Advantage eClinical

Advantage GlobalTrace User Guide

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Introduction to GlobalTrace

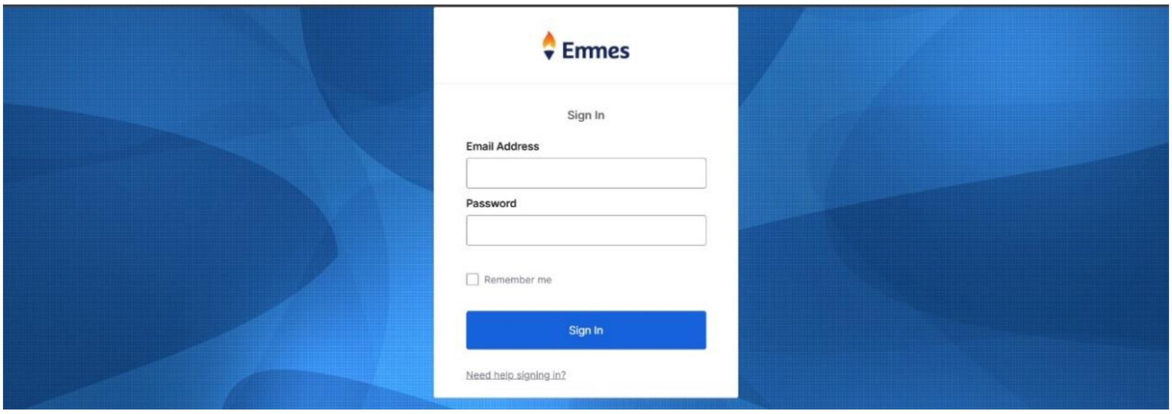
Advantage GlobalTrace (GT) enables clinical sites to manage and track specimens and artifacts in real time. It integrates seamlessly with the Advantage eClinical platform, allowing you to efficiently add, update, and ship specimens across multiple locations.

Logging in to GlobalTrace

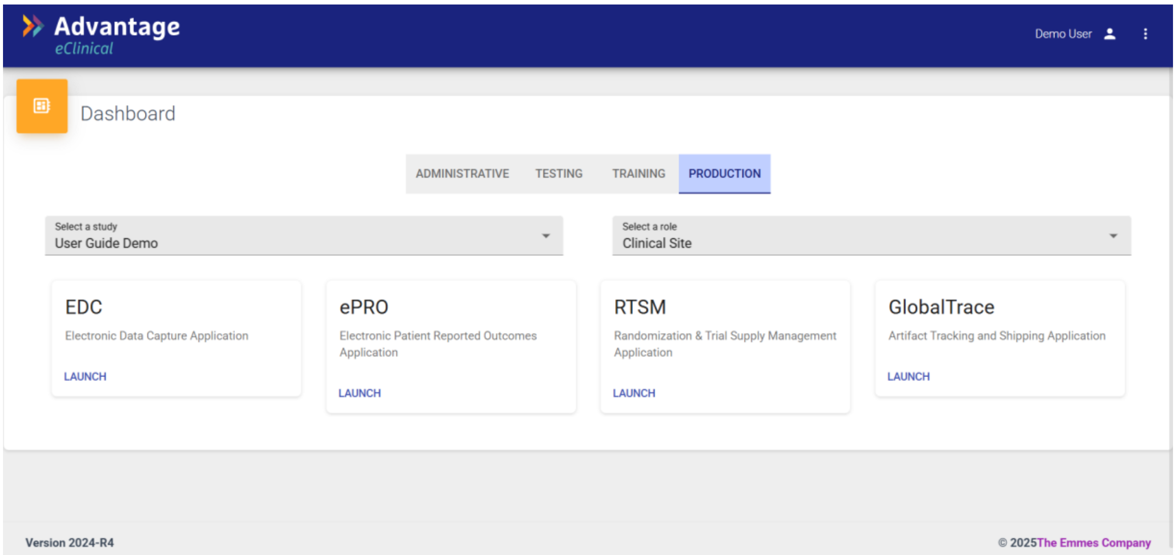
Use your Advantage eClinical credentials to log in to GlobalTrace and access study data.

Steps to log in:

1. Open your browser and go to emmes.advantage-eclinical.com. The login page appears.



2. Enter your credentials and select **Sign In**. The Advantage eClinical (AEC) dashboard appears.



3. From the AEC Dashboard, select your environment, study, and role, then select **LAUNCH** from the GlobalTrace tile. GlobalTrace opens in a new tab with the study, role, and site populated.

Navigating the Interface

The GlobalTrace interface provides a user-friendly design to simplify study data collection tasks. This section guides you through the main navigation tools, including profile settings, filters, and switching between studies or environments.

Top menu bar

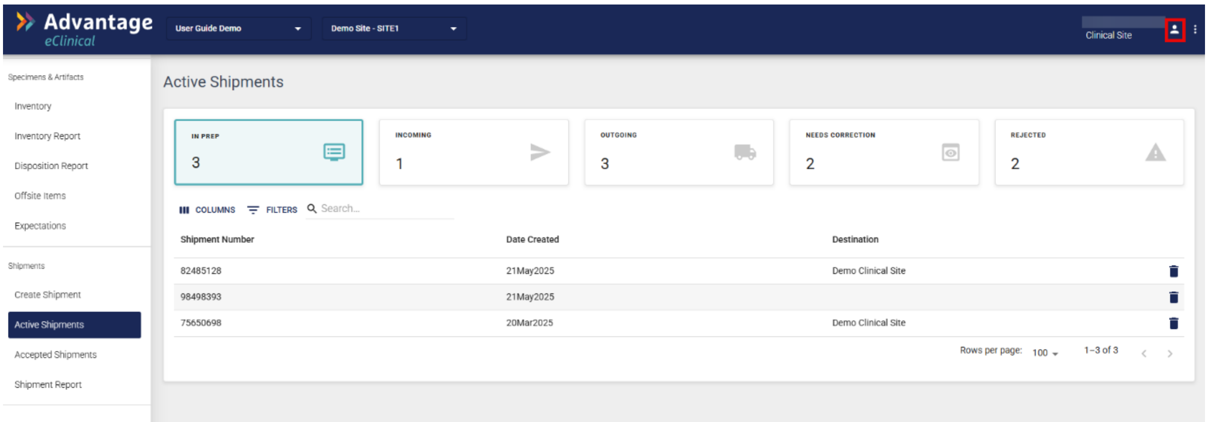
The top menu bar gives you quick access to essential navigation elements, including your username, environment, study, and role. Use these options to switch between studies or roles as needed.

Editing your profile

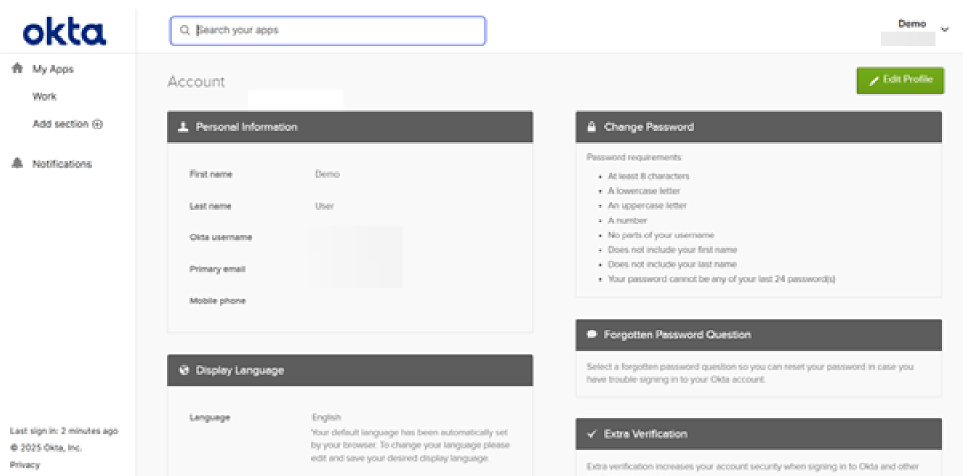
You can update your display name or password from your profile settings to ensure your account information remains up to date.

Steps to edit your profile:

1. Click the **person icon** in the top right corner. Your Okta account opens in a new tab.



2. Select **Edit Profile** to update your name or password, then select **Save**.



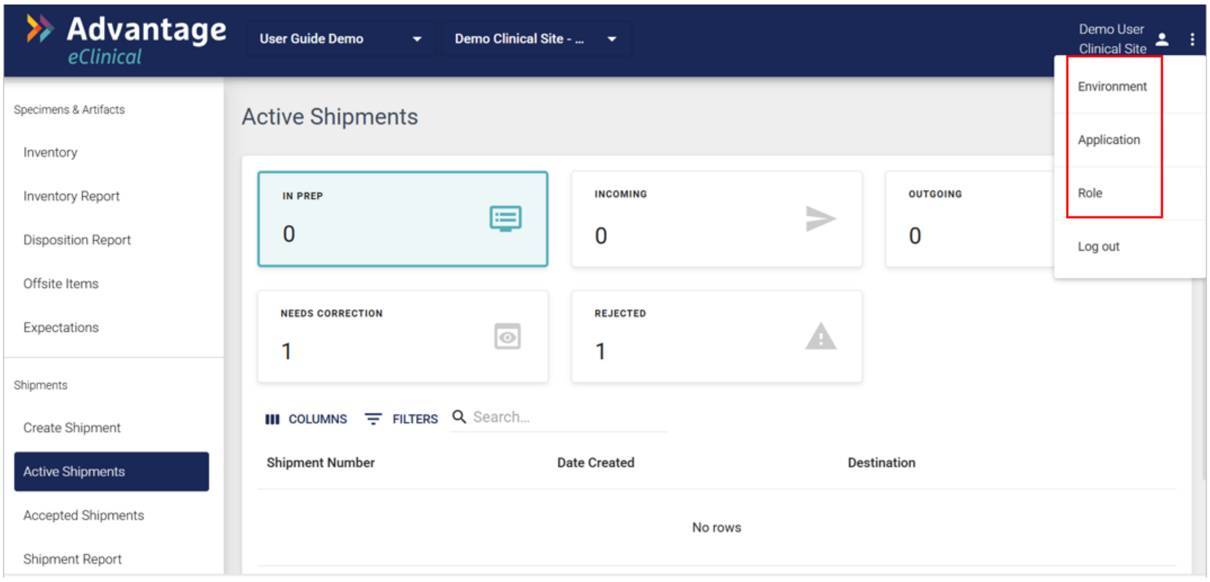
Overflow menu

The overflow menu (three dots) in the top right corner lets you switch environments, applications, or roles, and log out of the system.

Steps to switch environments, applications, or role:

1. Select **Environment** or **Application** from the drop-down options in the overflow menu.
2. Choose the desired option from the drop-down list. The system refreshes with the selected option applied.

> **NOTE:** If you select an application that you do not have access to, you will be redirected to OKTA for authentication.

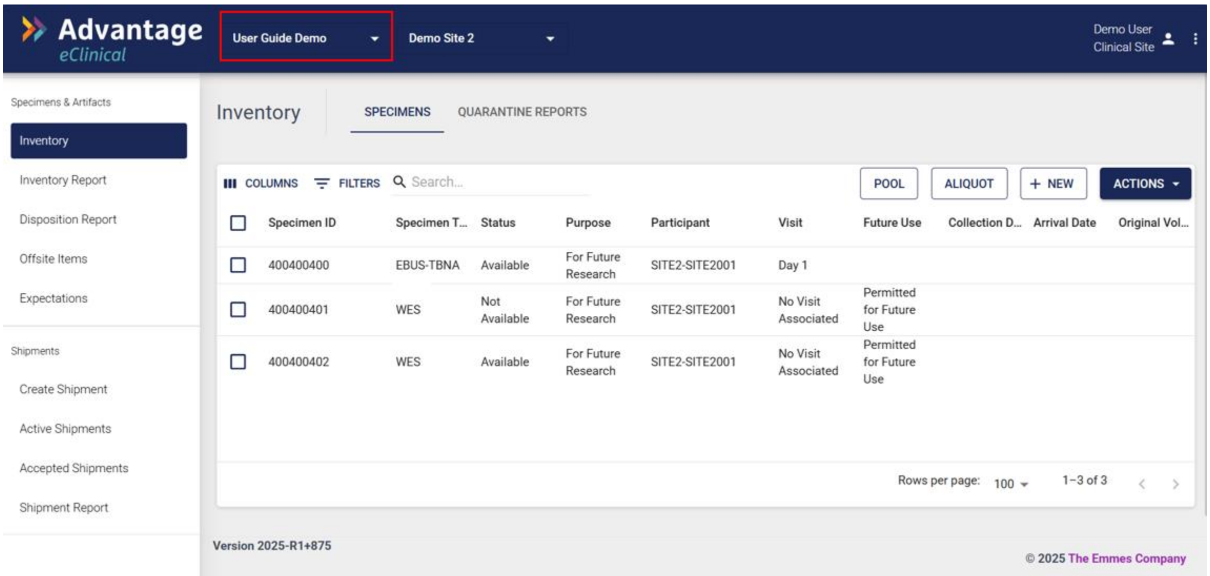


Steps to logout:

1. Select the **overflow menu** (three dots) in the top right corner.
2. Select **Log out**.

Accessing a study

Switch between studies as needed using the 'Study' dropdown in the top bar.



Managing Site Inventory

Each site manages its own inventory within GlobalTrace. The **Inventory** page allows you to view, filter, and update specimens and artifacts. You can manage individual or batch updates directly from this interface.

Using inventory table tools

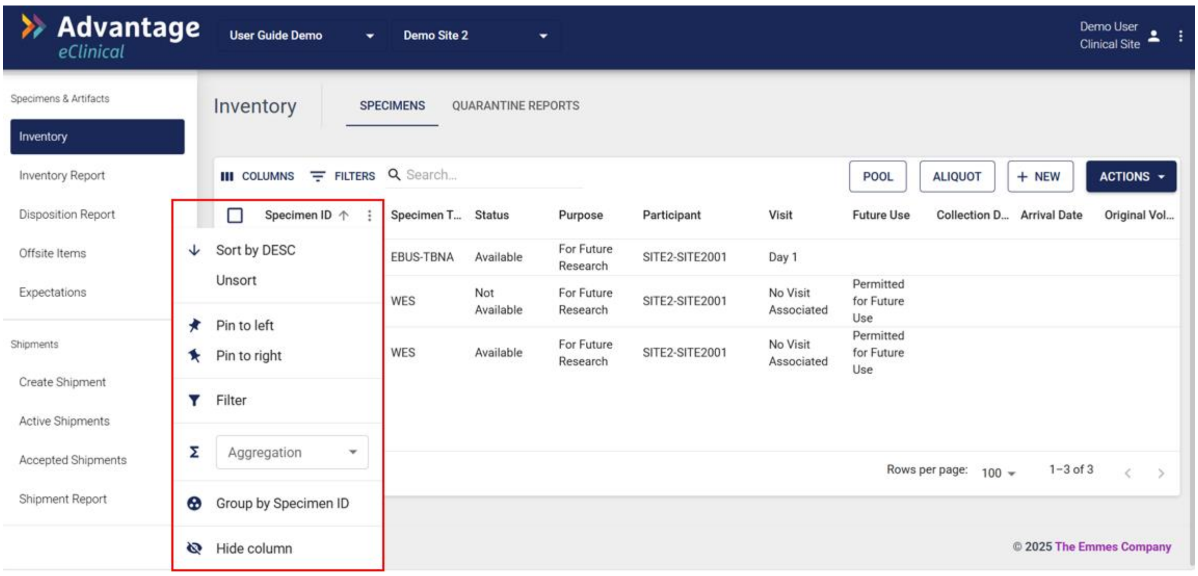
The Inventory table provides dynamic tools to manage and interact with specimens or artifacts.

Customizing columns

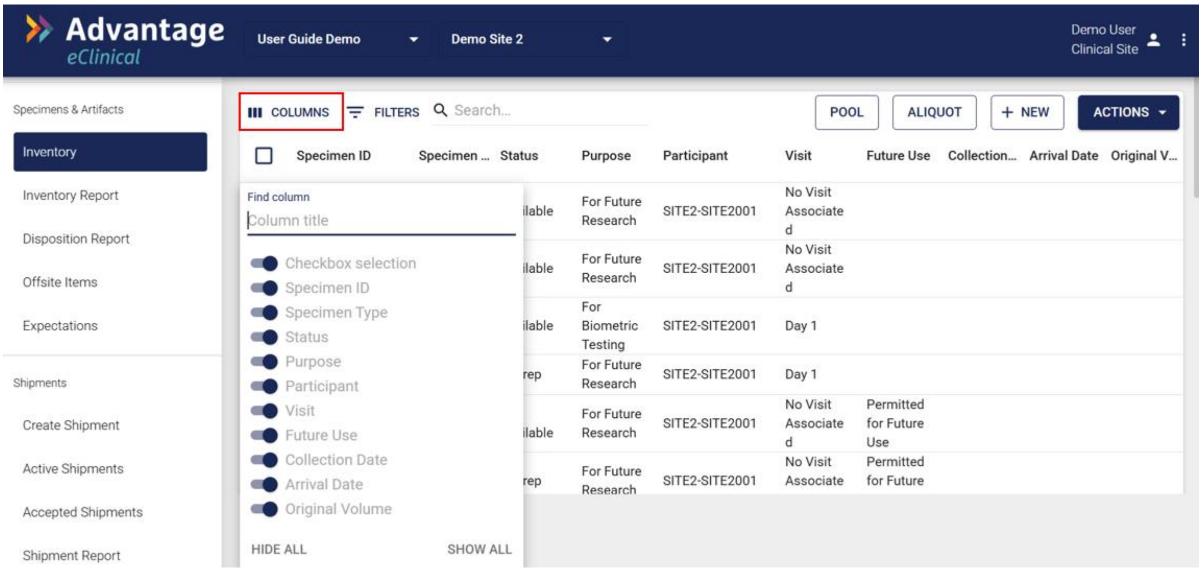
You can modify the display of columns to focus on relevant data.

Steps to customize columns:

1. Select **COLUMNS** above the table or select the **three-dot** menu in any column header.
2. If you select the three dots, choose from the following options:
   - Sort: Arrange data in ascending or descending order.
   - Pin to left/right: Fix important columns on either side of the table.
   - Filter: Apply filters to refine displayed data.
   - Aggregation: Summarize data within the column.
   - Group by Specimen ID: Organize data based on a Specimen ID.
   - Hide column: Remove a column from view.



3. If you select **MANAGE COLUMNS**, the Manage Columns panel appears. Use this panel to show or hide columns as needed. Select **SHOW ALL** to make all columns visible or **HIDE ALL** to hide them.

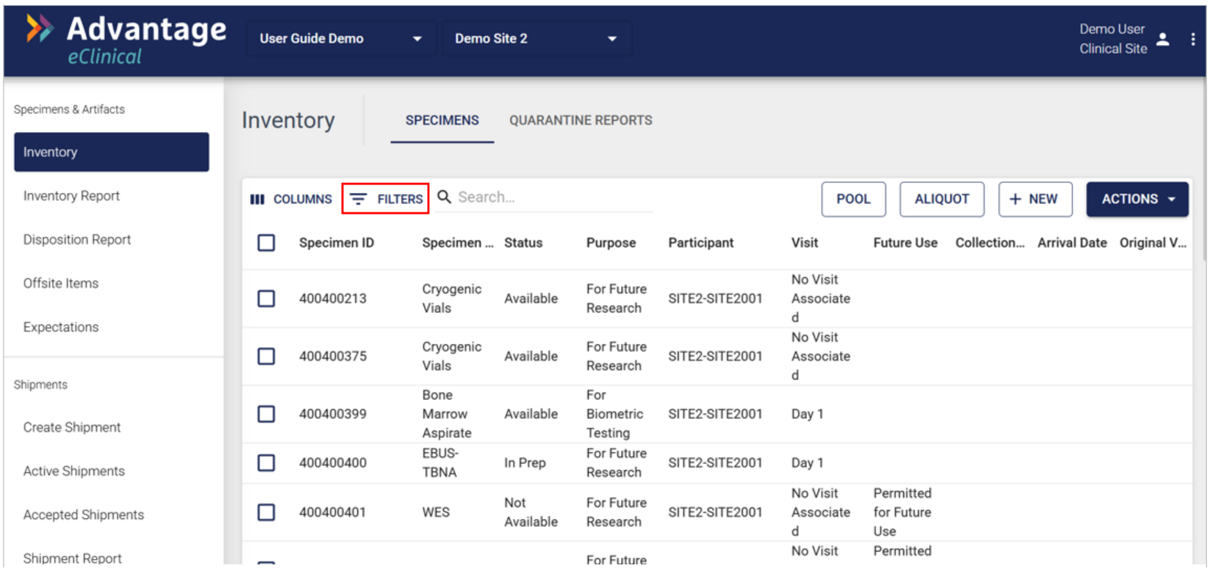


Filtering data

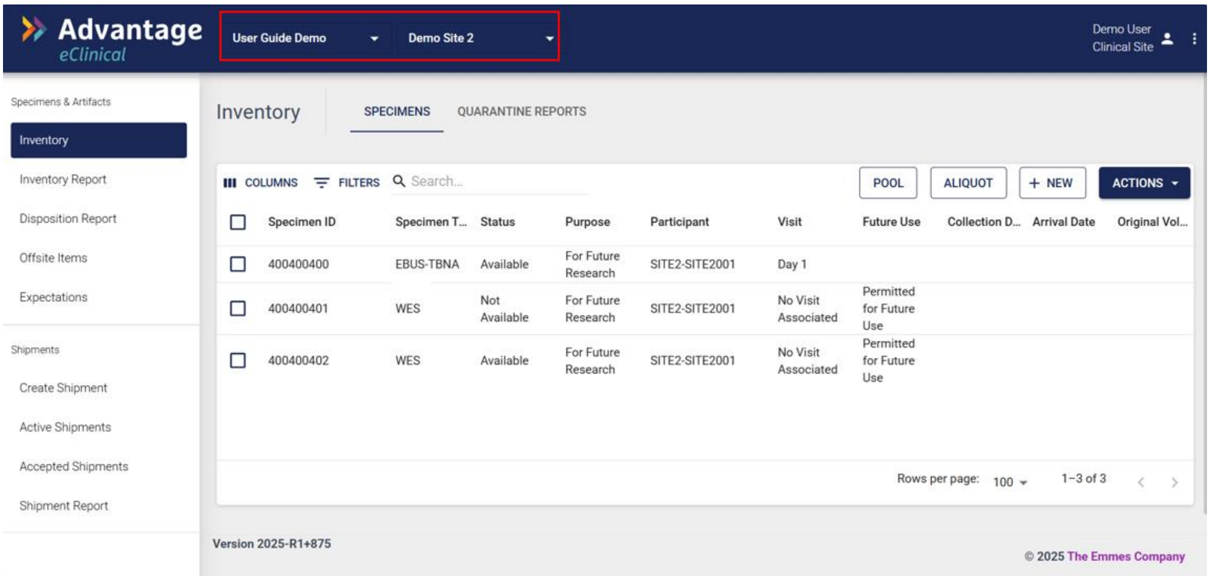
Apply filters to refine the displayed results.

Steps to filter data:

1. Select **FILTERS** in the Inventory table.
2. Apply filters based on key fields such as:
   - Specimen ID
   - Status
   - Participant
   - Other available attributes
3. Review the filtered results to ensure accurate data retrieval.



NOTE: Data becomes visible only after selecting a **Study** and **Site** from the top header. These selections persist across pages and help control what records appear throughout the system.



Performing actions

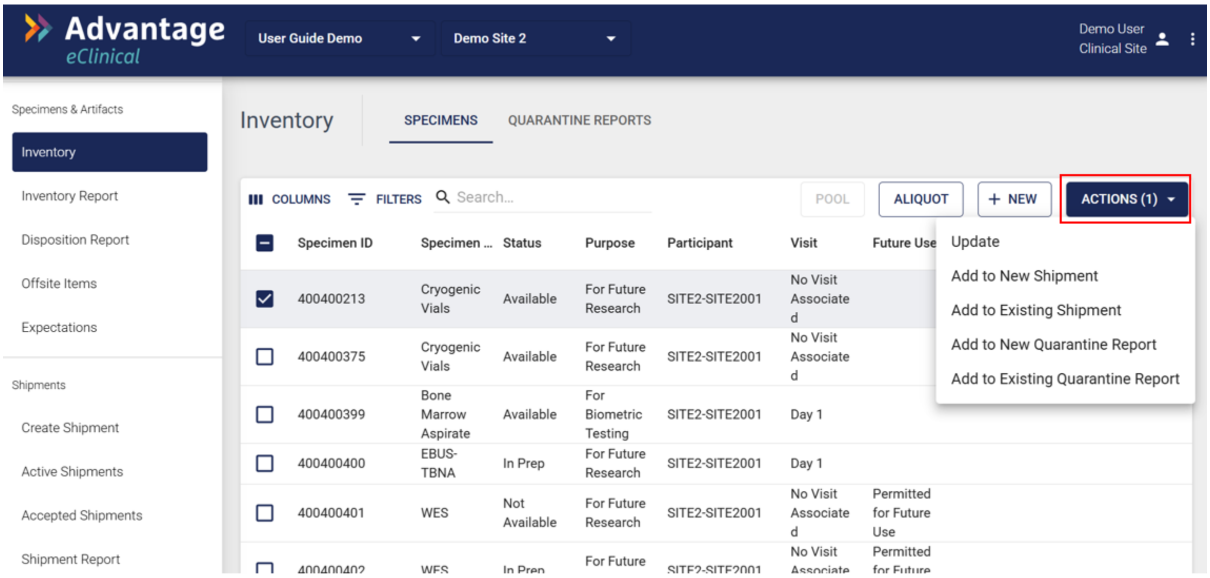
The **ACTIONS** menu enables bulk operations for managing specimens.

Steps to perform actions:

1. Select one or more specimens from the inventory.

   NOTE: If you select all specimens, then apply a filter, and select an action, the action will apply only to the original selection (all specimens), **not** to the filtered results.

2. Select **ACTIONS** and choose an operation:
   a. Updating inventory records to make quick bulk modifications.
   b. Add to New Shipment
   c. Add to Existing Shipment
   d. Add to New Quarantine Report (if report is configured for study)
   e. Add to Existing Quarantine Report (if report is configured for study)
3. Complete the required fields in the selected action dialog.
4. Select **SAVE** to apply changes.



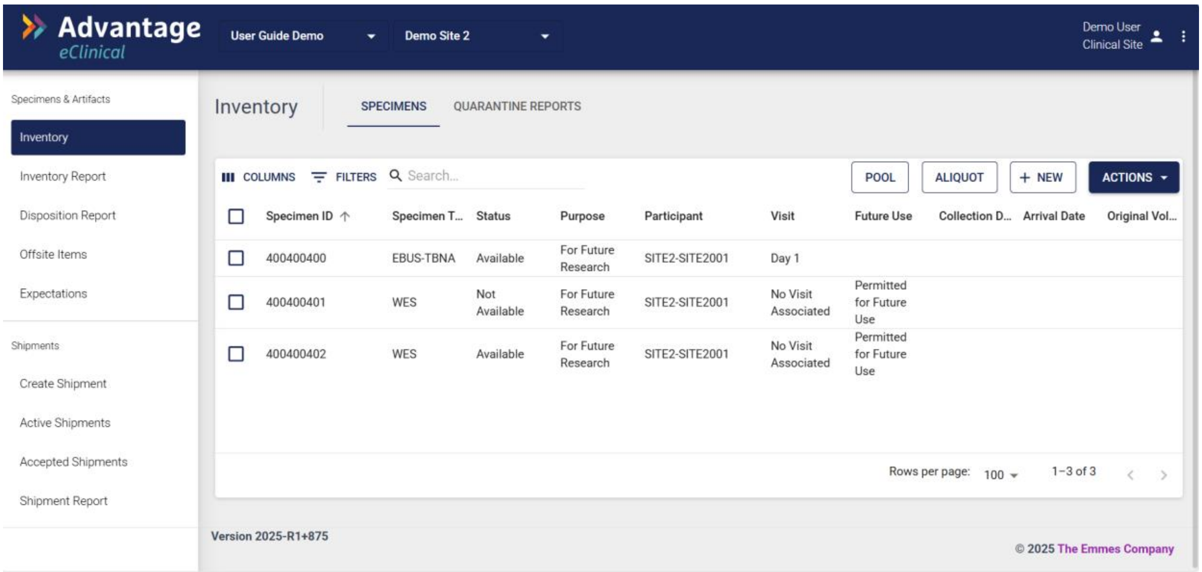
Adding specimens and artifacts

Add specimens or artifacts to your site's inventory to ensure they are ready for processing, shipping, or further action.

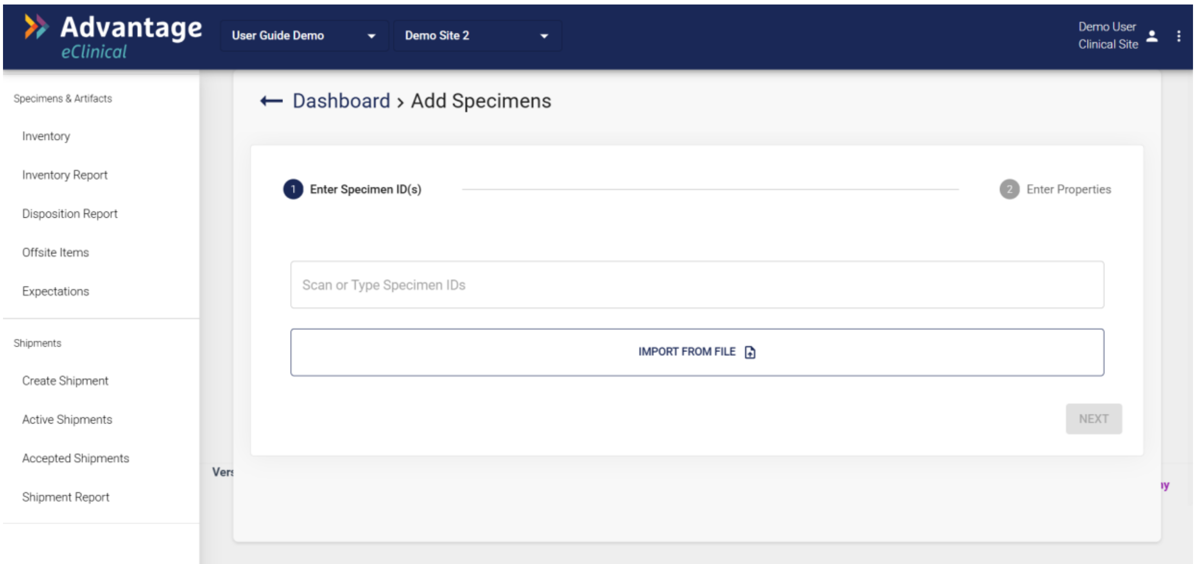
NOTE: The same steps outlined below also apply to artifacts when available.

Steps to add specimen or artifacts:

1. In GlobalTrace, select **Inventory** within the 'Specimens & Artifacts' section of the side navigation bar. The **Inventory** page appears. Use the tabs at the top of the inventory page to select the inventory items you would like to view.

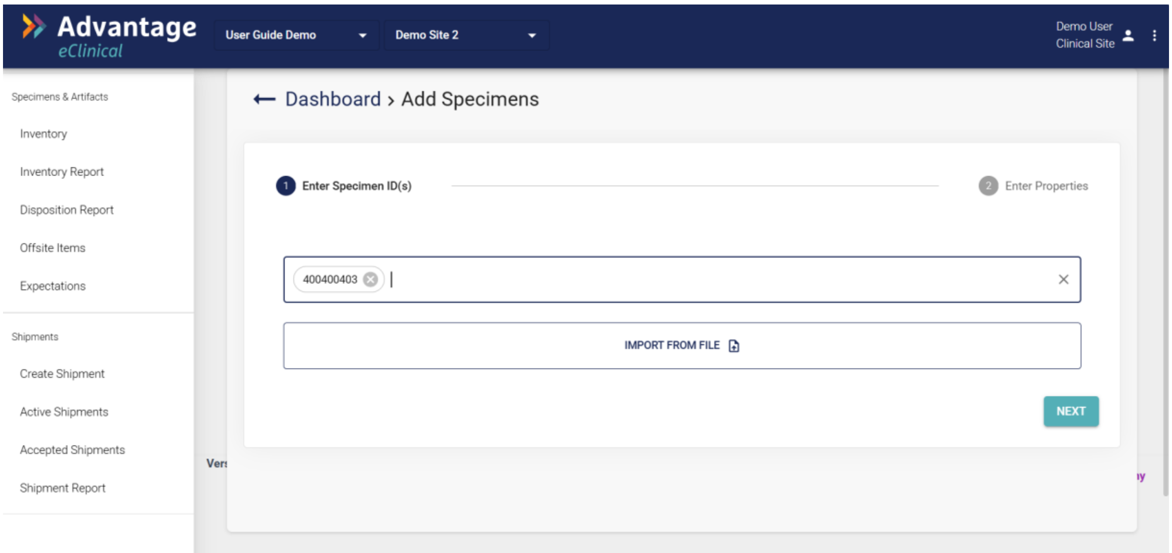


2. Select **+ NEW**. The **Add Specimens** page appears.



3. Type the barcode and press **Enter,** or scan the barcode to enter the specimen or artifact ID. Alternatively, select **IMPORT FROM FILE** to upload an Excel file containing identifiers.

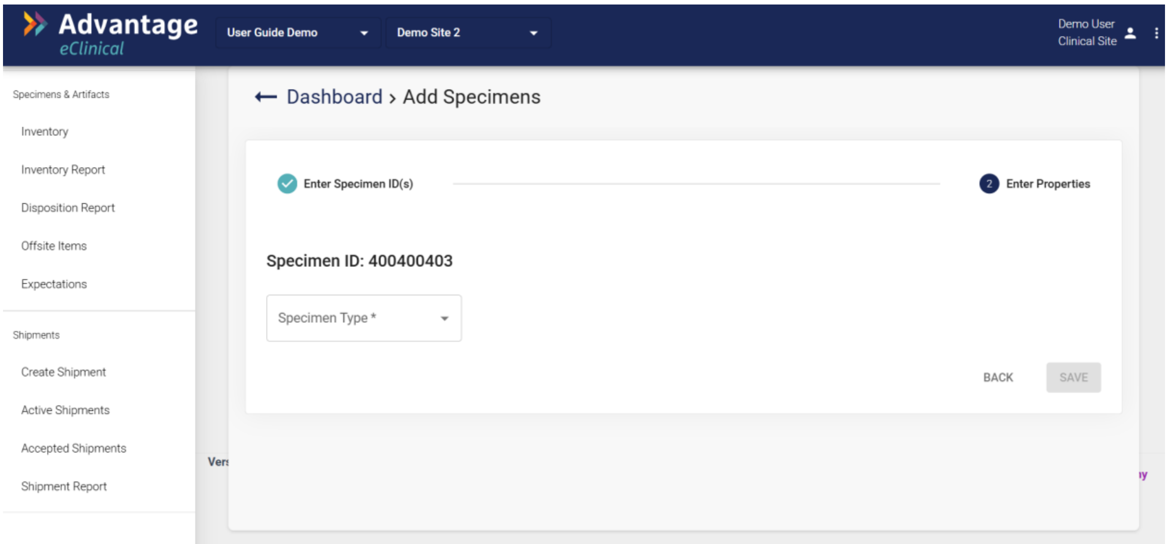
4. Select **NEXT**.



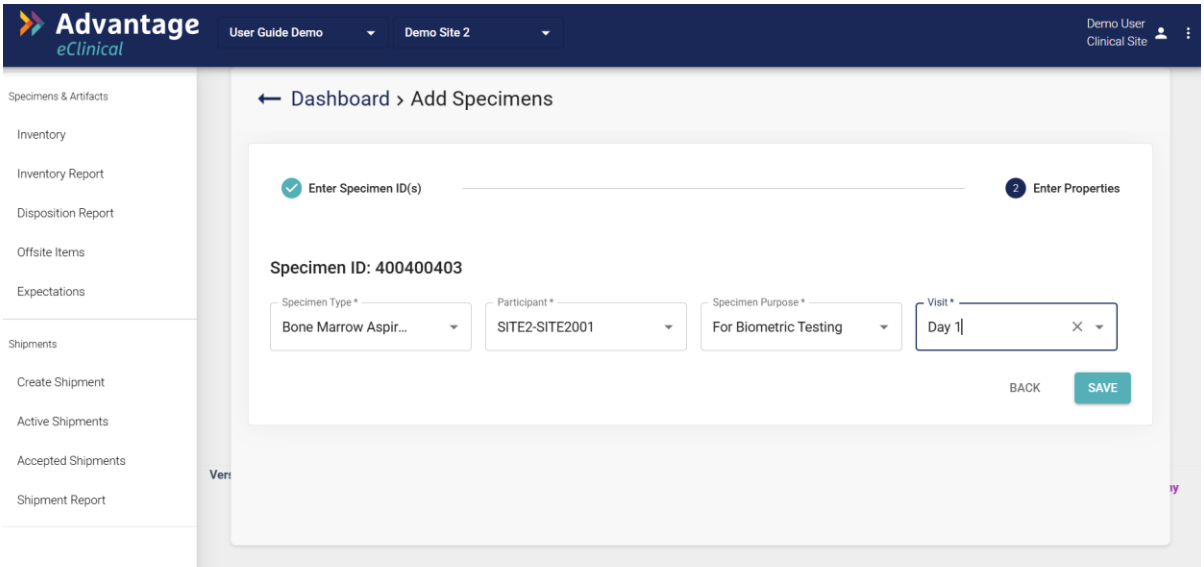
5. Select a 'Specimen Type' from the dropdown list. After you select a specimen type, additional fields appear:
   - Participant: Select the participant associated with the specimen.
   - Specimen Purpose: Choose the purpose for which the specimen will be used.
   - Visit

NOTE:

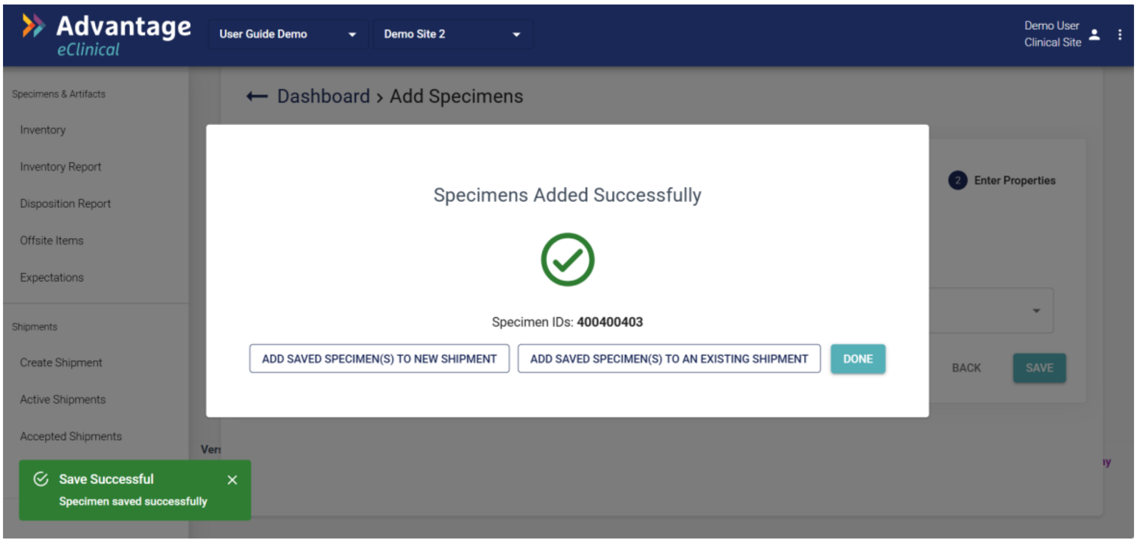
- If a drop-down has only one option, it is auto-selected for you.
- If a specimen is only collected at specific visits, you'll see only those visits in the drop-down. If it's assigned to certain cohorts, you'll only see participants from those cohorts. This helps you avoid selecting invalid visits or participants for a specimen type. The same rules apply to artifacts.



6. After you select a 'Participant', the **Visit** field appears. Select the appropriate 'Visit' for the specimen.



7. Confirm the 'Specimen Purpose' if not already pre-filled.
8. Review the entered details and select **SAVE** to finalize the specimen entry. A success message appears.



9. Choose the next action:
    - Select ADD SAVED SPECIMEN(S) TO NEW SHIPMENT to initiate a new shipment for the specimen.
    - Select ADD SAVED SPECIMEN(S) TO AN EXISTING SHIPMENT to include it in an ongoing shipment.
    - Select **DONE** to return to the inventory.

Adding saved specimens to a new shipment

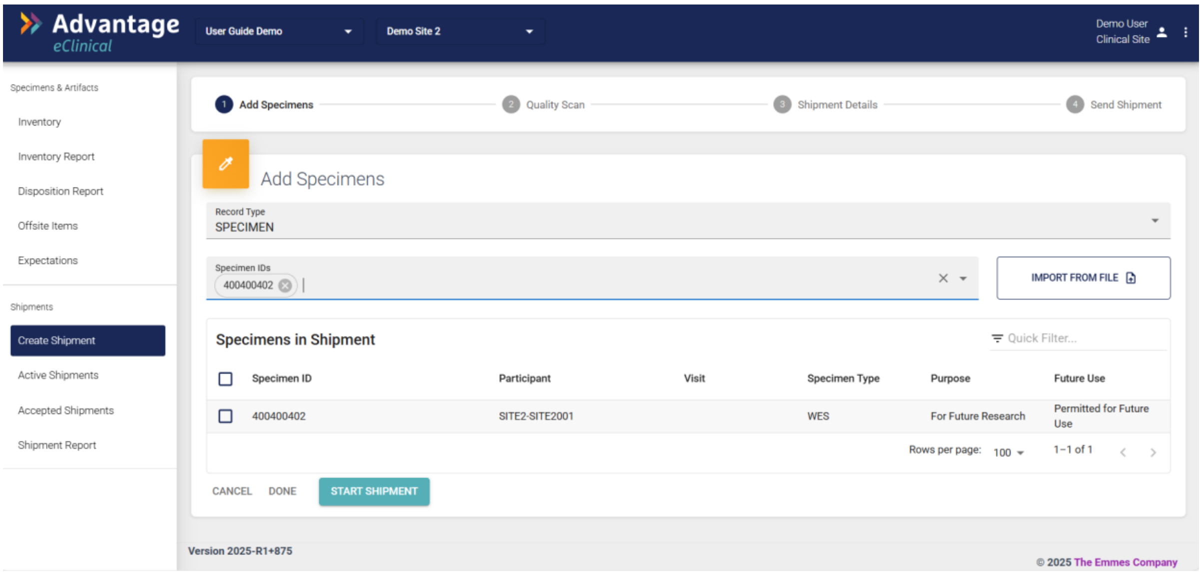
You can add the specimens you saved to a new shipment.

