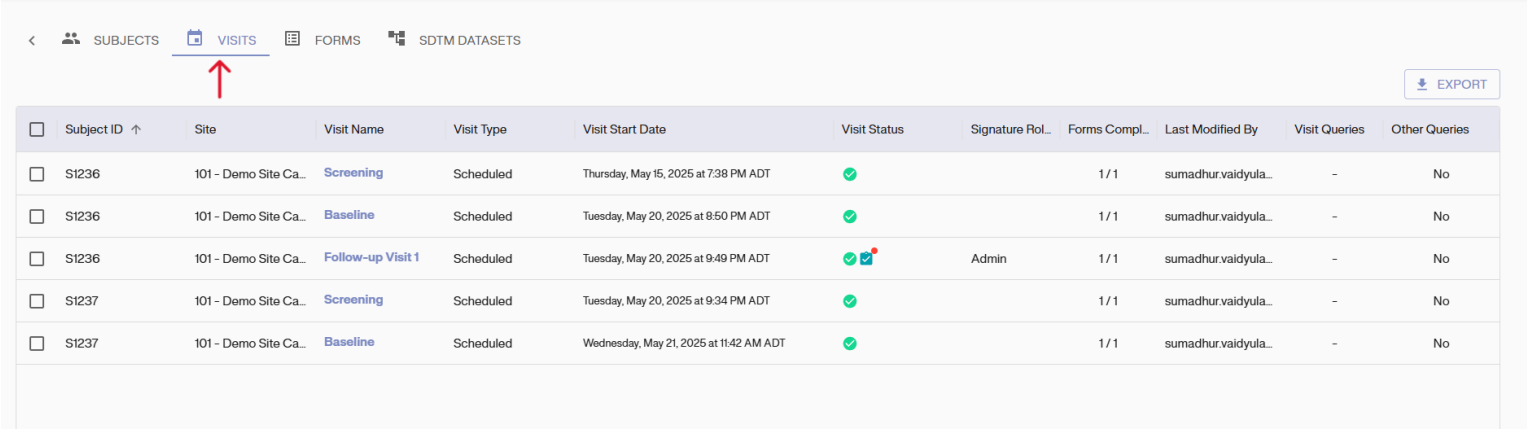
All the Signatures(Valid and Invalid) will be displayed on this dashboard.



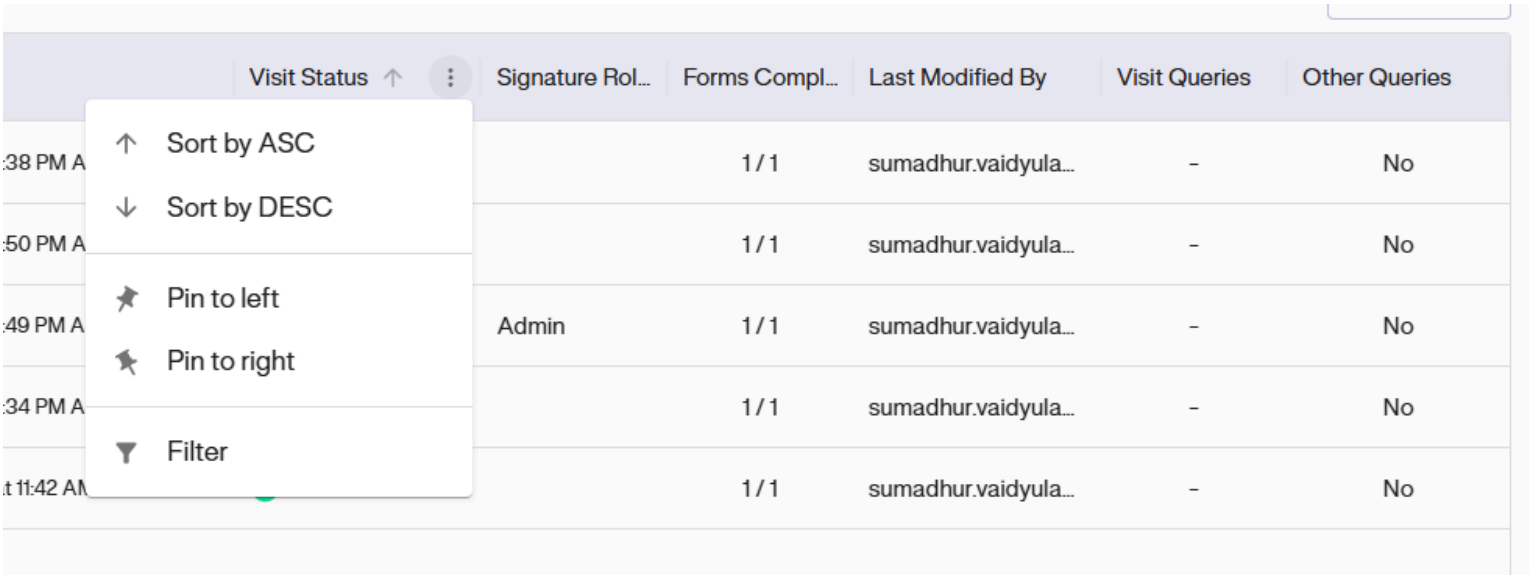
To check for invalid signatures, navigate to the Subject Details Dashboard. On the dashboard, an orange dot above the blue notepad icon (which represents the signature) indicates that the signature is invalid. Hover over the icon to view the signature's creator (e.g., Admin in the screenshot) and confirm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



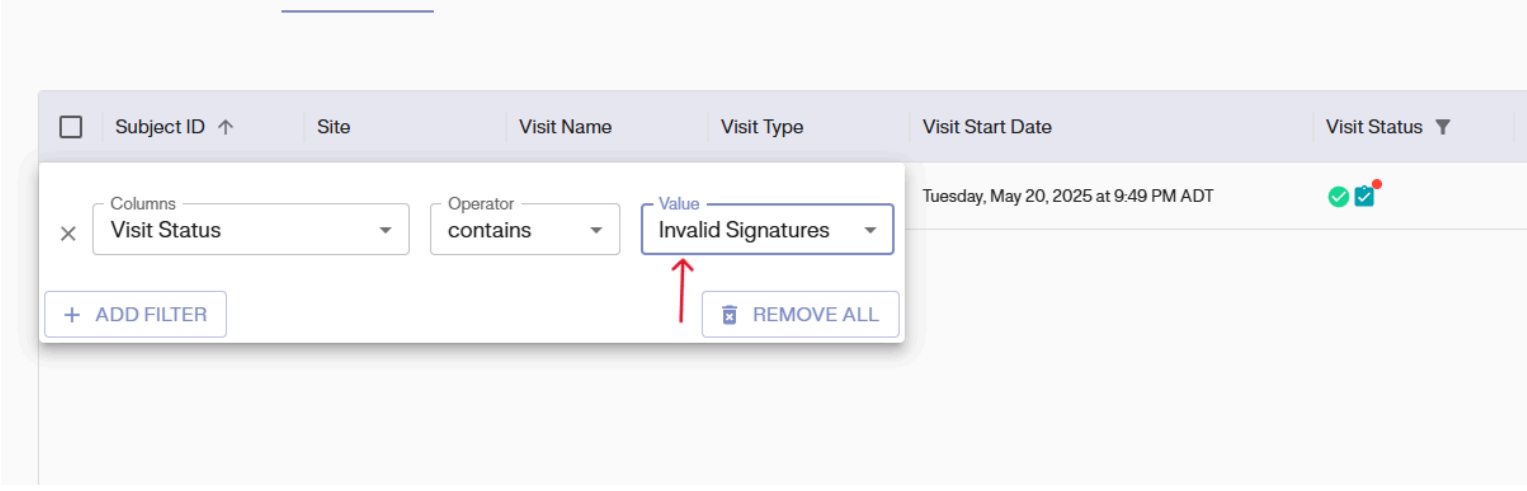
To use Data Explorer to check for invalid signatures, click on the grid icon in the top menu bar. The “Visits” option is selected for this demonstration.



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



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



The records with Invalid Signature are displayed on the table

EXPORT

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...	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