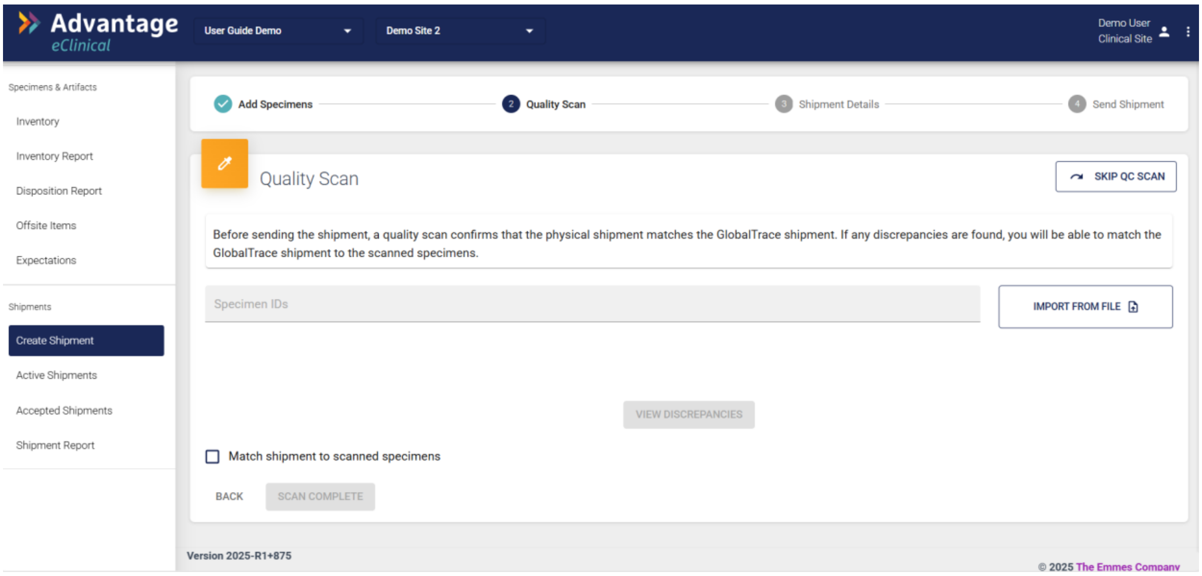
Steps to add the saved specimens to a new shipment:

1. Select **ADD SAVED SPECIMEN(S) TO NEW SHIPMENT** from the 'Specimens Added Successfully' confirmation message. The **Create Shipment** page appears.

   NOTE: The **Record Type** field shows SPECIMEN for specimen shipments and the **Specimen IDs** field shows the ID of the specimen that was created in the earlier steps.

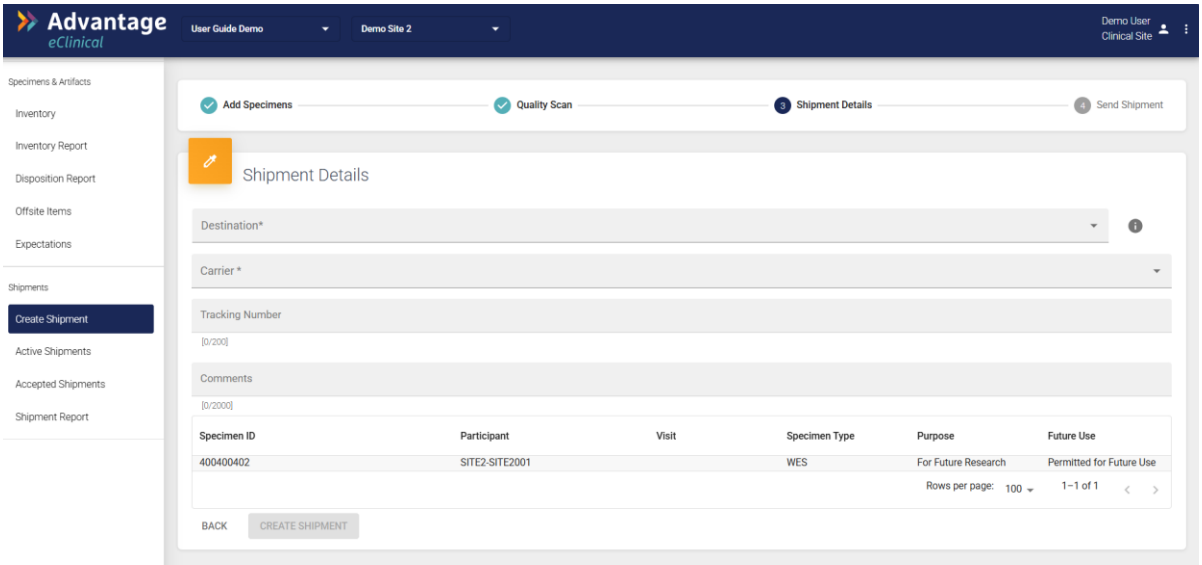
2. In the 'Add Specimens' section, select the specimens you want to add to a new shipment
3. After all the specimens are added to the shipment, select **START SHIPMENT**. The 'Quality Scan' section appears.
4. Optionally, to remove a specimen from the shipment, you can:
   - Click the **X** icon next to the specimen ID pill, or
   - Select the specimen(s) in the list and then select **REMOVE**.
     The **REMOVE** button shows the number of specimens selected for removal.



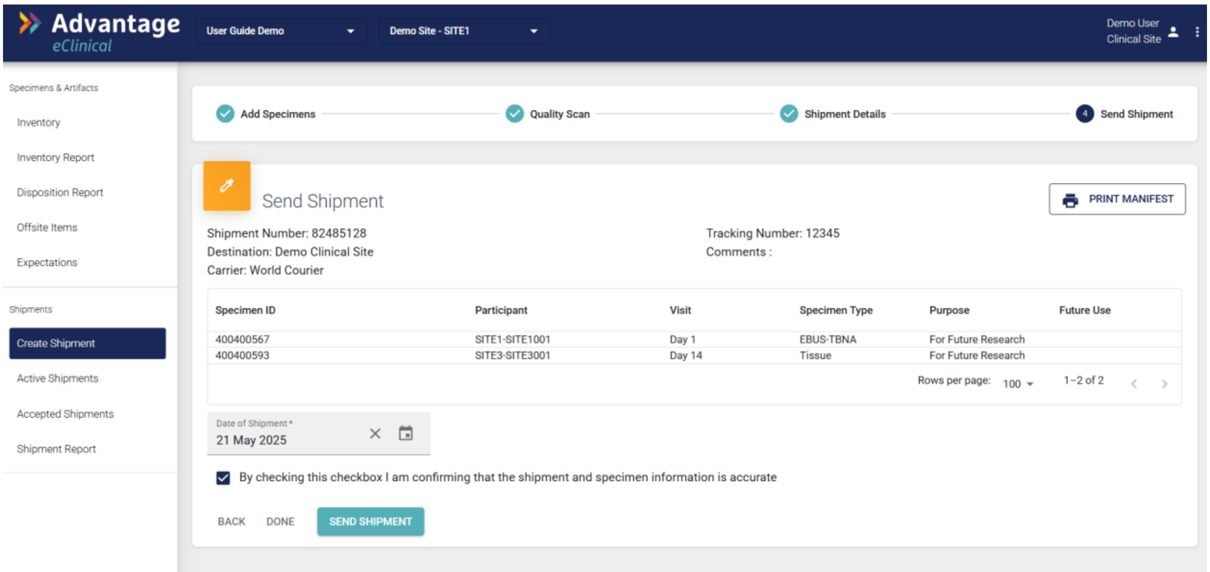


5. The quality scan is optional. To perform a quality scan, see Performing a quality scan.

To skip this step, select **SKIP QC SCAN**. The 'Shipment Details' section of the **Create Shipment** page appears.



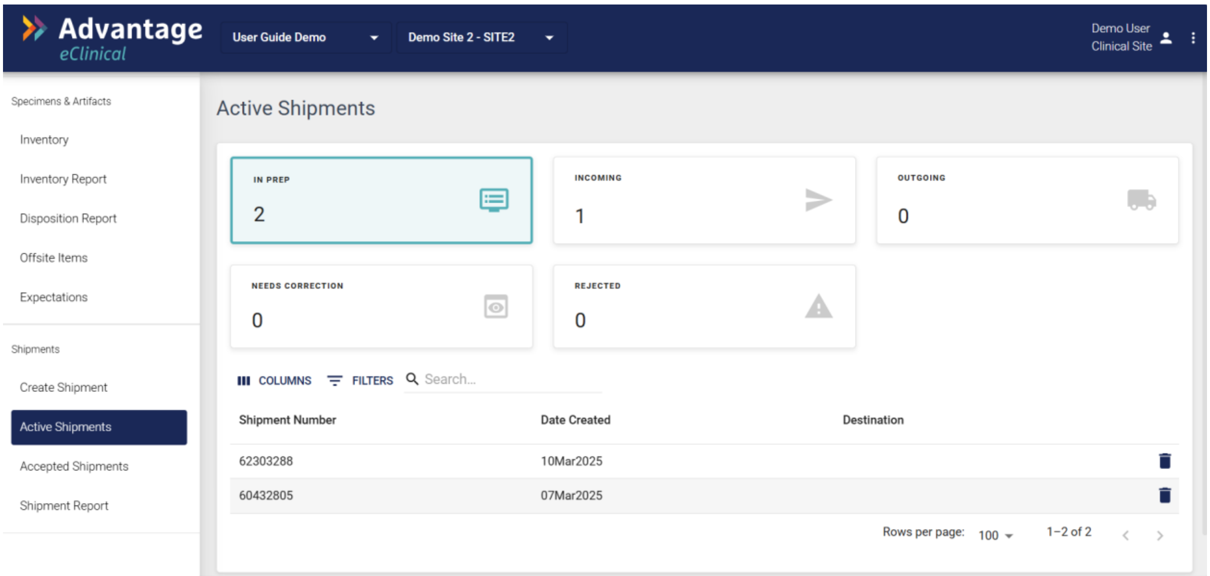
6. Select the destination, type of carrier, enter the tracking number, add your comments about the shipment, and then select **CREATE SHIPMENT**. The 'Send Shipment' section of the **Create Shipment** page appears.

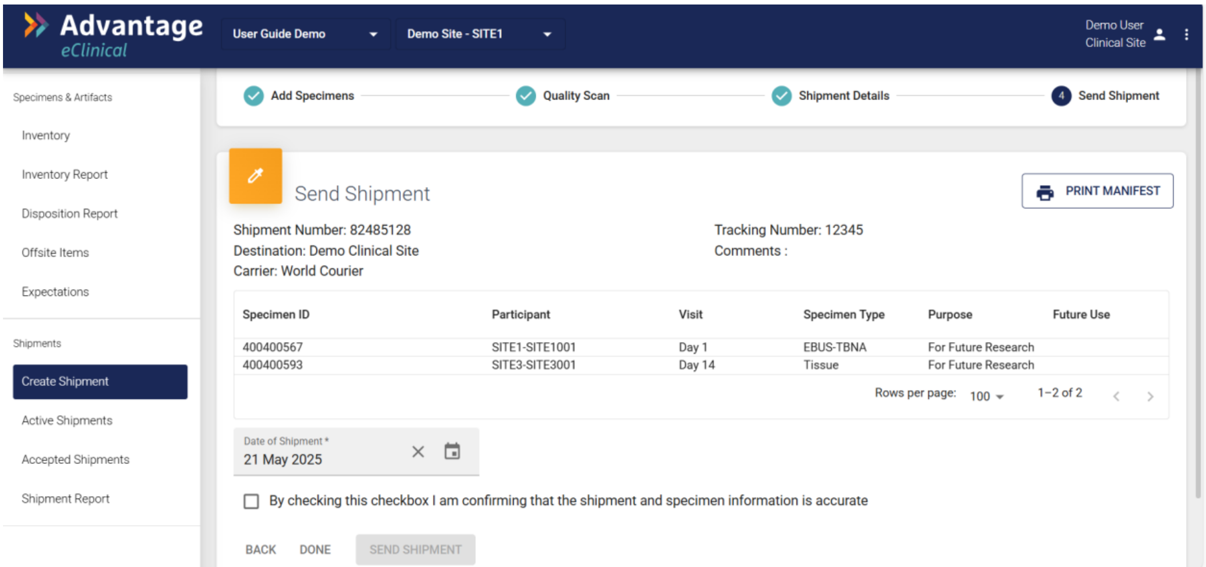


7. Optionally, select **PRINT MANIFEST** to generate a shipment manifest to confirm which protected fields should be included in the manifest. See Printing a shipment manifest.
8. Select **By checking this checkbox I am confirming that the shipment and specimen information is accurate**, and then:
   - To complete and send the shipment, select **SEND SHIPMENT**. The **Active Shipment** page appears.
   - To save the shipment as in progress, select **DONE**. This keeps the shipment in a draft state, allowing you to return and send it later—especially if external steps are required before finalization.

NOTE: Users often select **DONE** when they need to perform additional tasks outside GlobalTrace before completing the shipment.

9. To continue working on a draft shipment, in the **Active Shipments** page, locate your shipment number and select the relevant row. The shipment continues at the last step completed.





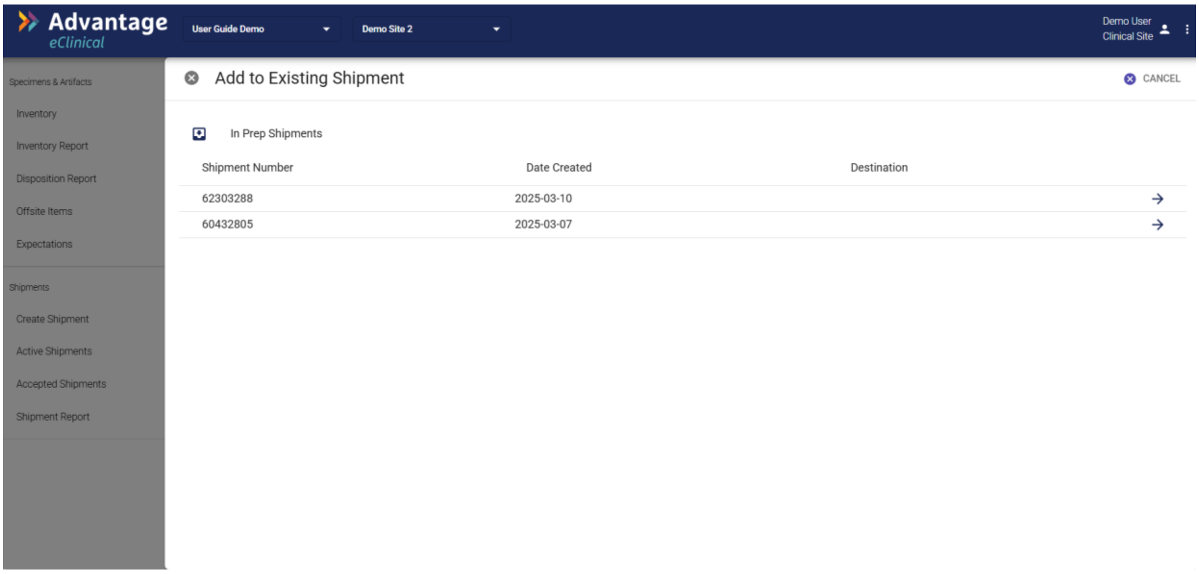
10. Select **PRINT MANIFEST** to generate a shipment manifest to confirm which protected fields should be included in the manifest. See Generating the shipment manifest.

Adding saved specimens to an existing shipment

You can add the specimens you saved to an existing shipment.

Steps to add the saved specimens to an existing shipment:

1. Select **ADD SAVED SPECIMEN(S) TO EXISTING SHIPMENT** from the 'Specimens Added Successfully' confirmation message. The **Add to Existing Shipment** page appears.

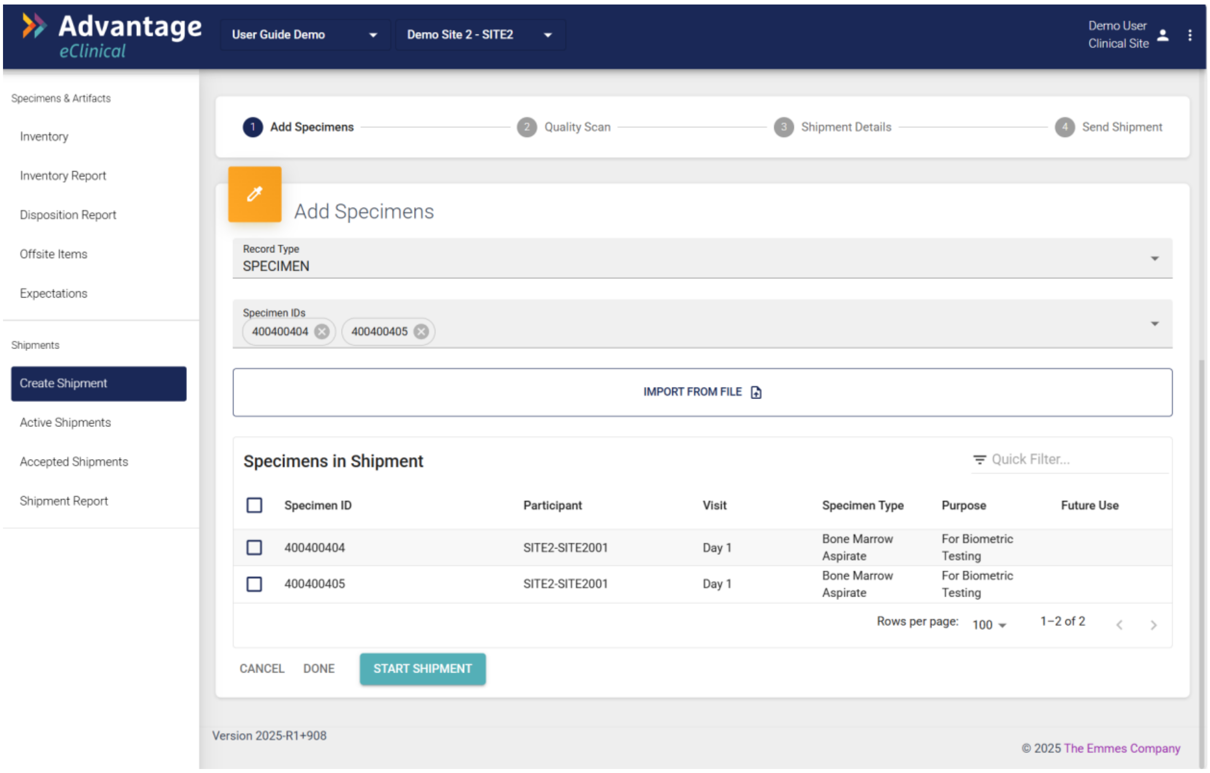


2. Select the applicable shipment number row. The **Create Shipment** page appears.

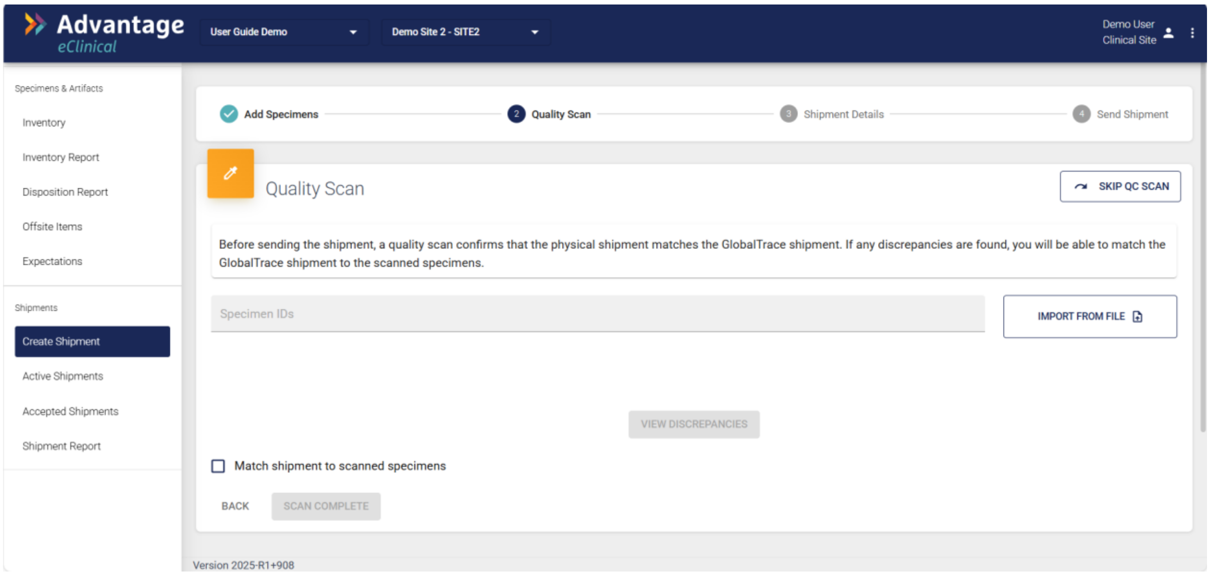
NOTE:

- Only shipments applicable to the specimen type and available shipping routes will appear.
- Specimens already added to the shipment will be listed here and can be removed at this stage if needed.
- The **Specimen IDs** field displays the IDs added during earlier steps.

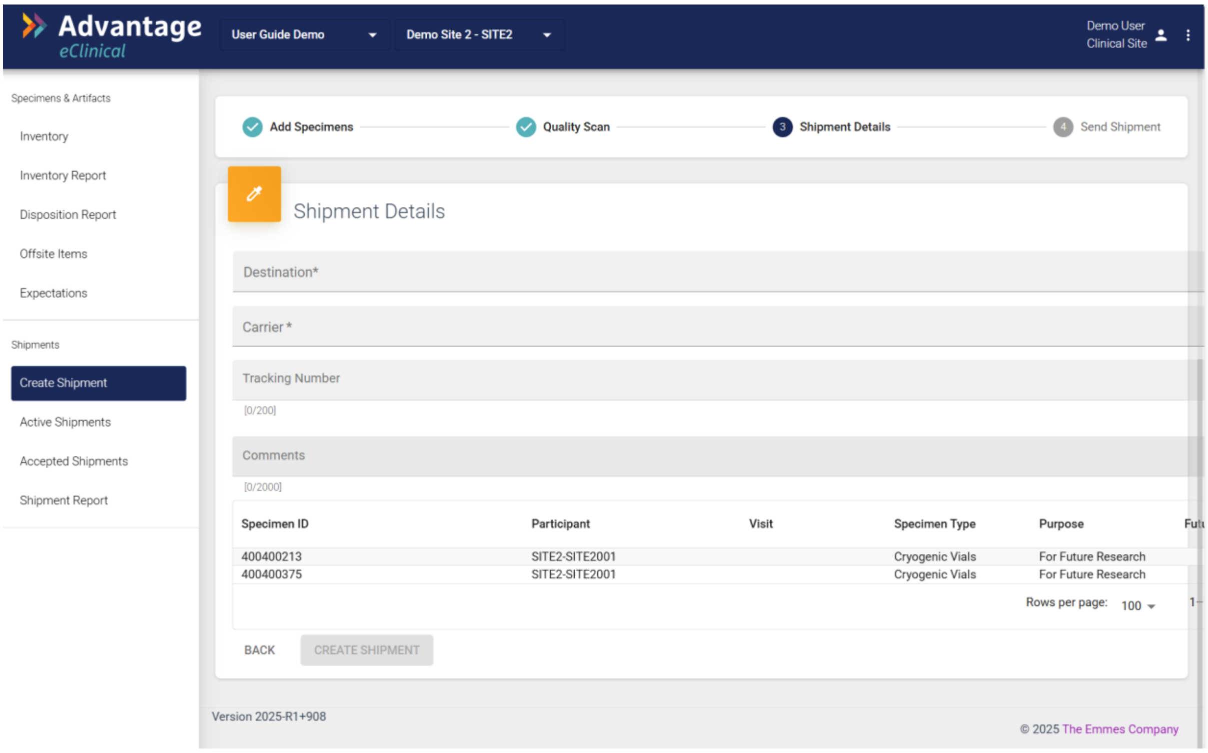
3. In the 'Add Specimens' section, select the specimens you want to add to the existing shipment.



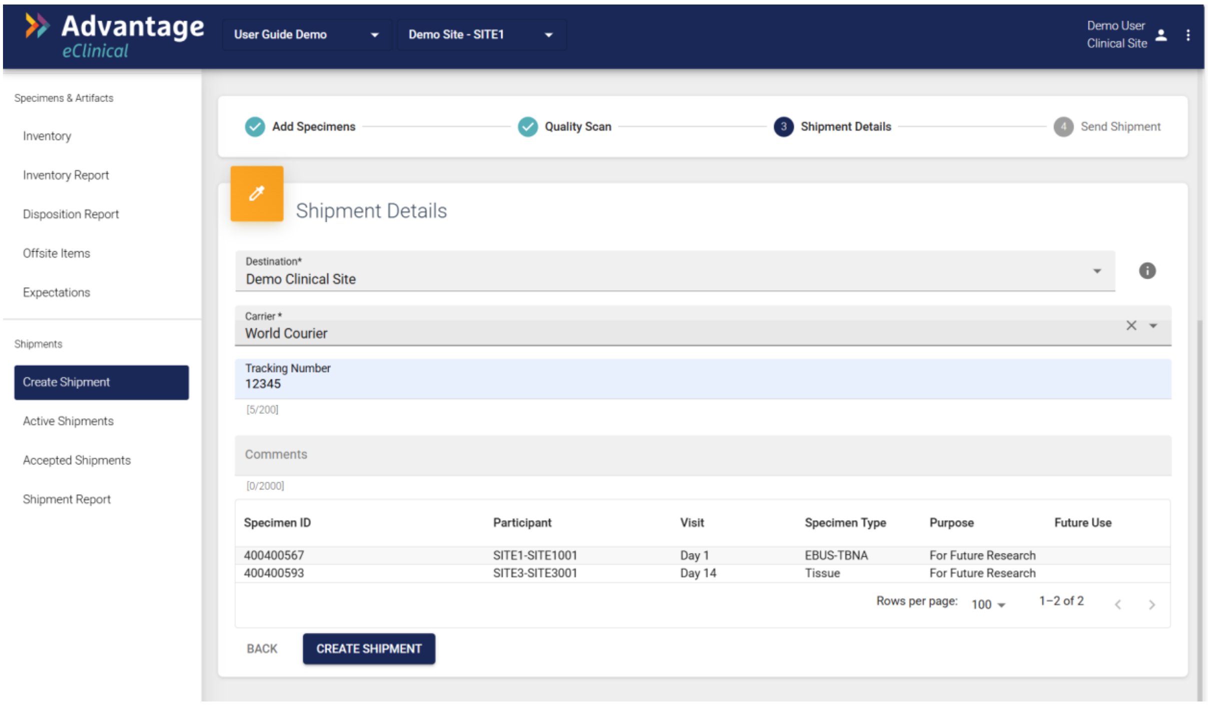
4. Select **START SHIPMENT**. The **Quality Scan** page appears.

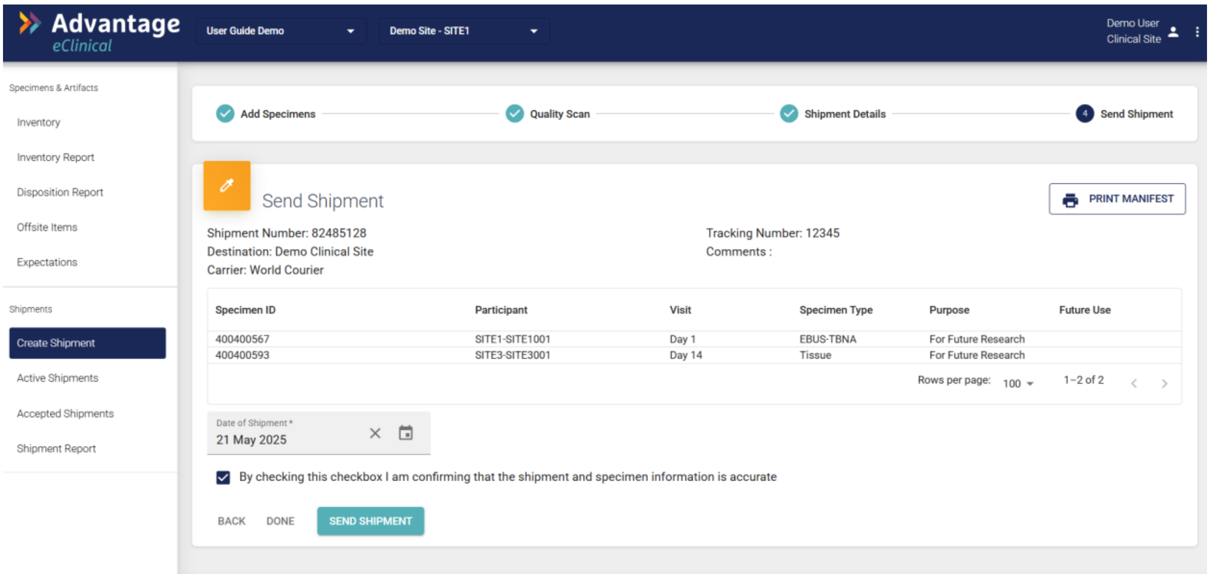


5. The quality scan is optional. To perform a quality scan, see Performing a quality scan.
To skip this step, select **SKIP QC SCAN**. The 'Shipment Details' section of the **Create Shipment** page appears.



6. Select the destination, type of carrier, enter the tracking number, add your comments about the shipment, and then select **CREATE SHIPMENT**. The 'Send Shipment' section of the **Create Shipment** page appears.





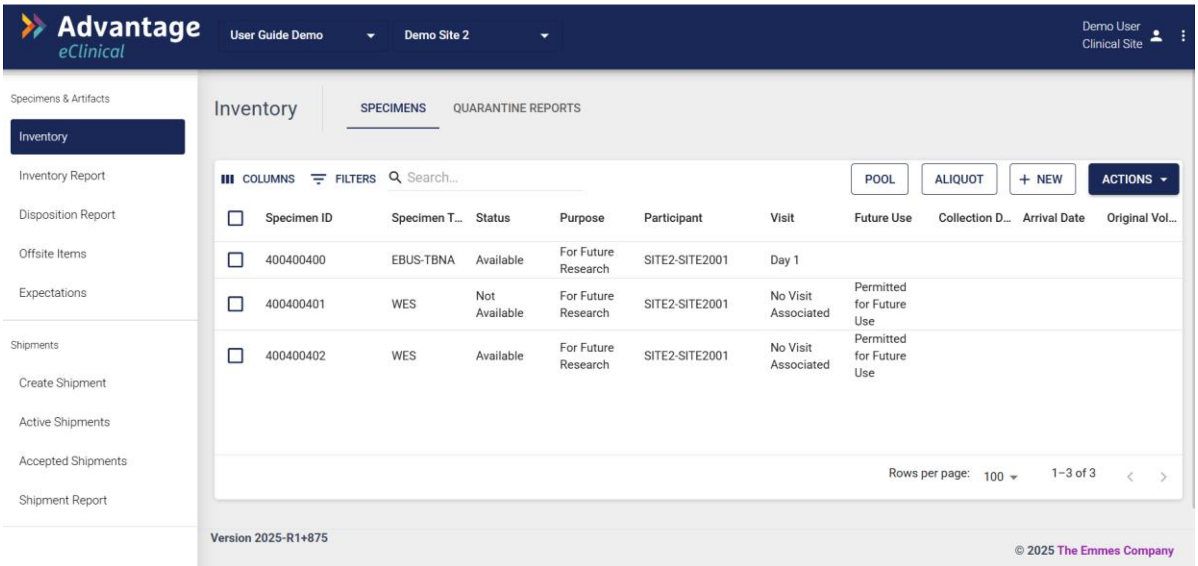
7. Select **PRINT MANIFEST** to generate a shipment manifest to confirm which protected fields should be included in the manifest. See Printing a shipment manifest.
8. Select **By checking this checkbox I am confirming that the shipment and specimen information is accurate** and then select **SEND SHIPMENT**. A success message appears confirming that your changes are saved.

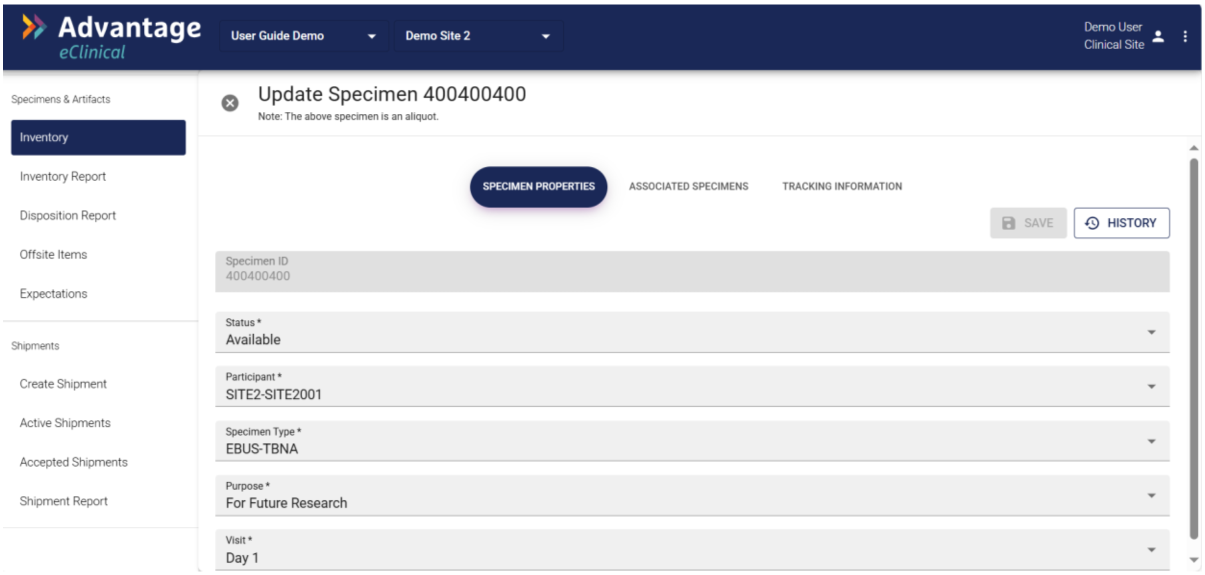
Viewing and updating existing specimen or artifact properties

Access and update detailed information about existing specimens or artifacts to ensure accurate records in your inventory.

Steps to view and update specimen or artifact properties:

1. Go to the **Inventory** page and select a specimen or artifact to open its details.





2. Review the information in the following tabs:
   - **SPECIMEN PROPERTIES**: Shows core details, including specimen type, status, and purpose.
   - **ASSOCIATED SPECIMENS**: Lists related specimens under the same participant.
   - **TRACKING INFORMATION**: Shows shipment history and movement if the item has been shipped
3. Update the details as needed.

   NOTE: You can only update specimens with status set to 'Available'. If the status has a reason associated, it will also display under the status field.

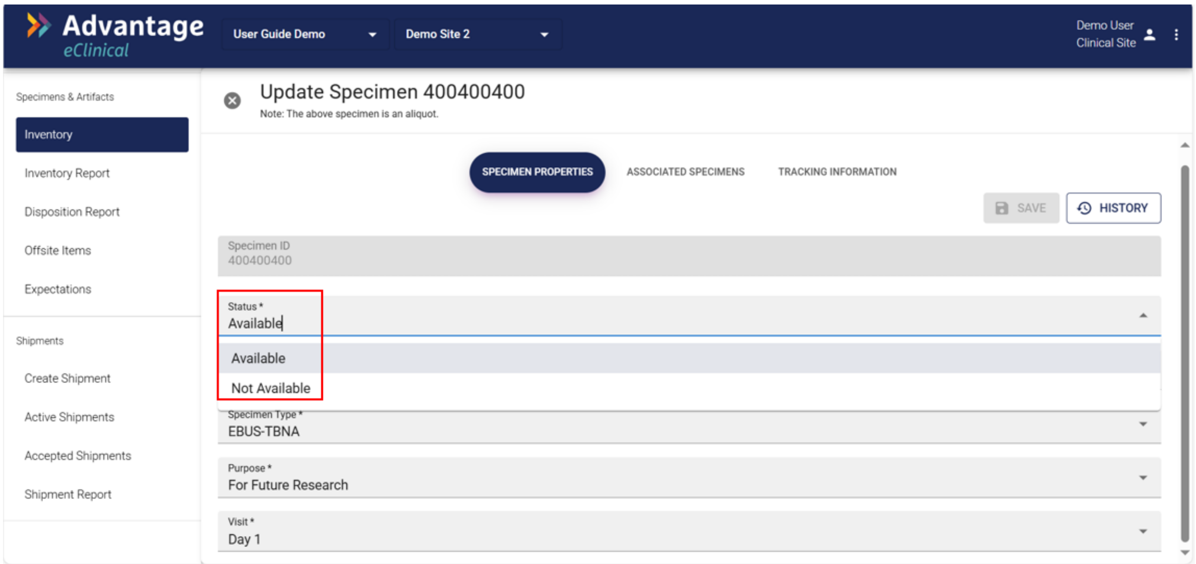
   If a change reason is required, select an option in the **Change Reason** dialog box, then select **OK**. A **triangle** icon appears next to the updated field to indicate a reason has been captured.
4. Select **SAVE** to confirm your changes. A success message confirms your change are saved.

Making specimens or artifacts unavailable

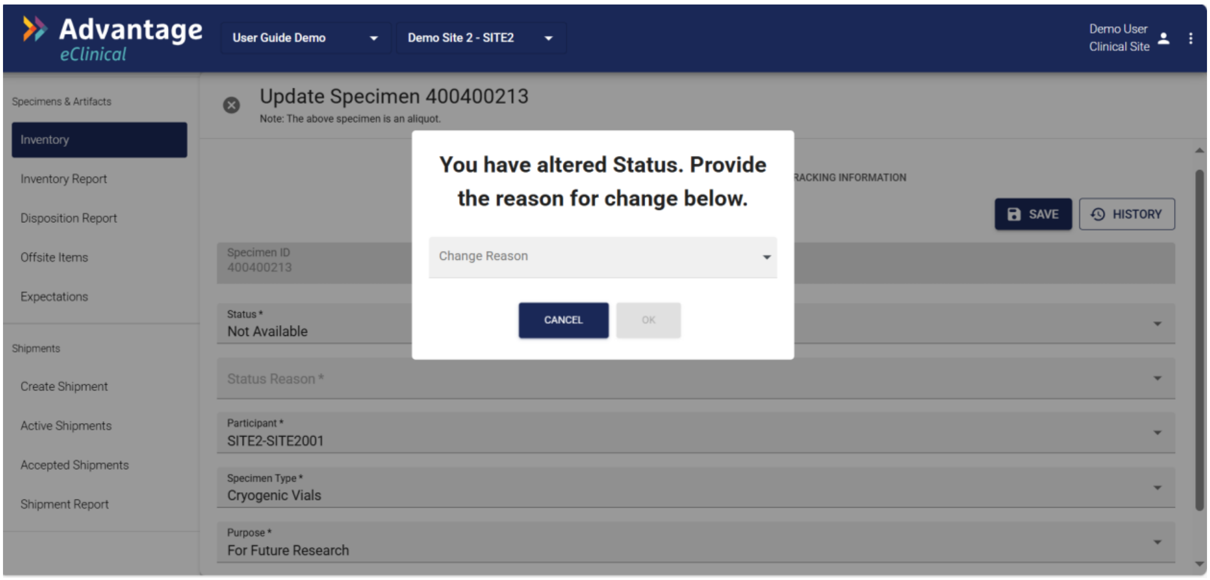
If a specimen or artifact is lost, damaged, or consumed, you can mark it as **Not Available** to ensure it cannot be shipped, aliquoted, or pooled.

Steps to making specimens or artifacts unavailable:

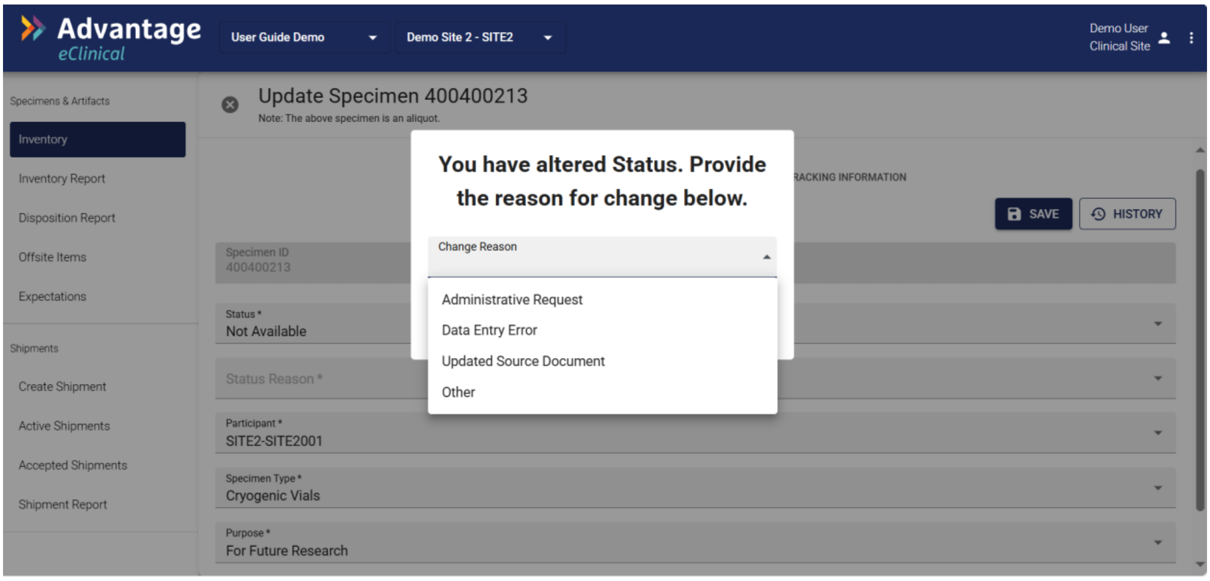
1. Go to the **Inventory** page and select the specimen or artifact to update.
2. Change the status to 'Not Available' and provide a reason for the change when prompted. If a change reason is required, select an option in the **Change Reason** dialog box and then select **OK**. A **triangle** icon appears next to the updated field, showing the reason when selected.