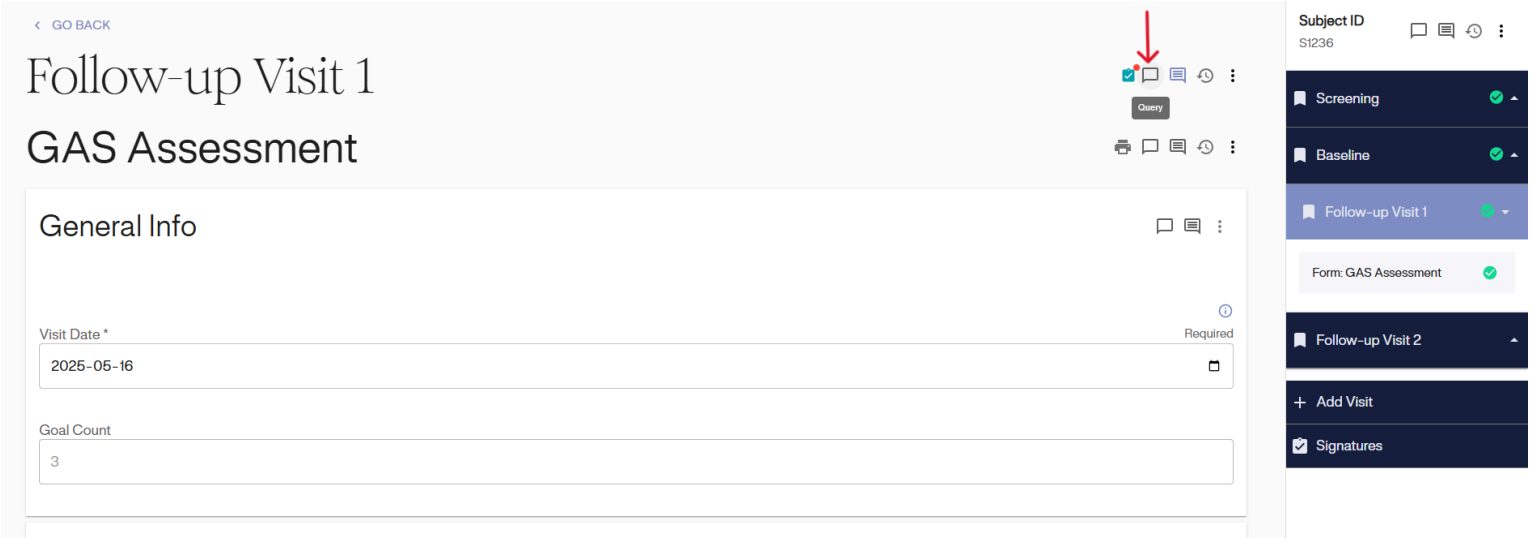
c Respond to GoalNav® Queries

d Close Queries

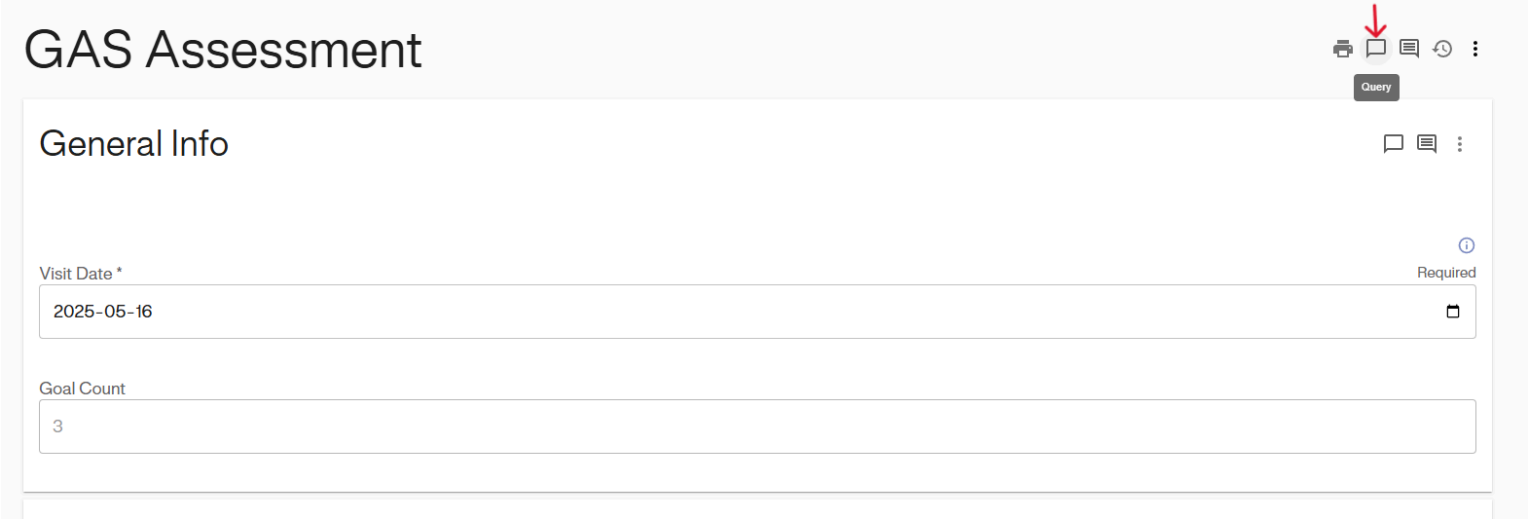
Managing Queries

Create a GoalNav® Query

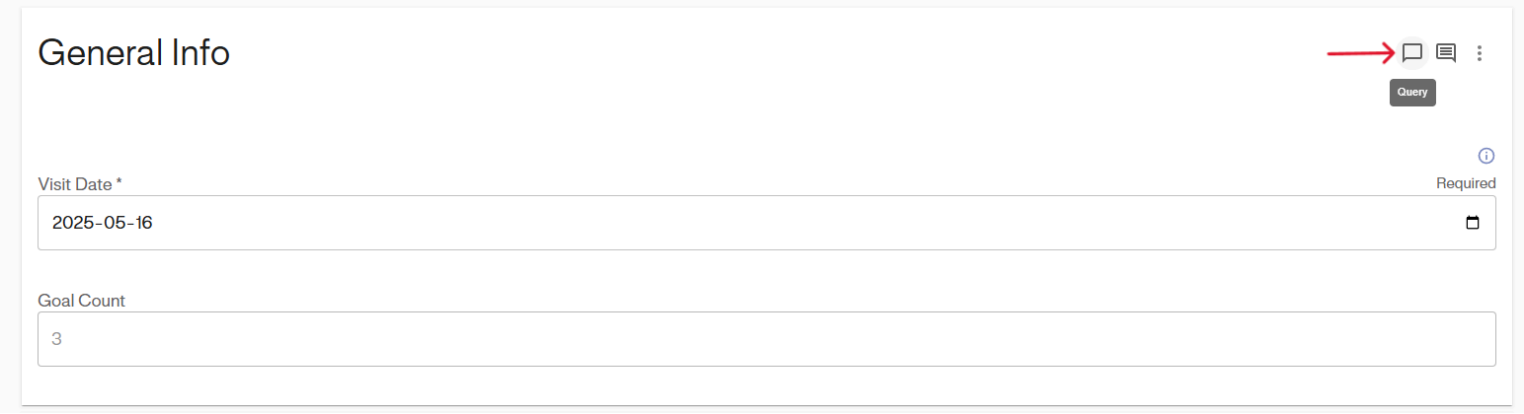
To create a new GoalNav® query on the visit level, click on the blank dialogue box icon right next to the name of the visit.



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.



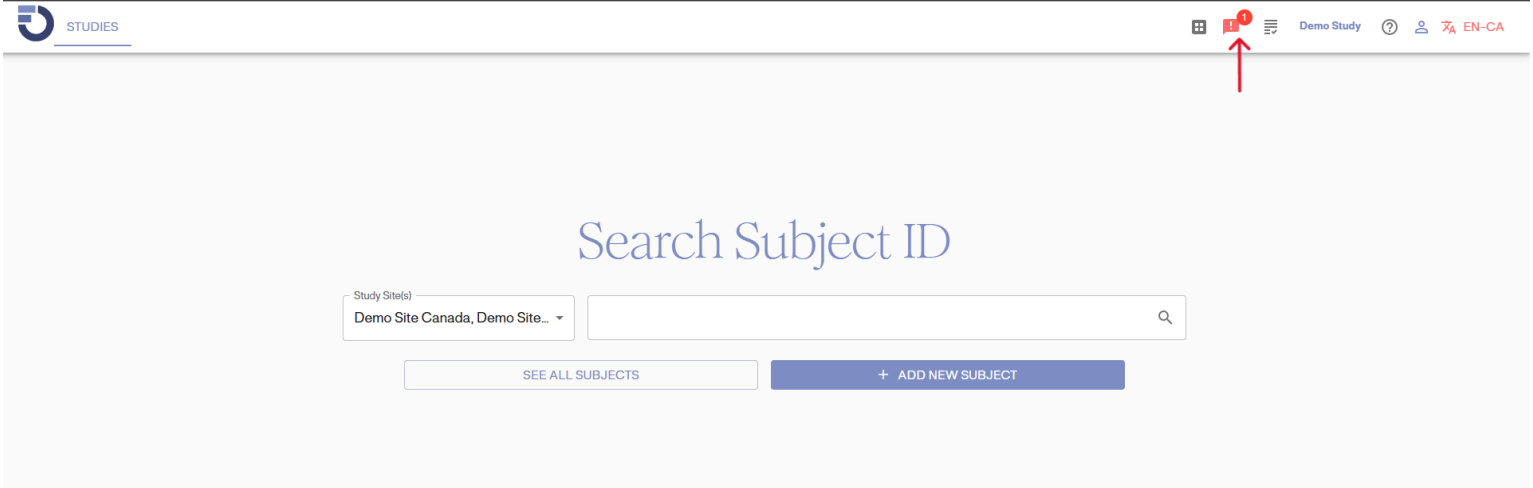
To create a new GoalNav® query on the section level, click on the blank dialogue box icon at the top of the form section.



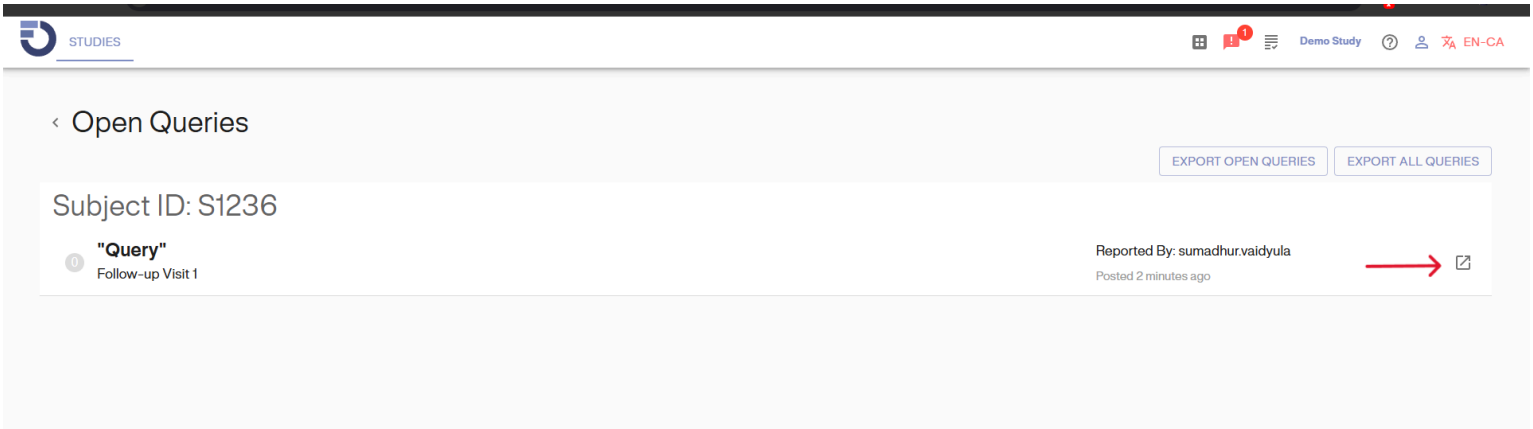
Click the icon to open a pop-up window. Here, start a new query thread in GoalNav® for the selected subject and visit. In the text box, enter the query. Then, click the “Post” button to submit it. When a new query is posted, the author of the visit will be notified.

View All GoalNav® Queries

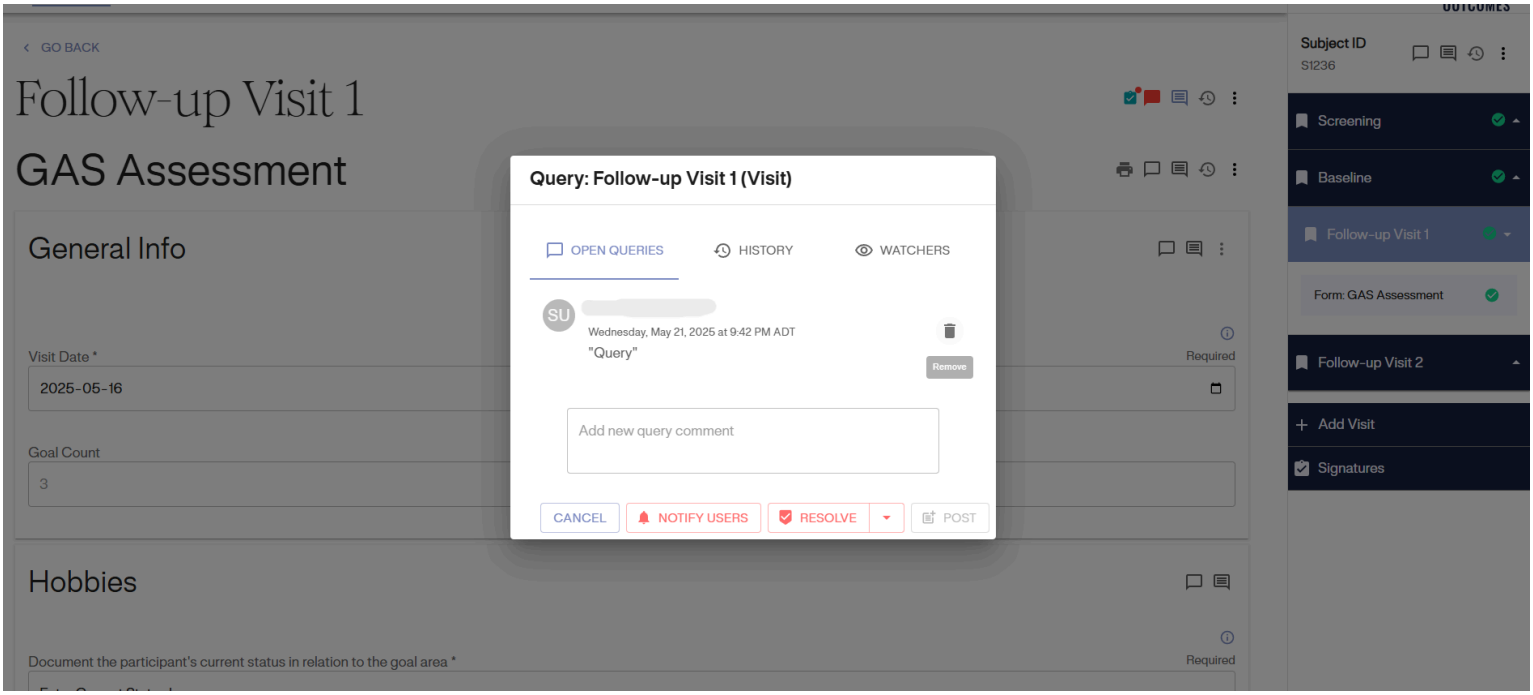
To view all open queries in GoalNav®, click the dialogue icon, which will be highlighted in red when unresolved queries are present within the study.



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.

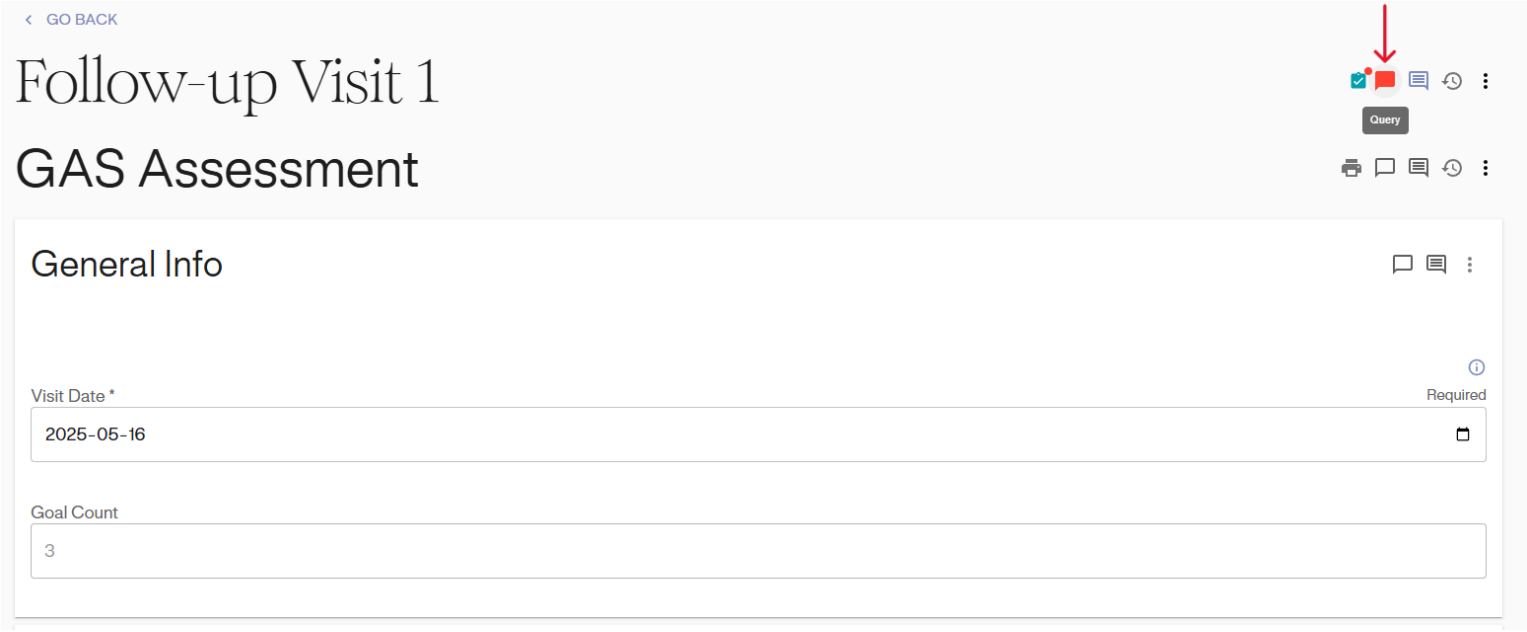


Click the link icon to open a pop-up window to display the visit, form, or form section where the query was created, including the entire query thread.

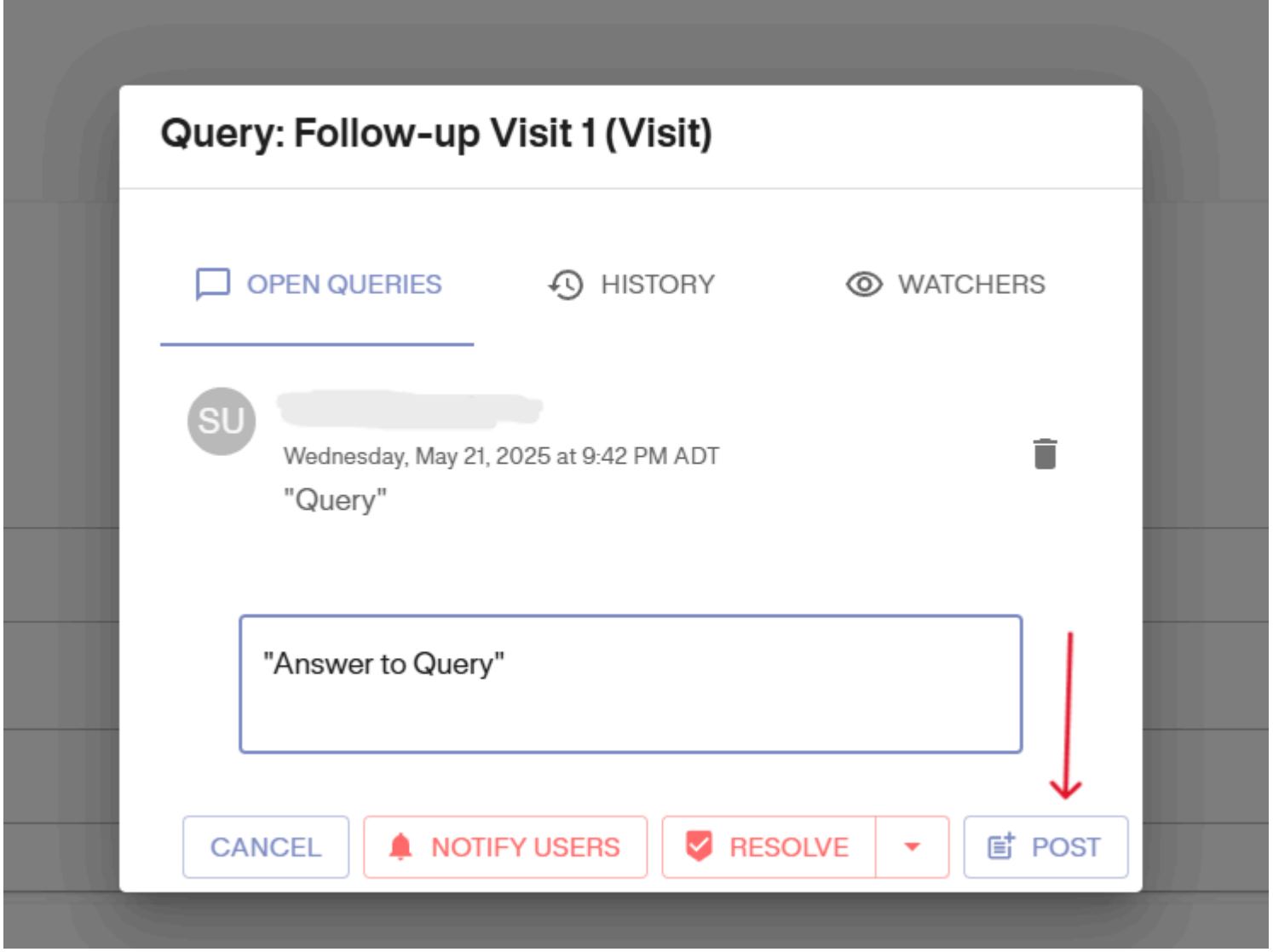


Respond to GoalNav® Queries

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.