3. If prompted, add a Status Reason.



4. Select the dropdown to choose the appropriate reason and then select **OK** to confirm the reason.



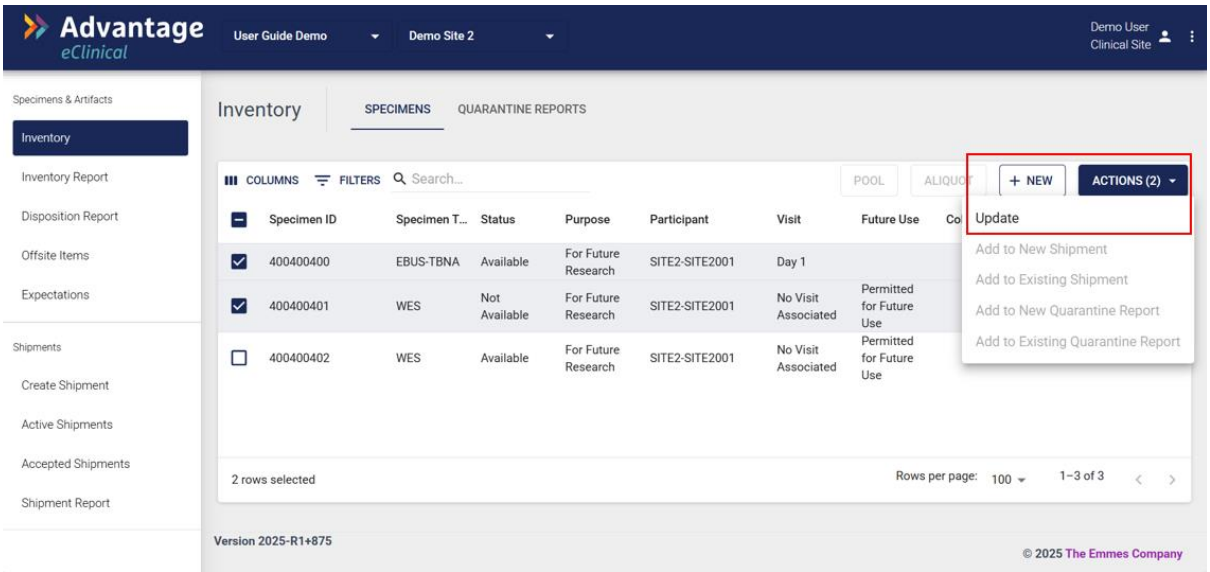
5. Select **SAVE** to confirm the update.

Batch updating specimens

You can update multiple specimens at once using the **Batch Update** feature.

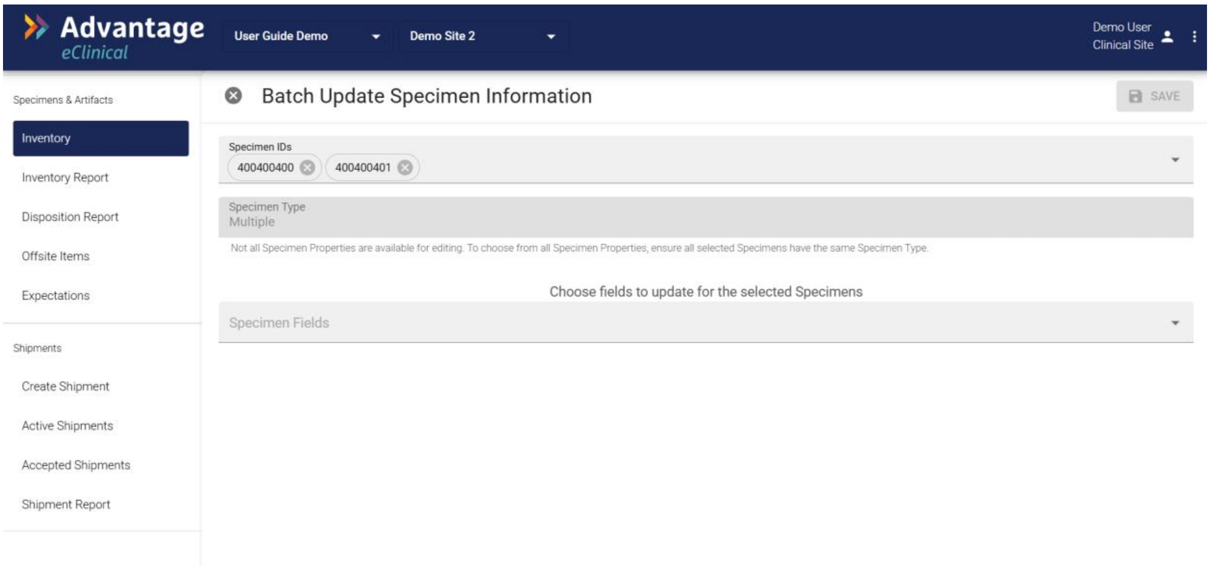
Steps to batch updating specimens:

1. Go to the **Inventory** page and select multiple specimens to update.
2. Select **Actions** and choose **Update**. The button will display a count of the number of specimens being updated.



3. Modify the required fields in the **Batch Update Specimen Information** dialog.

NOTE: Some fields may not be available if specimens of varying types are selected.



4. Select **SAVE** to apply changes to all selected specimens.

Executing actions on specimens and artifacts

The **Actions** menu in the **Inventory** page allows you to perform key operations on selected specimens or artifacts.

The following table details each action on the **Inventory** page, including its description and purpose.

Action	Description
Update	Modify details of the selected specimens or artifacts.
Add to New Shipment	Initiate a new shipment for the selected items.
Add to Existing Shipment	Include items in an active shipment.

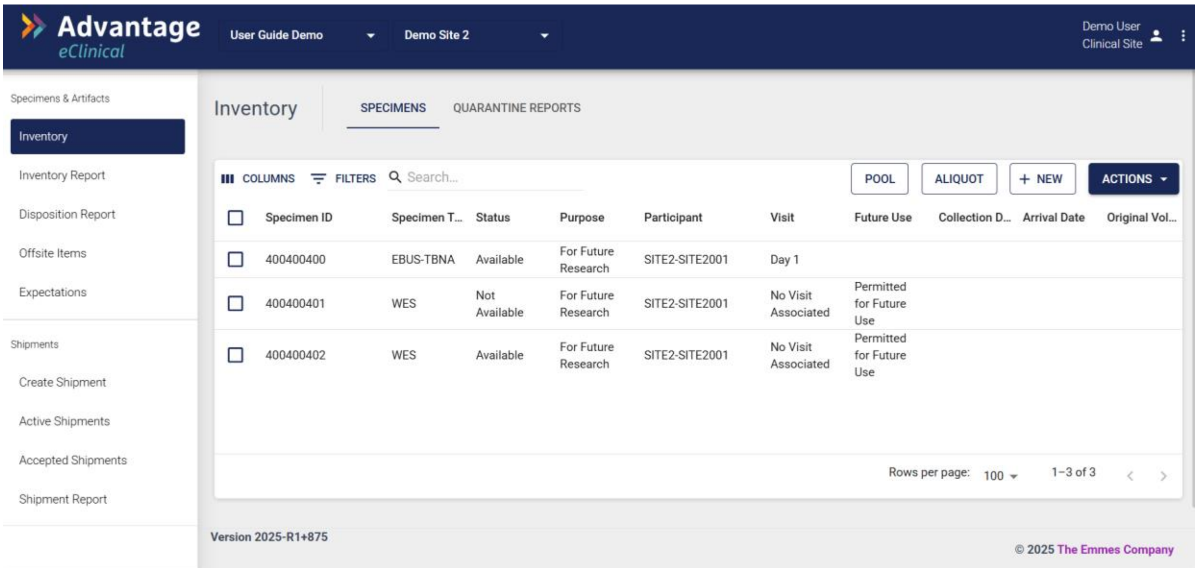
NOTE: The 'Aliquot' and 'Pool' options are not applicable for artifacts. The menu dynamically updates based on the selected items and their statuses.

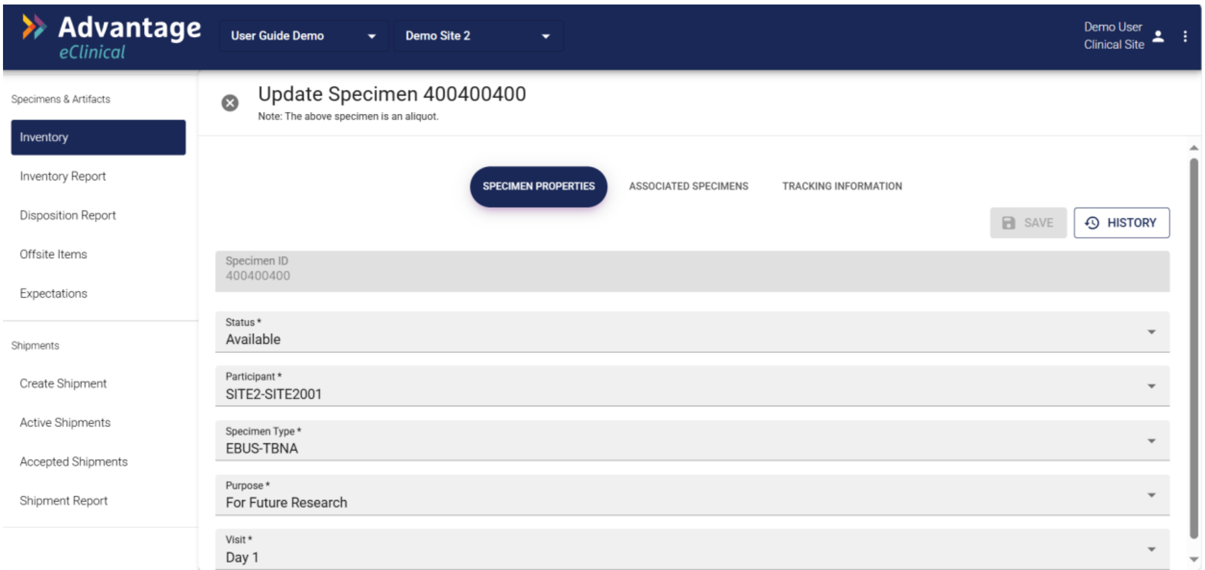
Viewing associated specimens or artifacts

You can view specimens or artifacts linked to the same participant to track associations efficiently.

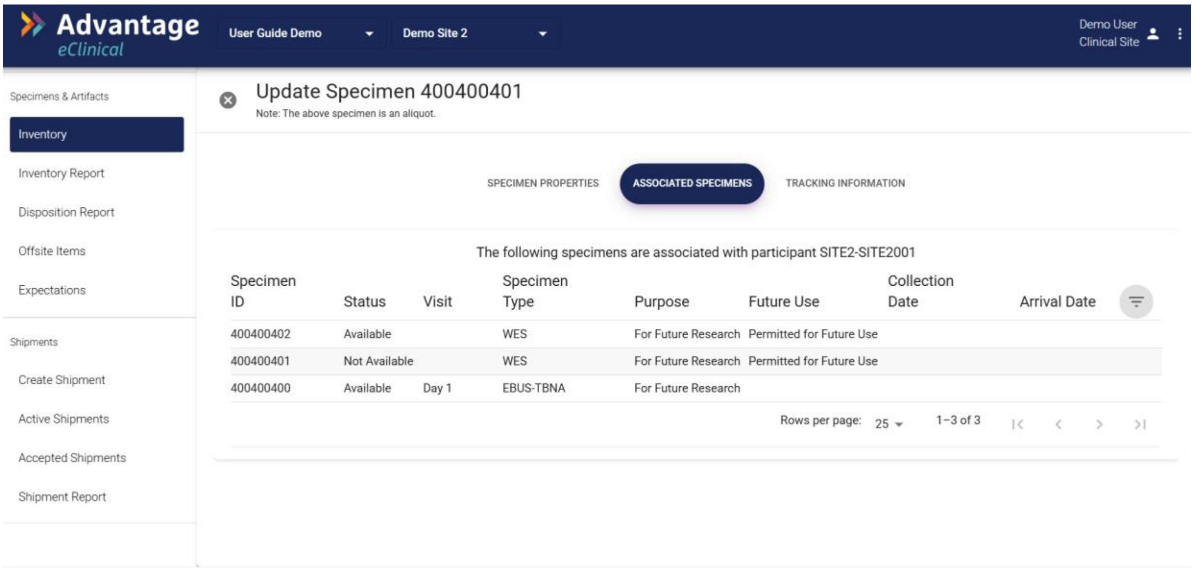
Steps to view associated specimens or artifacts:

1. Go to the **Inventory** page and select a specimen or artifact to open its details. The **Update Specimen [ID]** page appears.

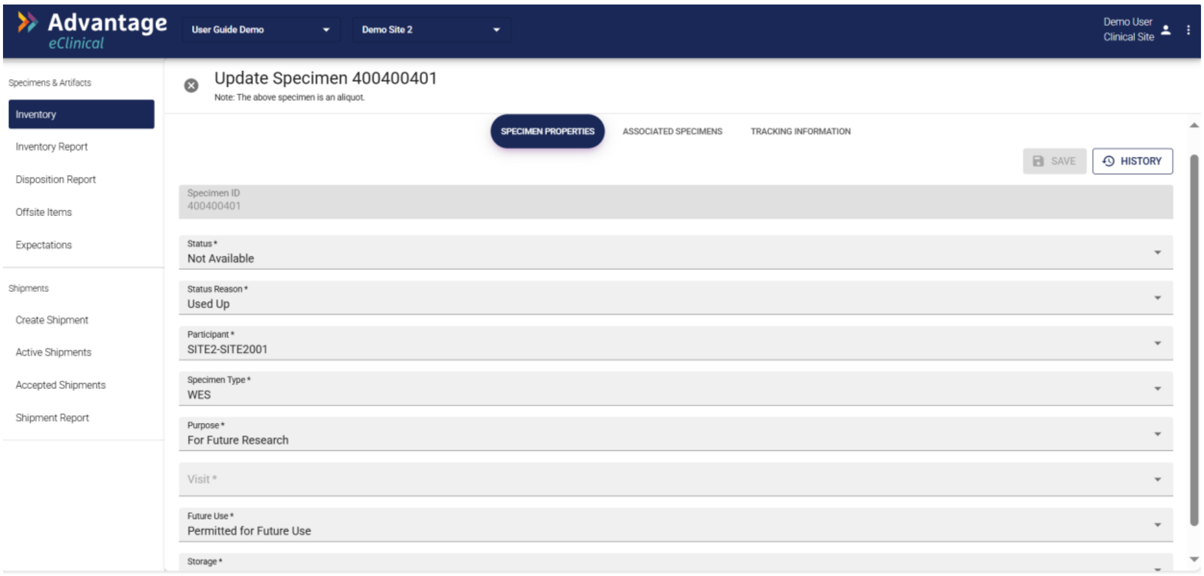




2. Select **ASSOCIATED SPECIMENS** and review the listed specimens or artifacts associated with the same participant.



3. Select any listed item to open its details. From here, you can update any available specimen/artifact or view anything else.

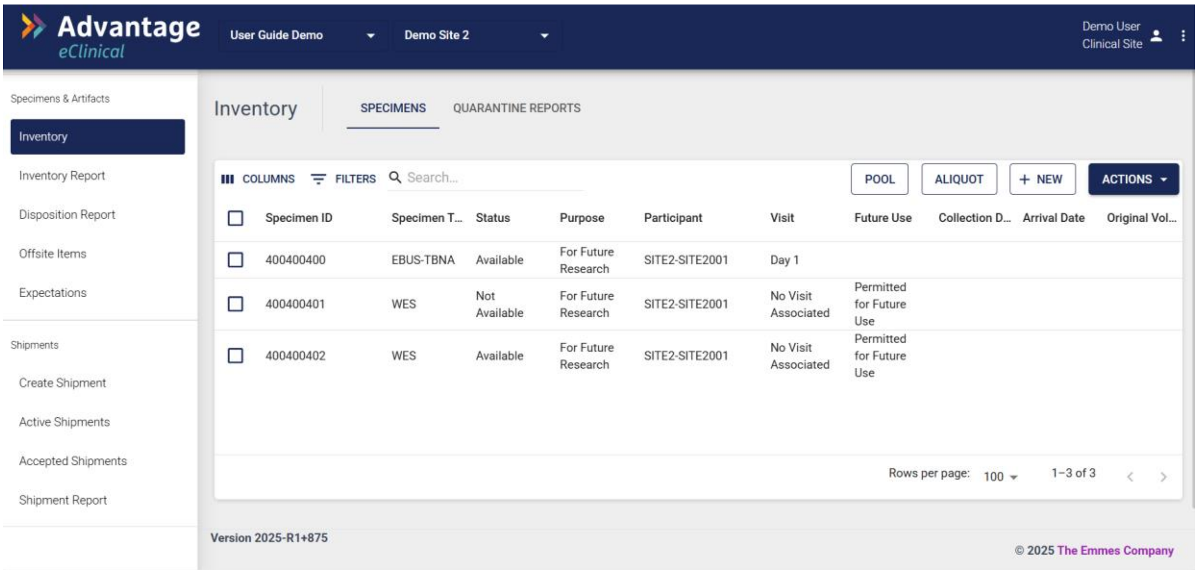


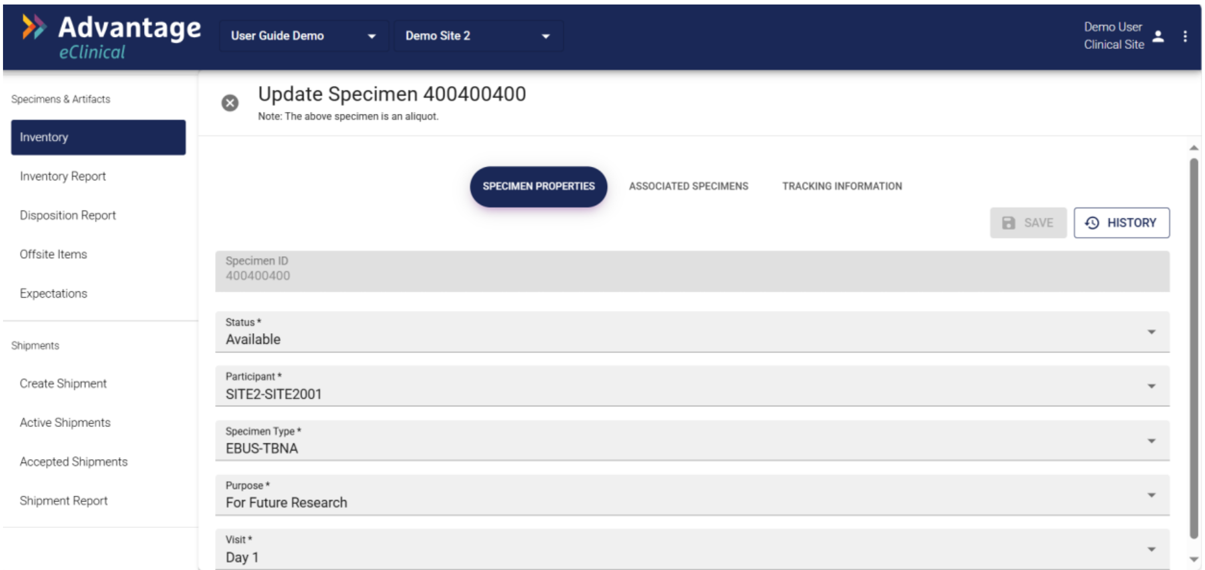
Tracking specimen information

You can track the movement of specimens across shipments to monitor status changes.

Steps to view tracking information:

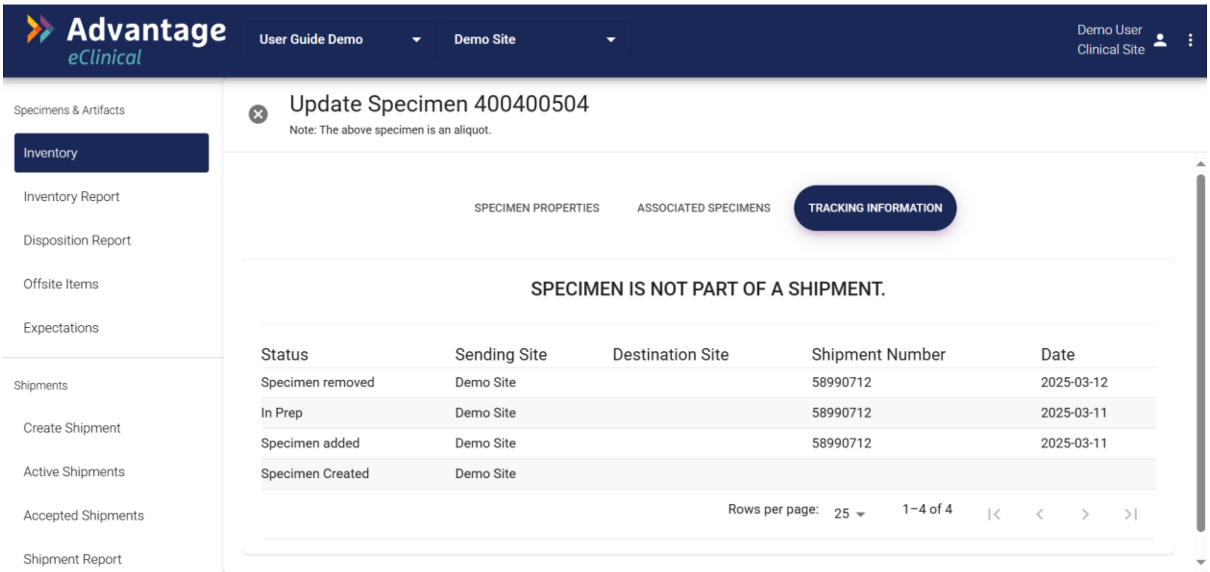
1. Go to the **Inventory** page and select a specimen or artifact to open its details. The **Update Specimen [ID]** page appears.





2. Select **TRACKING INFORMATION** and review shipment details, including:
   - Status (e.g., In Transit, In Prep)
   - Sending Site
   - Destination Site
   - Shipment Number
   - Date

NOTE: If the specimen is not part of a shipment, a message will appear indicating that no tracking information is available.



Completing a Linked CRF

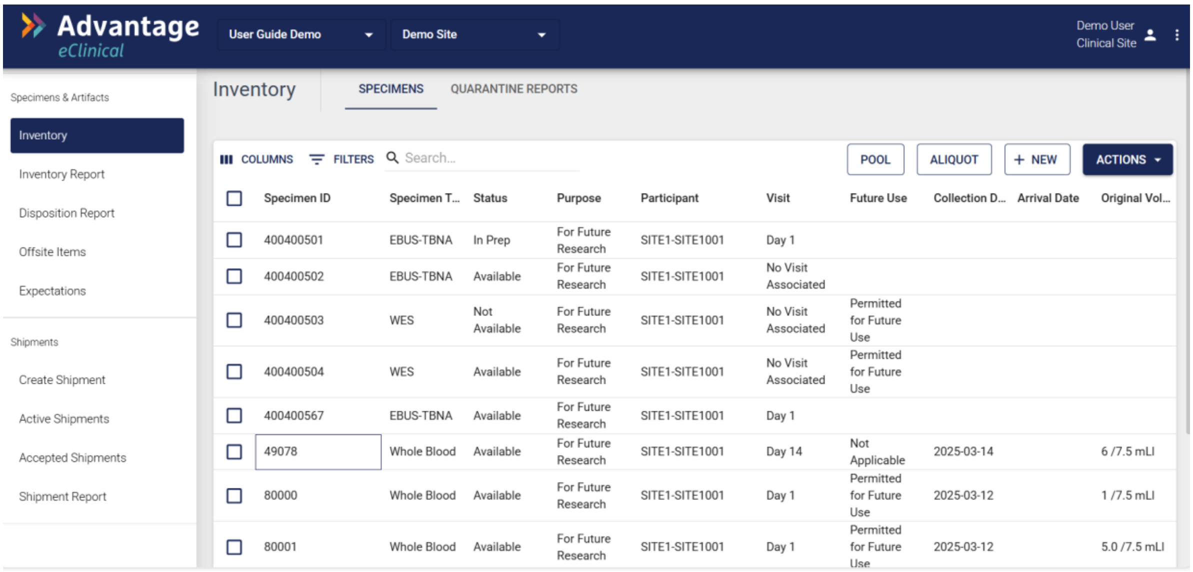
If additional attributes are required for the specimens or artifacts beyond the standard properties, a 'Linked CRF' will follow in the 'Add Specimen or Artifact' process. The Linked CRF is defined in Study Builder based on the Specimen or Artifact Type, meaning different Linked CRFs may appear depending on the study configuration for the specimen.

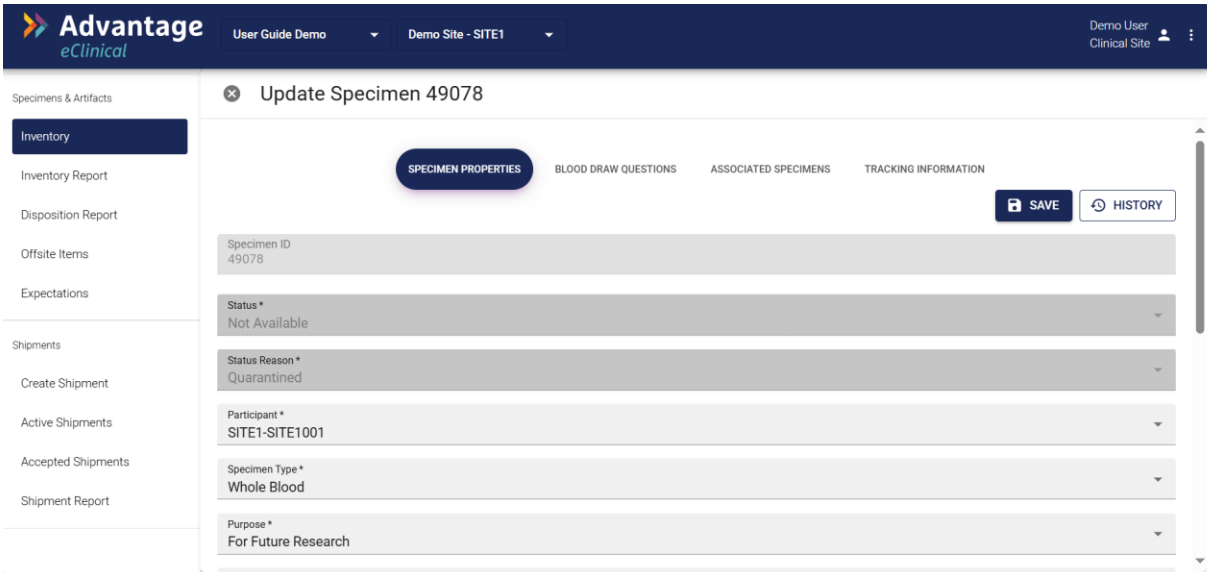
Changing existing data in Linked CRFs

When modifying data in a Linked CRF, the system requires a 'Change Reason' due to autosaving functionality.

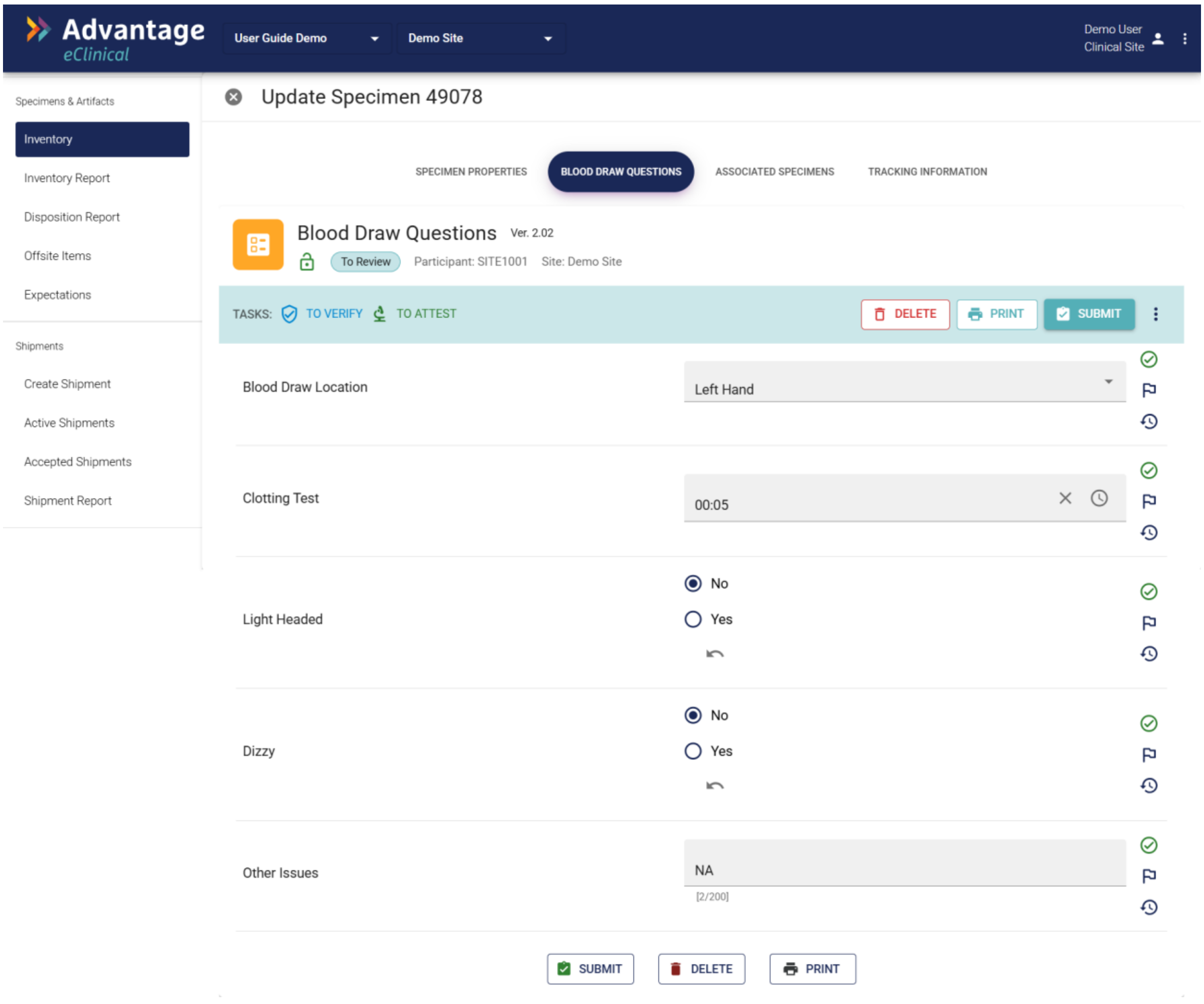
Steps to change data in Linked CRFs:

1. Go to the **Inventory** page and select a specimen or artifact to open its details. The **Update Specimen [ID]** page appears.

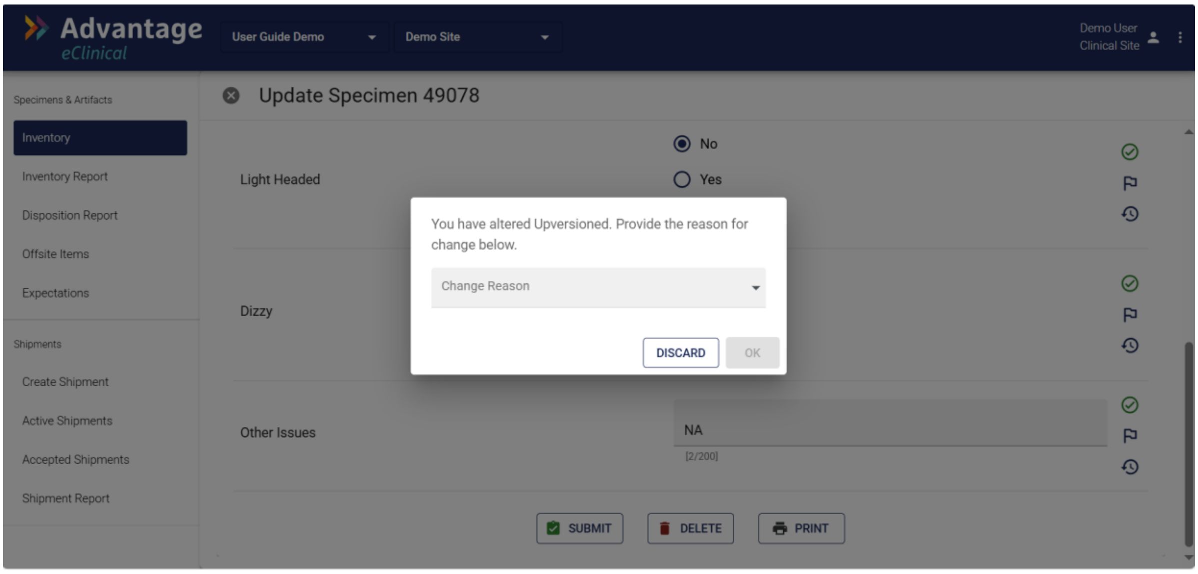




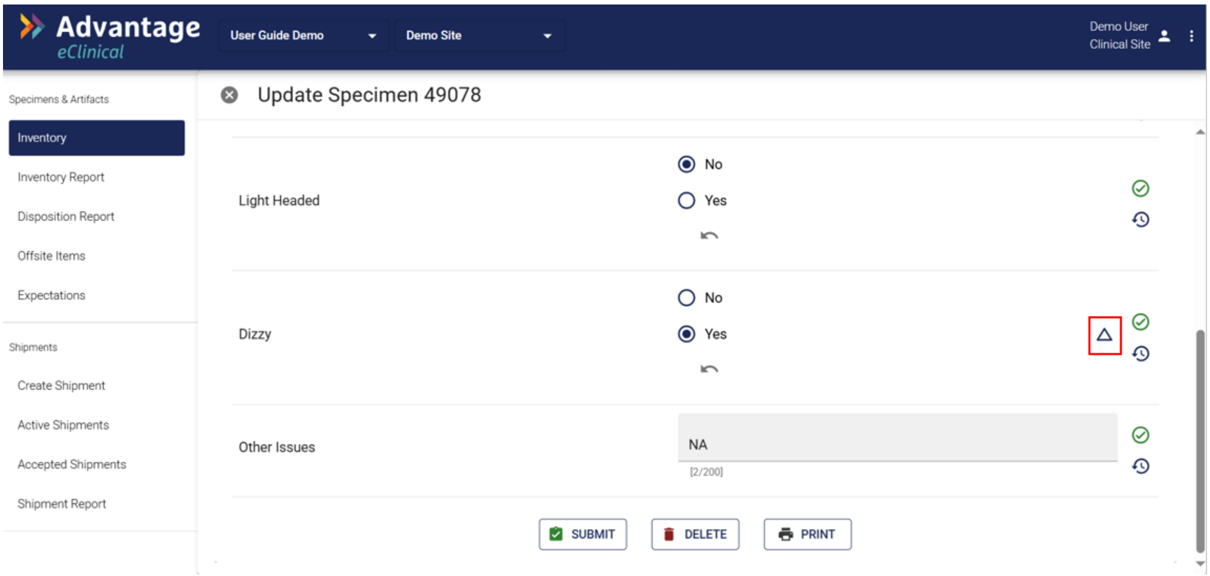
2. Select **<CRF NAME>** and edit the data in the Linked CRF fields.



A dialog box will prompt you to select a ‘Change Reason’ for each field updated or added.



3. Choose the appropriate reason and select **OK**.
4. The updated or new value will display with an indicator (triangle) beside it. Hover over the **triangle** icon to review the change reason, if needed.



Submitting a Linked CRF

To finalize data entry, you must submit Linked CRFs before clinical data is created.

Steps to submit a Linked CRF:

1. Complete all required fields in the Linked CRF.
2. Select **SUBMIT** at the top or bottom of the form.

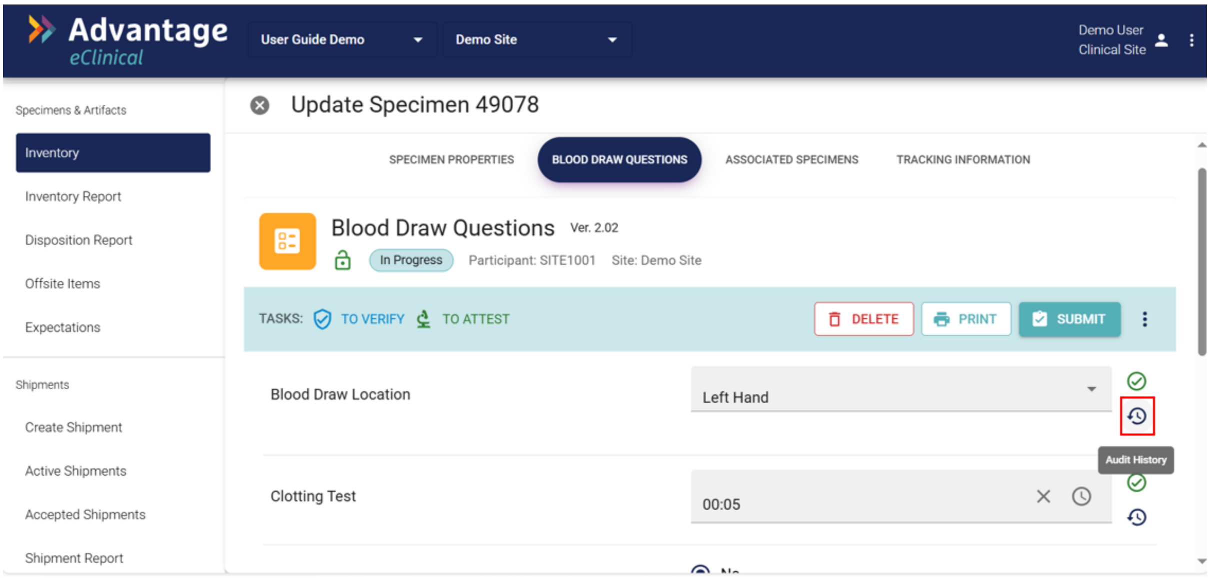
NOTE: After you submit a Linked CRF, you can still modify it, but the changes will not appear in the clinical data until you resubmit the CRF.

Linked CRF question audit history

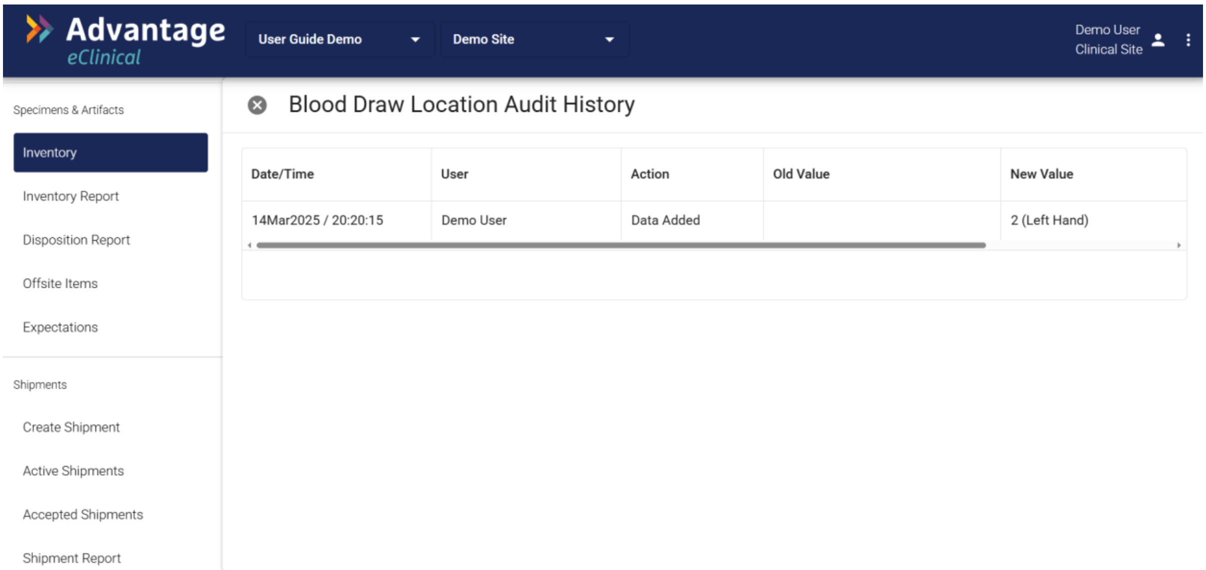
Each question in a Linked CRF has a detailed audit history.

Steps to view audit history:

1. Hover over the **Audit History** icon (circular arrow) next to the question and select.



2. Review the history, which includes:
   - Date or time of changes.
   - User who made the changes.
   - Action
   - Old and new values.
   - Change reason, if applicable.

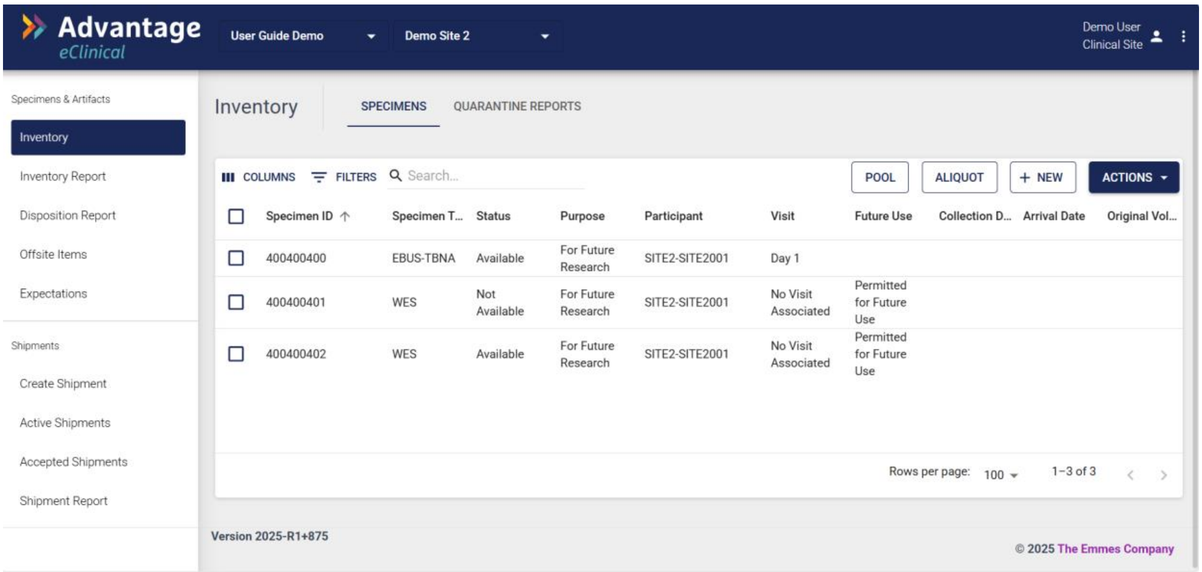


Creating quarantine reports

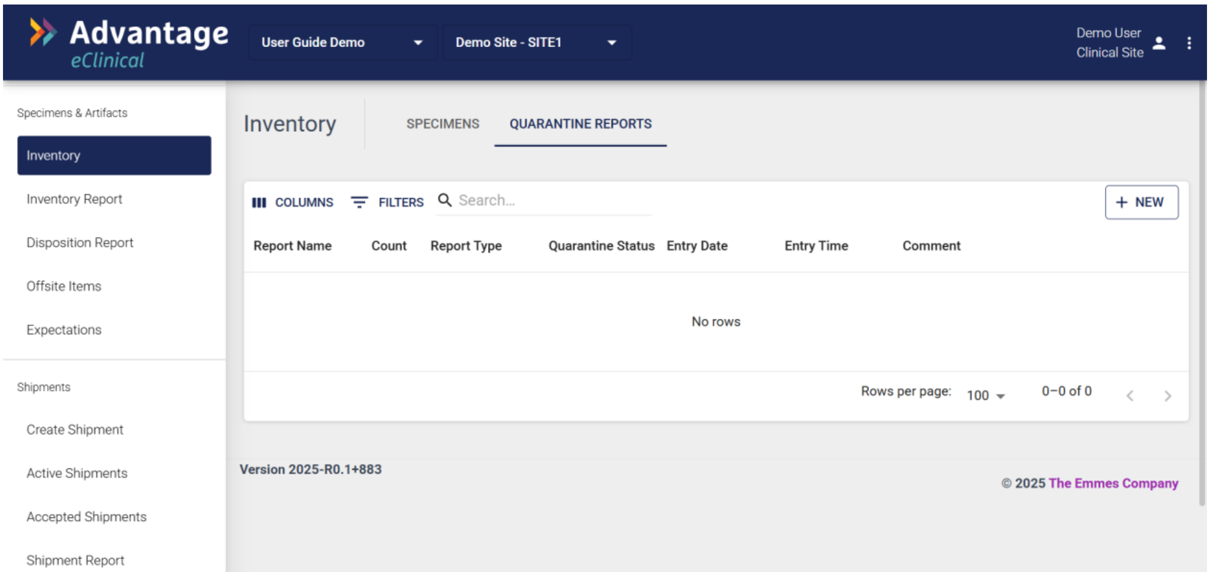
Generate quarantine reports to track specimens flagged for quarantine due to contamination, labeling errors, or storage issues.