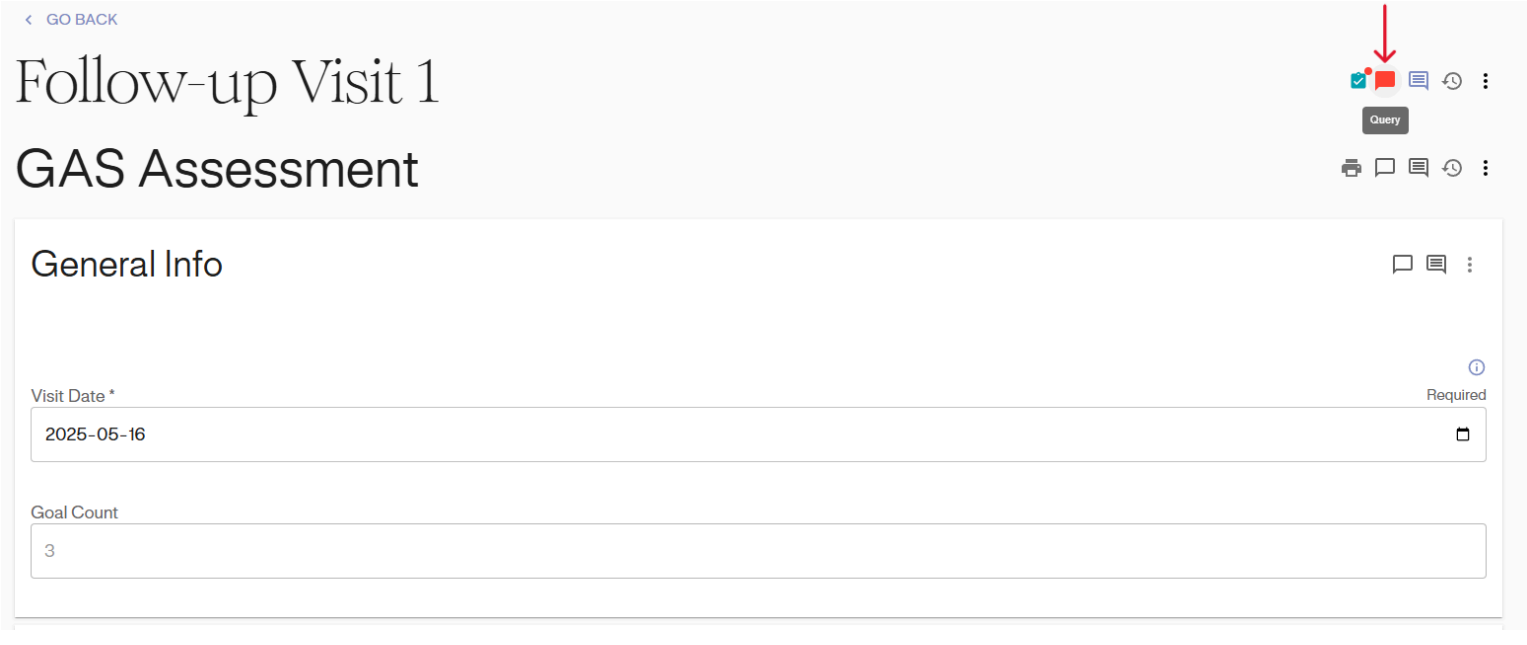
Click on the red dialogue icon to open a pop-up window that displays the active query thread. In the text box, enter the answer to the query. Click on “Post” to post the response. Posting a response will notify the author of the data and any users who have previously responded/participated in the query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



Close Queries

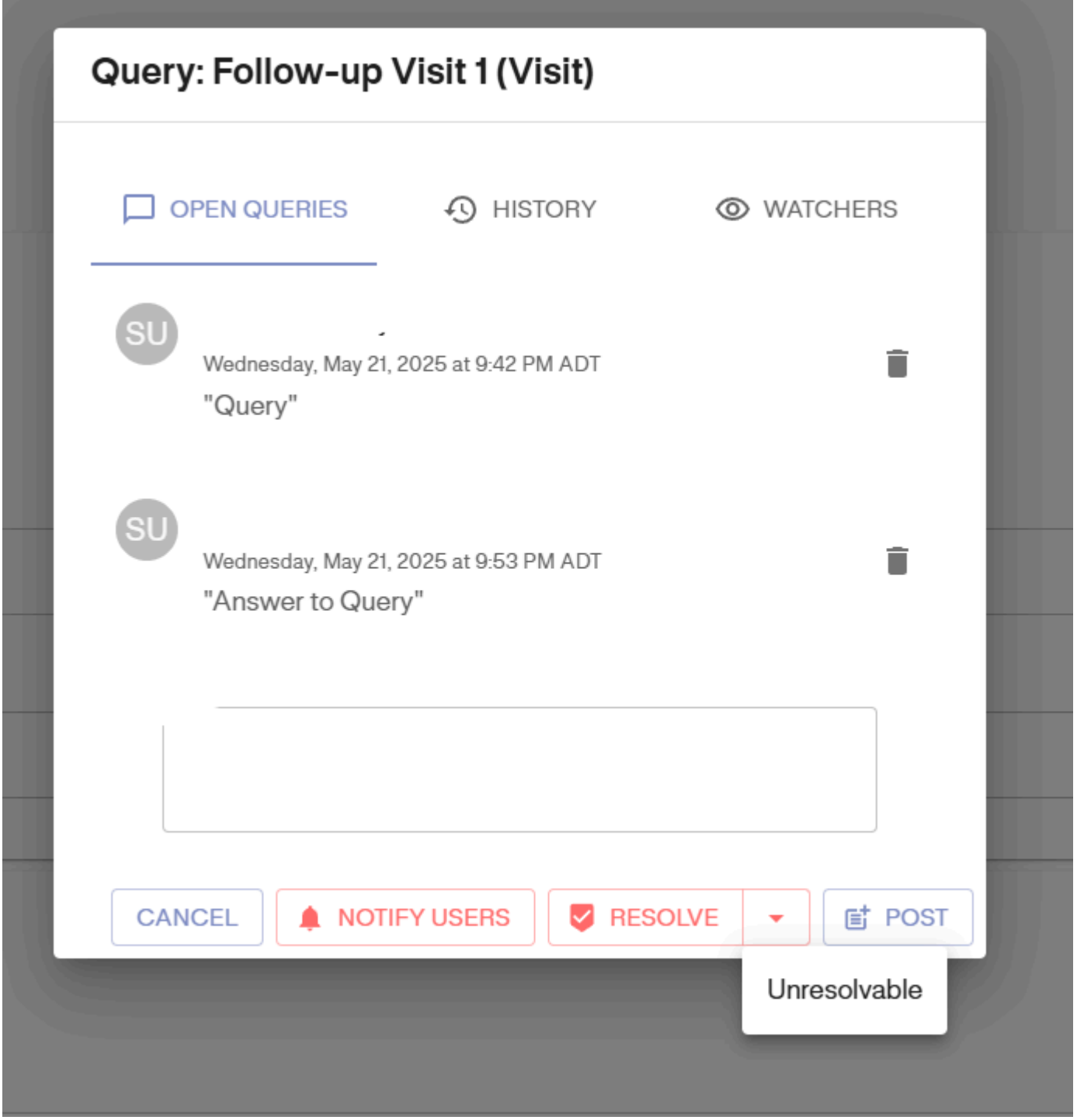
Once an answer to a query is accepted and validated, click the “Resolve” button to close the query. Once “Resolve” is selected, the resolved query will disappear. Note: The Data Monitors should only close queries they created themselves or those that have been resolved. They should not close any unanswered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

Click on the Query Icon on the visit details page.



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

IN THIS CHAPTER

1 Reviewing and Managing Data
   a Data Explorers
      a Overview
      b View Data
      c Export Data
   b Data Locking