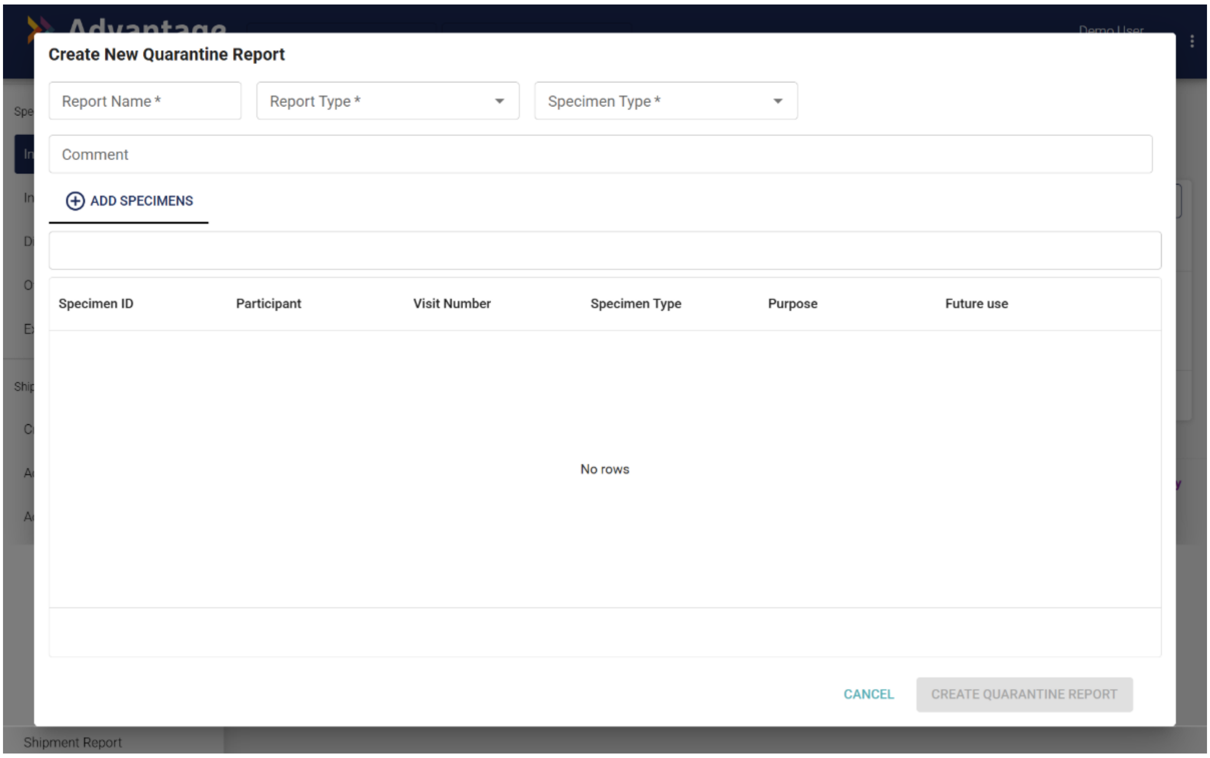
Steps to create a new quarantine report:

1. In GlobalTrace, select **Inventory** within the 'Specimens & Artifacts' section of the side navigation bar. The **Inventory** page appears.

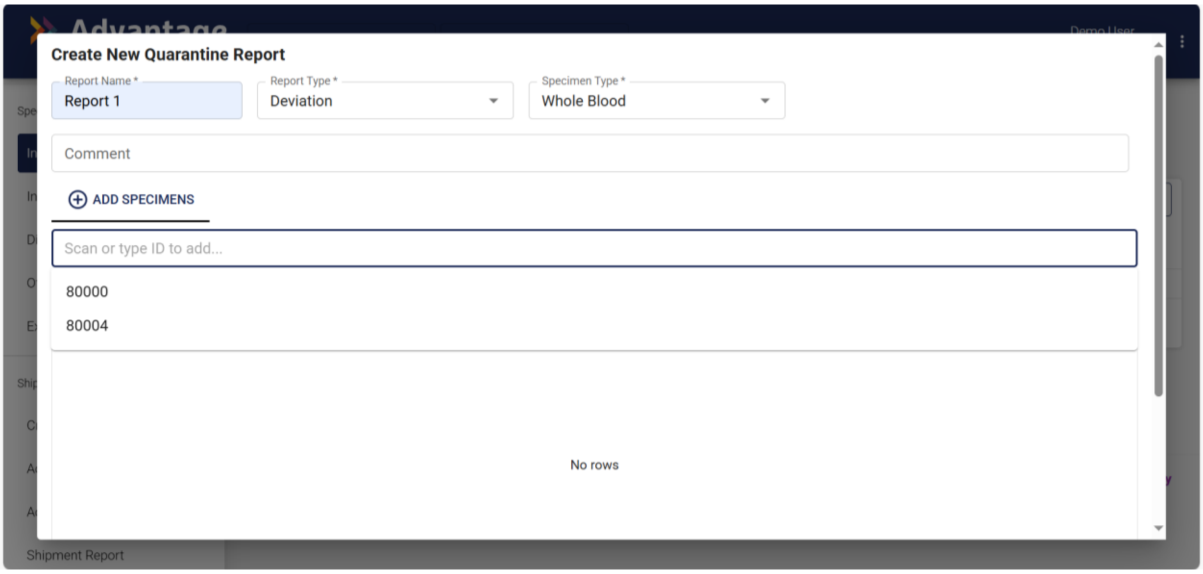


2. Select **QUARANTINE REPORTS** and then select **+ NEW**. The **Create New Quarantine Report** page appears.

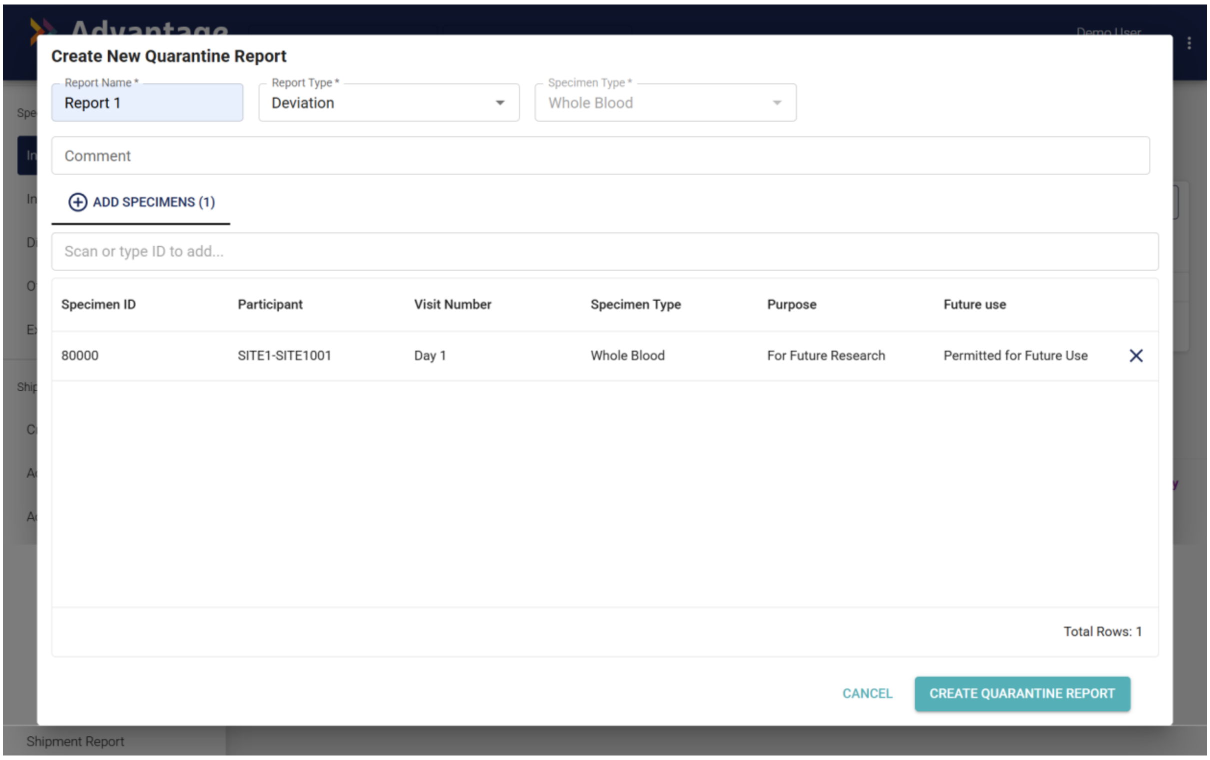


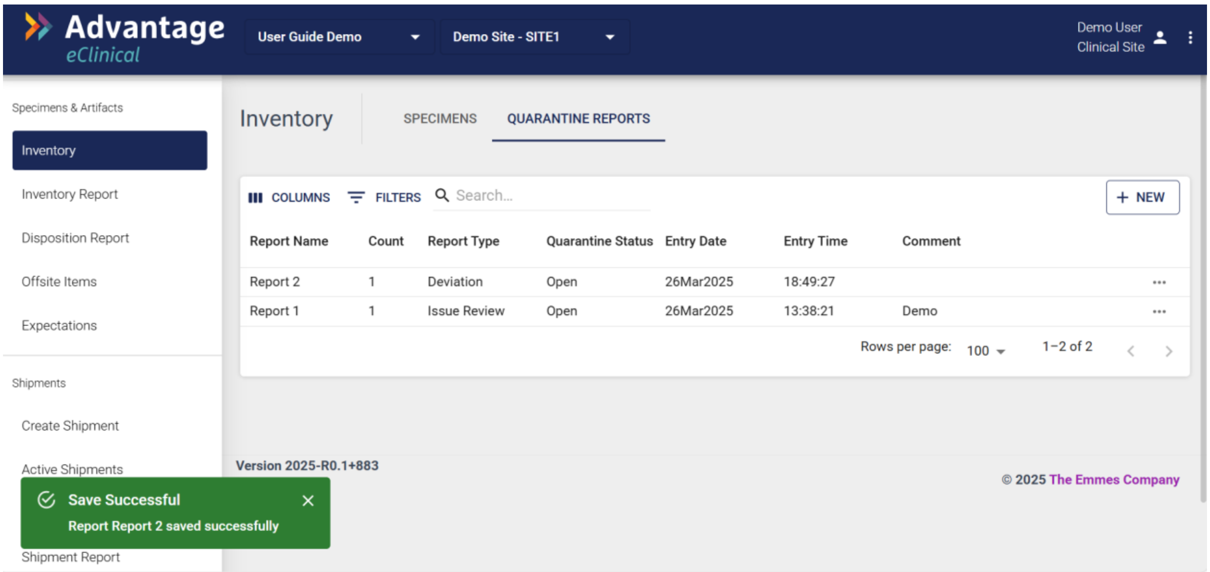


3. Add a name for the report, select the report type and specimen type, and then (optionally) add your comments for the report.
4. Enter one or more offspring specimens by scanning or manually inputting specimen IDs in the **Scan or type ID to add** field under 'ADD SPECIMENS'.



5. Select **CREATE QUARANTINE REPORT**. The report gets added to the reports table.



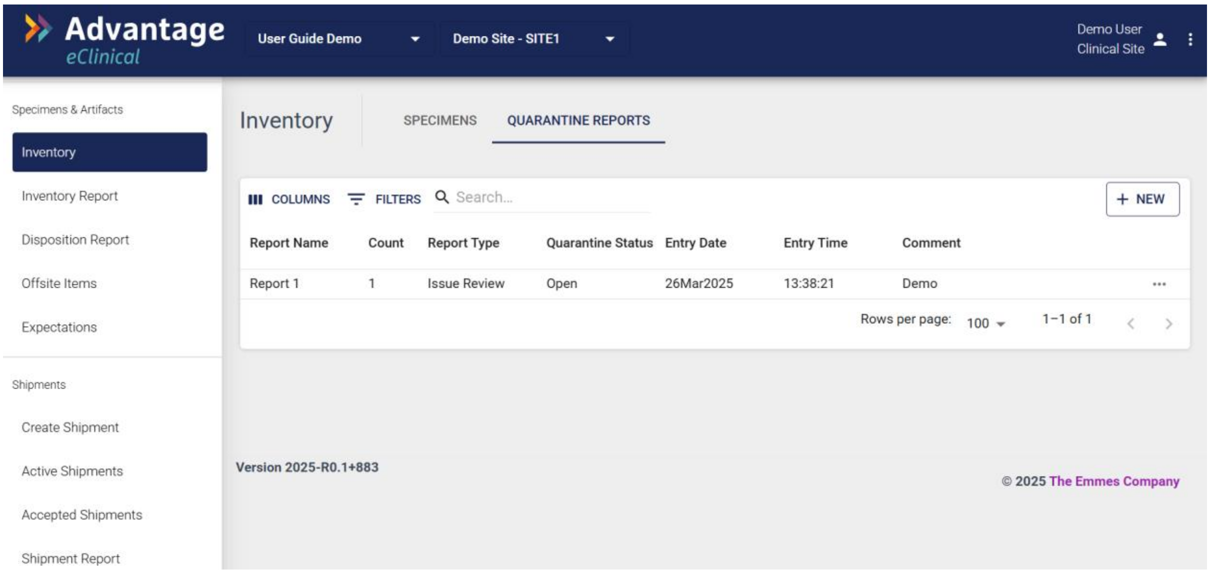


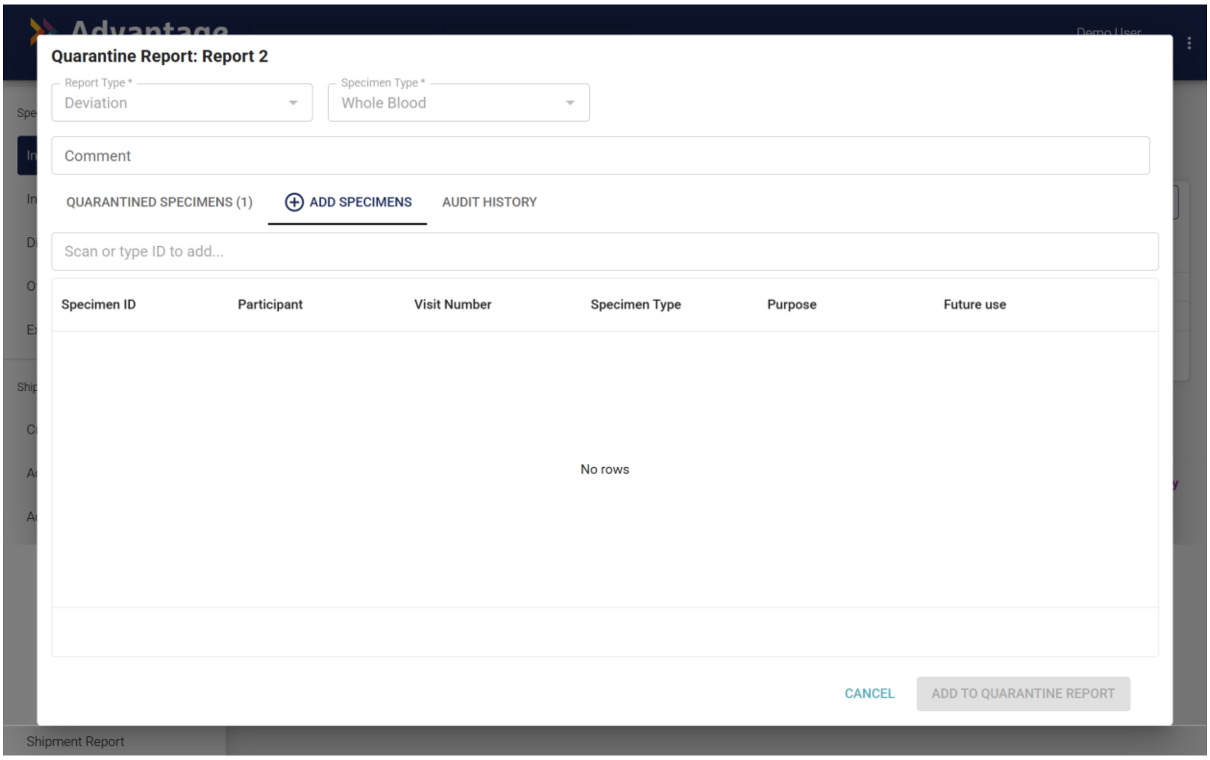
Updating quarantine reports

Update existing quarantine reports and review quarantine statuses to ensure compliance with study protocols and quality control measures.

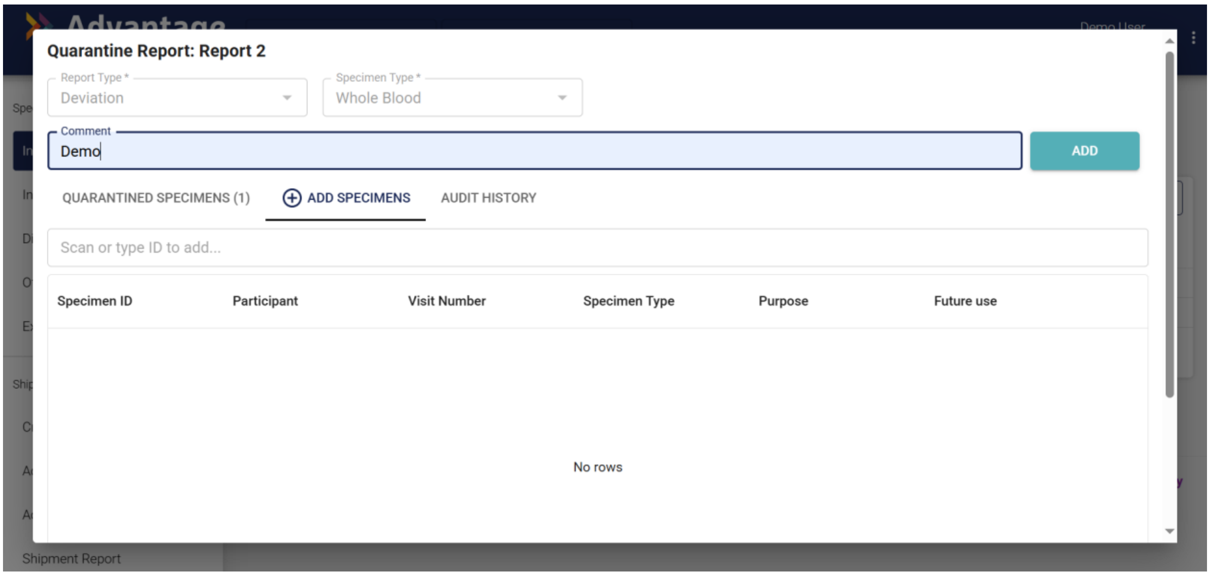
Steps to update a new quarantine report:

1. Select a report that you want to update. The details of the report appear.

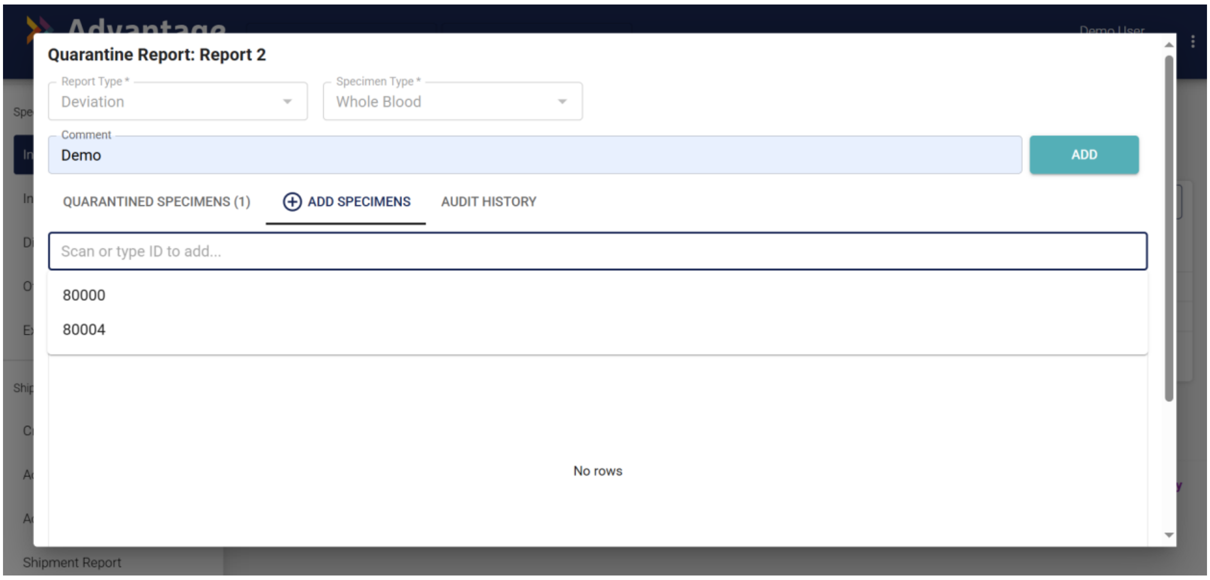




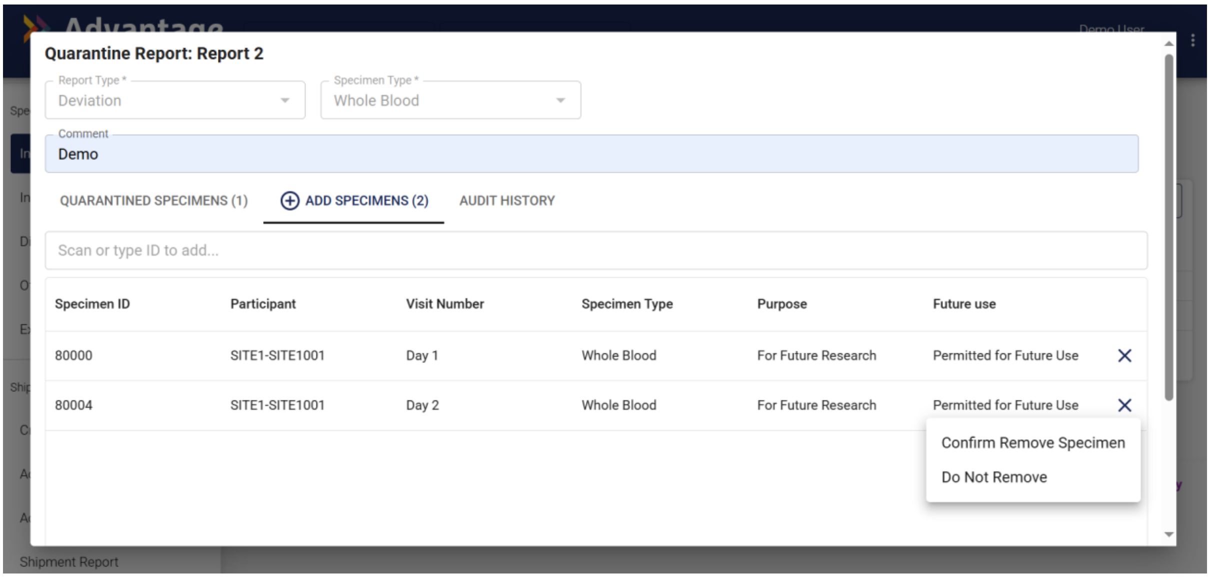
2. To (optionally) add comments, enter a comment and select **ADD**.



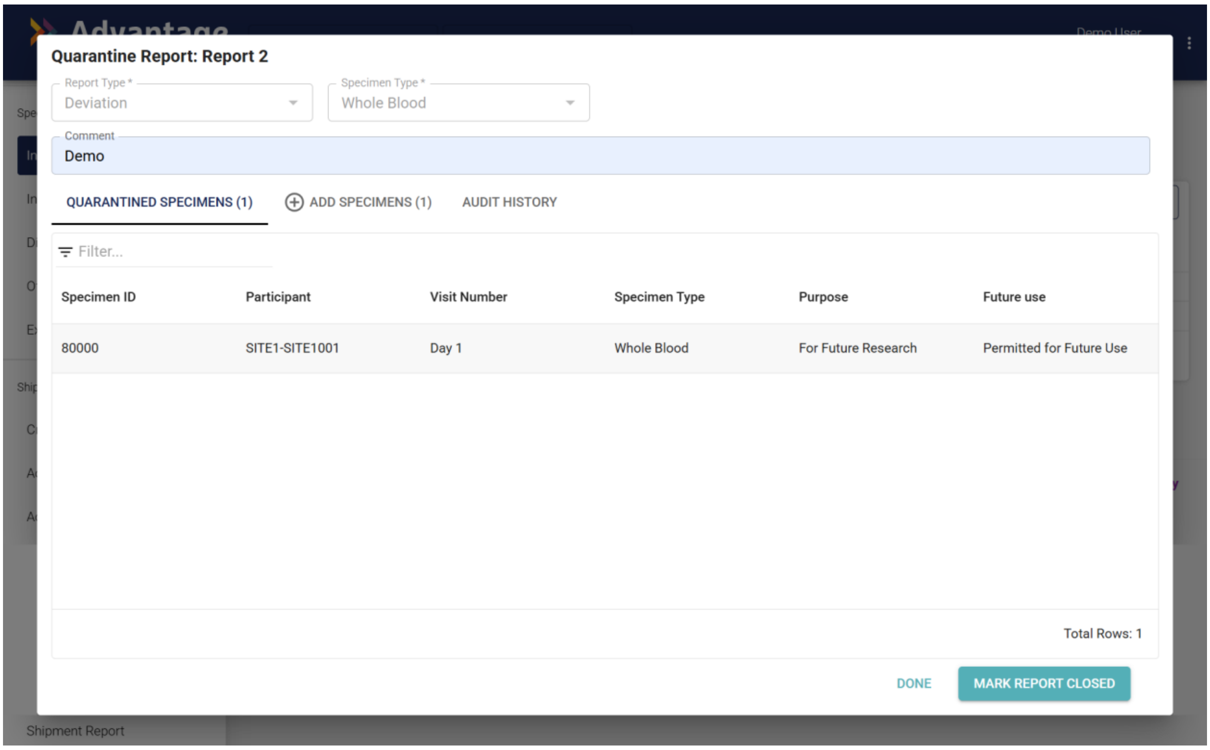
3. Add specimens if necessary.



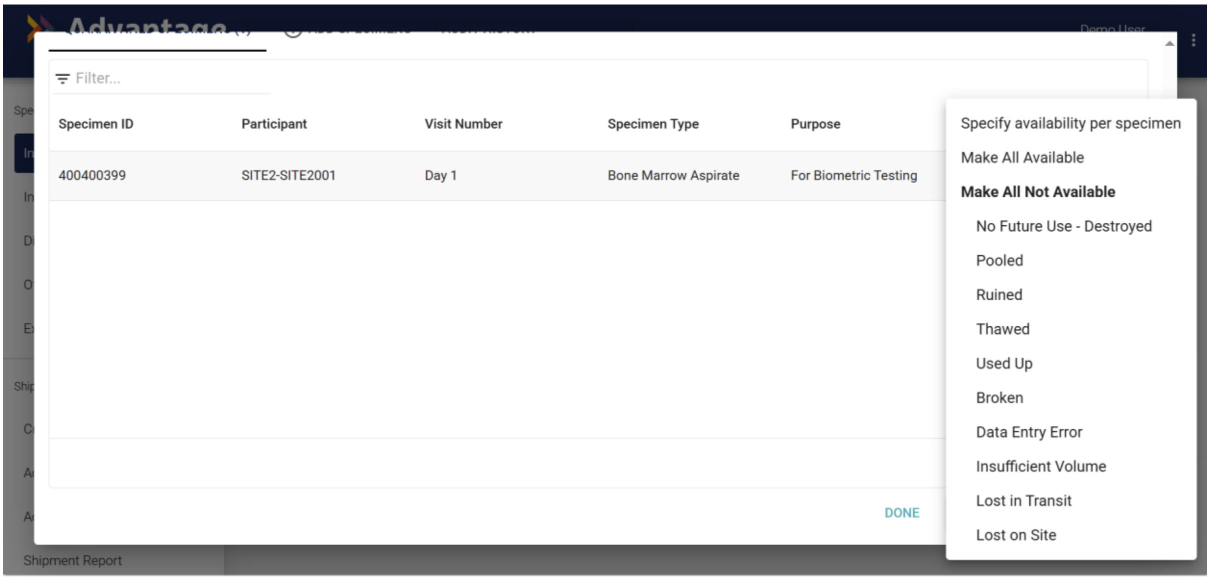
4. In the confirmation menu, select **Confirm Remove Specimen** to delete it or **Do Not Remove** to cancel.



5. Select **QUARANTINED SPECIMENS** (N) to review the details of the specimen that is quarantined. The (N) is the count/number of specimens in the current report.



6. Select **MARK REPORT CLOSED** to close the report. A new panel opens, prompting you to specify availability for each specimen.



7. Choose the appropriate availability status (e.g., *Pooled, Ruined, Thawed*, etc.). You can use **Make All Not Available** or update each specimen individually.
8. Select **DONE** to save your changes and close the report.

NOTE:

- You can mark a report as closed only if you have the 'Close Report' permission.
- Select **AUDIT HISTORY** to view the audit history of an existing report.

Generating specimen reports

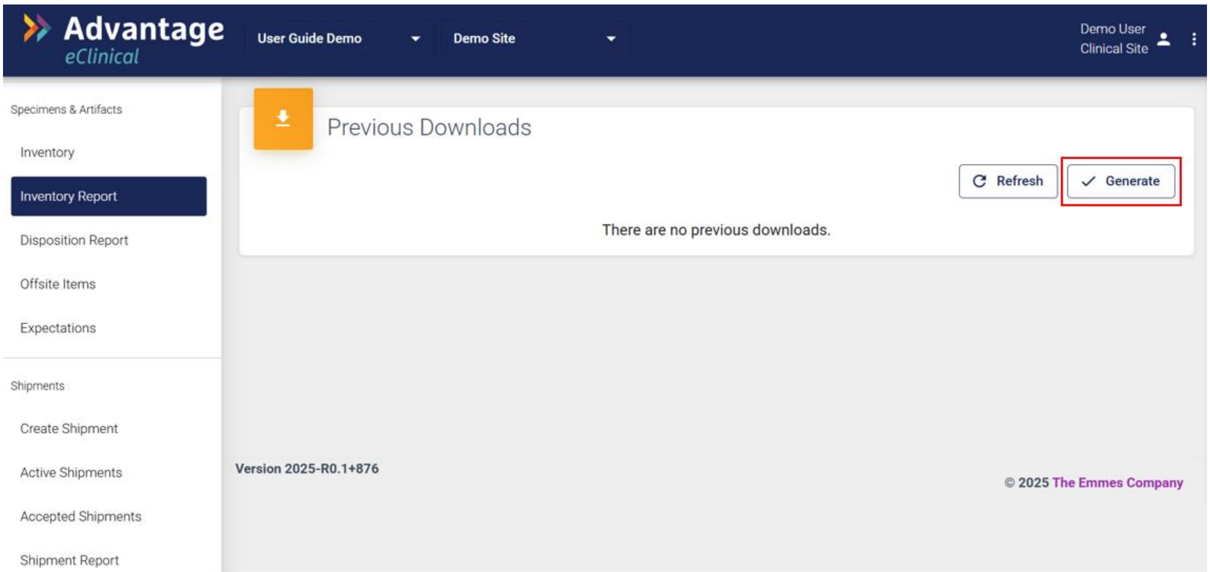
You can generate inventory and disposition reports to track specimen status and availability.

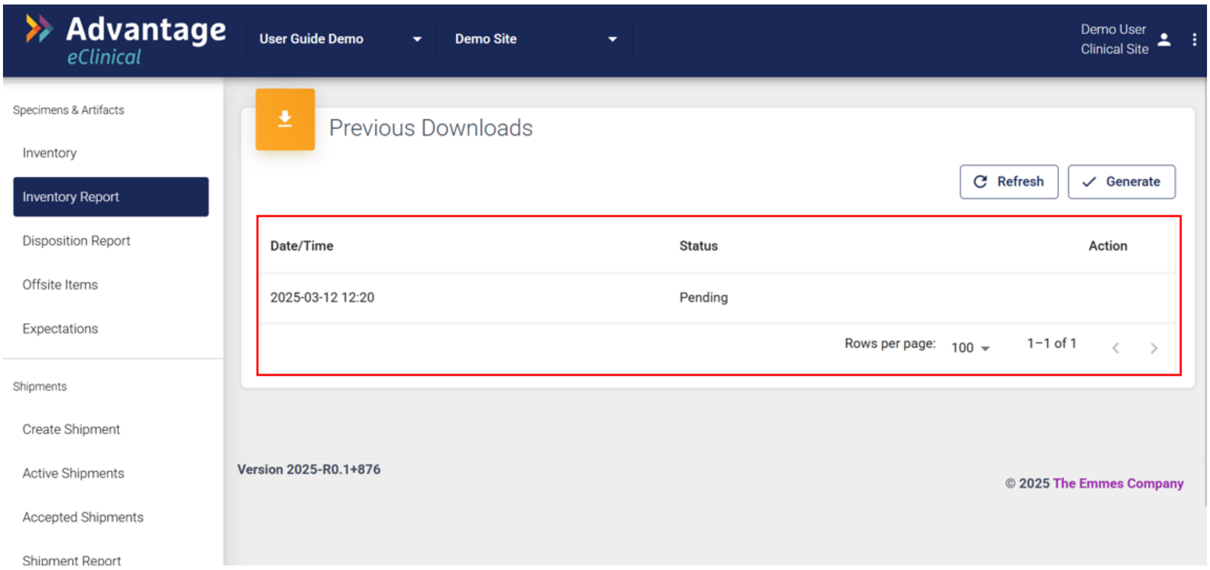
Specimen inventory report

The specimen inventory report provides a comprehensive view of all specimens in inventory.

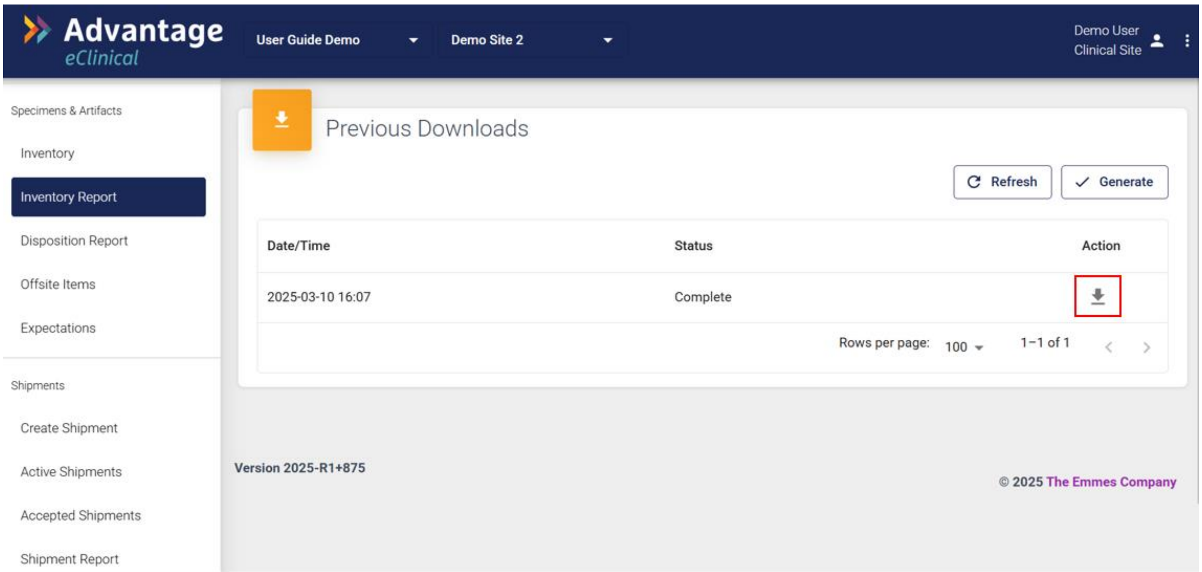
Steps to generate a Specimen Inventory report:

1. Go to **Inventory Report** from the side menu and select **Generate** to request a new report. The request will appear in the 'Previous Downloads' table with a processing status.





2. Select **Refresh** to update the status.
3. When the report is ready, download it by clicking the **Action** icon next to the request.

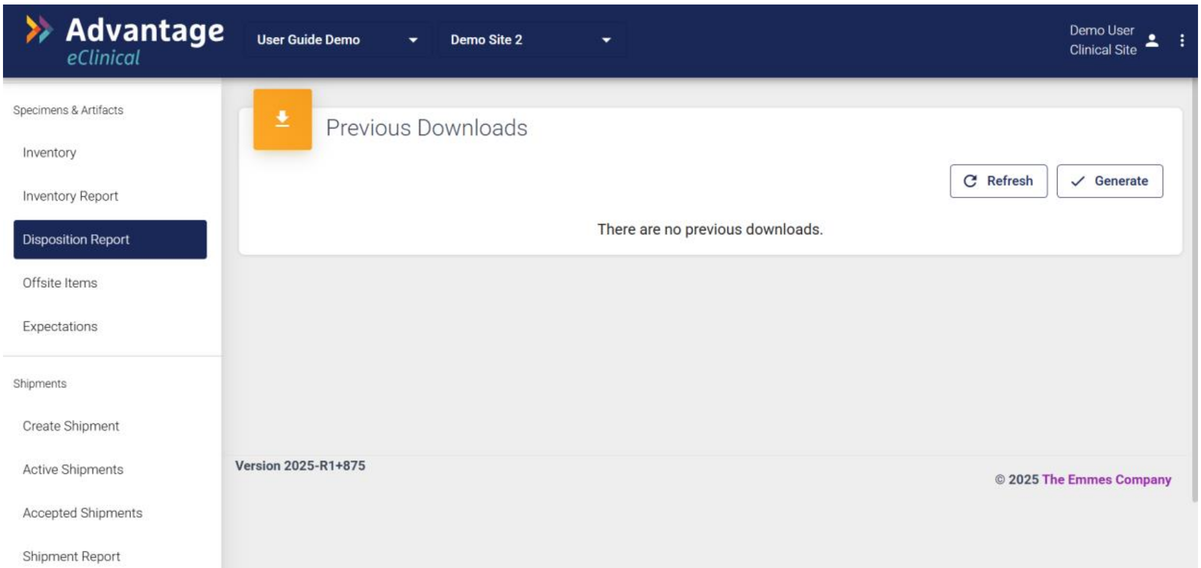


Specimen disposition report

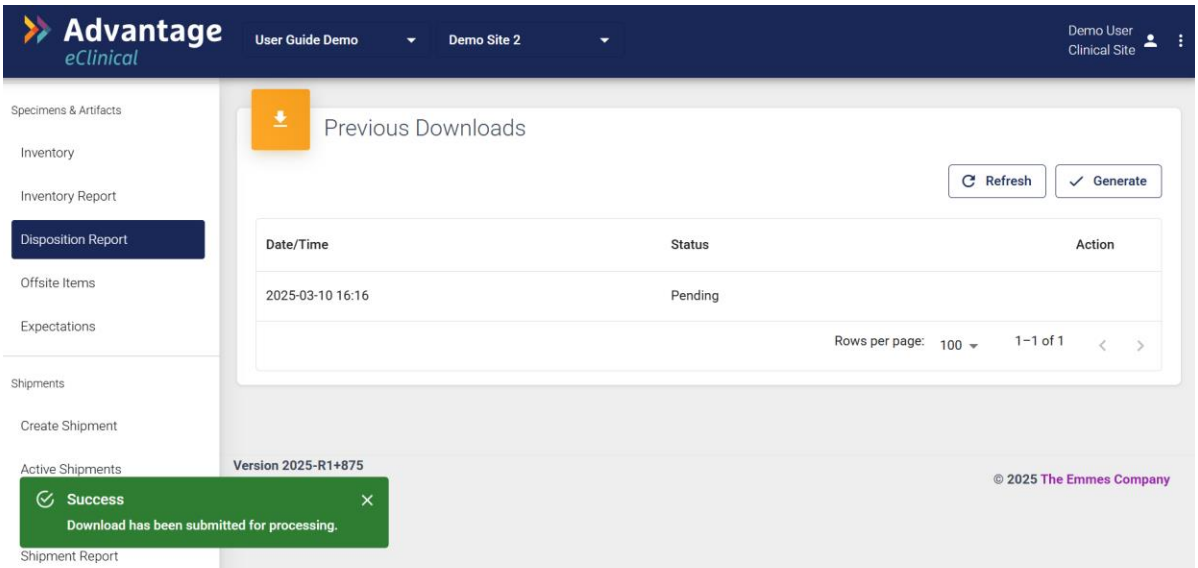
The specimen disposition report tracks the availability of specimens and the specimen location.

Steps to generate a specimen disposition report:

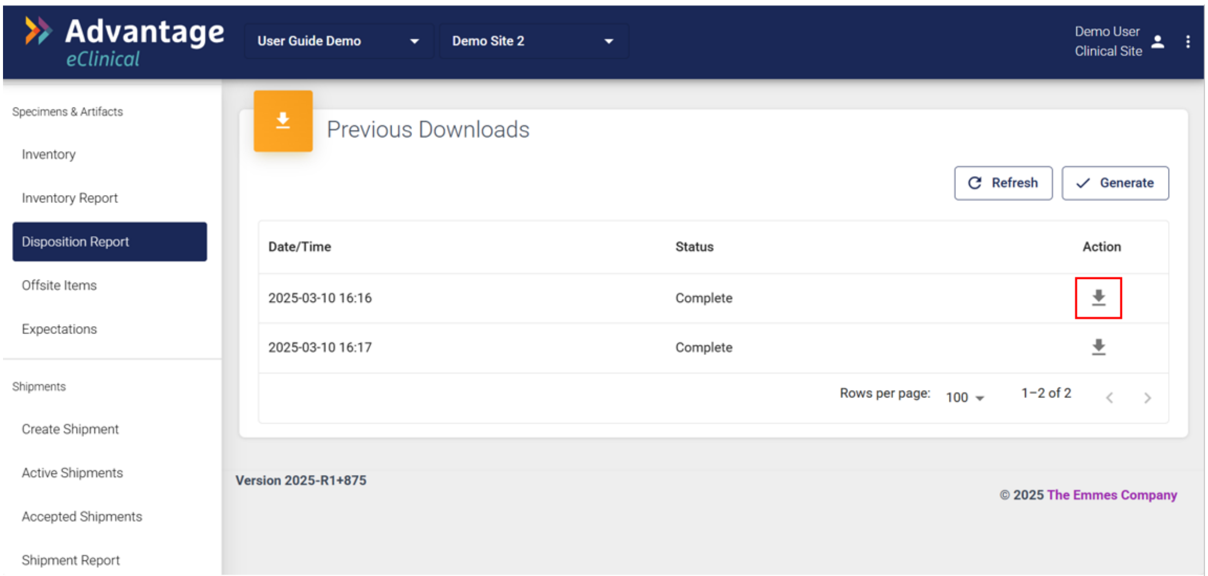
1. Go to **Disposition Report** from the side menu.



2. Select **Generate** to request a new report. The request will appear in the 'Previous Downloads' table with a Processing status.



3. Select **Refresh** to update the status.
4. When the report is ready, download it by clicking the **Action** icon next to the request.



Aliquoting Specimens

Aliquoting allows you to create offspring specimens from parent specimens while maintaining detailed records in Global Trace. This helps you track specimen usage and availability accurately.

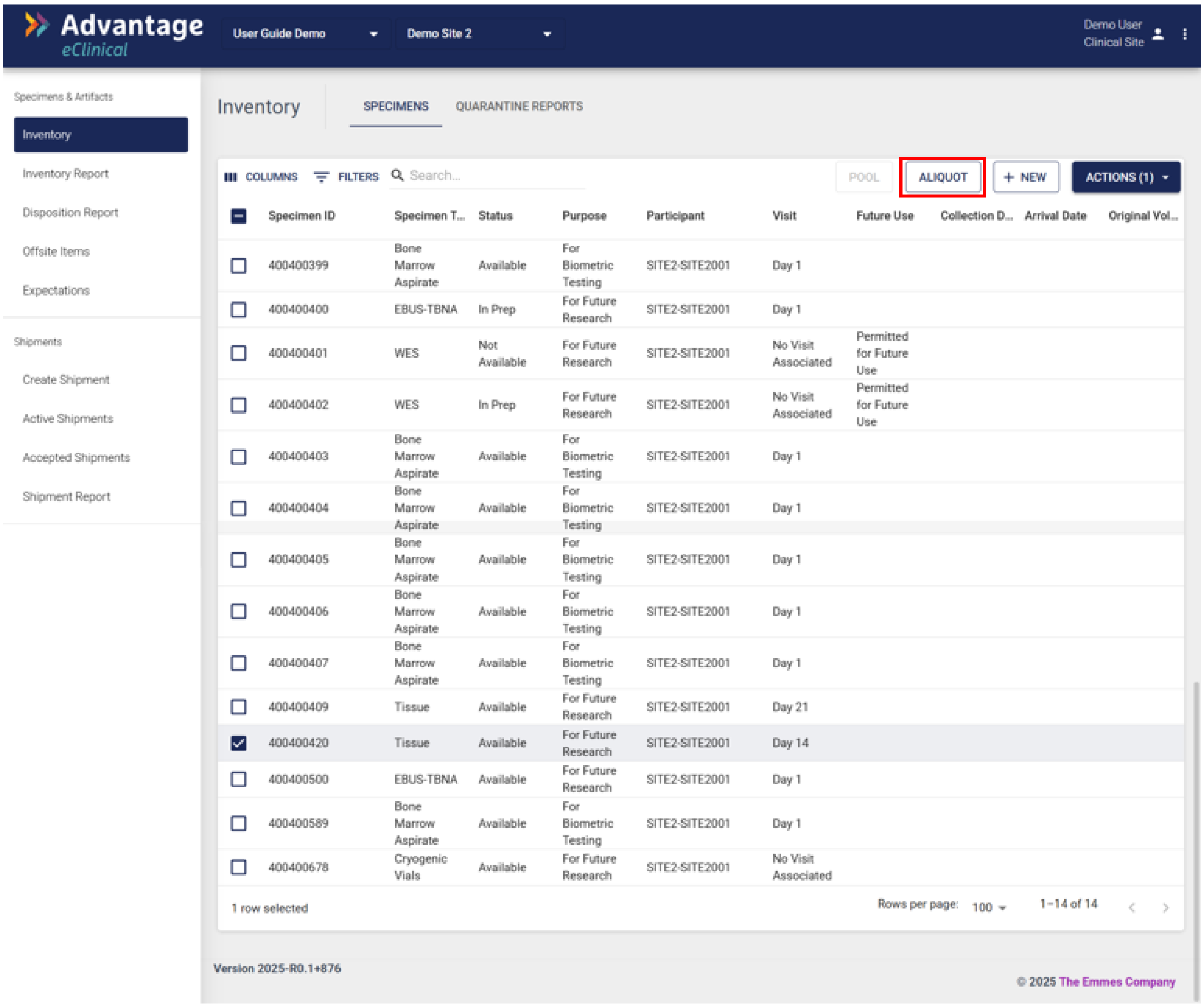
Entering offspring details

You can create one or more offspring specimens from a parent specimen in inventory.

NOTE: If a specimen is already an aliquot, you can further aliquot it. Specimens that are aliquot-only will also be available for aliquoting. Each aliquot can be split further as long as there is residual volume, allowing you to continue the aliquoting process as needed.

Steps to enter offspring details:

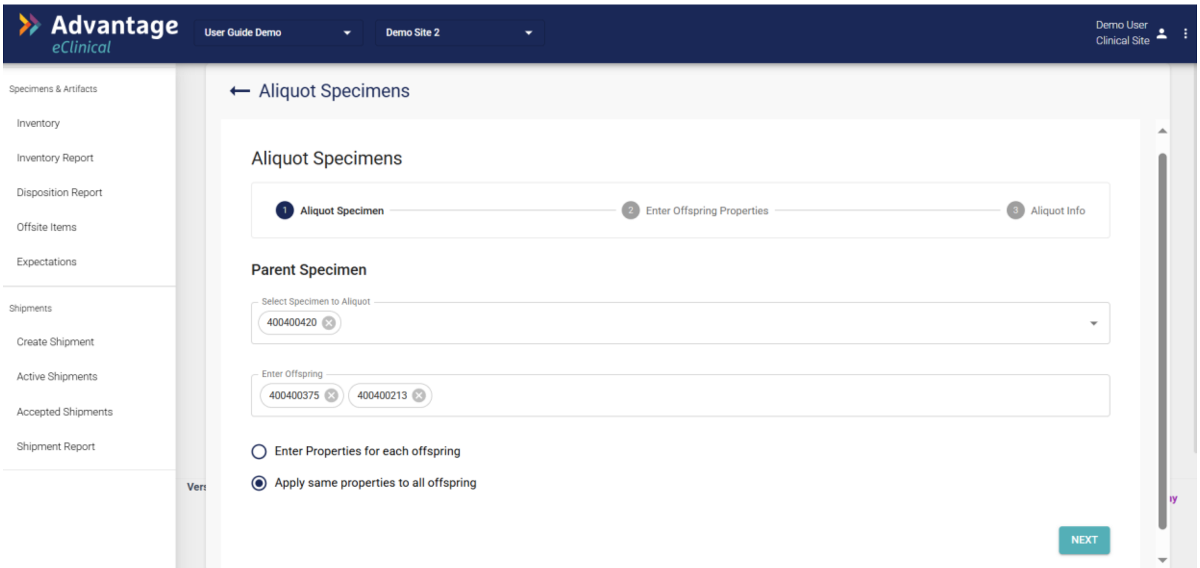
1. Go to **Inventory**, select 1 specimen that is available, then select **ALIQUOT**.



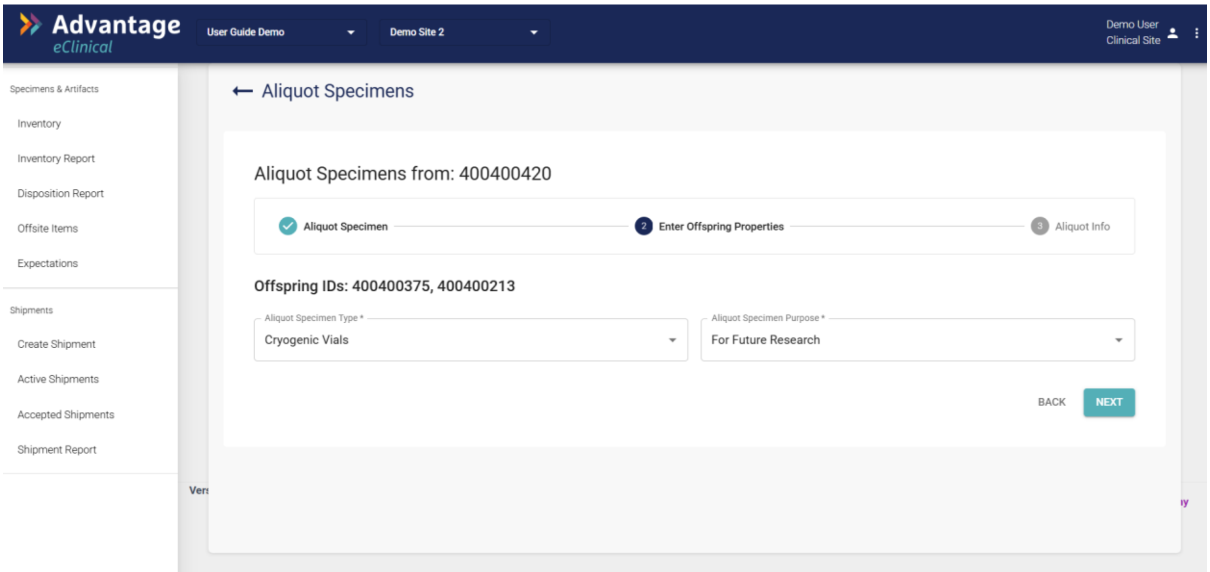
2. In the **Aliquot Specimens** page that appears, enter or scan valid Offspring ID(s).

If aliquoting into multiple specimens, choose one of the following:

- Enter properties for each offspring (requires defining attributes separately).
- Apply same properties to all offspring (applies the same attributes to all entries).

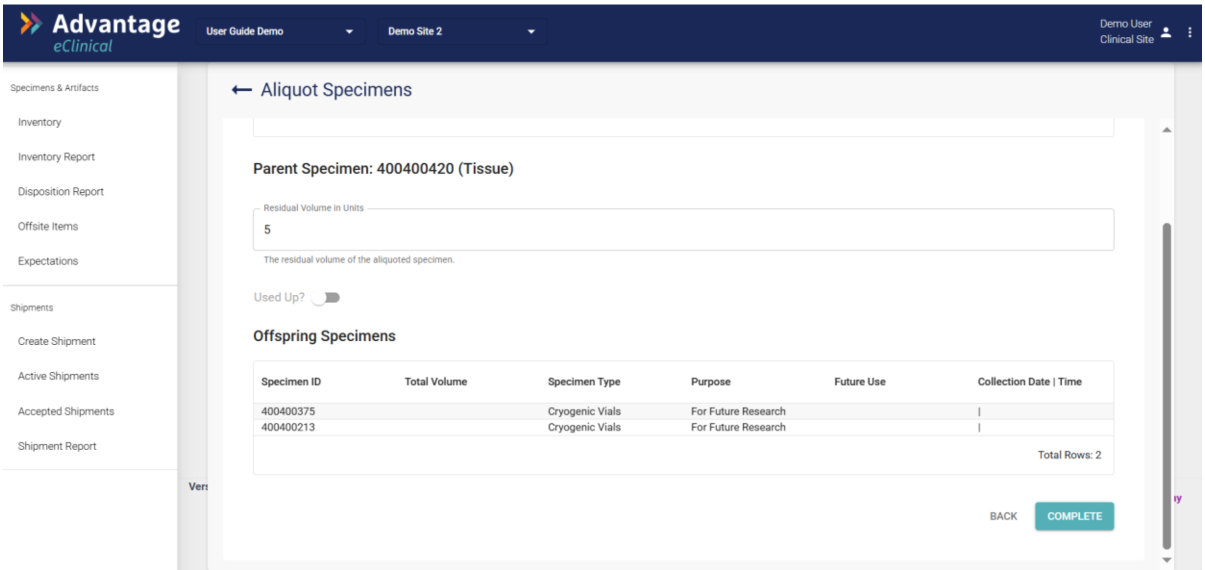


3. Select **NEXT** to proceed to offspring properties.
4. Select the applicable ‘Aliquot Specimen Type’ and ‘Aliquot Specimen Purpose’ from the available options and then select **NEXT**.

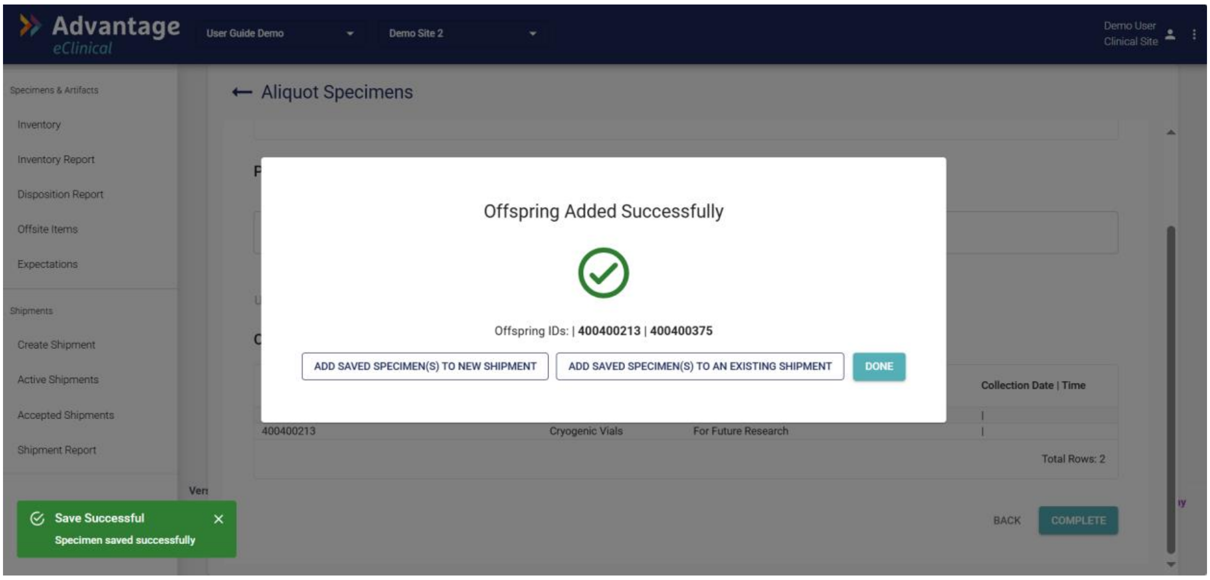


5. Enter the ‘Residual Volume in Units’, if applicable or turn on **Used Up?** if the parent specimen is fully consumed.

NOTE: You must complete **either** the residual volume field **or** select **Used Up?** to proceed. The system will update inventory records, marking the parent specimen as ‘Not Available’ if fully consumed.



6. Select **COMPLETE** to finalize the offspring creation. A success message confirms that the offspring specimen has been added successfully.



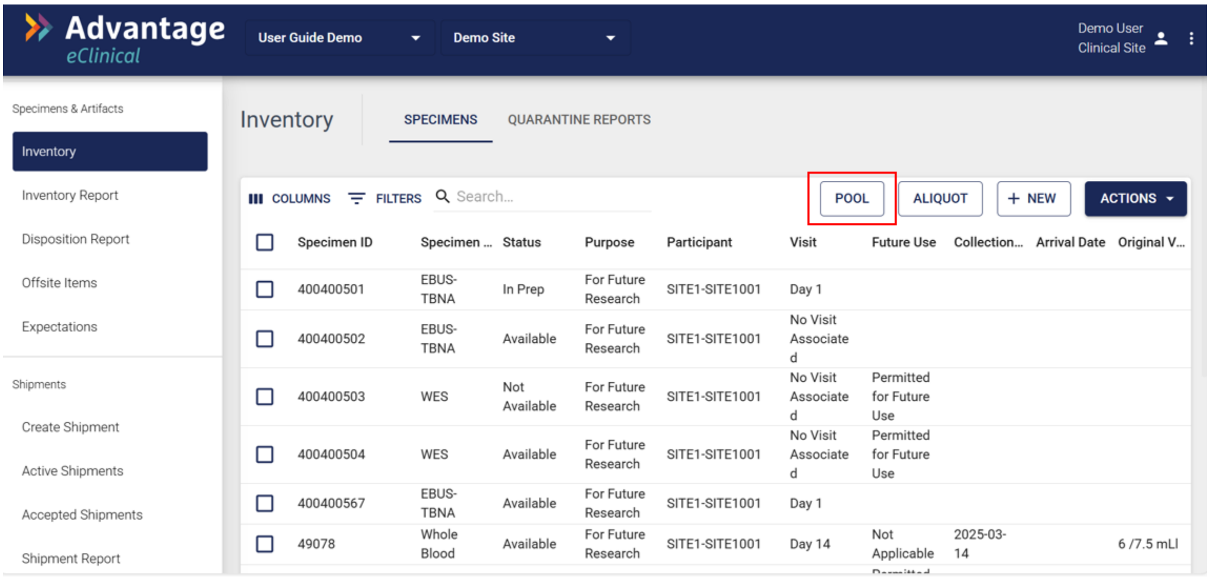
7. Choose the next action:
   - Select **ADD SAVED SPECIMEN(S) TO NEW SHIPMENT** to initiate a new shipment for the specimen.
   - Select **ADD SAVED SPECIMEN(S) TO AN EXISTING SHIPMENT** to include it in an ongoing shipment.
   - Select **DONE** to return to the inventory.

Pooling Specimens

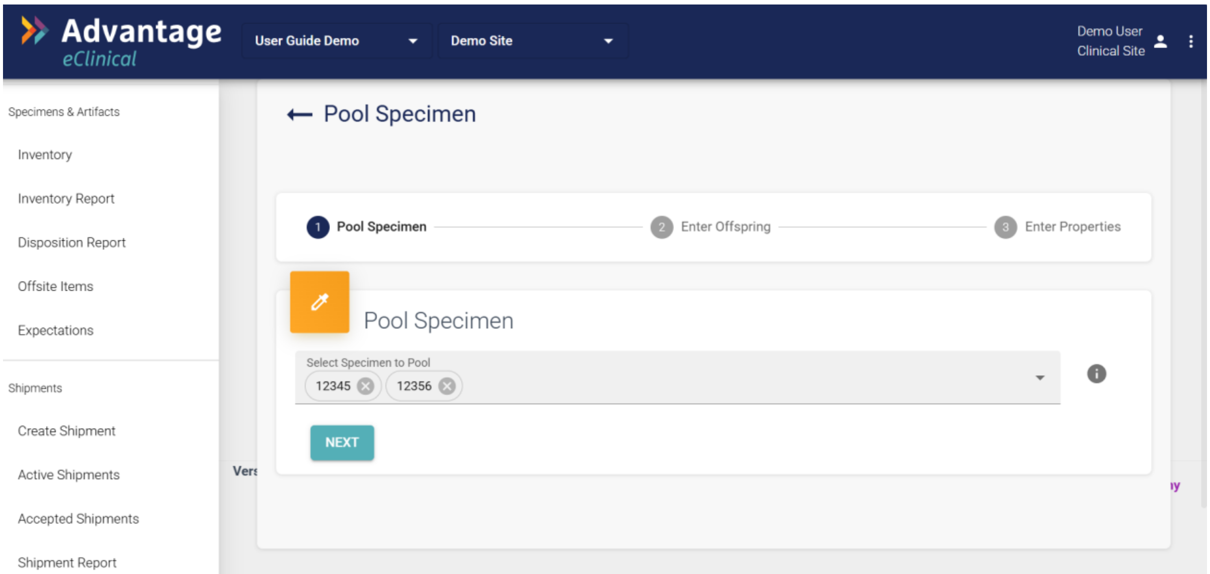
Pooling allows you to combine multiple parent specimens into a single or multiple new specimens while maintaining detailed records in GlobalTrace. This helps you accurately track pooled specimens in the inventory.

Steps to pool specimens:

1. Go to **Inventory** and select **POOL**. The **Pool Specimens** page appears.



2. Select the parent specimens to pool and then select **NEXT** to proceed to offspring details.



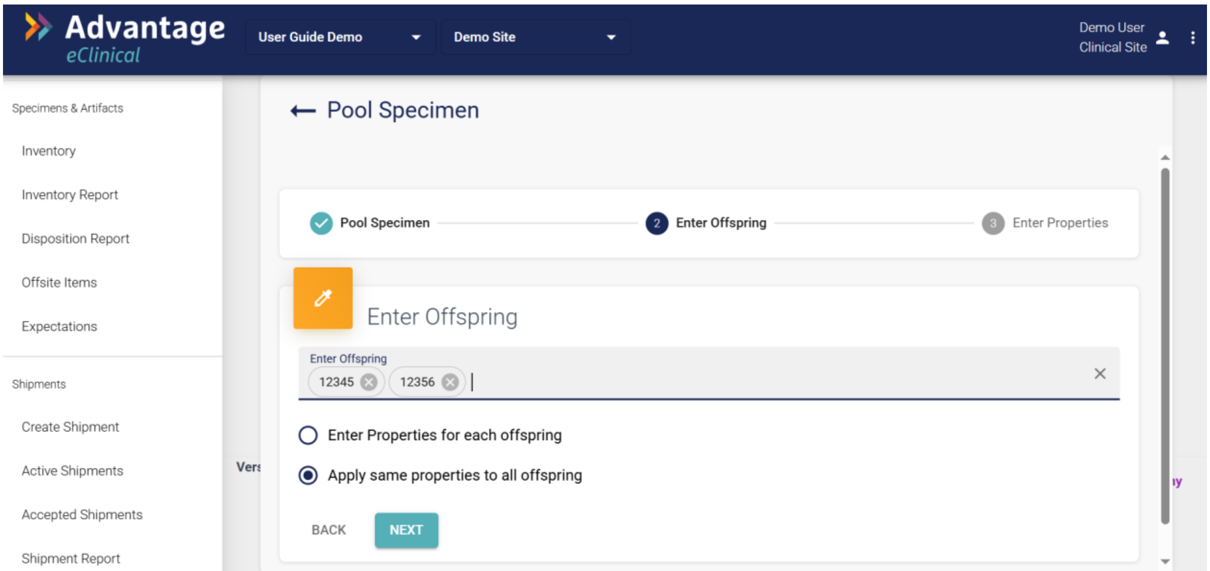
Entering offspring details

You can enter one or more offspring specimens by scanning or manually inputting specimen IDs.

Steps to enter offspring details:

1. In the **Enter Offspring** page, scan or manually enter the offspring specimen ID.

   NOTE: You can enter only valid specimen IDs.



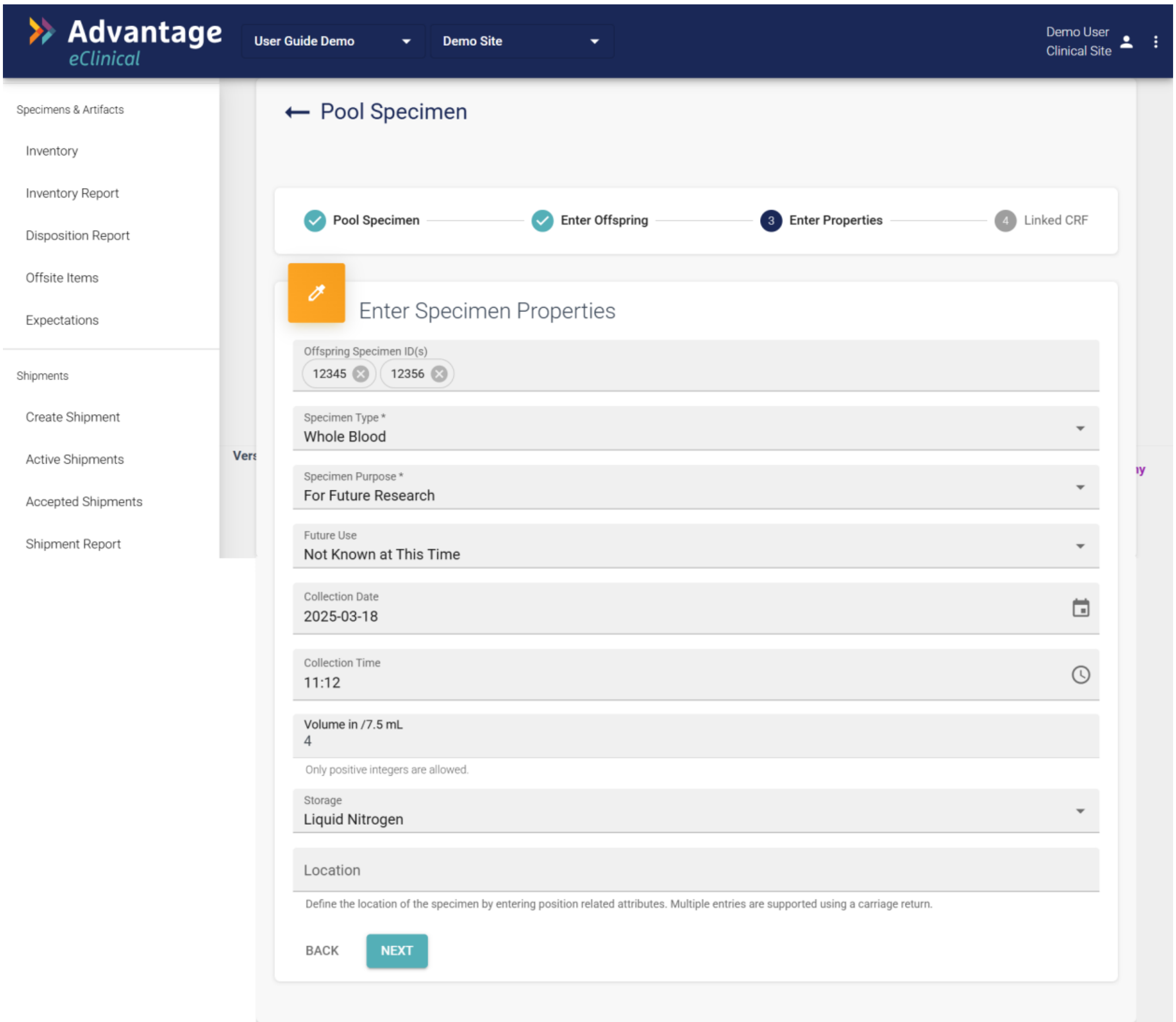
2. If pooling multiple specimens, choose one of the following:
   - **Apply same properties to all offspring** (applies the same attributes to all entries).
   - **Enter properties for each offspring individually** (requires defining attributes separately).
3. Select **NEXT** to proceed to specimen properties.

Setting offspring properties

You must define attributes for each offspring specimen before adding it to inventory.

Steps to set offspring properties:

1. Choose a 'Specimen Type' and 'Purpose' for the offspring specimen.



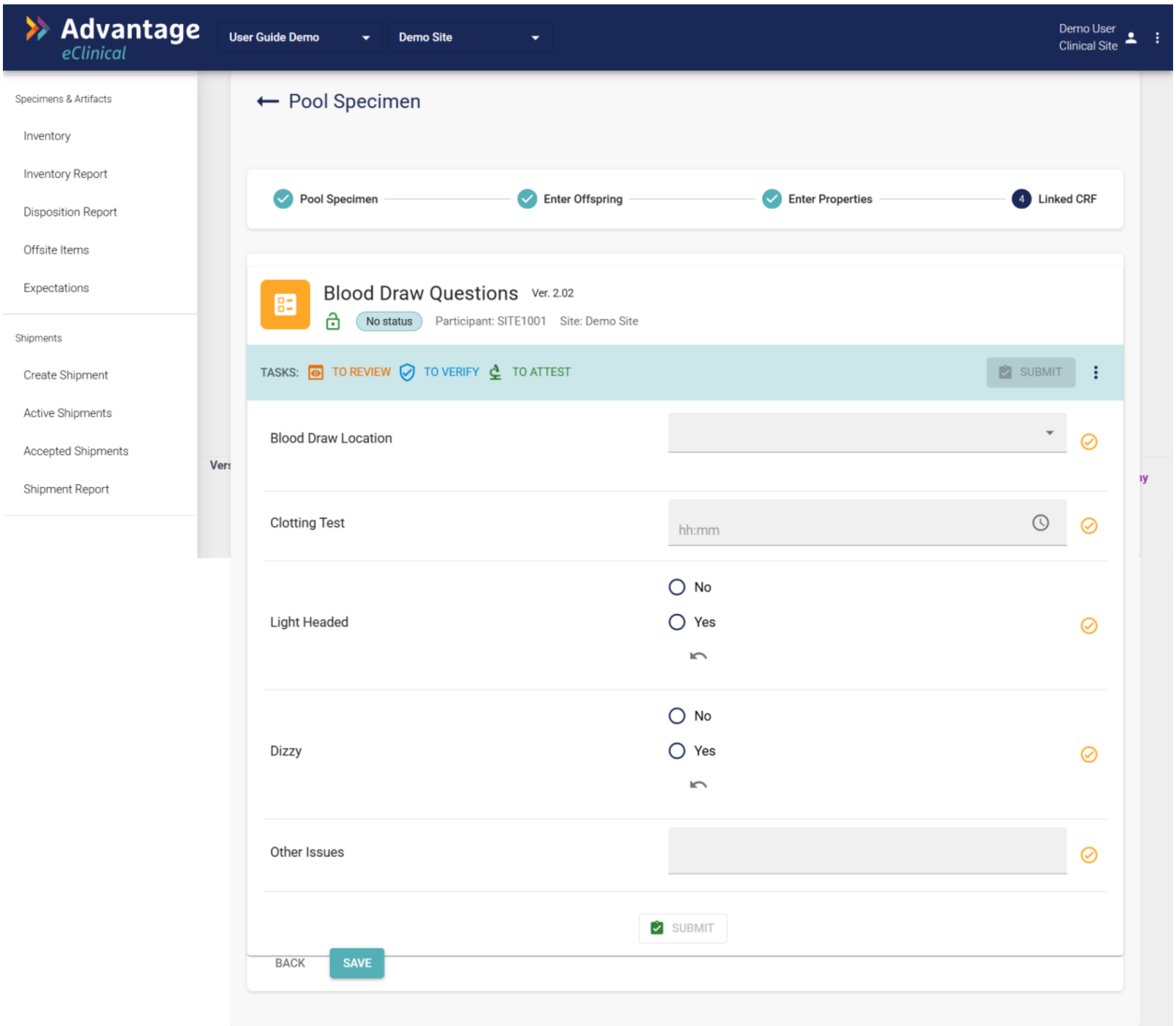
2. If entering multiple offspring specimens:
   - If **Apply same properties to all offspring** is selected, all offspring IDs appear at the top of the page, and the same properties apply to each.
   - If **Enter properties for each offspring individually** is selected, only one offspring ID appears at a time. You must enter attributes separately for each specimen.
3. If needed, enable **Carry over offspring properties** to auto-populate values for subsequent entries.
   - If selected, previously entered attributes are automatically copied to the next specimen but can be modified without affecting earlier entries.
   - This setting remains active unless manually disabled.
4. Select **NEXT** or **SAVE** to confirm offspring properties and proceed to the linked CRF form.

Completing linked CRFs

If additional attributes are required, GlobalTrace displays a linked CRF based on the specimen type. Depending on the study, different Linked CRFs may appear for different specimens in a batch.

Steps to complete a linked CRF:

1. Fill in the required details in the linked CRF form.



2. If modifying existing CRF data, select a ‘Change Reason’ when prompted.
3. Select **SUBMIT** to save and finalize the CRF entry.
4. To review changes, check the **Linked CRF Audit History**.

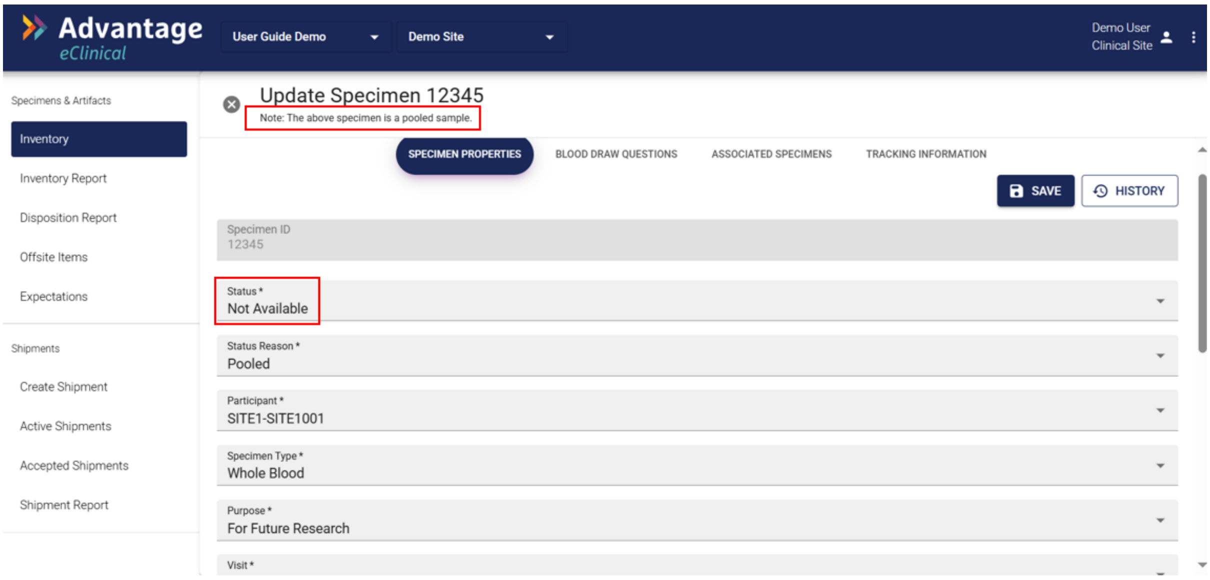
To know more, see Completing a linked CRF.

Finalize pooled specimen information

Complete creating the pooled specimens.

Steps to finalize pooled specimen information:

1. Select **SAVE** to finalize the pooled specimen creation. The system updates inventory records, marking parent specimens as ‘Not Available’ if fully consumed.

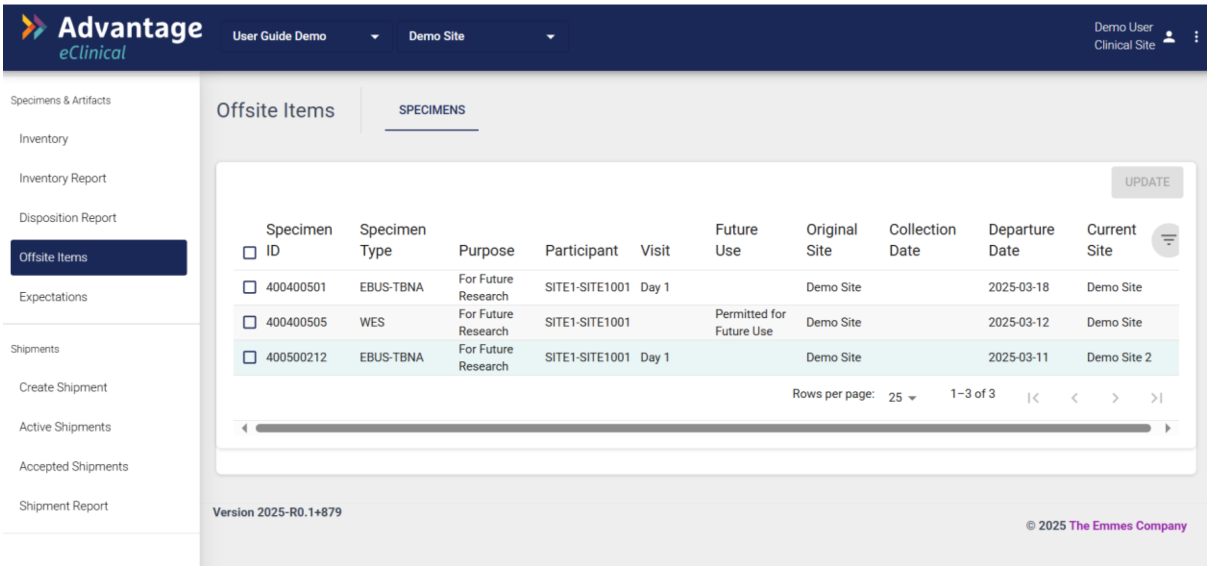

Advantage
eClinical
User Guide Demo
Demo Site
Demo User
Clinical Site
Specimens & Artifacts
Inventory
Inventory Report
Disposition Report
Offsite Items
Expectations
Shipments
Create Shipment
Active Shipments
Accepted Shipments
Shipment Report
Update Specimen 12345
Note: The above specimen is a pooled sample.
SPECIMEN PROPERTIES
BLOOD DRAW QUESTIONS
ASSOCIATED SPECIMENS
TRACKING INFORMATION
SAVE
HISTORY
Specimen ID
12345
Status *
Not Available
Status Reason *
Pooled
Participant *
SITE1-SITE1001
Specimen Type *
Whole Blood
Purpose *
For Future Research
Visit *

Managing Offsite Items

The **Offsite Items** page provides a centralized view of **Specimens** and **Artifacts** (if configured) that have been transferred to an offsite location. You can navigate between **Specimens** and **Artifacts** using the tabs at the top of the page to monitor and manage offsite inventory efficiently.

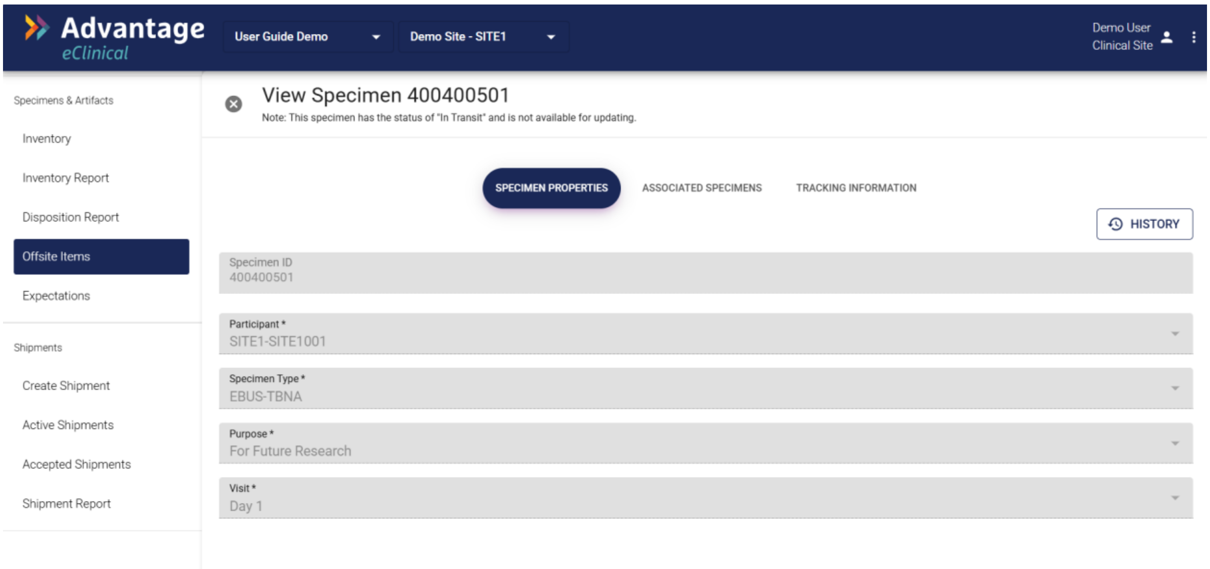
Viewing offsite specimens

Offsite specimens are those that have been shipped to and received by another site. The **Offsite Specimens** page allows you to track, view, and update specimen details as needed. Updates should be infrequent since specimens undergo a thorough review before shipment.



Steps to view an offsite specimen:

1. Go to the **Offsite Items** page. The 'SPECIMENS' section shows the specimens that were previously at your site but have since been shipped offsite.
2. Select a specimen to view its details. By default, the **SPECIMEN PROPERTIES** tab is selected when viewing an offsite specimen.



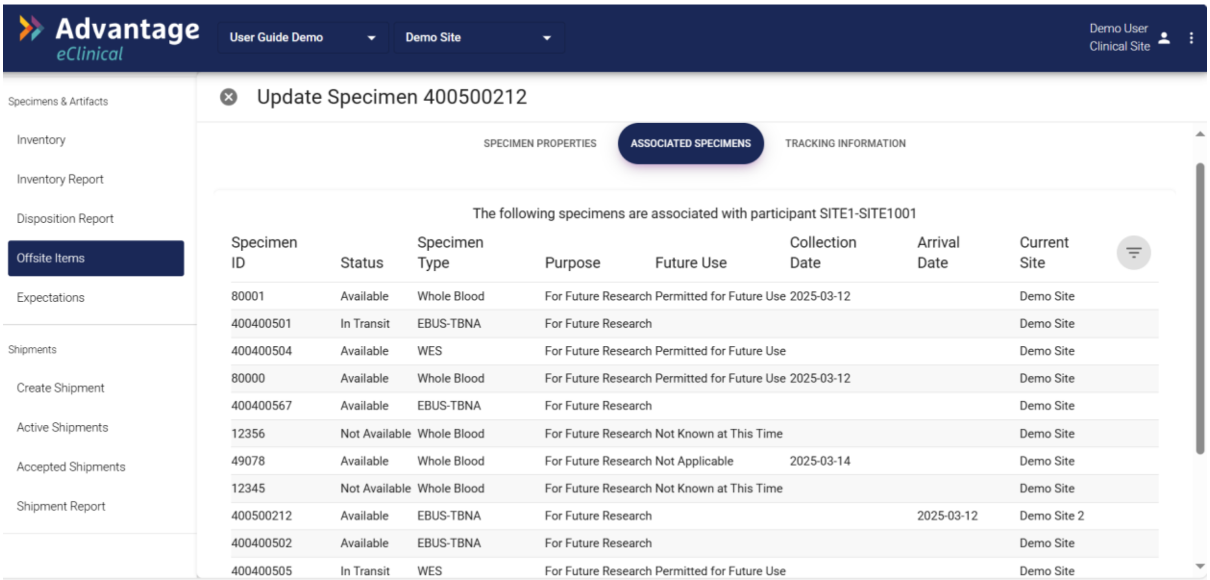
3. Select the **ASSOCIATED SPECIMENS**, **TRACKING INFORMATION**, and linked CRF (if available) tabs for additional details.