Reviewing and Managing Data

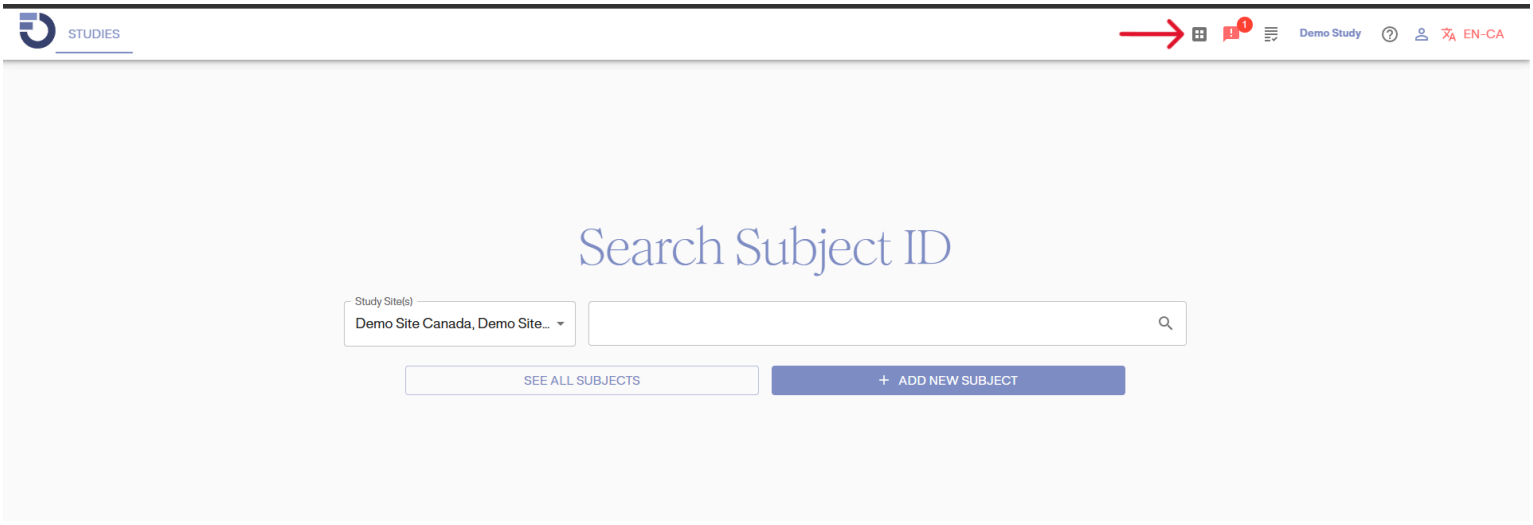
Data Explorers

OVERVIEW

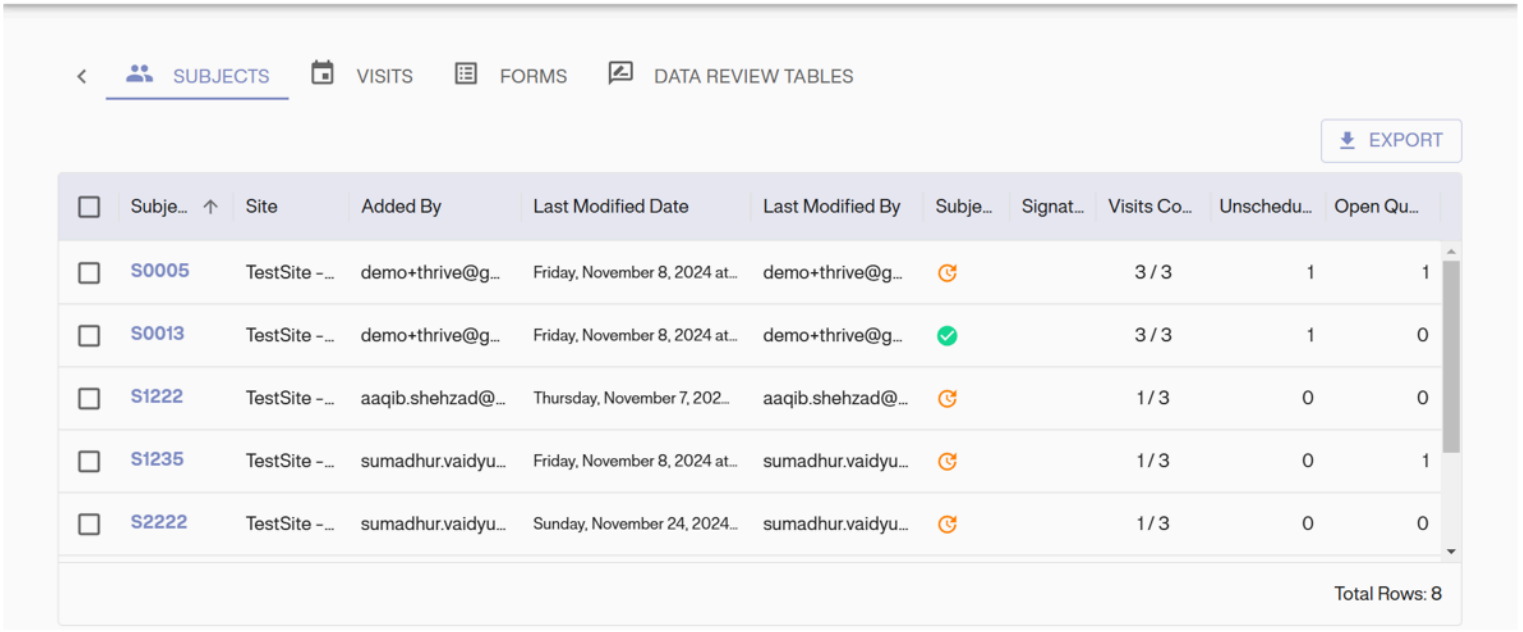
The data explorer section in GoalNav® enables users to search for records efficiently using queries and apply specific filters for data retrieval. Instructions to access the data explorer are provided below.

VIEW DATA

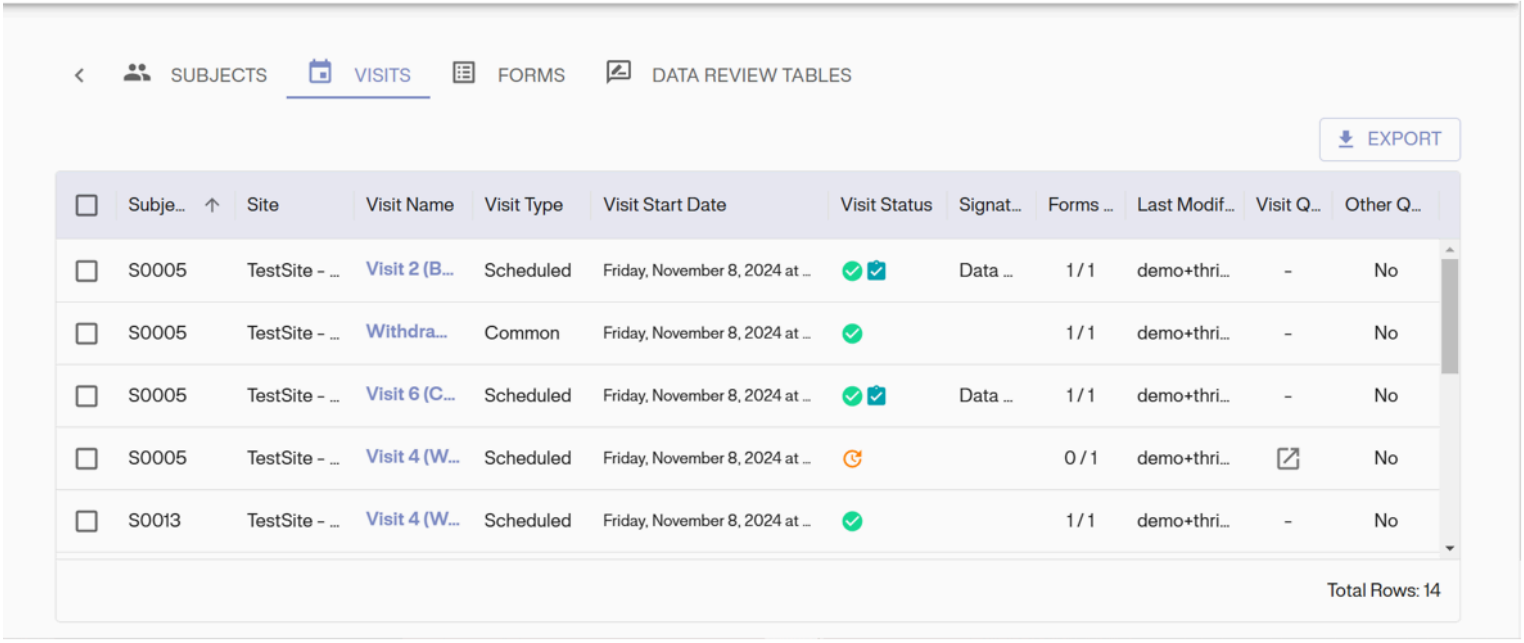
On the Trial homepage, click the grid icon in the menu bar to access the data explorer.



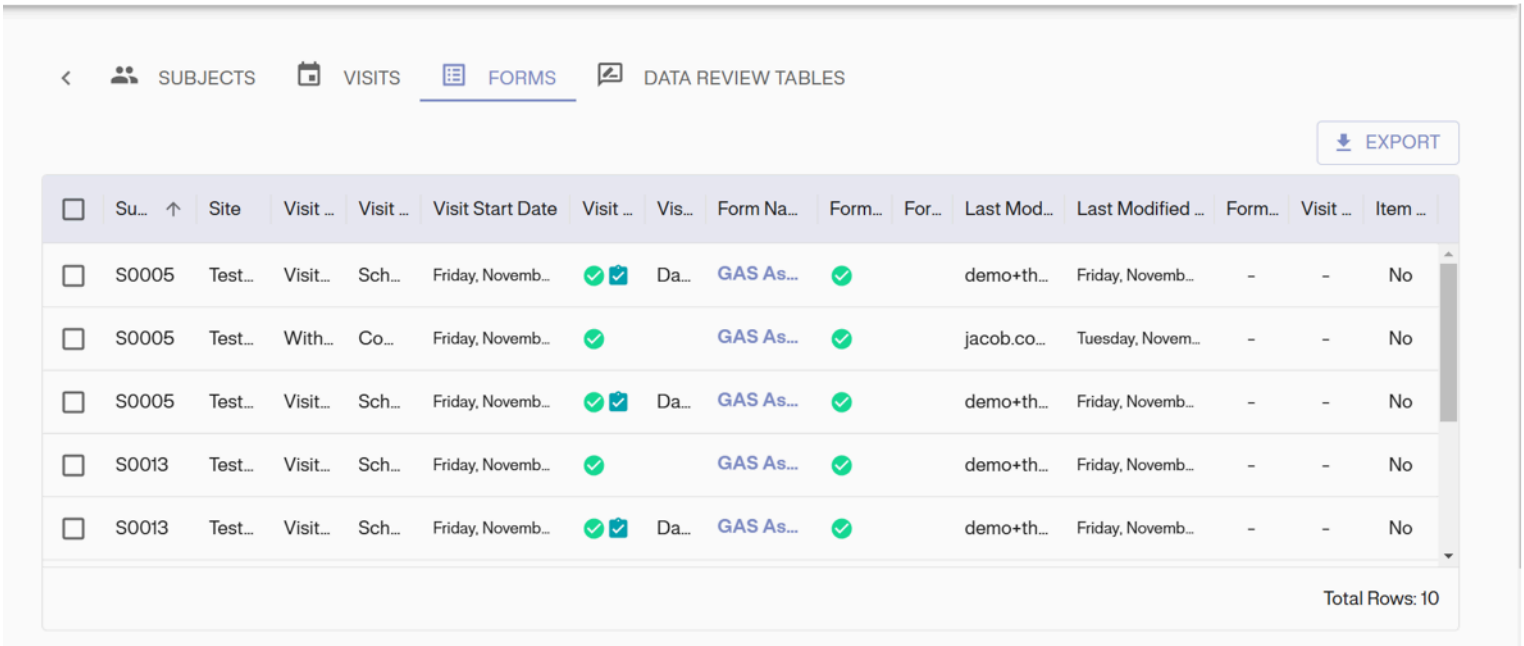
Click the grid button to open the data explorer dashboard, as shown in the image below. This dashboard displays records for Subjects and Visits and data review tables that show records based on the selected visit. For example, the table below shows the records related to “Subjects”.



Visits Record:

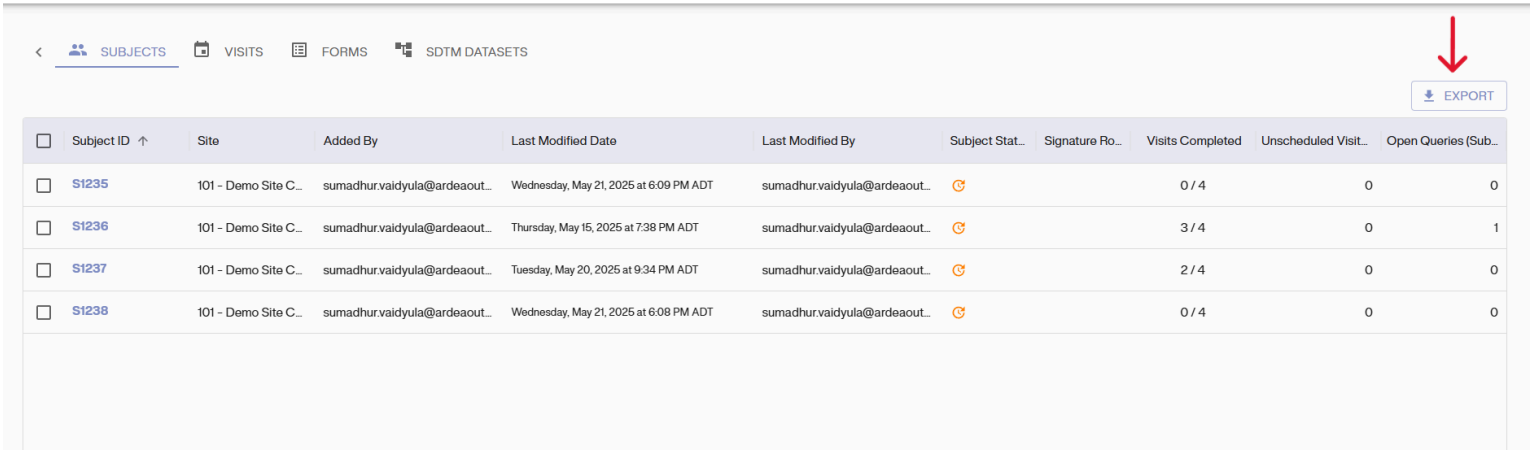


Forms Record:



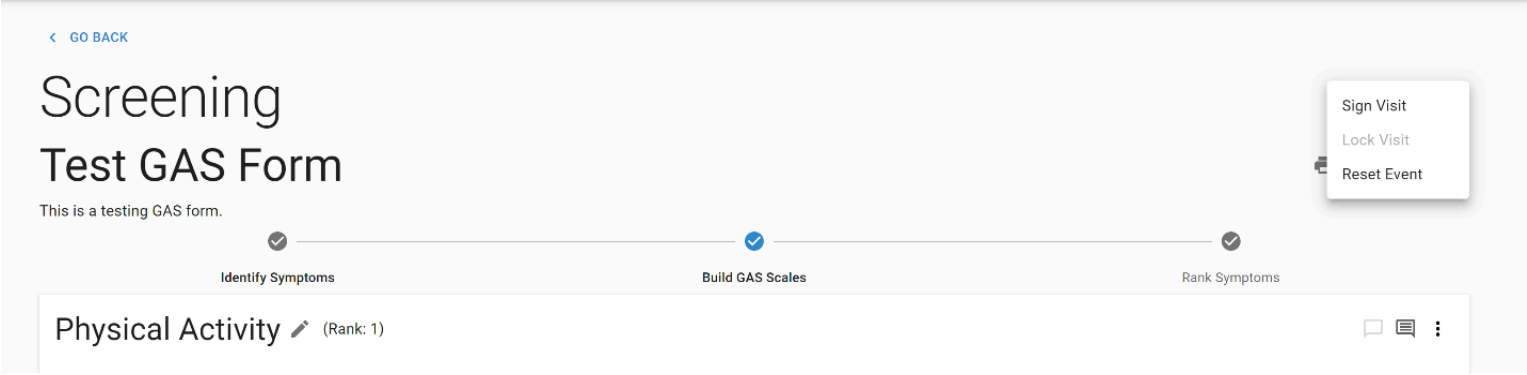
EXPORT DATA

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.



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:



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:

GO BACK

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

Subject ID
S1236

Screening

Baseline

Follow-up Visit 1

Form: GAS Assessment

Follow-up Visit 2

Add Visit

Signatures

IN THIS CHAPTER

1 Managing Queries

a Create a GoalNav® Query

b View All GoalNav® Queries

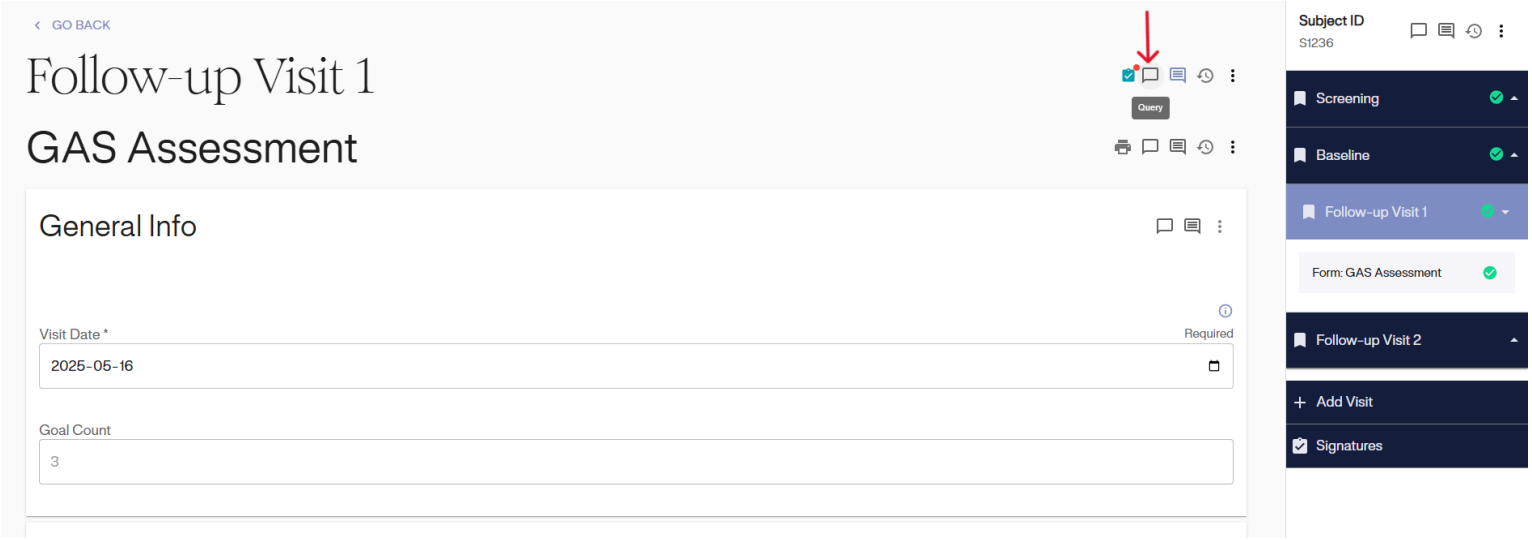
c Respond to GoalNav® Queries

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.



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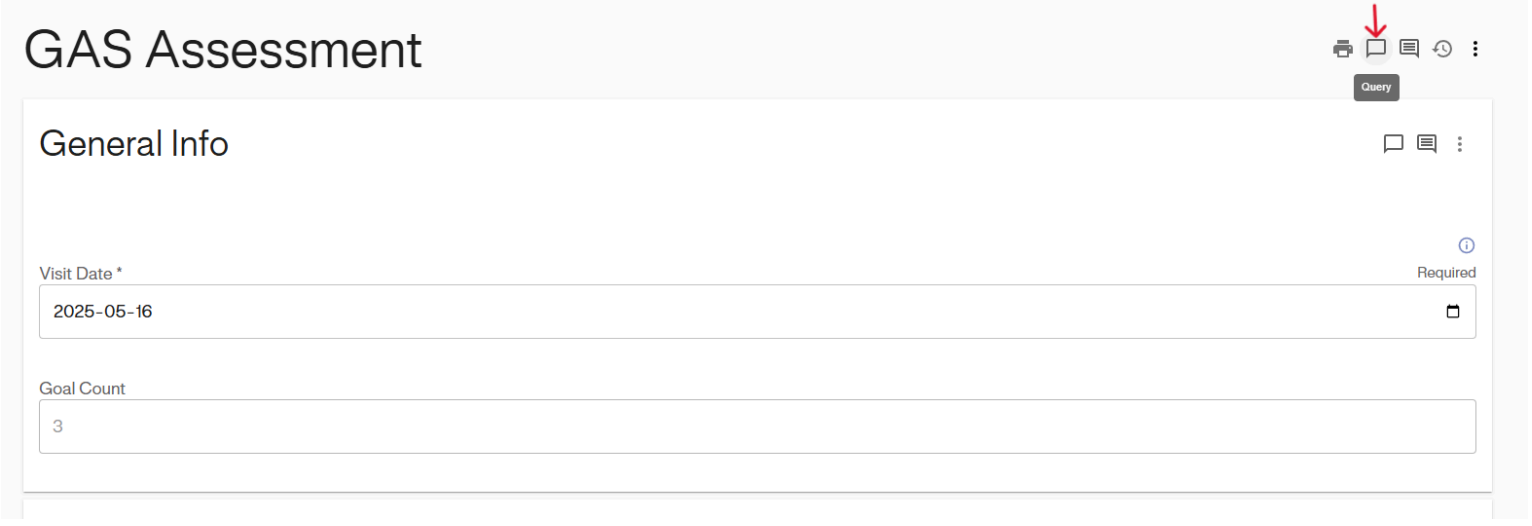

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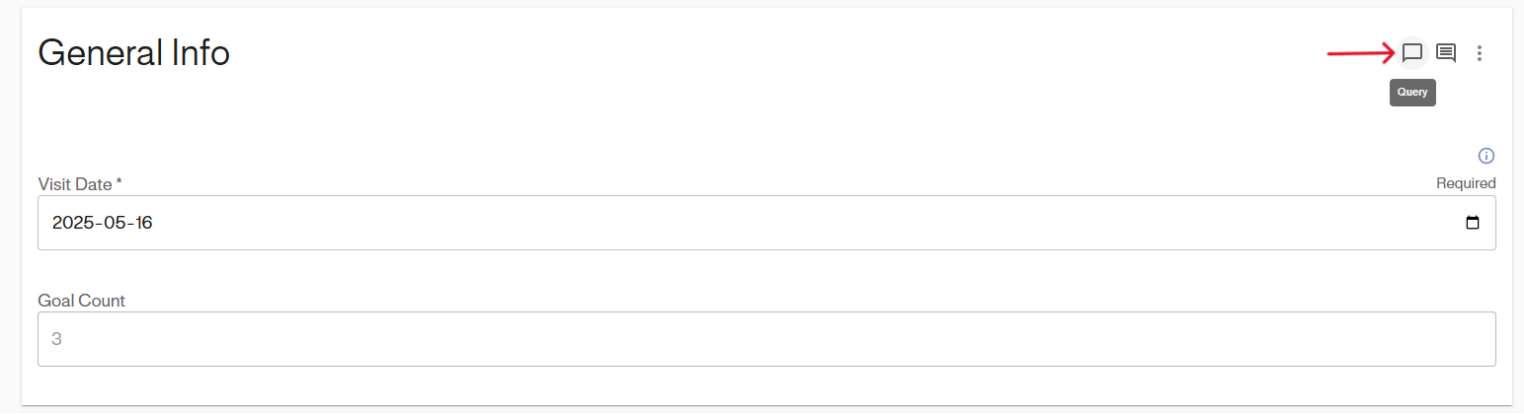

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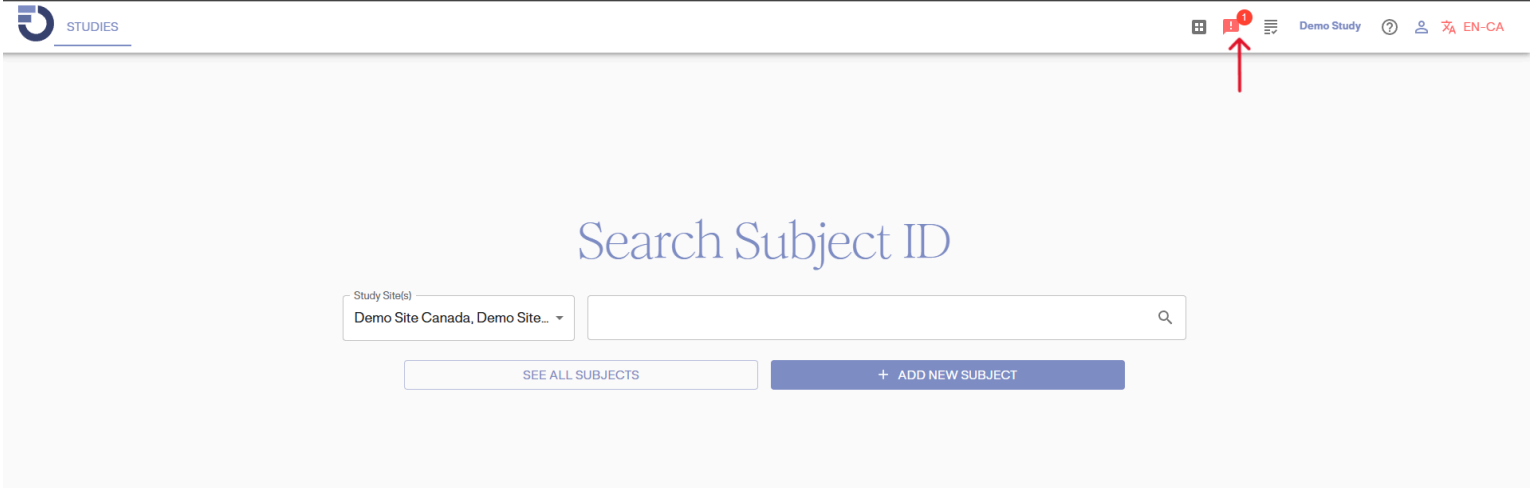

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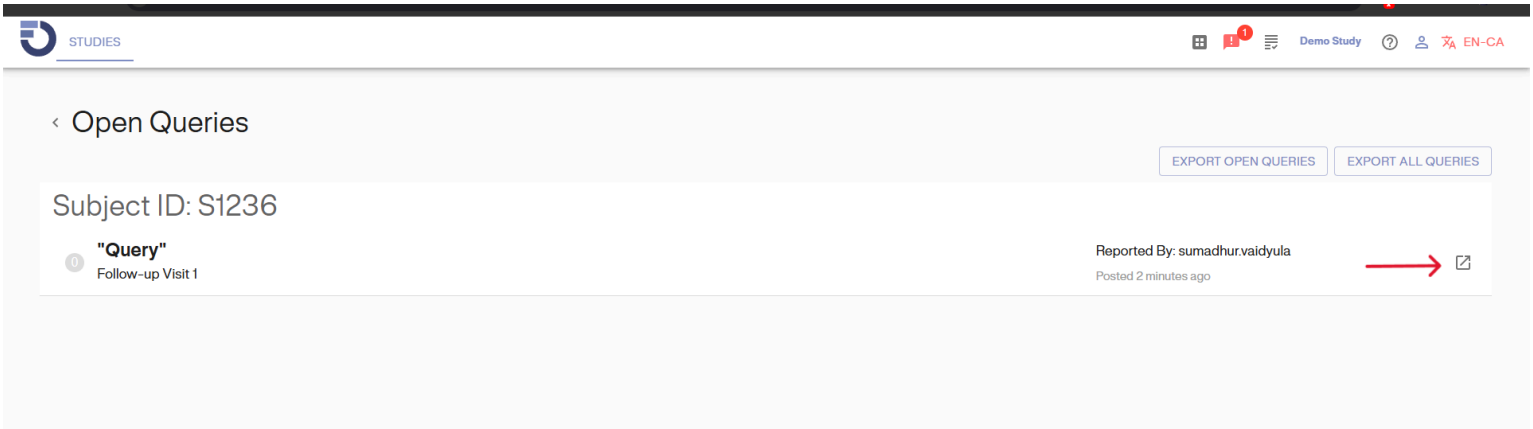

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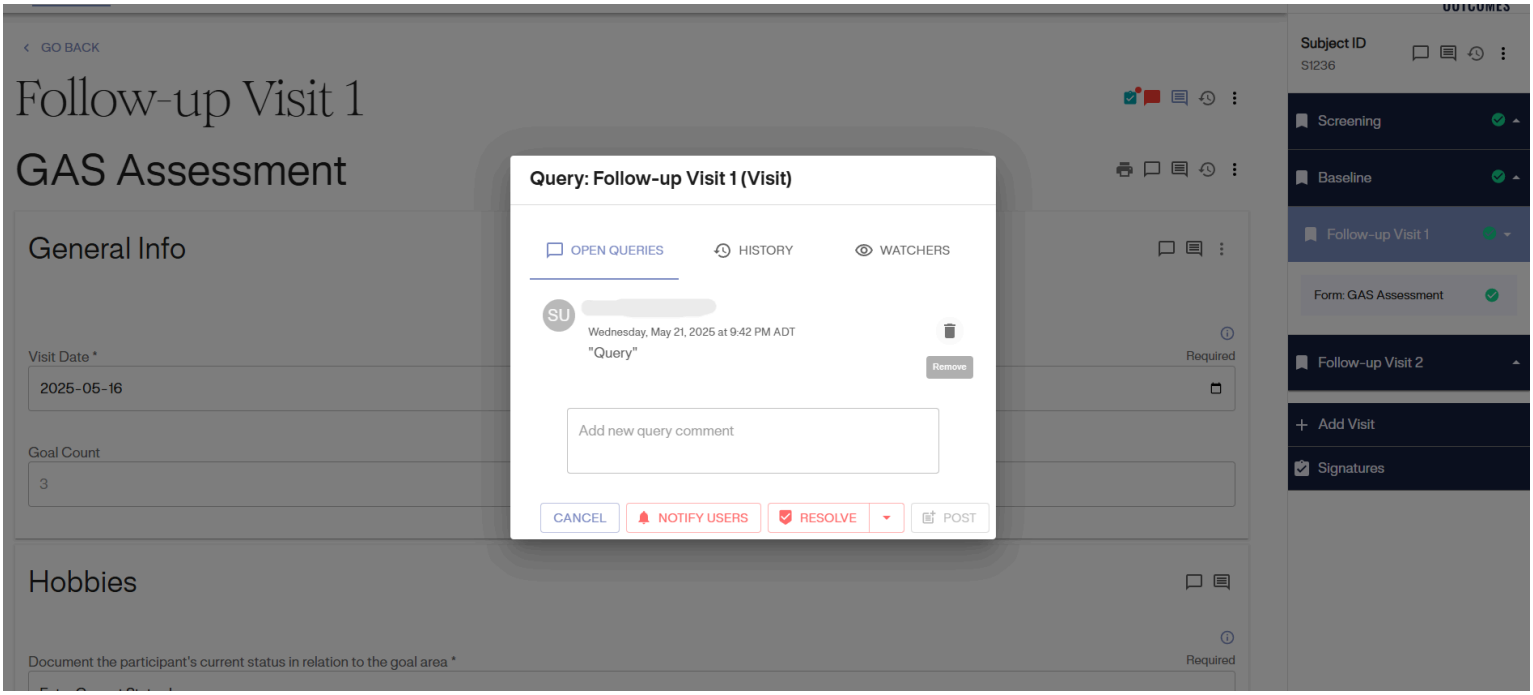

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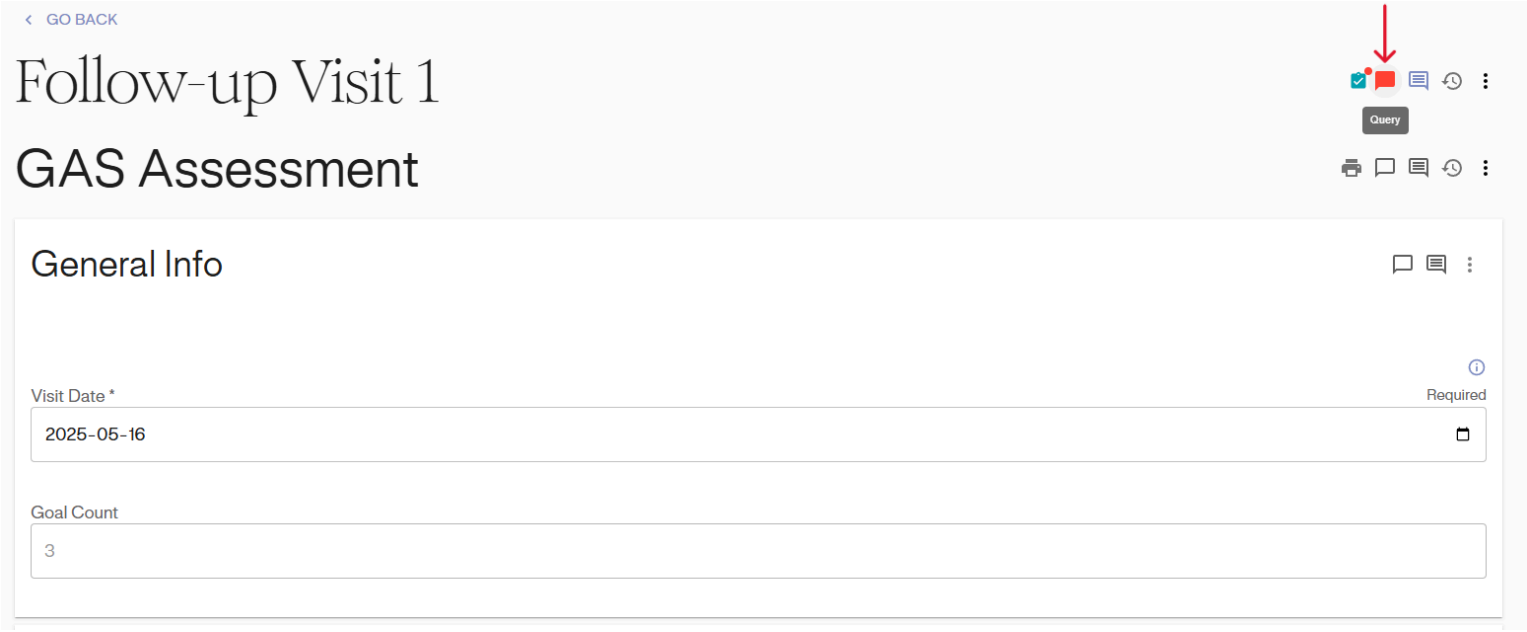