Viewing associated specimens

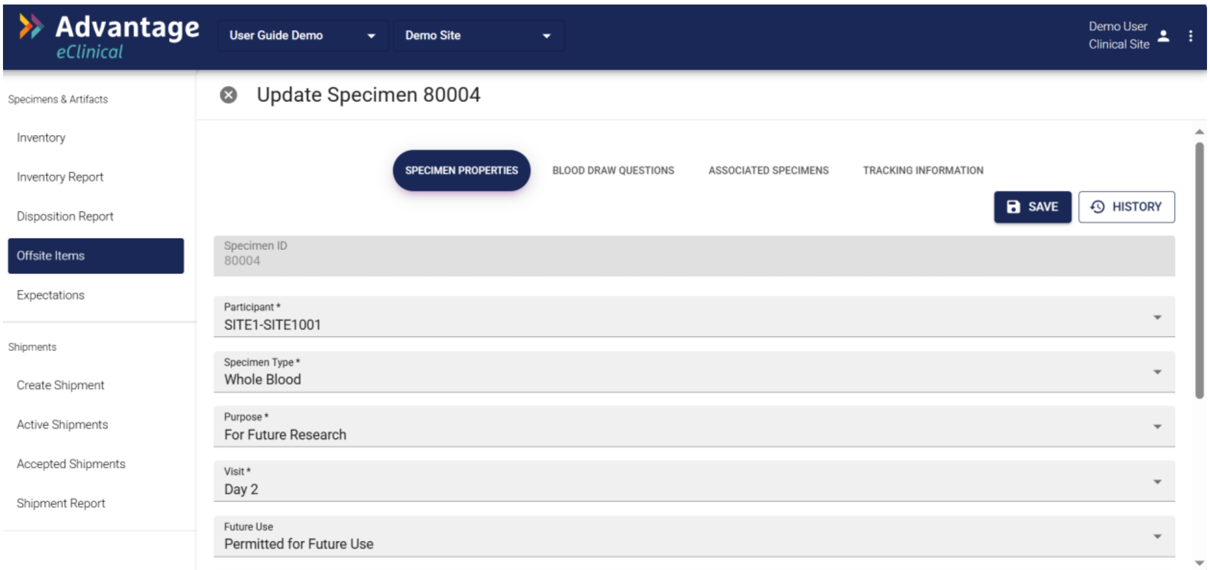
You can view other specimens associated with the same participant.

Steps to view associated specimens:

1. Select the **ASSOCIATED SPECIMENS** tab from the 'View/Update Specimen' window. The list displays all specimens linked to the same participant.



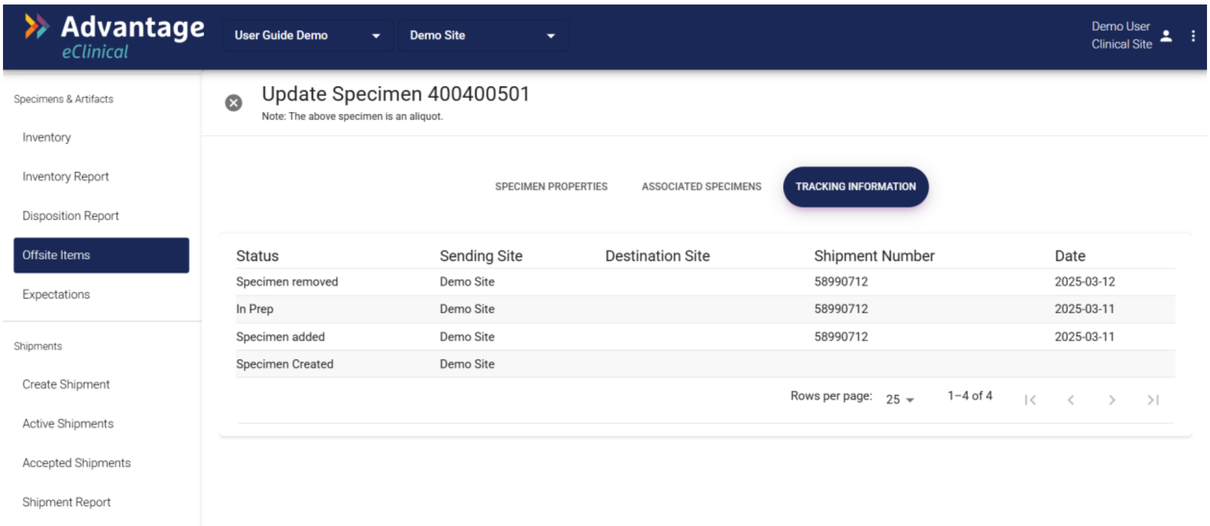
2. Select a specimen in the list to update the 'View/Update' window to see the specimen details.



Tracking offsite specimens

Steps to view tracking information:

1. Select the **TRACKING INFORMATION** tab from the View/Update Specimen window. The table shows all shipment-related details for the selected specimen.



Linked CRFs for offsite specimens

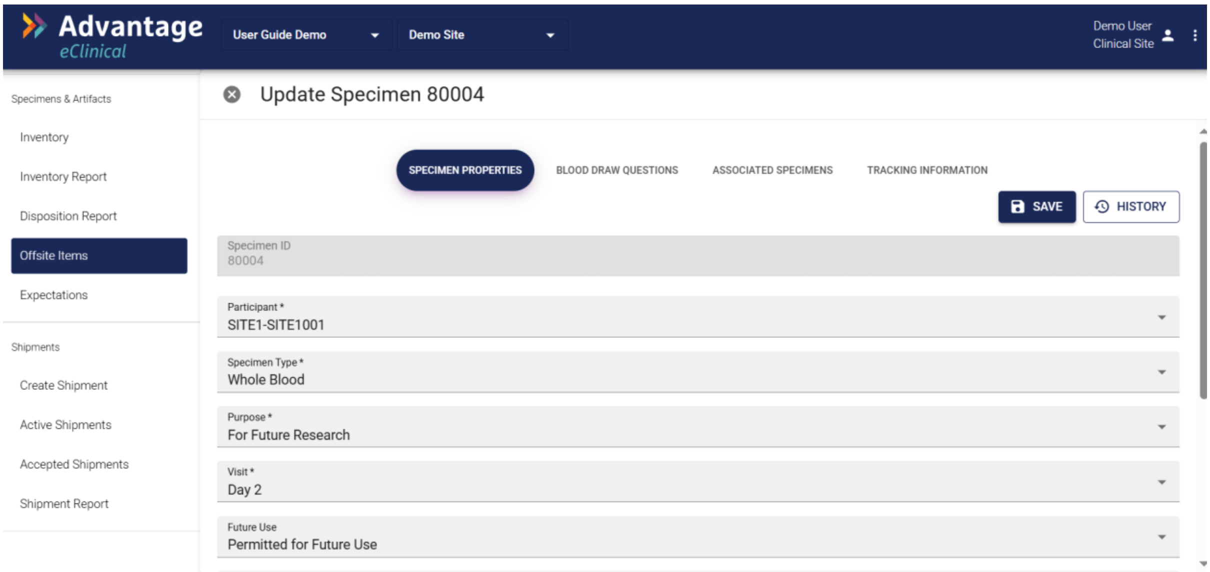
If a specimen has an associated linked CRF, it appears as a separate tab when viewing the specimen. For details, see Completing a Linked CRF.

Updating offsite specimens

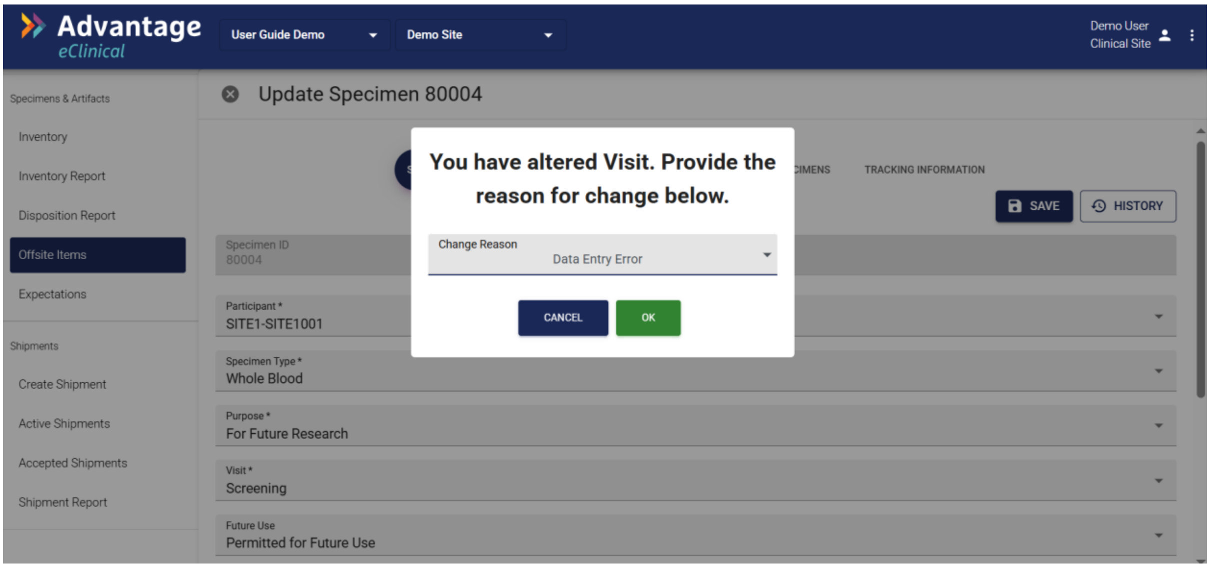
You can modify fields on the **Specimen Properties** page or within **Linked CRFs**, if you have the 'Update off-site' permission. You need to provide a **Change Reason** for all modifications.

Steps to update an offsite specimen:

1. Go to the **SPECIMEN PROPERTIES** tab or linked CRF and edit the necessary fields.

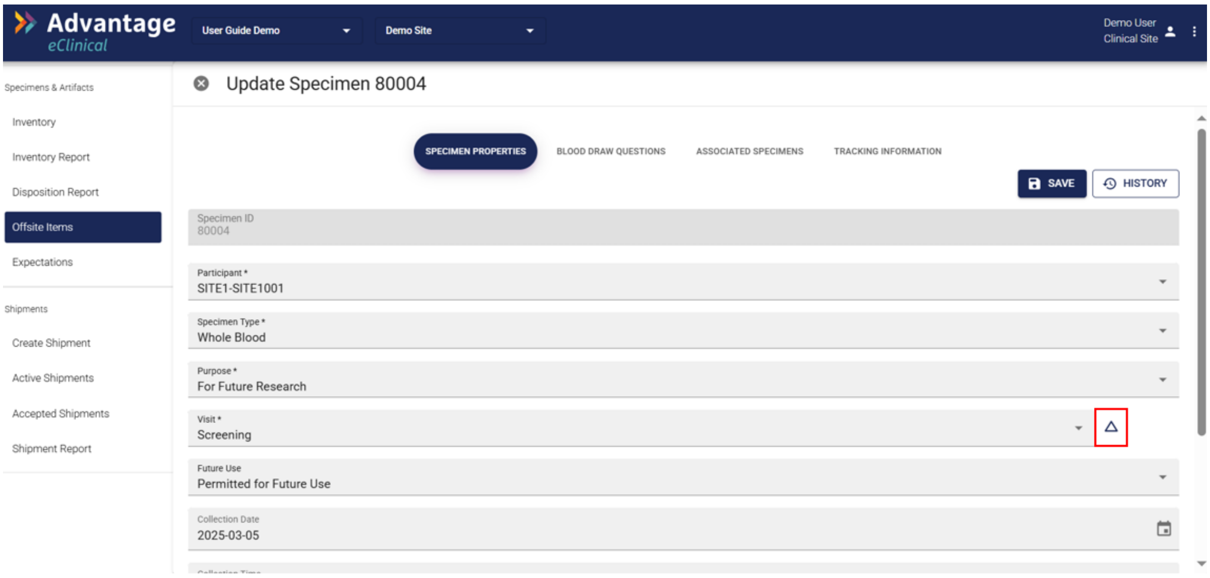


2. The **Change Reason** dialog appears. Select a reason and then select **OK**.



3. Updated fields are marked with a **triangle**. Clicking the **triangle** shows the change reason.

NOTE: When you update an offsite specimen, an automatic email alert is sent to the defined contact list at the specimen's site, detailing the update, if configured

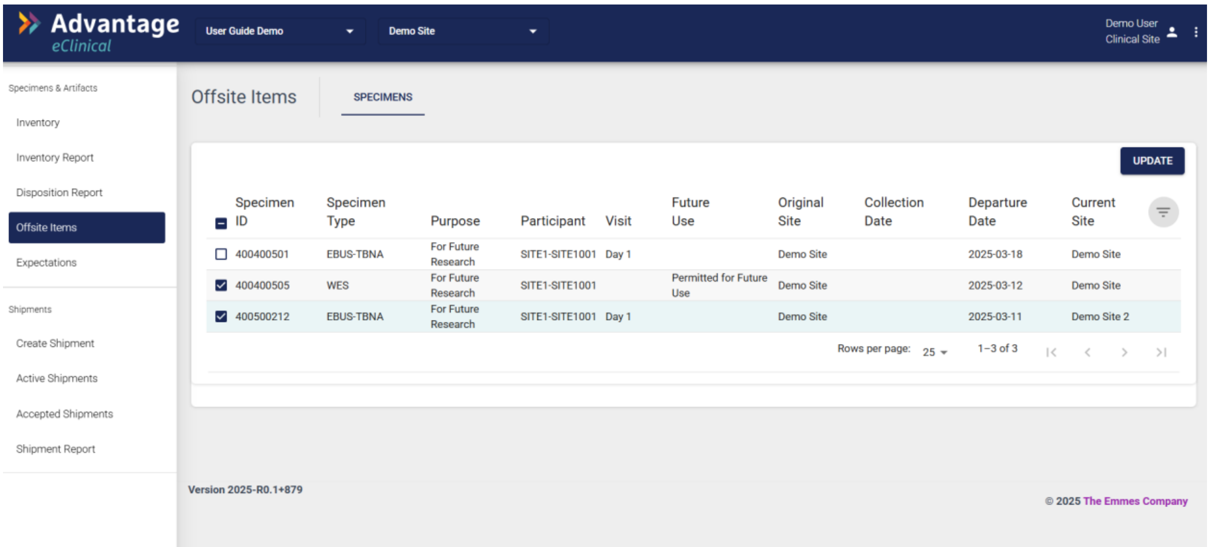


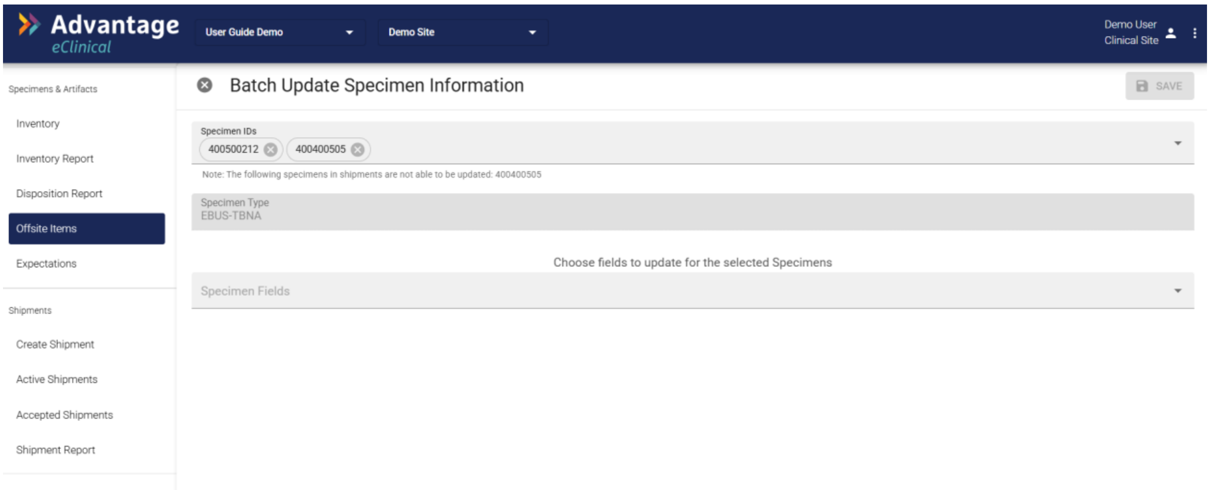
Batch updating offsite specimens

You can update multiple specimens simultaneously. You need to provide a **Change Reason** for all modifications.

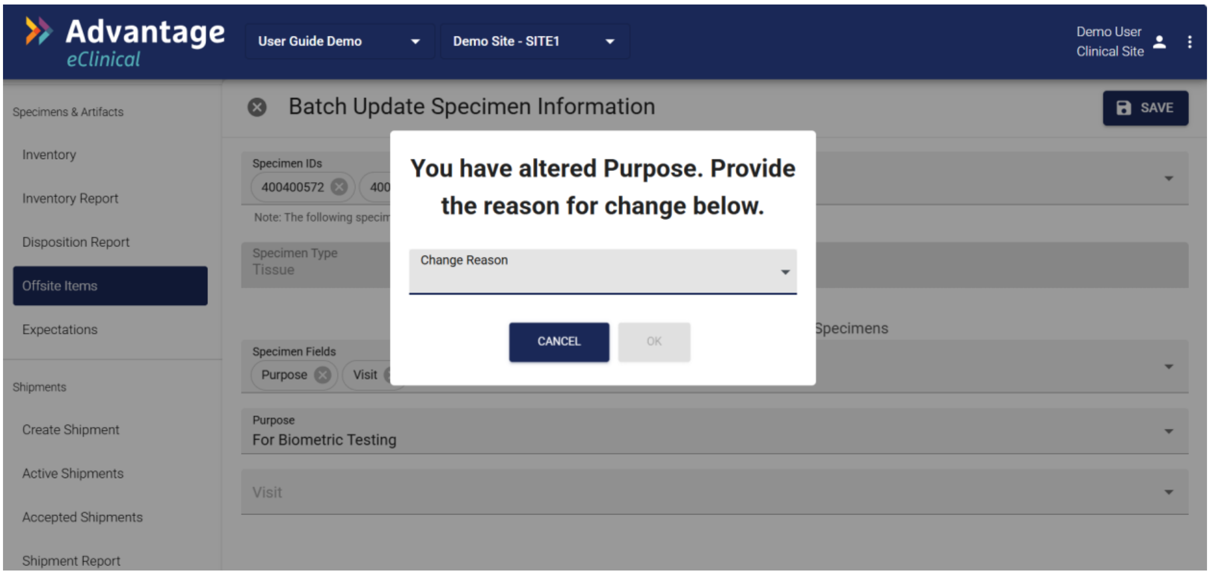
Steps to batch update specimens:

1. Select the specimens to update and then select **UPDATE**. The **Specimen ID** field populates with selected specimens.

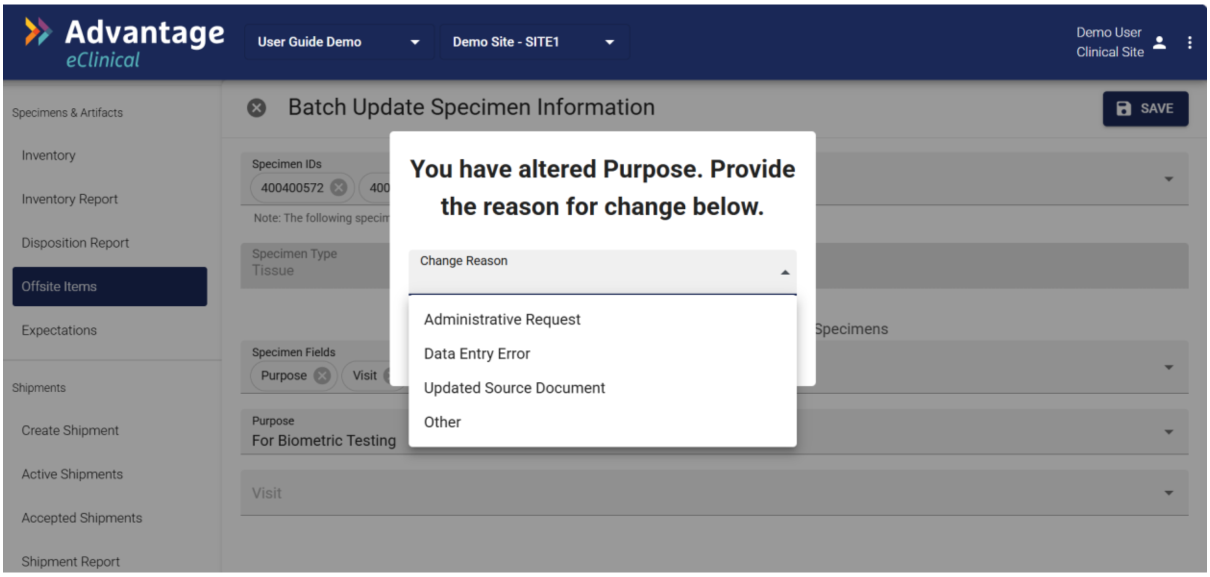




2. The **Specimen Type** field displays the type if all specimens are the same; otherwise, it shows 'Multiple'. If multiple types are selected, only fields common to all selected specimen types will be available for batch updates.
3. Selecting the specimen fields causes them to appear on the **Batch Update Specimen Information** page.
4. Edit the necessary fields. The **Change Reason** dialog appears.

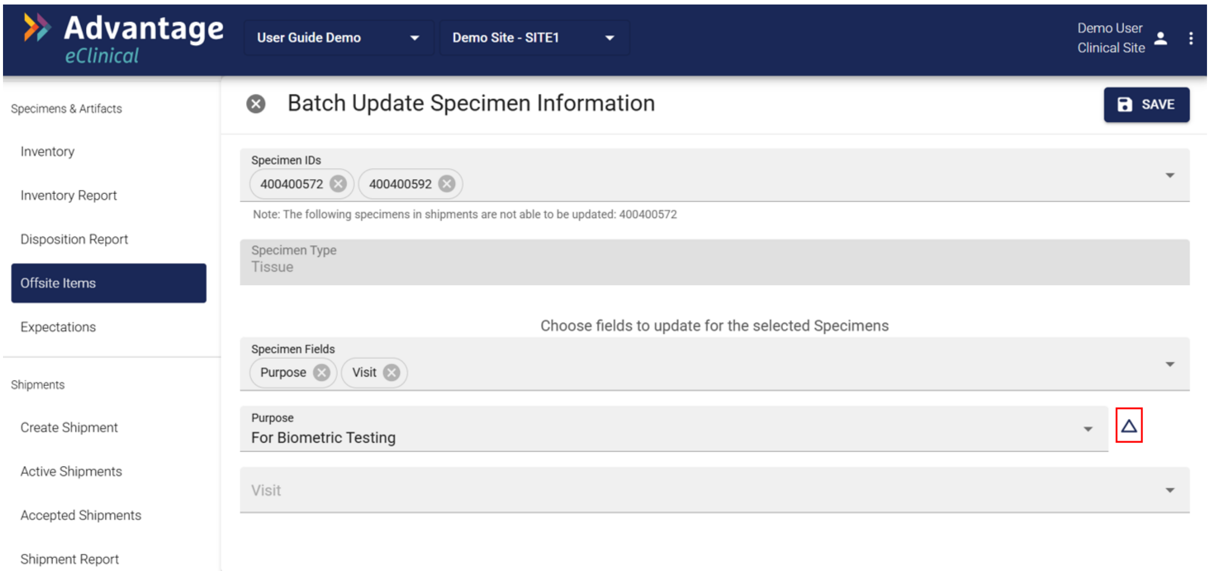


5. Select a reason and then select **OK**.



6. Updated fields are marked with a **triangle**. Clicking the **triangle** shows the change reason.

NOTE: When you batch update an offsite specimen, an automatic email alert is sent to the defined contact list at the specimen's site, detailing the update, if configured



Viewing offsite artifacts

You can view offsite artifacts (if configured) previously located at the selected site but now shipped offsite.

Steps to view offsite artifacts:

1. Go to the **Offsite Items** page and select **ARTIFACTS**.
2. View details of offsite artifacts.

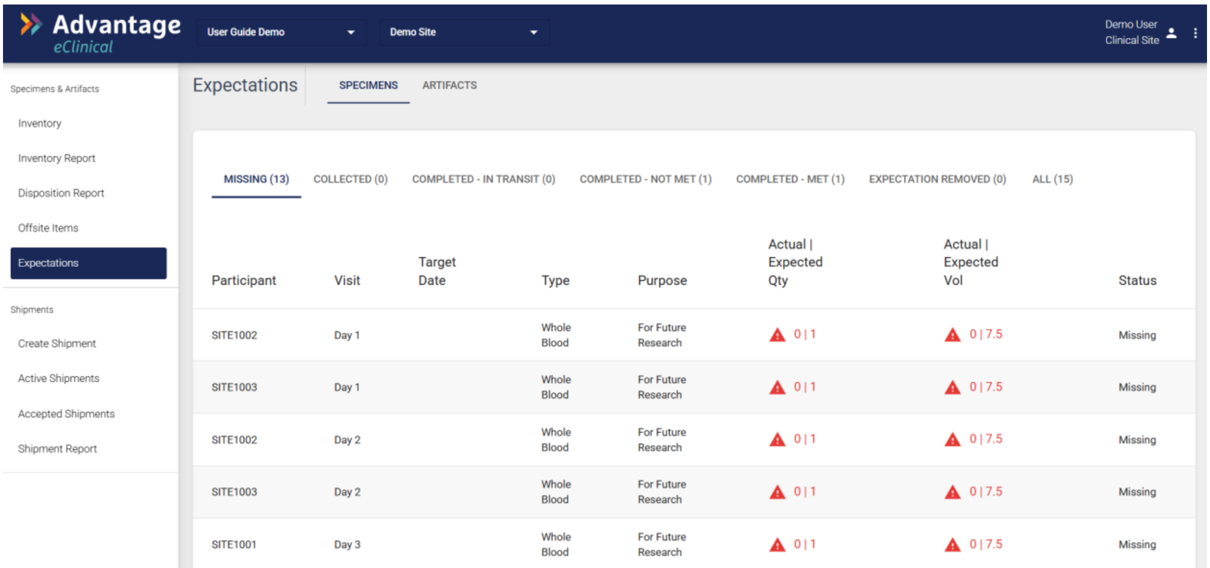
Managing Specimen Expectations

You can view all expected specimens or artifacts and their status in GlobalTrace. This includes both self-collected and site-collected specimens or artifact expectations. The system updates expectation statuses dynamically based on user actions in ePRO.

Viewing specimen expectations

You can access specimen expectations in GlobalTrace under the **Expectations** page. The **Specimens** tab displays all expected specimens along with their status. Specimen statuses include:

- Missing: The specimen is expected but has not been collected.
- Collected: The collection date is recorded in either ePRO or GlobalTrace.
- Completed- In Transit: The drop-off or shipment date has been recorded in ePRO.
- Completed- Not Met: The specimen was collected but did not meet the expected quantity or volume.
- Completed- Met: The collected specimen matched the expected quantity and volume.
- Expectation Removed: The expectation was removed due to an unexpected rule.

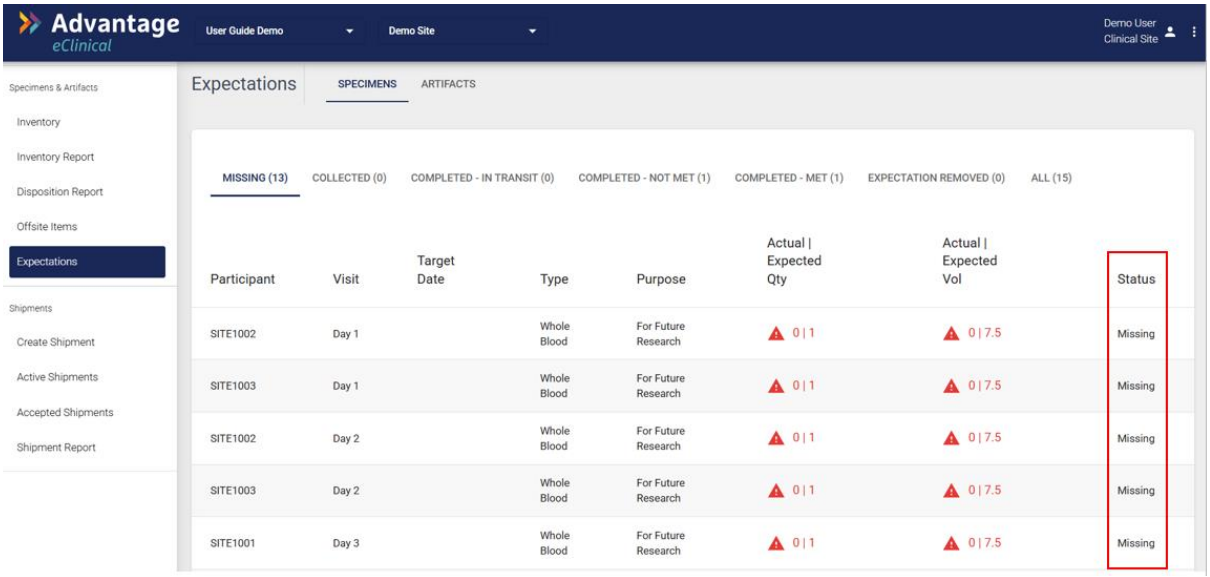


Understanding status updates

GlobalTrace updates expectation statuses automatically based on ePRO actions. Each status reflects the latest activity on a specimen, providing visibility into its collection and shipment process.

- When a specimen task is created in ePRO, it appears as ‘Missing’ in GlobalTrace.
- If the task is started but not completed, the status remains ‘Missing’.
- If the collection date is entered, the status updates to ‘Collected’.
- When the drop-off or shipment date is recorded, the status changes to ‘Completed- In Transit’.

- If the specimen does not meet the expected quantity or volume, the system assigns ‘Completed – Not Met’.
- If all requirements are met, the status updates to ‘Completed – Met’.
- If an expectation is removed, it appears as ‘Expectation Removed’ in GlobalTrace.



Updating a specimen’s expectation status

You can manually update specimen expectation statuses by recording collection and shipment details in ePRO. This ensures that GlobalTrace reflects real-time specimen tracking.

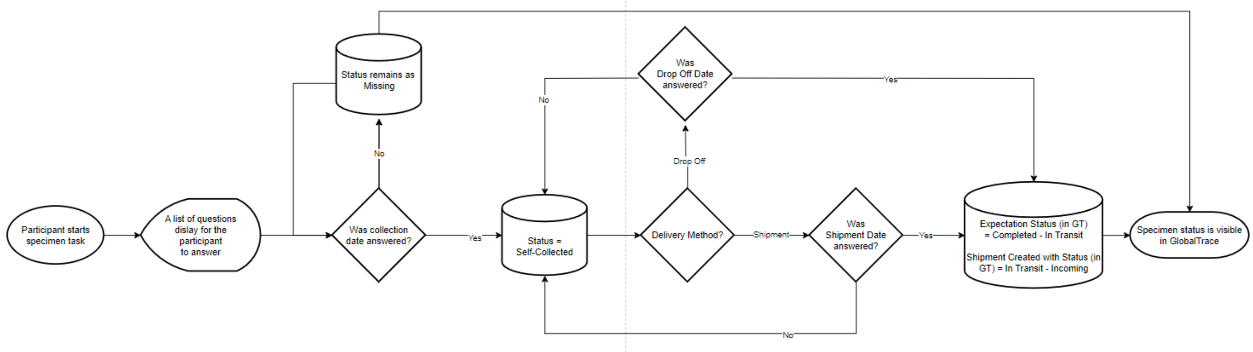
Steps to update the expectation status of a specimen:

1. Locate the specimen task under the **Expectations** page in GlobalTrace.
2. If the specimen is ‘Missing’, initiate the collection process in ePRO.
3. Enter the collection date in ePRO to update the status to ‘Collected’.
4. If the specimen is being shipped, enter the drop-off date or shipment details in ePRO.
5. After the shipment details are recorded, the status updates to ‘Completed- In Transit’ in GlobalTrace.
6. If the collected specimen does not meet the required quantity or volume, the system updates the status to ‘Completed-Not Met’.
7. If the specimen meets the expected criteria, the status updates to ‘Completed – Met’.

Workflow for self-collected specimens

The system tracks self-collected specimens based on participant actions in **ePRO**. The status updates dynamically as participants collect, package, and ship their specimens.

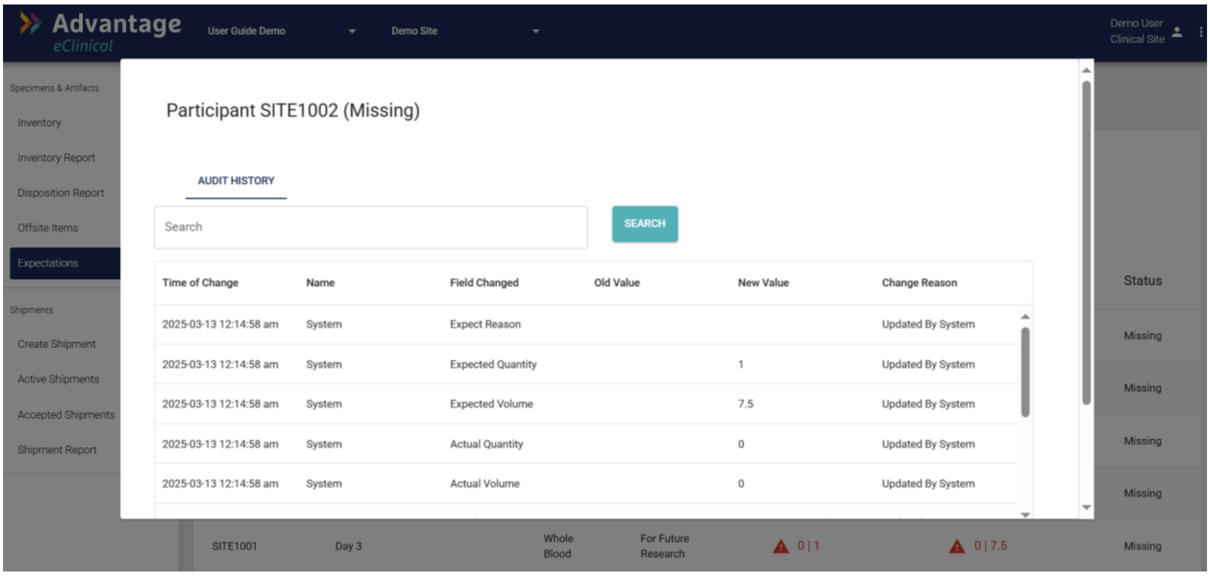
1. The participant starts a specimen task in ePRO.
2. A list of questions appears for the participant to answer.
3. If no collection date is entered, the status remains ‘Missing’.
4. When the collection date is provided, the status updates to ‘Self-Collected’.
5. If the drop-off date is provided, the status updates to ‘Completed- In Transit’.
6. If a shipment is created, the status updates to ‘In Transit – Incoming’.
7. Once the shipment is received and verified, the system updates the status to ‘Completed – Met’ or ‘Completed- Not Met’ depending on the collected quantity and volume.



Viewing specimen and artifact expectation audit history

You can view the audit history of specimen expectations by selecting a specimen in GlobalTrace. The audit history includes:

- Timestamps for each status change.
- User actions that triggered the update.
- ePRO data entries that affected the specimen status.



Troubleshooting status issues

You may encounter status discrepancies due to missing or incorrect data. Verifying collection dates, shipment details, and expectation rules can help resolve these issues.

- If a specimen remains Missing, confirm whether the collection date was entered in ePRO.
- If a specimen is marked Completed- Not Met, verify that the recorded quantity and volume meet expectations.
- If a shipment status does not update, check if the drop-off date or shipment details were entered in ePRO.
- For removed expectations, review the system rules that triggered the removal.

Creating Shipments

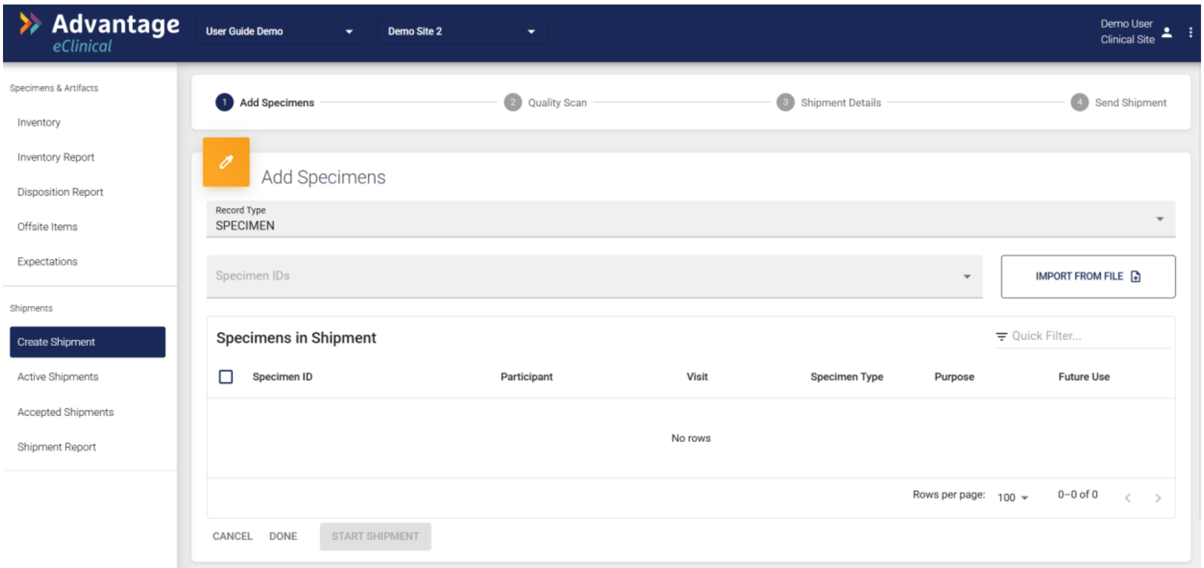
You can create and manage specimen shipments in GlobalTrace. The shipment process includes adding specimens, performing a quality scan, entering shipment details, and sending the shipment. This ensures proper tracking and documentation throughout the shipping workflow.

Adding specimens to a shipment

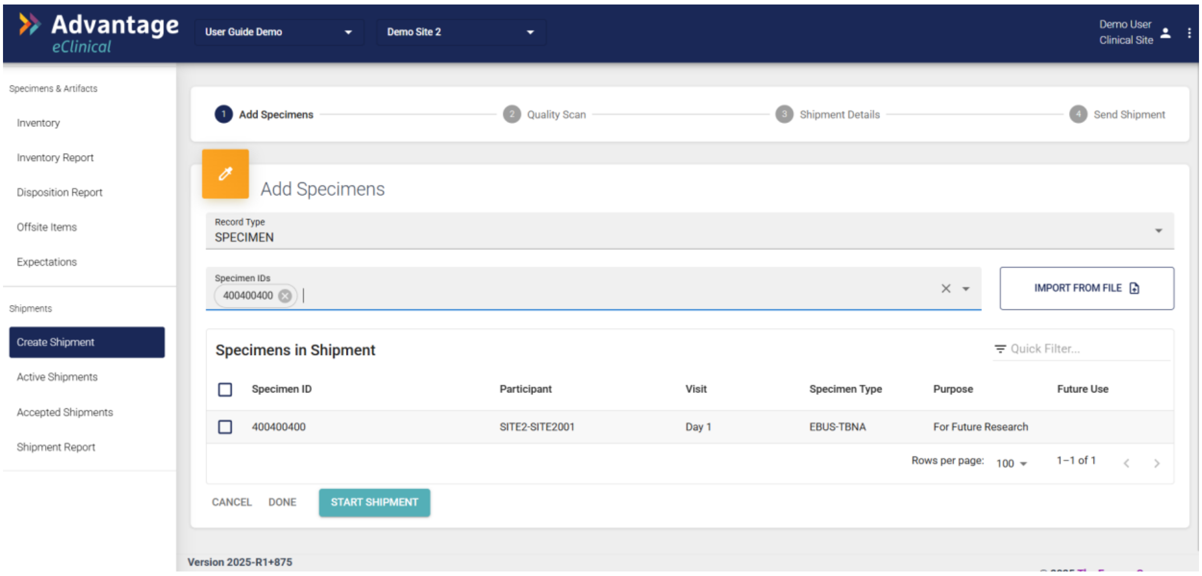
You must add specimens or artifacts to the shipment before proceeding to ensure that all items included are properly recorded in GlobalTrace.

Steps to add specimens to a shipment:

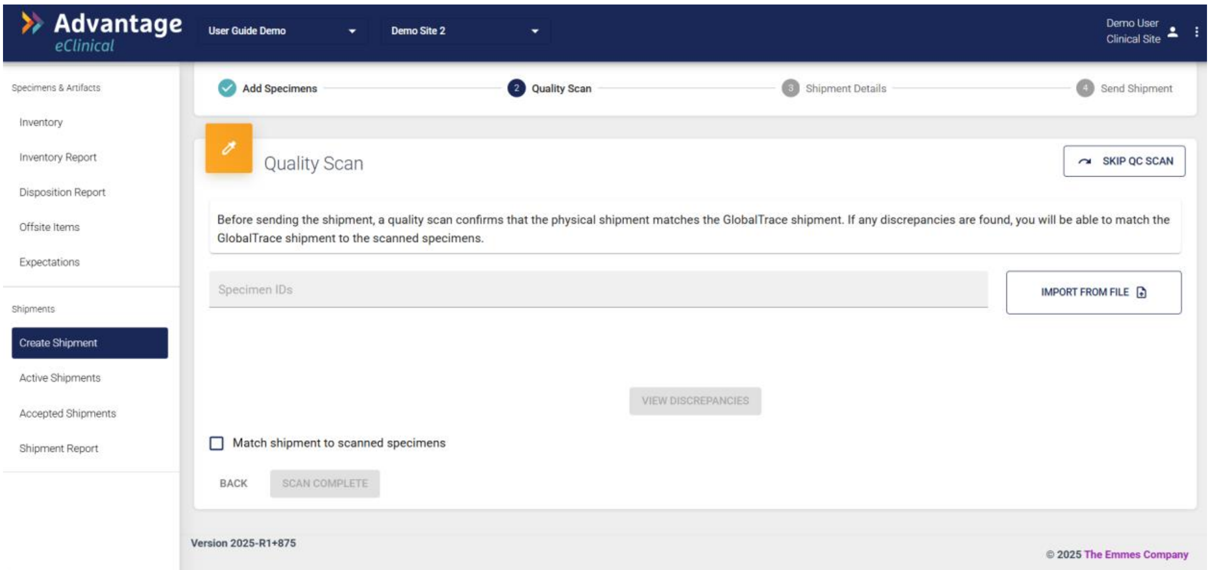
1. Select **Create Shipment** from the side navigation menu. The **Add Specimens** page appears.



2. On the **Add Specimens** page, choose the 'Record Type' (Specimen or Artifact).
3. Add specimens or artifacts using the drop-down menu or the **IMPORT FROM FILE** option. The drop-down lists all available specimens or artifacts at the current site.
   TIP: You can also scan barcodes to add specimens. Only valid specimens from the current site will be accepted into the shipment.
4. After at least one specimen is added, the **START SHIPMENT** button becomes available.



5. Select **START SHIPMENT.** The **Quality Scan** page appears.

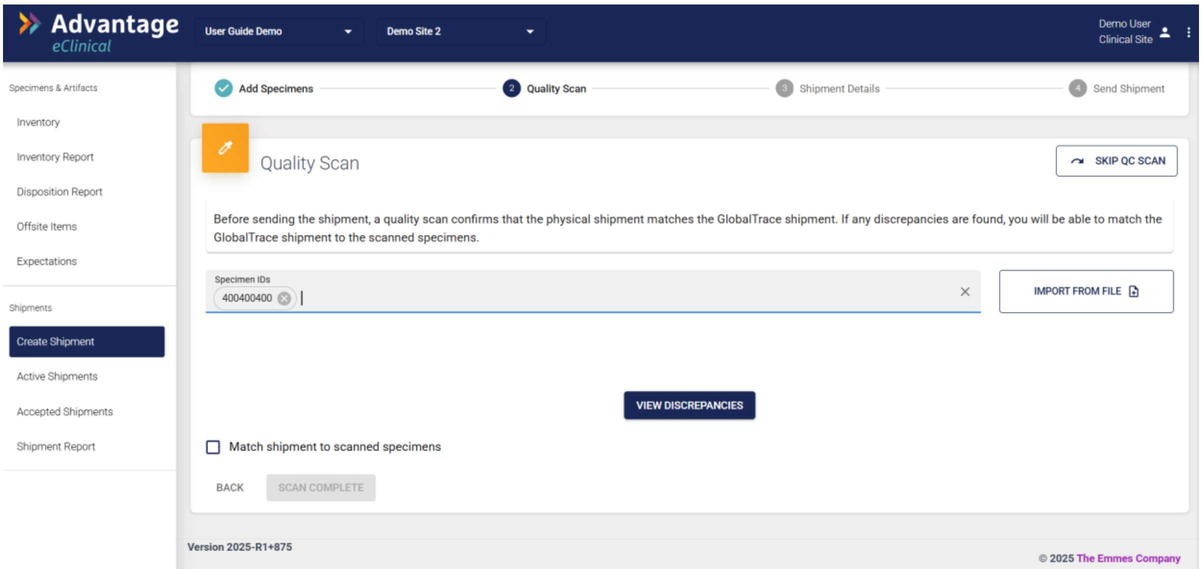


Performing a quality scan

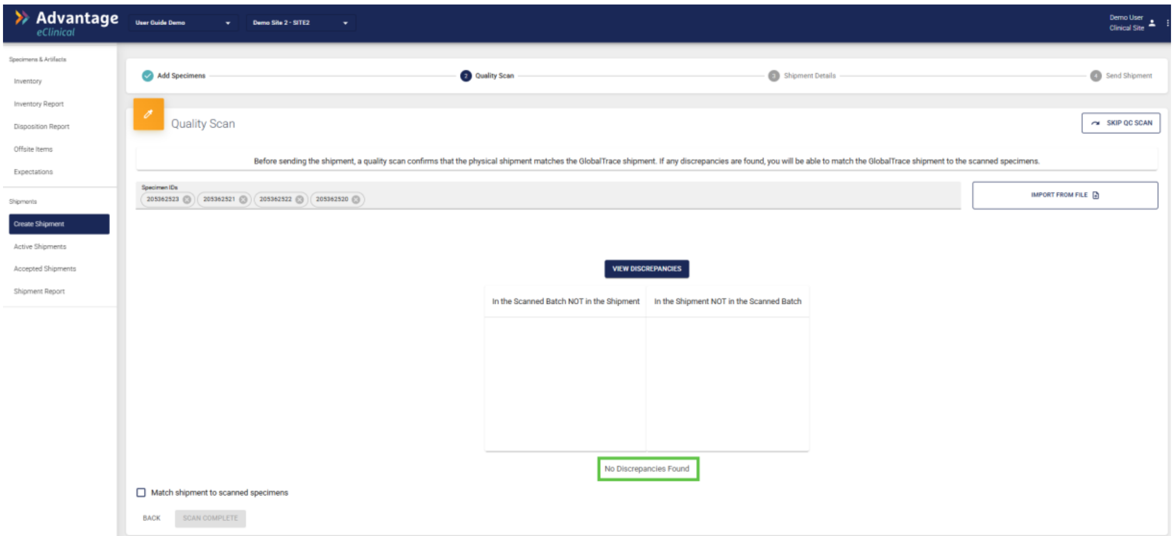
The quality scan verifies that the physical specimens match the electronic shipment records, helping you to identify and resolve discrepancies.

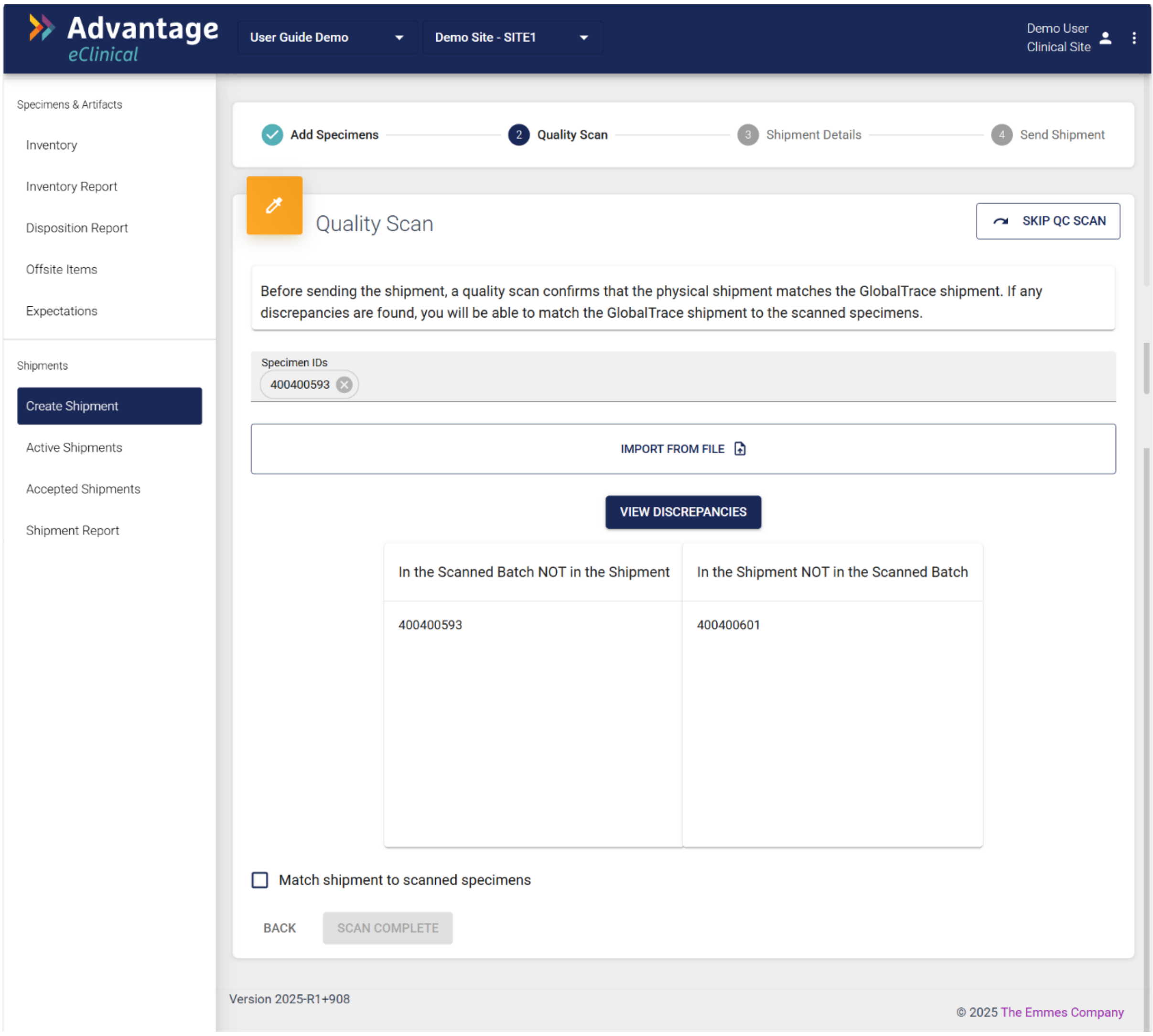
Steps to perform a quality scan:

1. Enter one or more offspring specimens by scanning or manually inputting specimen IDs. Alternatively, select **IMPORT FROM FILE** to upload an Excel file containing identifiers.

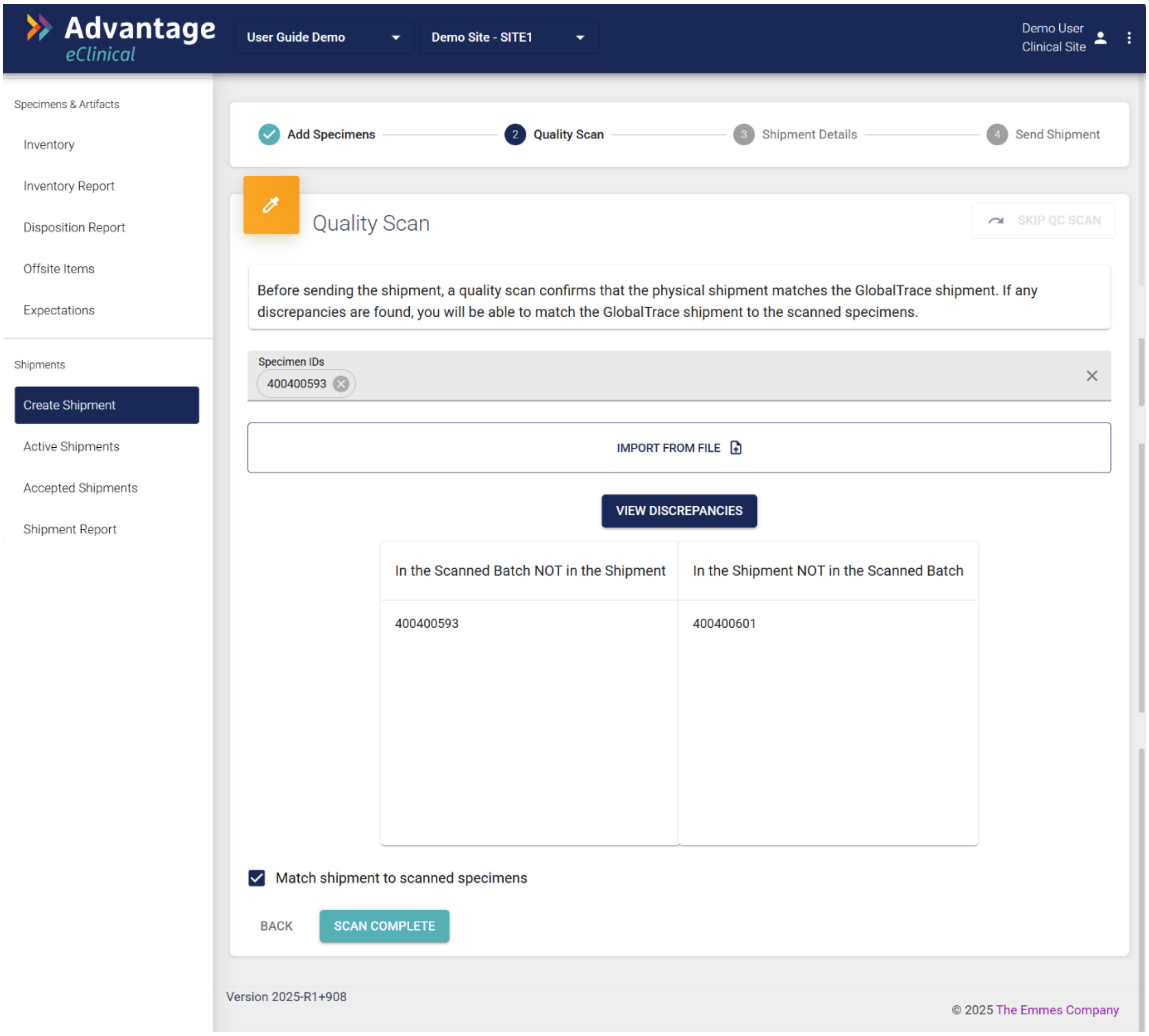


1. Select **VIEW DISCREPANCIES** to check for:
   - Specimens scanned but not in the electronic shipment.
   - Specimens in the electronic shipment but not scanned.
   - No Discrepancies Found

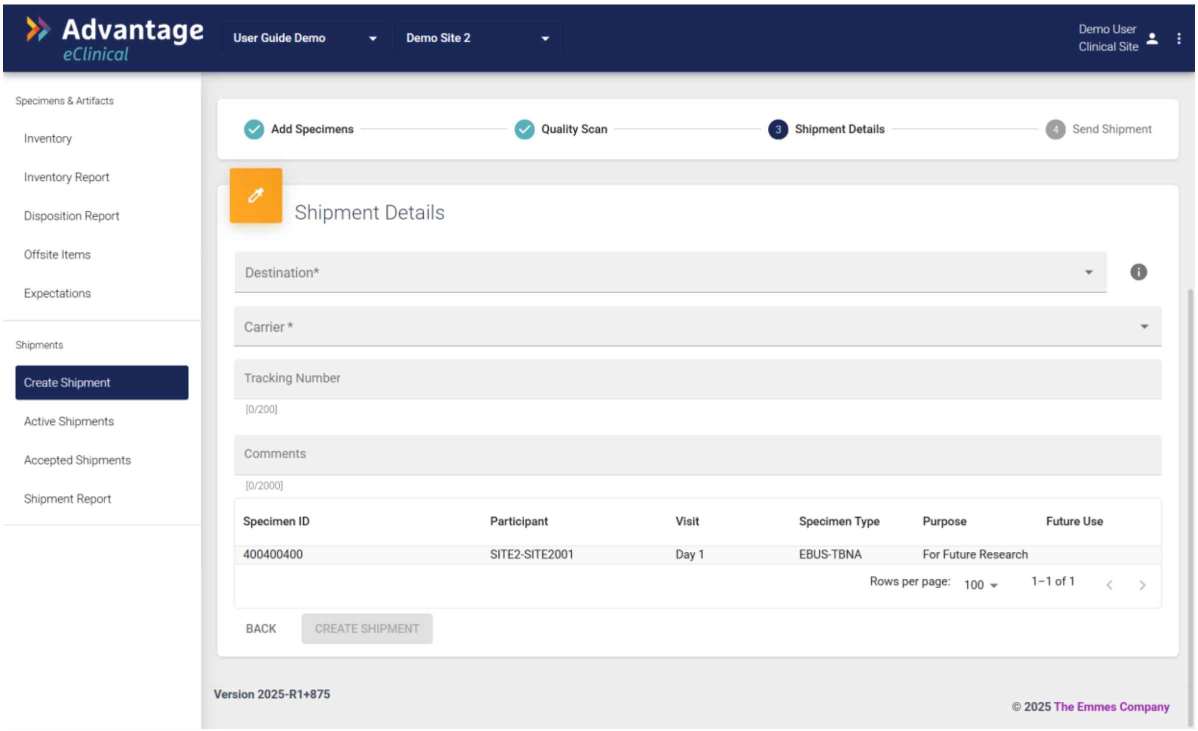




2. If discrepancies exist, determine the correction, add or remove the specimens as needed. The discrepancies listing updates as specimens are added or removed.
3. Or, select **Match shipment to scanned specimens** to override and continue.



4. Select **SCAN COMPLETE** to proceed. Optionally, select **SKIP QC SCAN** to bypass this step and continue. The **Shipment Details** page appears.

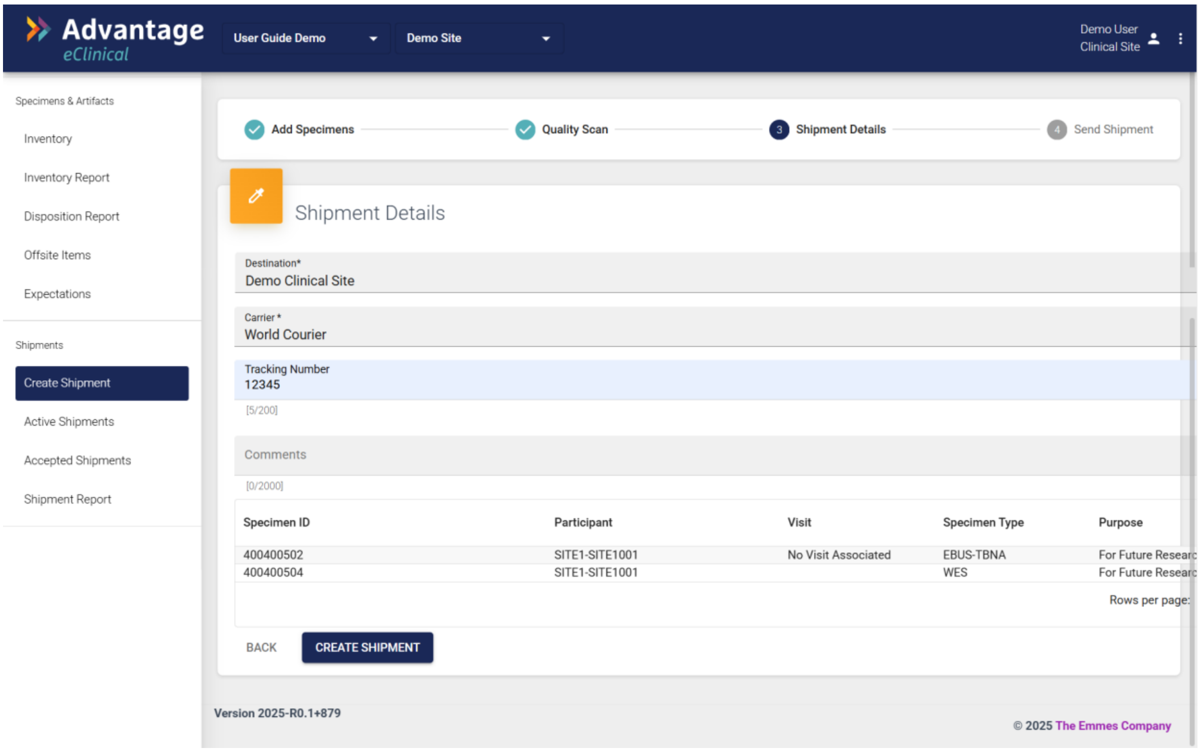


Entering shipment details

You must enter key shipment details, including the destination, carrier, to ensure proper routing and tracking of the shipment.

Steps to enter shipment details:

1. On the **Shipment Details** page, enter the following required fields:
   - Destination: Select from a dynamic list filtered by specimen type and purpose.
   - Carrier: Choose the shipping carrier.
   - Tracking Number (optional): If entered, GlobalTrace links to the carrier’s system for real-time tracking.
   - Comments (optional): Add relevant shipment notes.



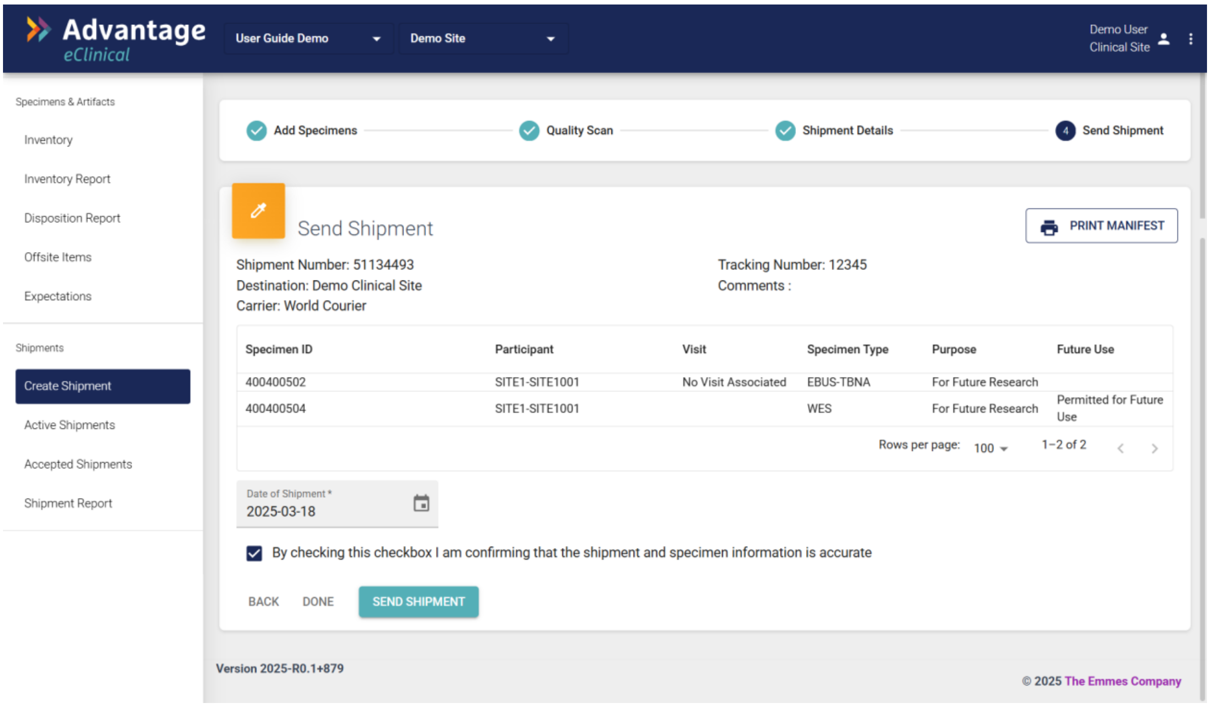
2. Review the list of specimens in the shipment and select **CREATE SHIPMENT**.

Sending the shipment

Before shipping, you must review the shipment details and confirm accuracy. The shipment is then finalized, and a manifest can be generated for documentation.

Steps to send a shipment:

1. Review the shipment details for accuracy.



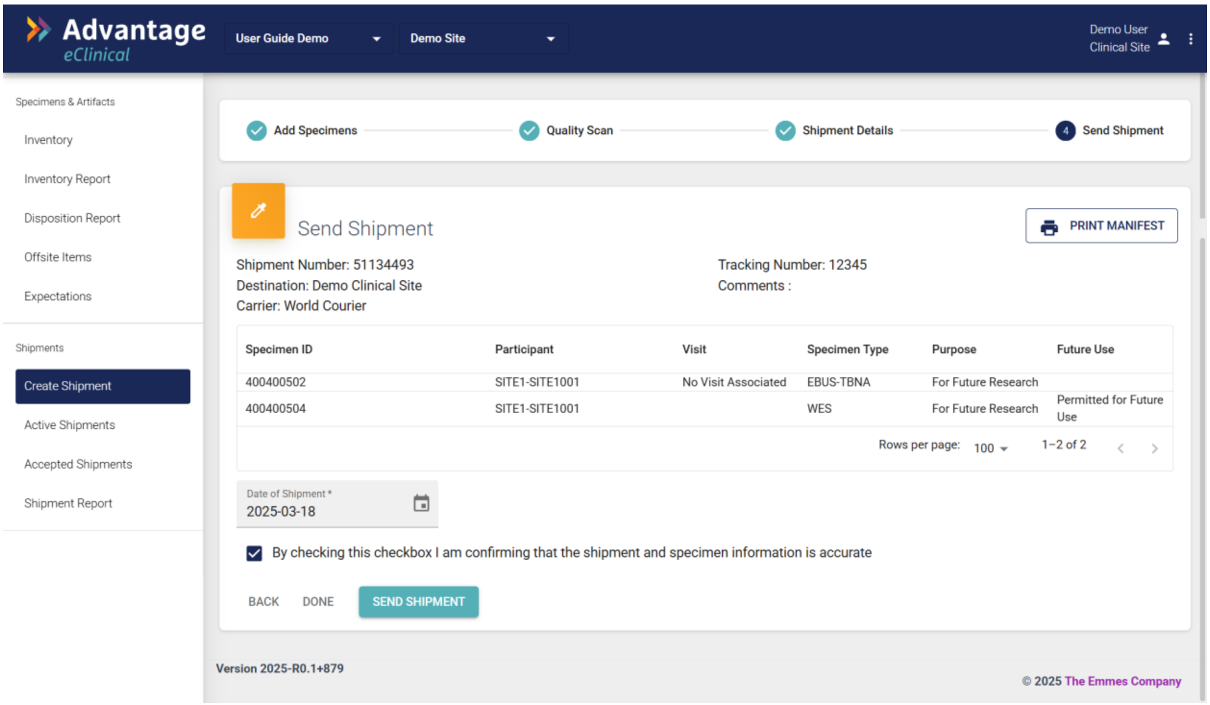
2. Check the **By checking this checkbox I am confirming that the shipment and specimen information is accurate** checkbox.
3. Select **PRINT MANIFEST** to generate the shipment manifest for documentation.
4. Select **SEND SHIPMENT** to finalize and send the shipment.

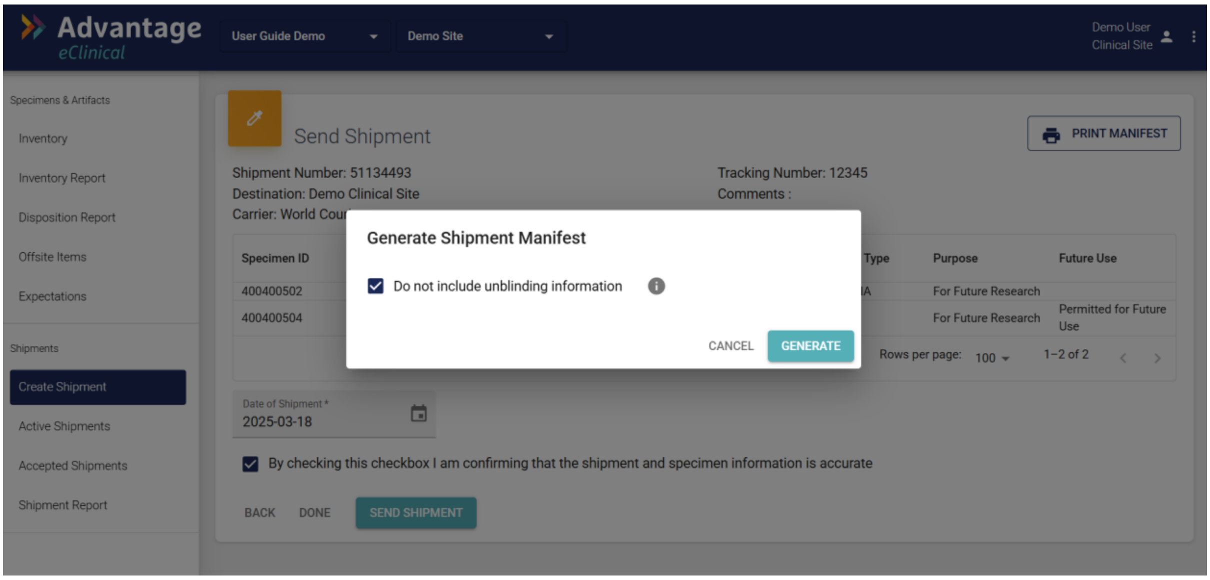
Generating the shipment manifest

You can generate a shipment manifest to document the shipment contents. The manifest can include optional unblinding information if needed.

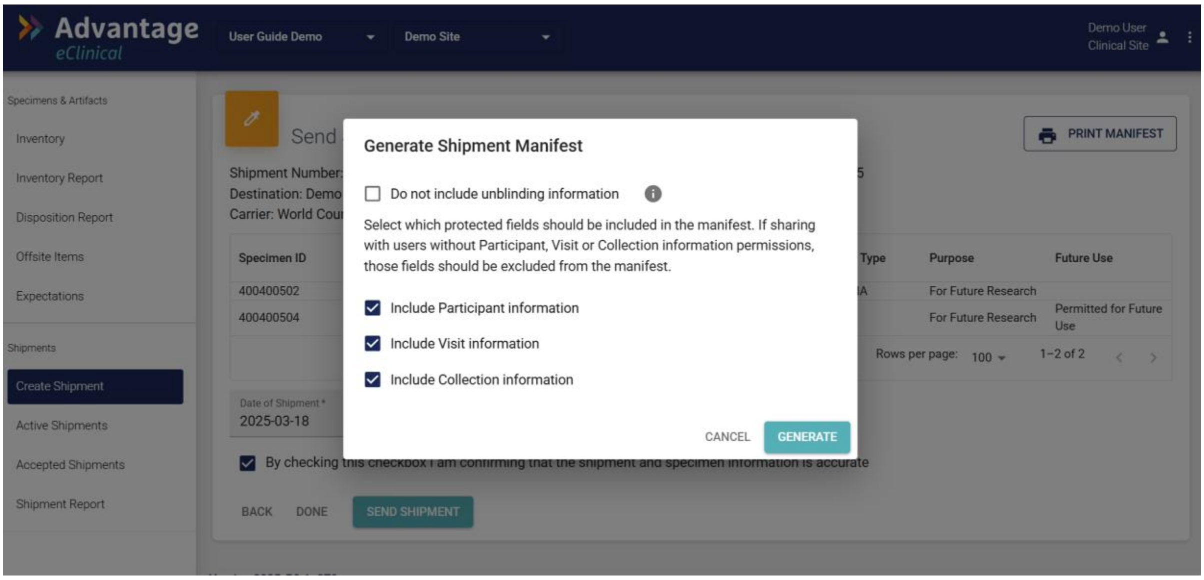
Steps to generate a shipment manifest:

1. Select **PRINT MANIFEST**. The **Generate Shipment Manifest** window appears.





2. By default, unblinding information is excluded. To include unblinding information:
   a. Uncheck **Do not include unblinding information**.
   b. Select any of the following fields to include:
      - Participant information (Participant ID)
      - Visit information (Visit number)
      - Collection information (Collection date and time)



3. Select **GENERATE**. The manifest downloads.

3/19/25, 10:47 AM Global Trace

Advantage eClinical GlobalTrace

Study: User Guide Demo

Shipment Number: 51134493	Date of Shipment: 2025-03-18
Date Created: 2025-03-18	Tracking Number: 12345
Carrier: World Courier	Comments:
From: Demo Site	Address: 100 Main St. Baltimore, MD 12345
To: Demo Clinical Site	Address: 123 Main St. Rockville, MD 20850

Specimen ID	Participant	Visit	Specimen Type	Purpose	Future Use	Collection Date	Volume
400400502	SITE1-SITE1001	No Visit Associated	EBUS-TBNA	For Future Research			
400400504	SITE1-SITE1001		WES	For Future Research	Permitted for Future Use		

Total: 2

Managing Active Shipments

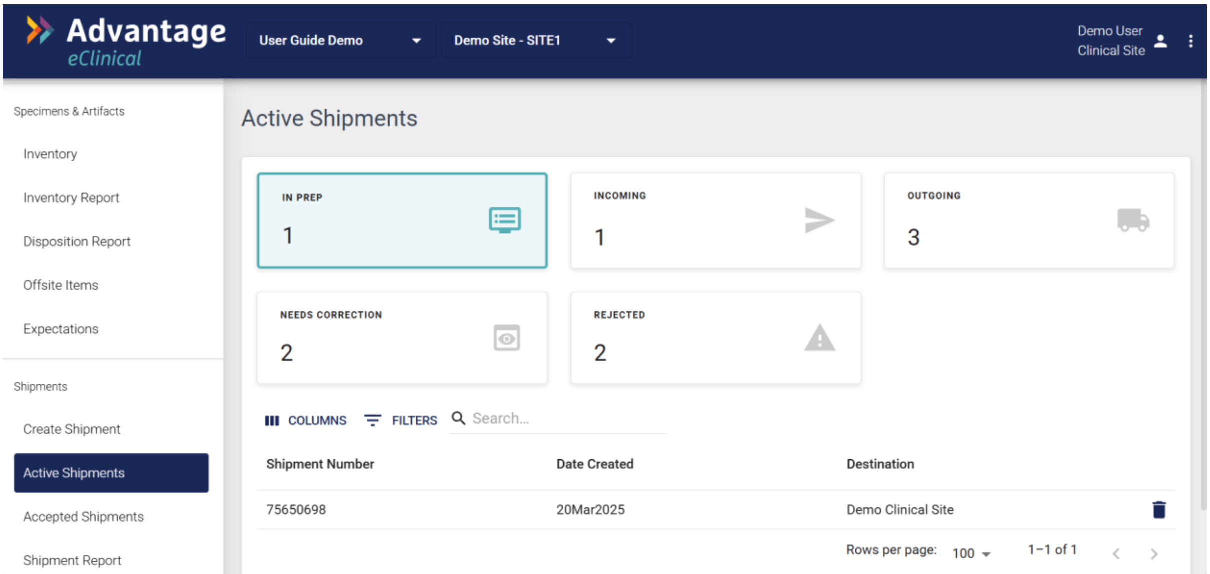
You can manage active shipments in GlobalTrace, including shipments in preparation, in transit, and rejected shipments requiring correction. The system tracks shipment statuses to help users ensure compliance, accuracy, and timely processing.

Viewing and updating in prep shipments

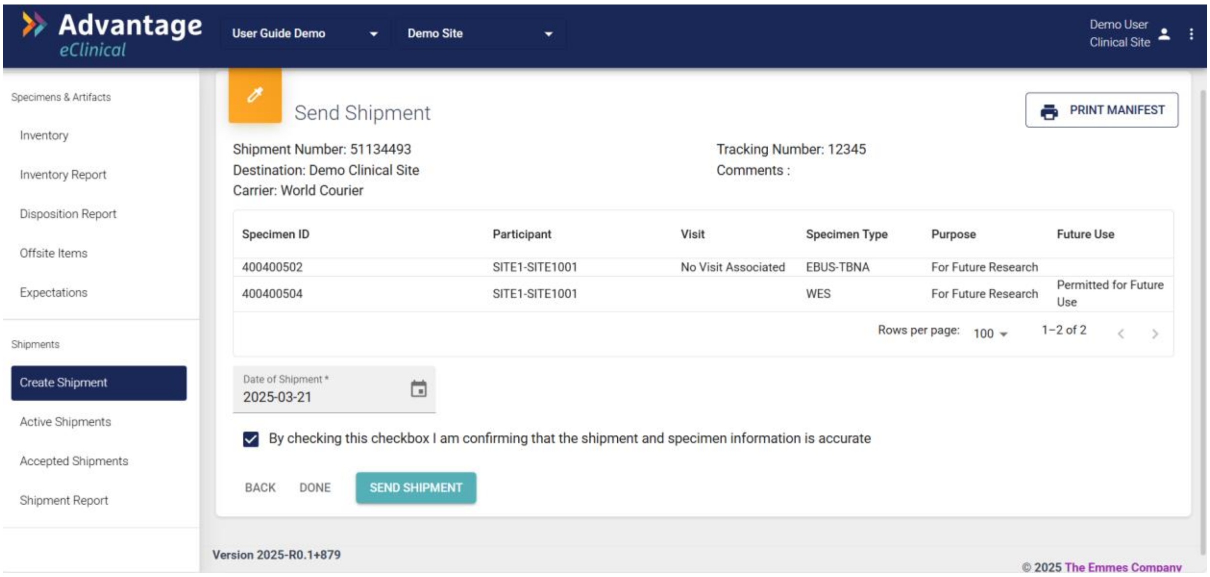
You can track and update shipments that have been created but not yet sent.

Steps to view and update in prep shipments:

1. Go to the **Active Shipments** page.
2. In the 'IN PREP' section, locate shipments that are still being prepared.
3. Select a shipment to continue the shipment process from where it was left off.



4. Make the necessary updates and select the **By checking this checkbox I am confirming that the shipment and specimen information is accurate** checkbox.
5. Select **SEND SHIPMENT**.



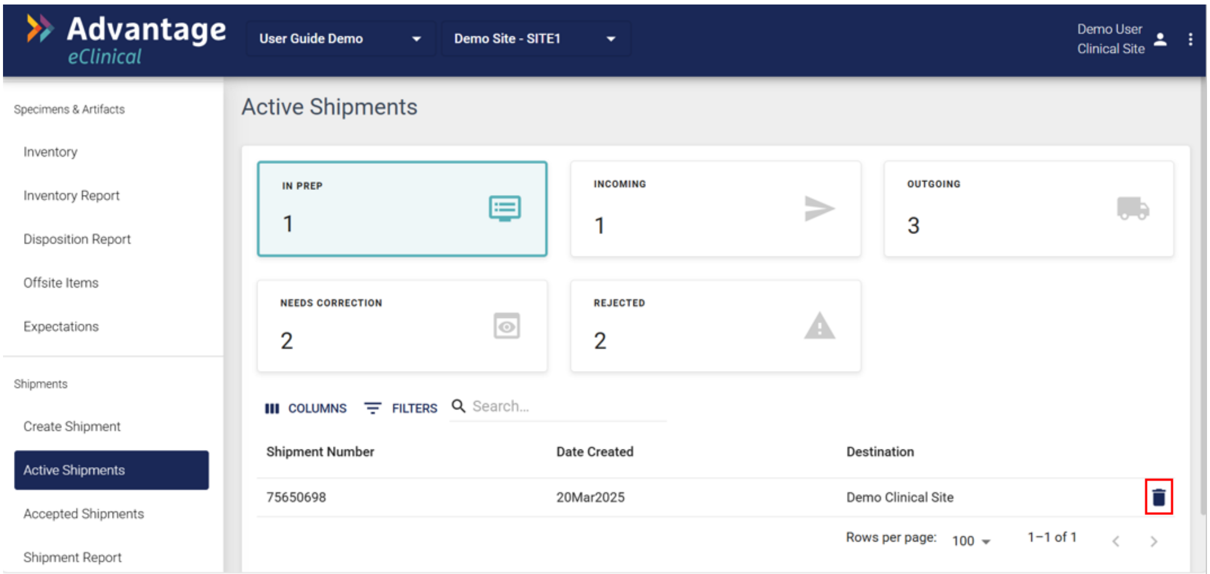
Deleting in prep shipments

You can remove shipments from ‘In Prep’ if you have the ‘Delete Shipments’ permission.

Steps to delete in prep shipments:

1. Locate the shipment under ‘In Prep’ and click the **trash can** icon to delete the shipment.

   NOTE: Deleting a shipment returns all specimens or artifacts to ‘Available’ status in inventory.



Viewing in transit shipments

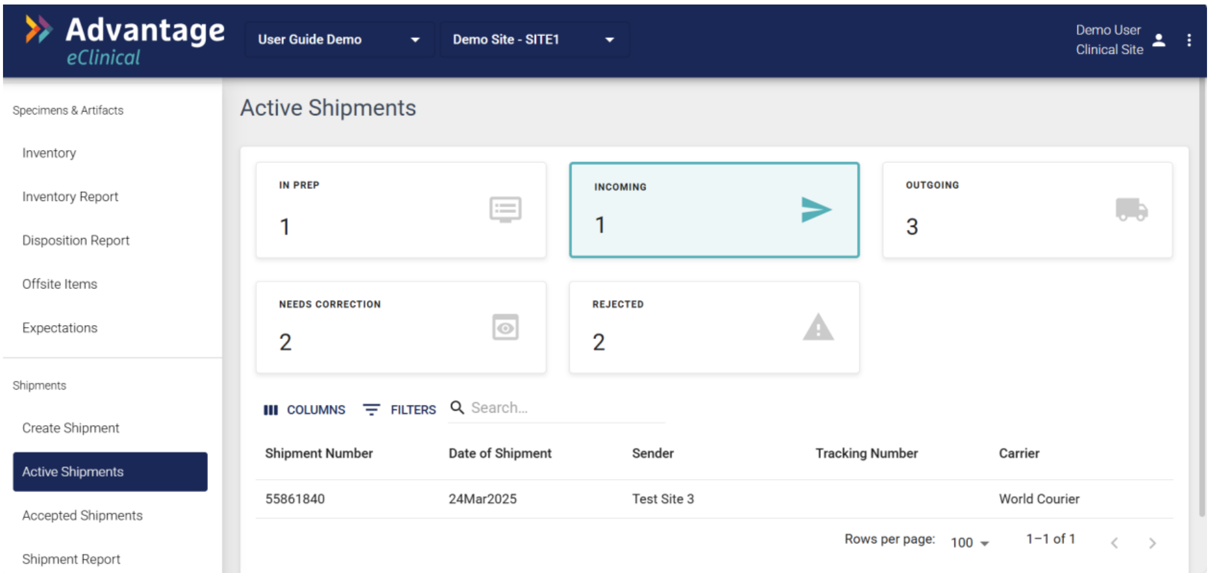
You can monitor shipments currently in transit, whether incoming to their site or outgoing to another, to ensure timely receipt or delivery.

Incoming shipments

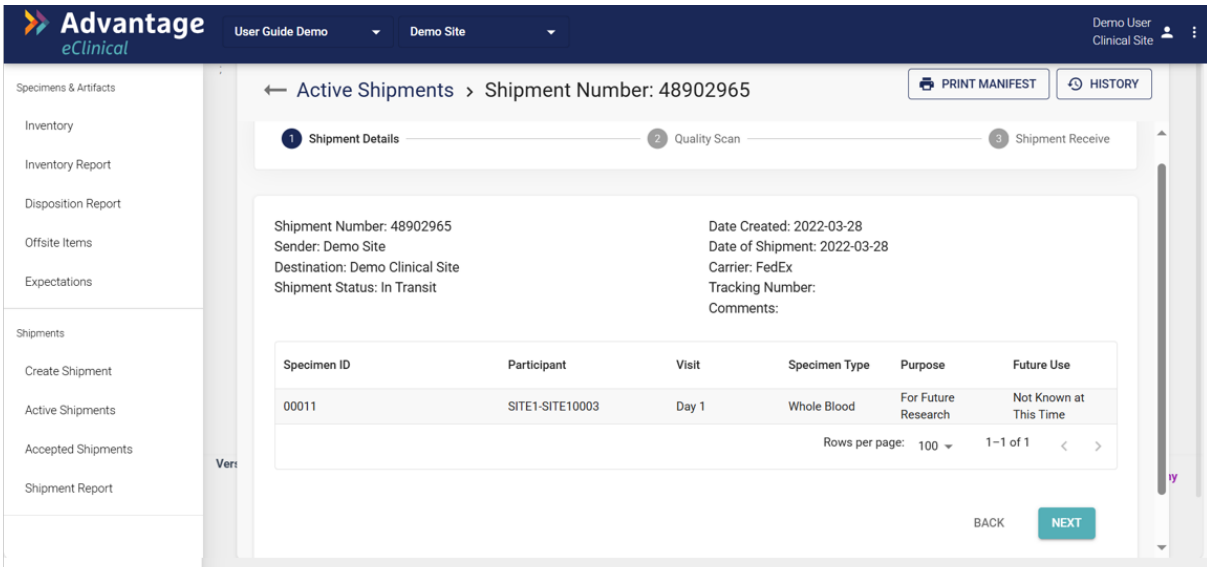
You can track shipments being sent to your site.