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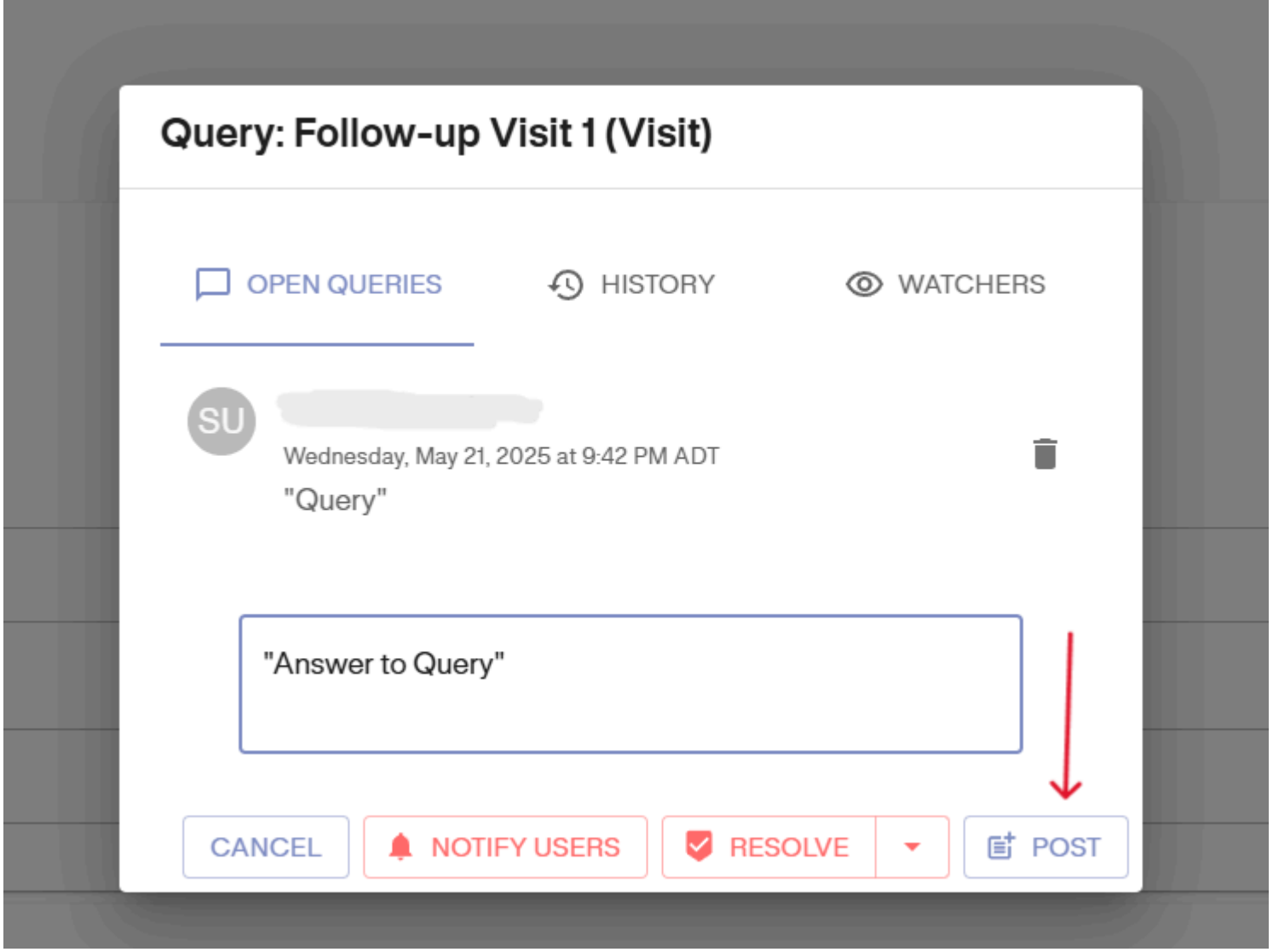

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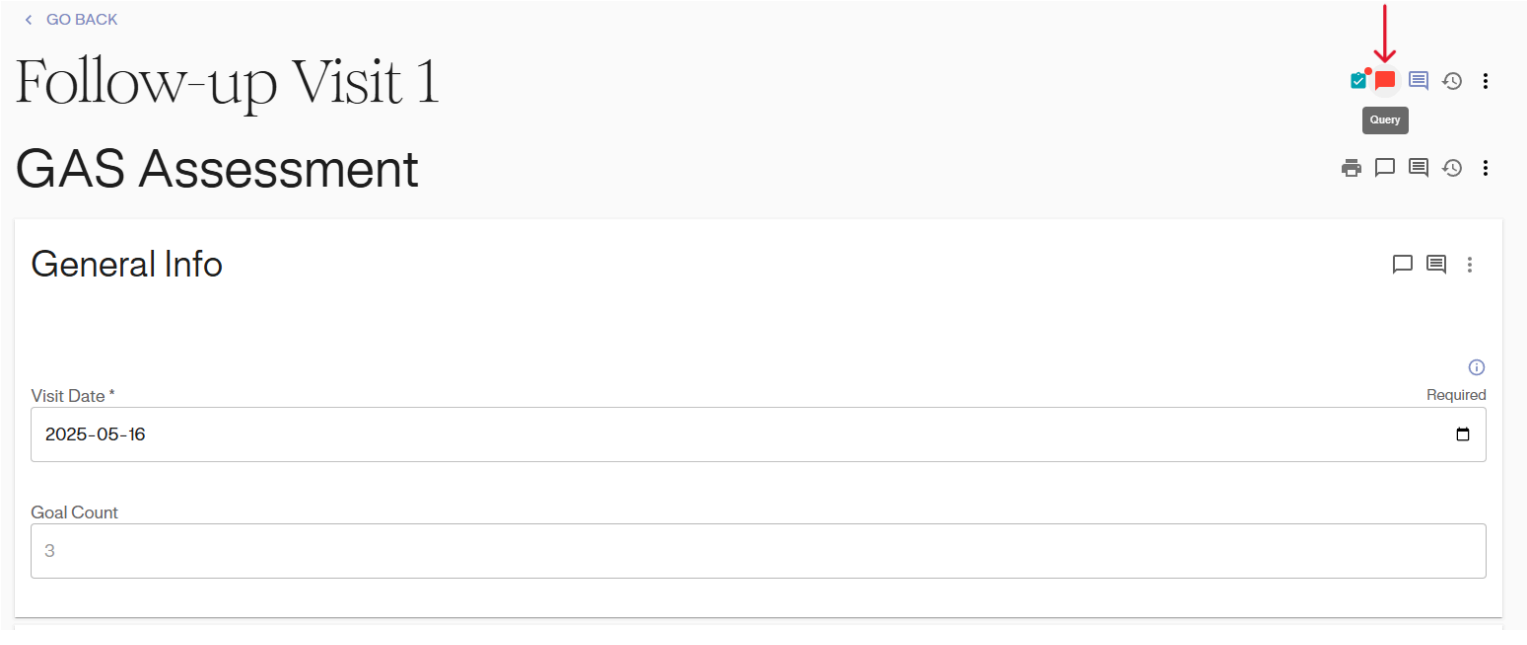

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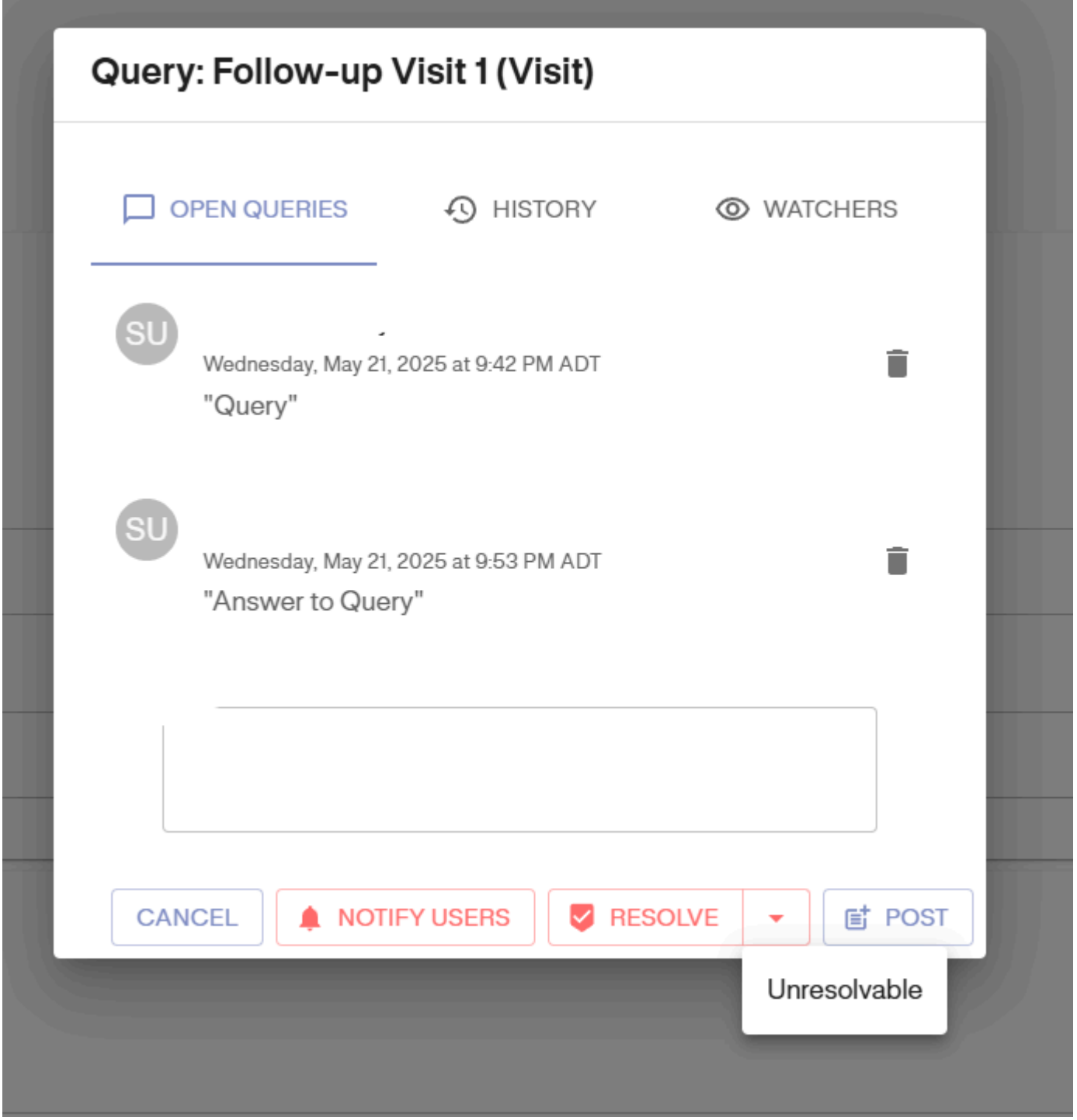
Query: Follow-up Visit 1 (Visit)
OPEN QUERIES
HISTORY
WATCHERS
SU
Wednesday, May 21, 2025 at 9:42 PM ADT
"Query"
SU
Wednesday, May 21, 2025 at 9:53 PM ADT
"Answer to Query"
CANCEL
NOTIFY USERS
RESOLVE
POST
Unresolvable

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.

TABLE OF CONTENTS

- System Manual version - July 2025

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