Steps to track incoming shipments:

1. Locate the shipments under 'INCOMING' in the **Active Shipments** page.



2. Select a shipment to view its details.

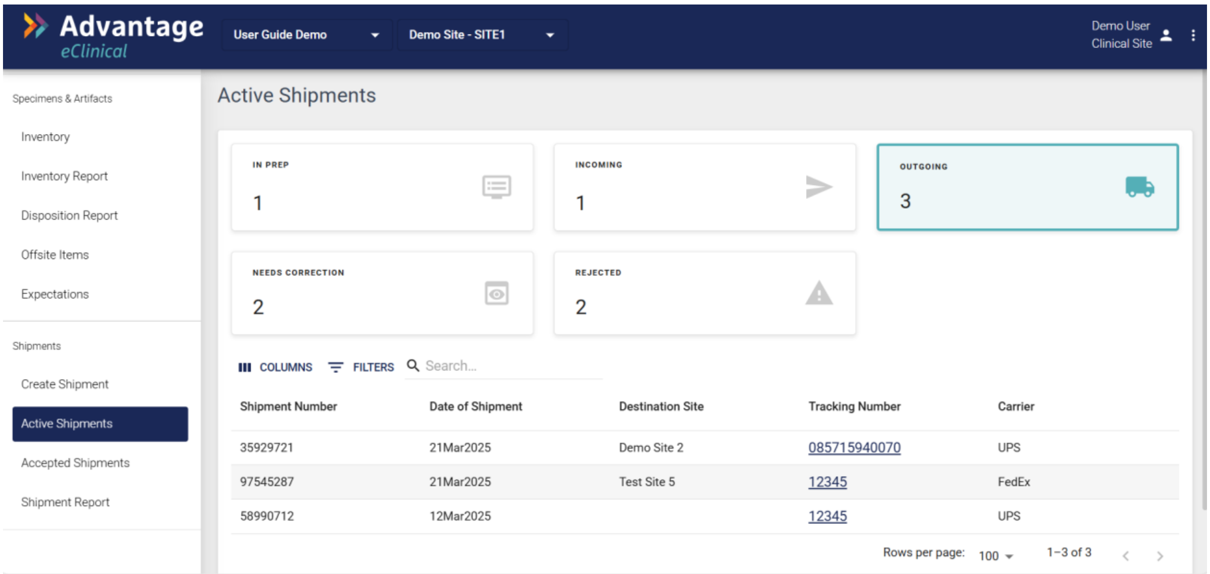


Outgoing shipments

You can track shipments that have been sent from your site but not yet received by the destination.

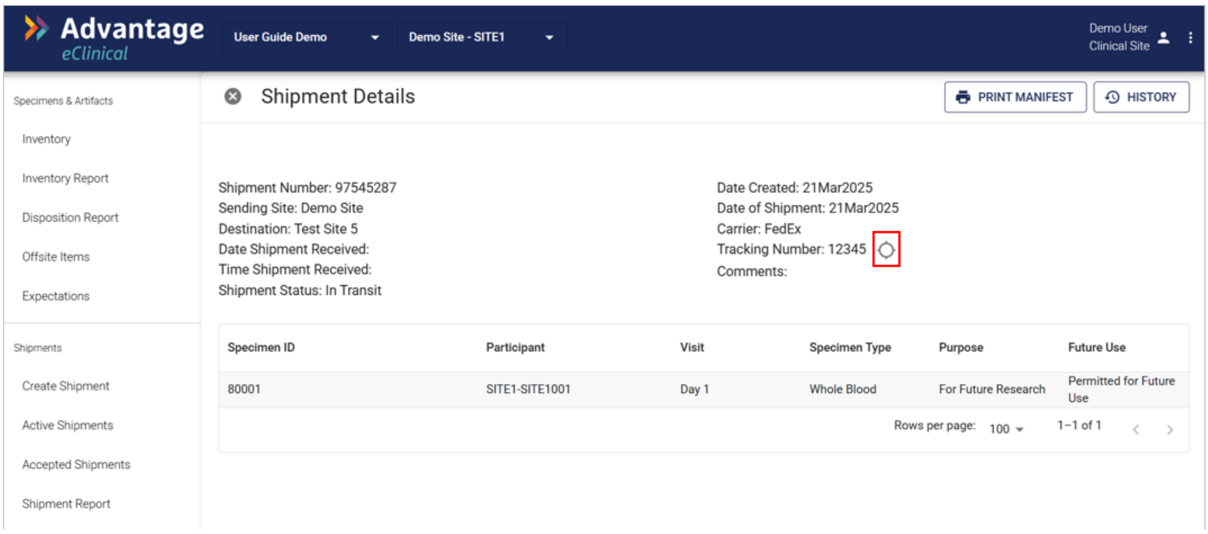
Steps to track outgoing shipments:

1. Locate the shipments under 'OUTGOING' in the **Active Shipments** page.



2. View shipments that are still in transit to other sites.
3. Select a shipment to open its shipment details.

NOTE: You can click the **tracking status** icon to open the official courier page, where you can view real-time tracking details for the shipment.

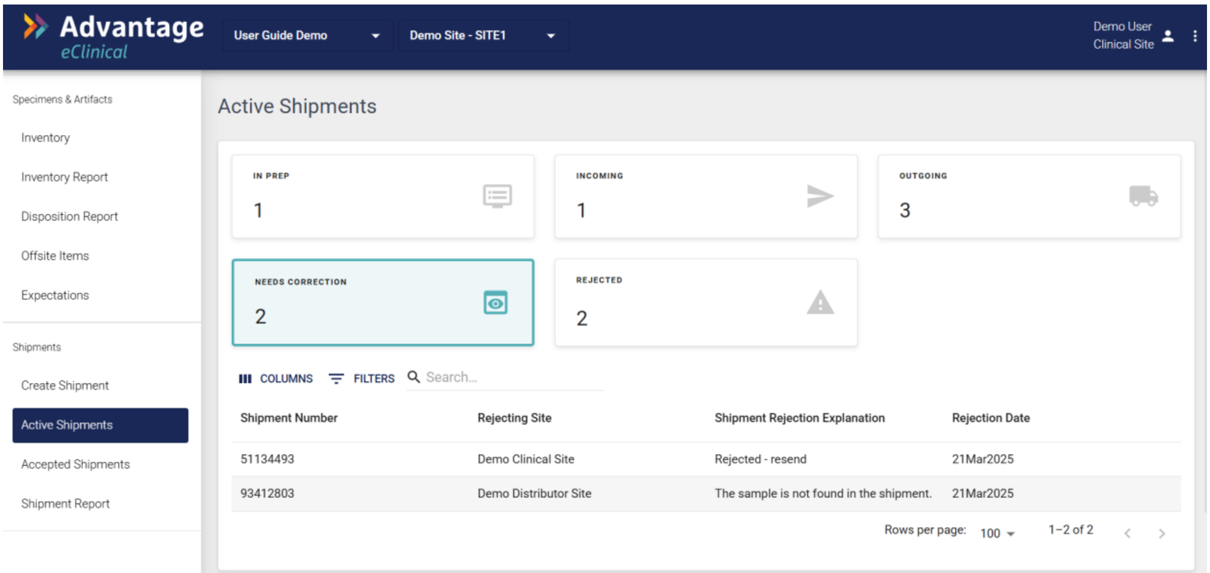


Viewing and updating rejected shipments requiring correction

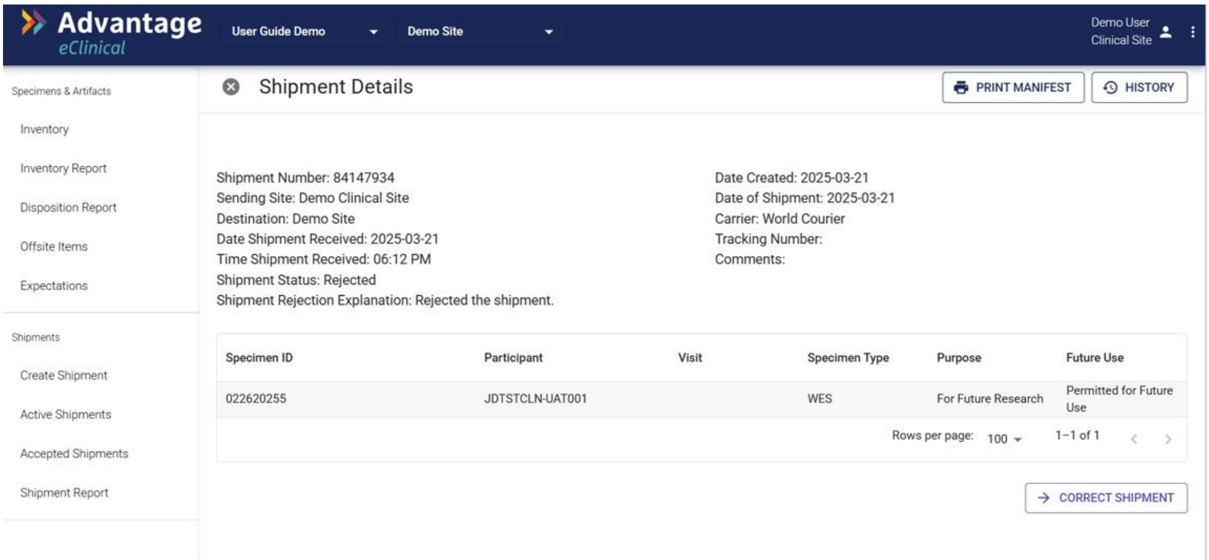
You can track and correct shipments rejected by the receiving site due to discrepancies.

Steps to view and correct rejected shipments that require correction:

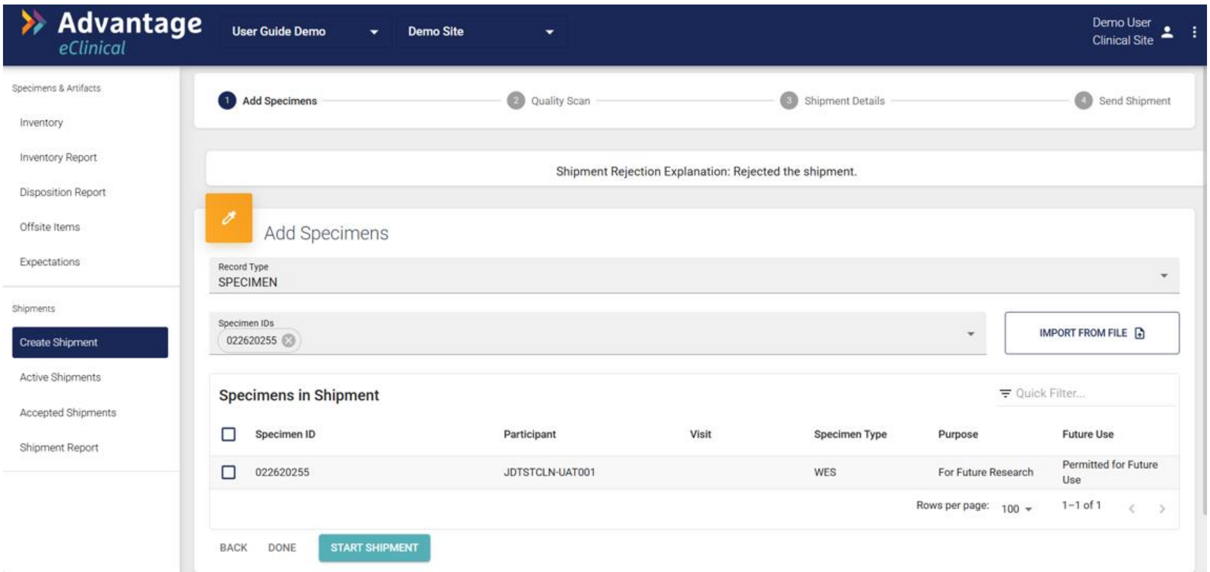
1. Locate the shipments under 'NEEDS CORRECTION' in the **Active Shipments** page.



2. Select a shipment to open its shipment details.



3. Select CORRECT SHIPMENT to review the rejection explanation and required corrections.
4. Make necessary updates based on the rejection reason:
   - Remove extra specimens from the shipment.
   - Add missing specimens to the shipment.
   - Modify specimen details if needed.



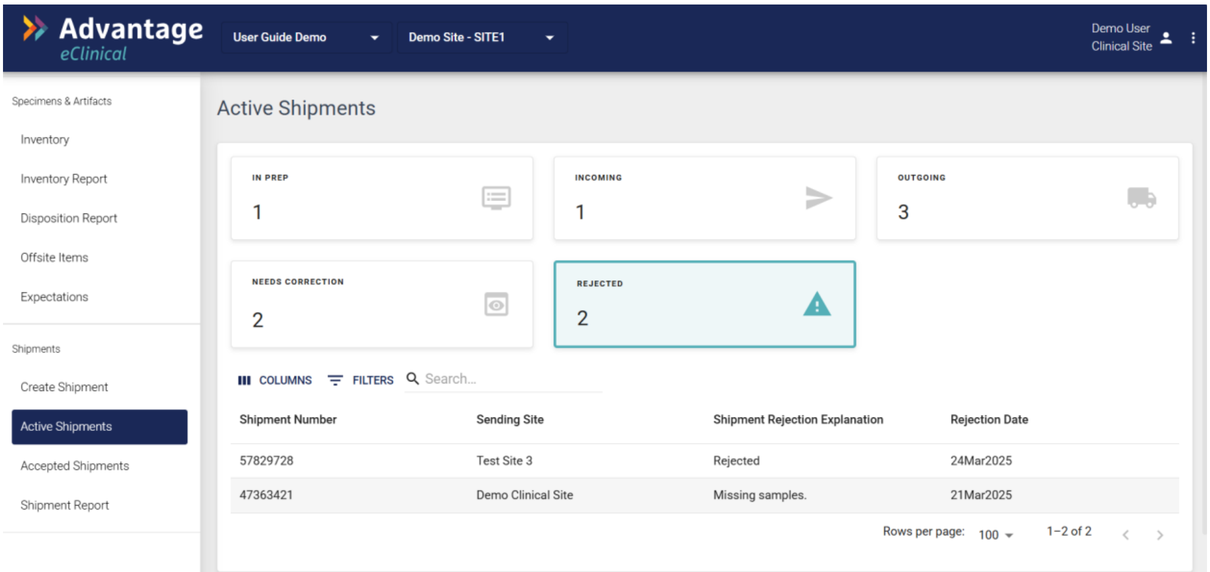
5. Select **START SHIPMENT** to navigate through the shipment process and resend the corrected shipment.

Viewing rejected shipments awaiting correction by sending site

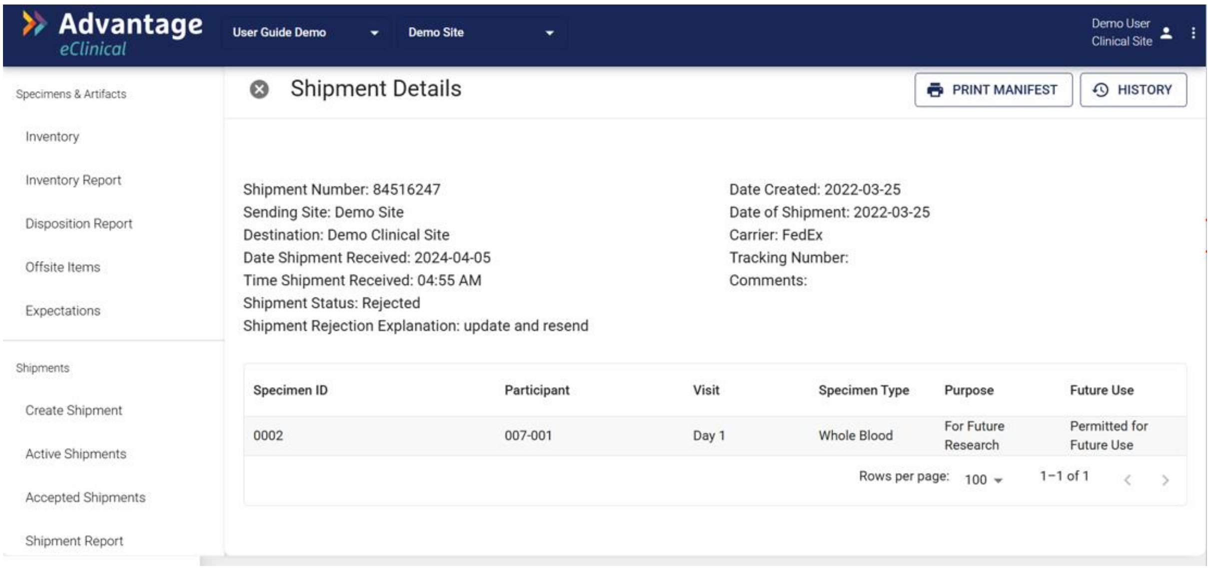
You can view shipments rejected by the receiving site and awaiting correction from the sending site.

Steps to view rejected shipments awaiting correction:

1. Locate the shipments under 'REJECTED' in the **Active Shipments** page.



2. View shipments pending updates from the sending site.
3. Select a shipment to open its shipment details.


Advantage
eClinical
User Guide Demo
Demo Site
Demo User
Clinical Site
Specimens & Artifacts
Inventory
Inventory Report
Disposition Report
Offsite Items
Expectations
Shipments
Create Shipment
Active Shipments
Accepted Shipments
Shipment Report
Shipment Details
PRINT MANIFEST
HISTORY
Shipment Number: 84516247
Sending Site: Demo Site
Destination: Demo Clinical Site
Date Shipment Received: 2024-04-05
Time Shipment Received: 04:55 AM
Shipment Status: Rejected
Shipment Rejection Explanation: update and resend
Date Created: 2022-03-25
Date of Shipment: 2022-03-25
Carrier: FedEx
Tracking Number:
Comments:
Specimen ID
Participant
Visit
Specimen Type
Purpose
Future Use
0002
007-001
Day 1
Whole Blood
For Future Research
Permitted for Future Use
Rows per page:
100
1–1 of 1

Accepting or Rejecting Shipments

You can accept or reject a shipment after selecting it from the 'Incoming' section on the **Active Shipments** page.

Site shipment acceptance process

Site shipments come from a site, lab, or repository. The process involves three steps:

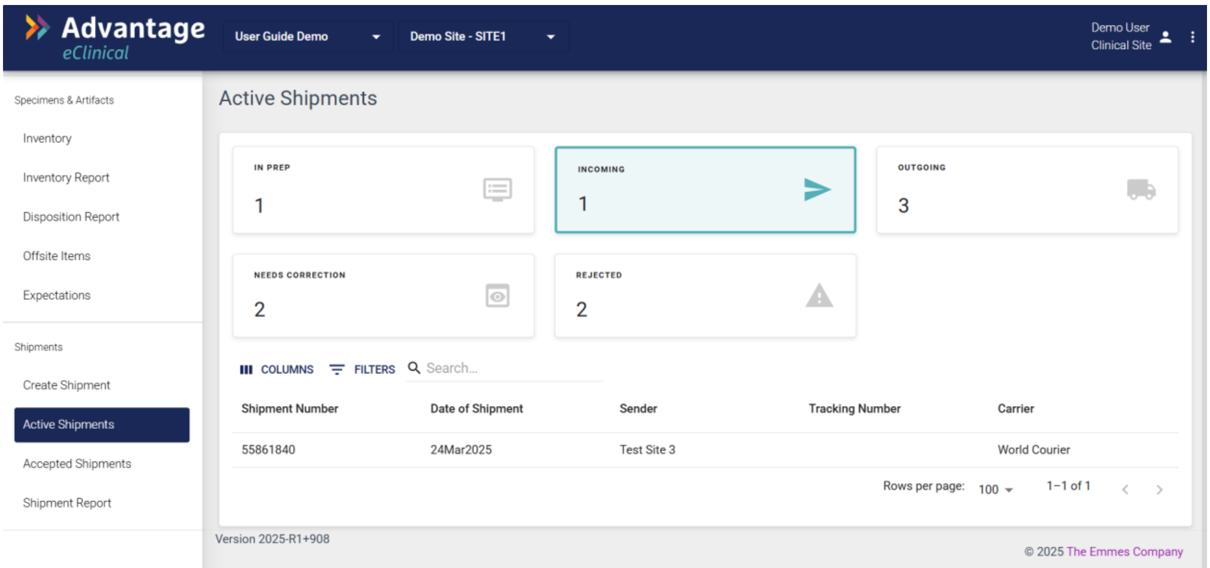
Viewing shipment details → Performing a quality scan → Receiving the shipment

Viewing shipment details

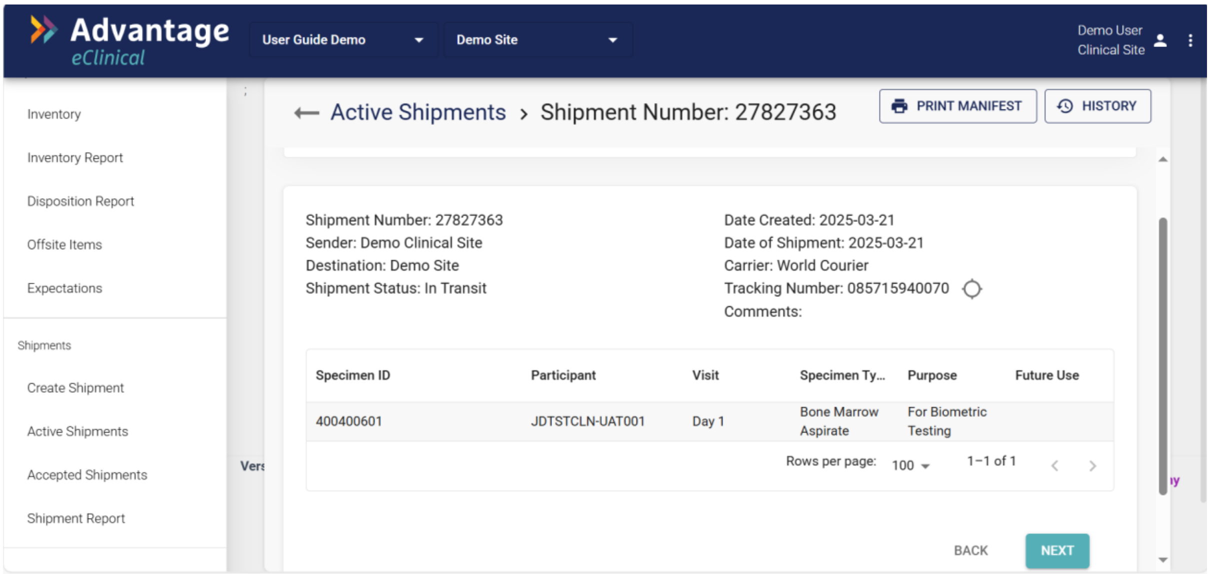
Review shipment details before accepting or rejecting the shipment.

Steps to view shipment details:

1. Select the shipment from the 'INCOMING' section on the **Active Shipments** page.

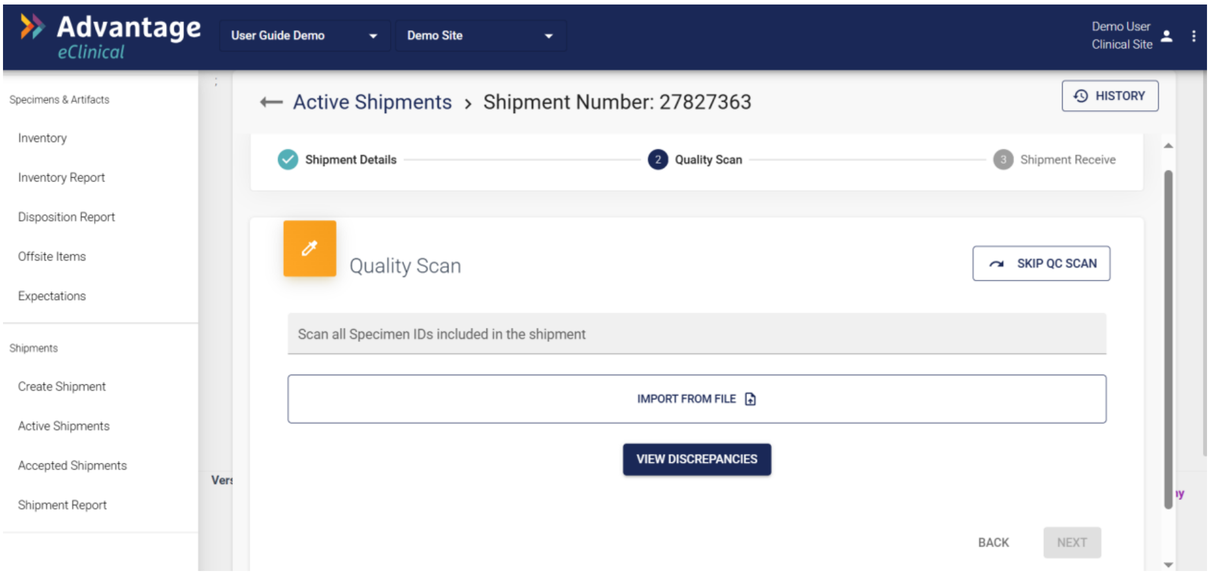


2. Review the **Shipment Details** page to confirm the correct shipment.



If correct, select **NEXT** to proceed. If incorrect, close the page to return to the ‘Active Shipments’ list.

If you select **NEXT**, the **Quality Scan** page appears. The quality scan is optional. To perform a quality scan, see Performing a quality scan. To skip this step, select **SKIP QC SCAN**. The ‘Shipment Details’ section of the **Create Shipment** page appears.



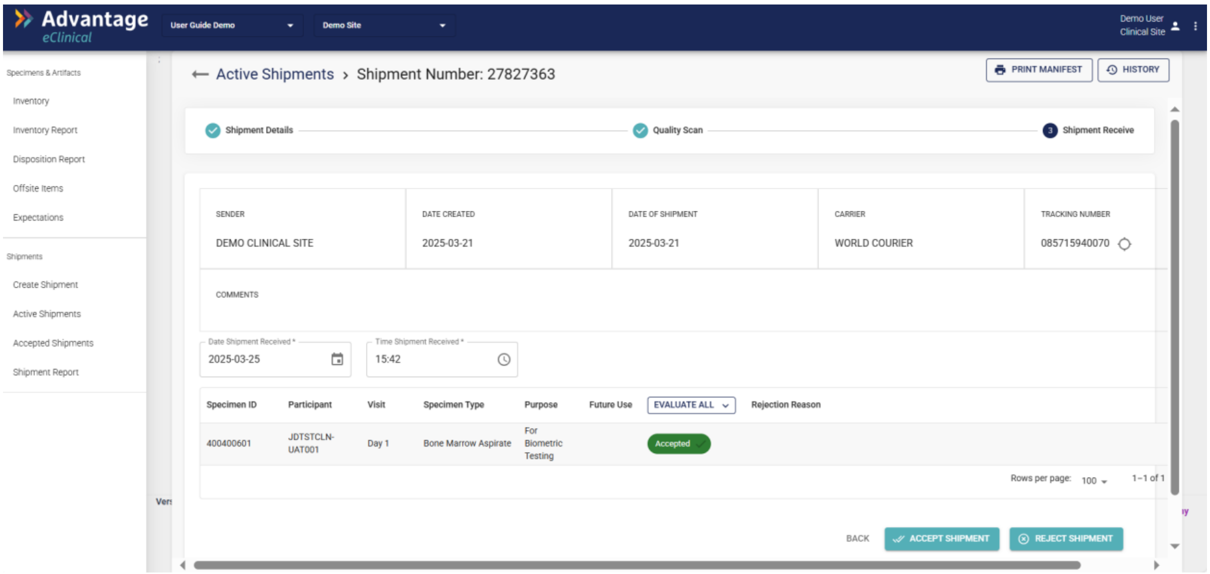
Accepting the shipment

Finalize the shipment by accepting or rejecting the specimens.

NOTE: The system auto-populates the ‘Date and Time Received’ but allows updates if necessary.

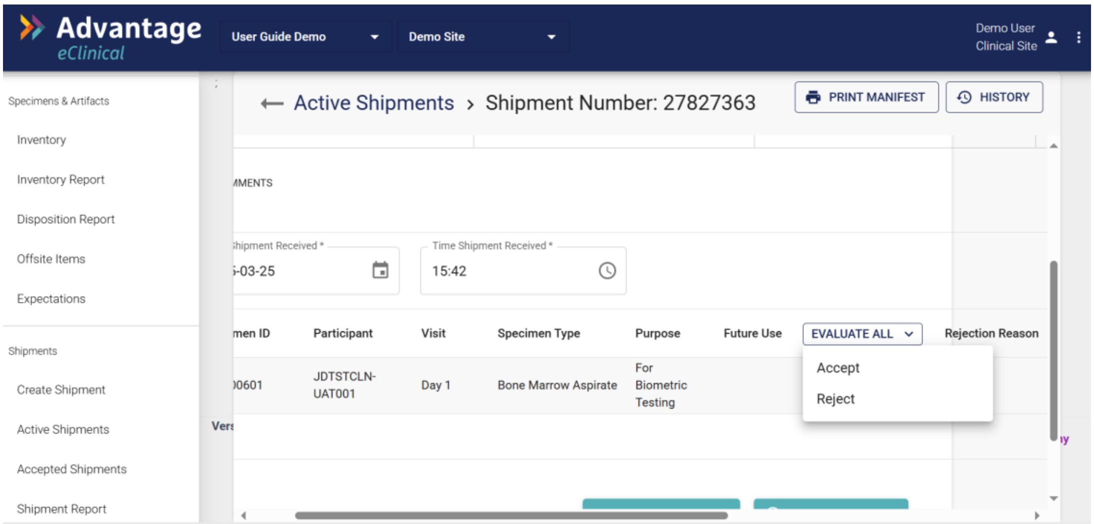
Steps to accept a shipment:

1. Review the list of specimens in the **Shipment Receive** page.

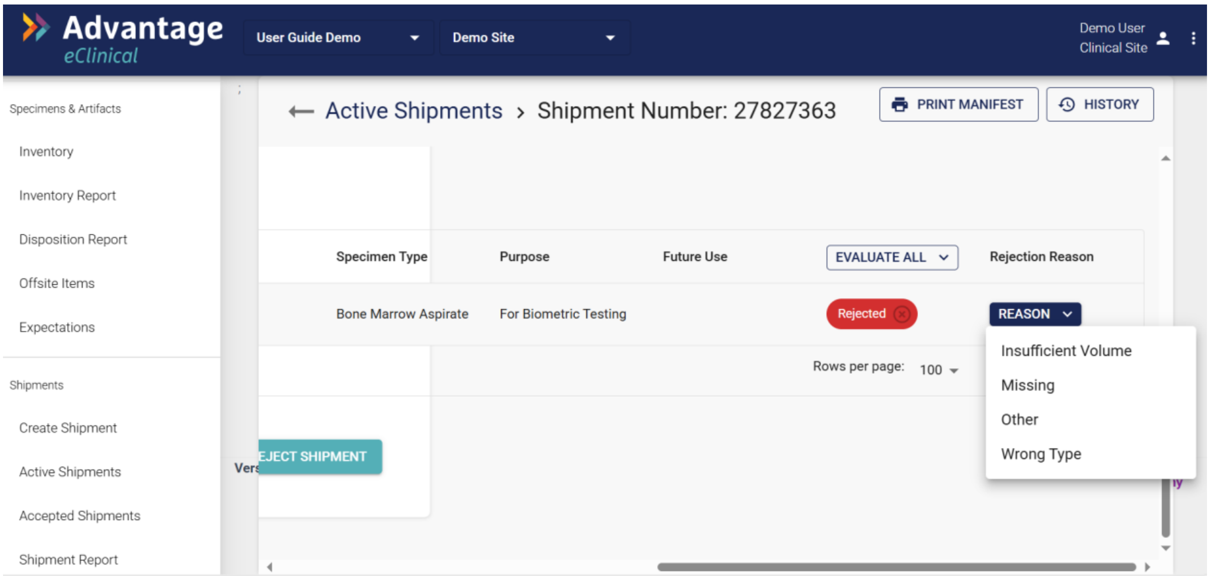


2. Select **EVALUATE ALL** to bulk accept or reject specimens.

> **NOTE:** To accept a shipment, all specimens must be marked either Accepted or Ruined in Transit.



3. If rejecting, provide a ‘Rejection Reason’.



4. Select **ACCEPT SHIPMENT** to finalize the shipment transfer.

   NOTE: If specimens were 'Ruined in Transit', their status updates to 'Not Available'.

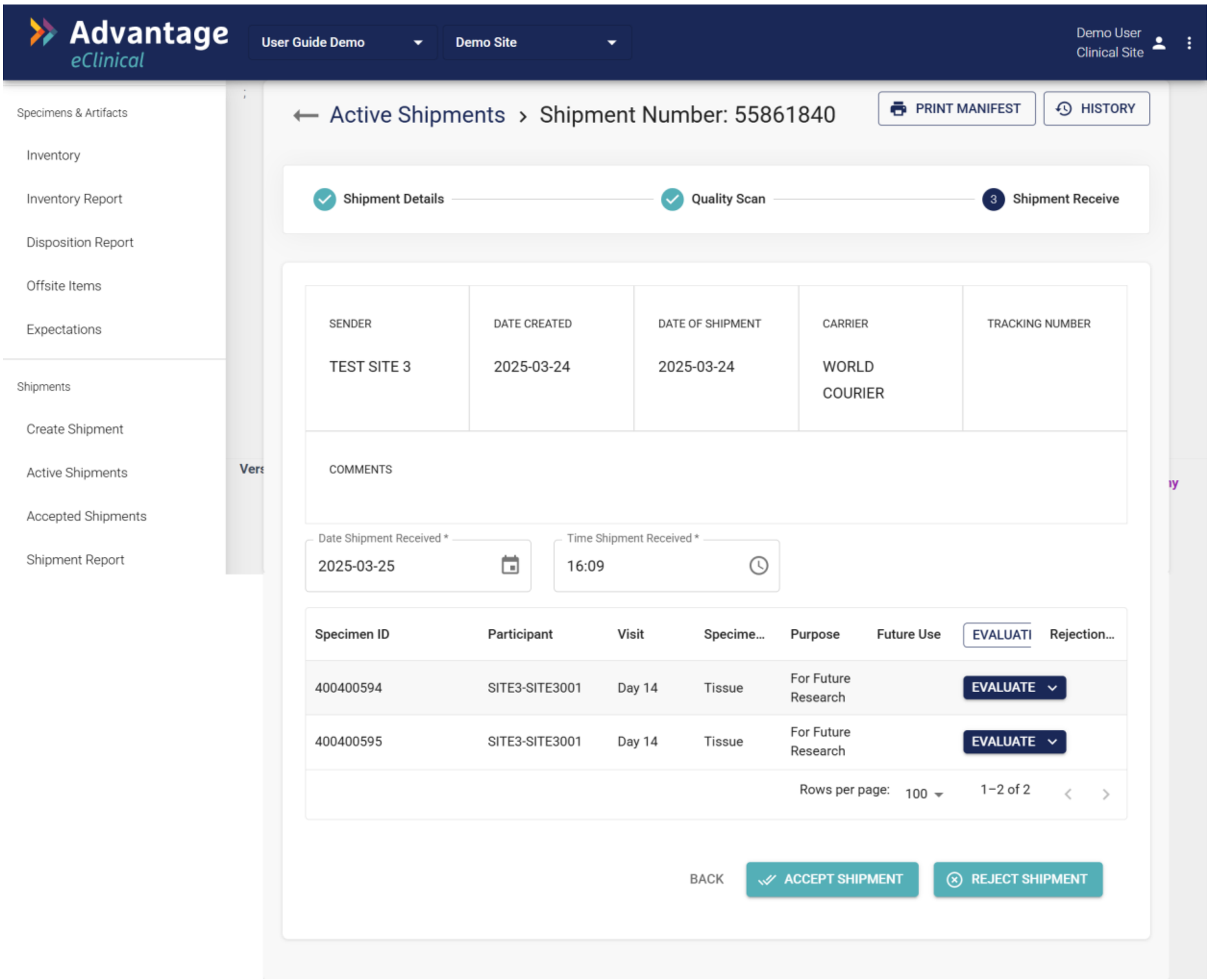
   If rejecting the entire shipment, select **REJECT SHIPMENT** and provide a reason.

Rejecting a shipment

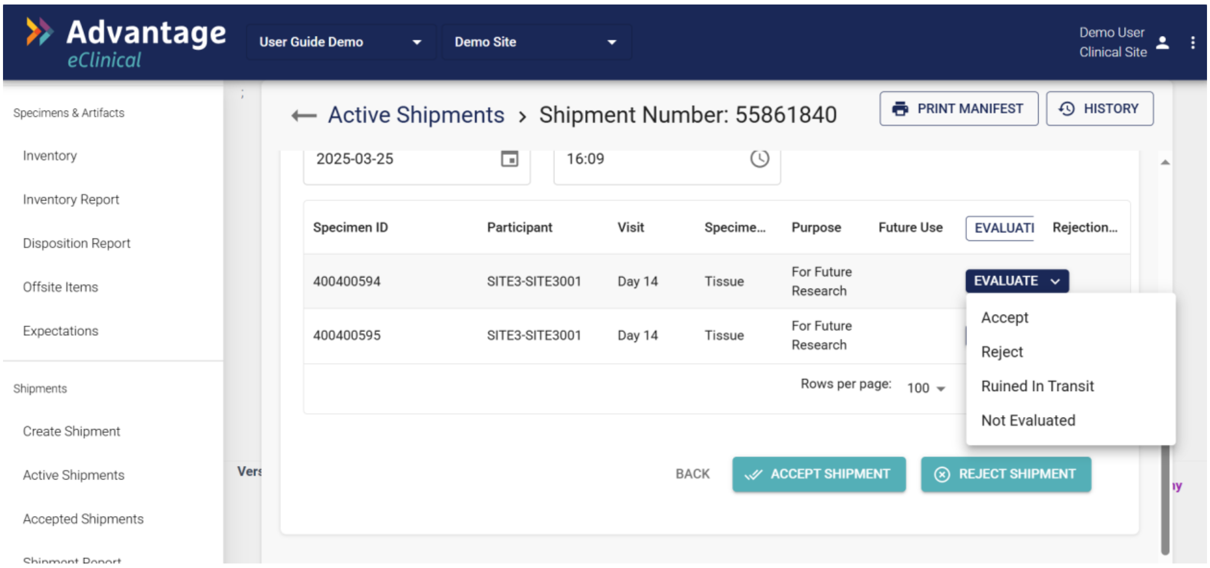
Rejecting a shipment requires providing a reason so the sender can correct any issues.

Steps to reject a shipment:

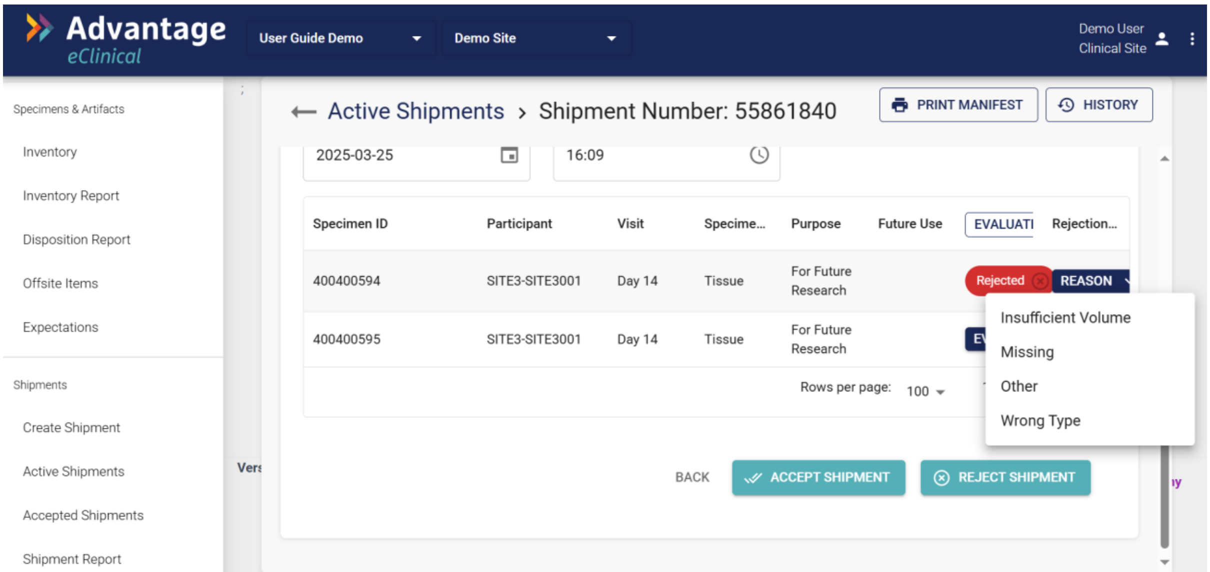
1. On the **Shipment Receive** page, evaluate all specimens in the selected shipment.



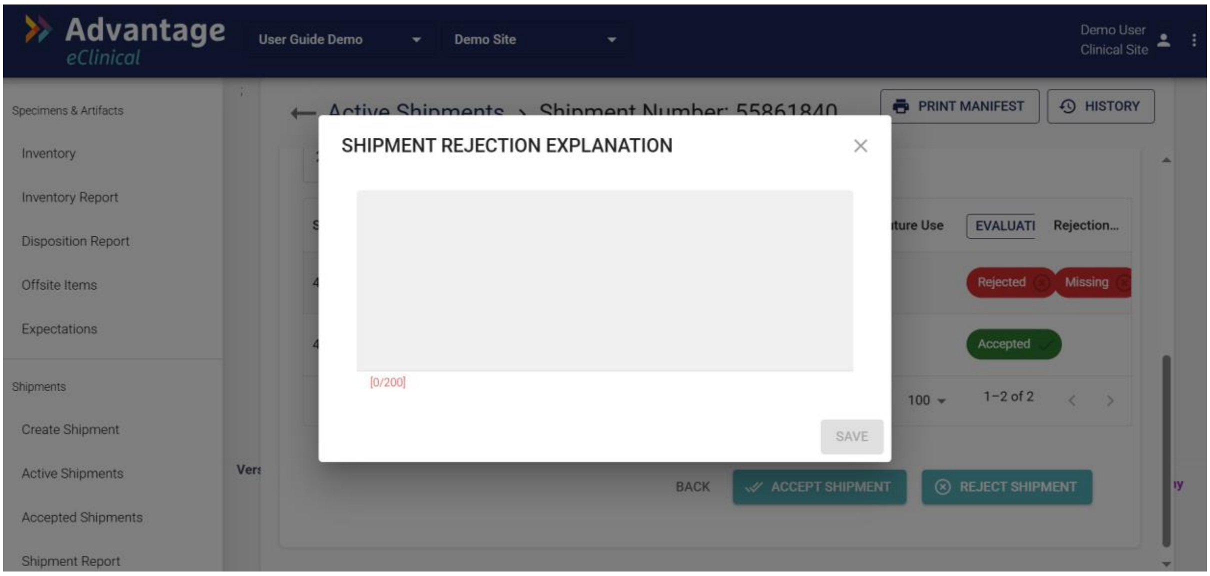
2. Select the **EVALUATE** dropdown for the specimen and then select one of the options provided.



3. If rejecting, provide a ‘Rejection Reason’.



4. Select **REJECT SHIPMENT** to reject the entire shipment.
5. Enter the reason for rejection when prompted.



6. Provide additional comments if necessary.
7. Select **SAVE** to finalize the rejection.

NOTES:

- The recipient does not need to return the physical shipment to the sender. However, the electronic shipment must be rejected in GlobalTrace with a rejection reason so the sender can make corrections.
- If a shipment contains missing or extra specimens, list these in the **SHIPMENT REJECTION EXPLANATION** field.
- If individual specimens are rejected due to missing items, incorrect types, or insufficient volume, enter the details in the **Rejection Reason** field. This information appears to the sender when they view the rejected shipment.

- Rejecting a shipment does not require rejecting all specimens. Accept the ones that are correct and reject only those that need correction. This approach makes it easier for the sender to correct issues and resubmit the shipment.
- After the sender corrects the electronic shipment, it returns to the ‘In Transit – Incoming’ section of the **Active Shipments** page.

Accepted Shipments

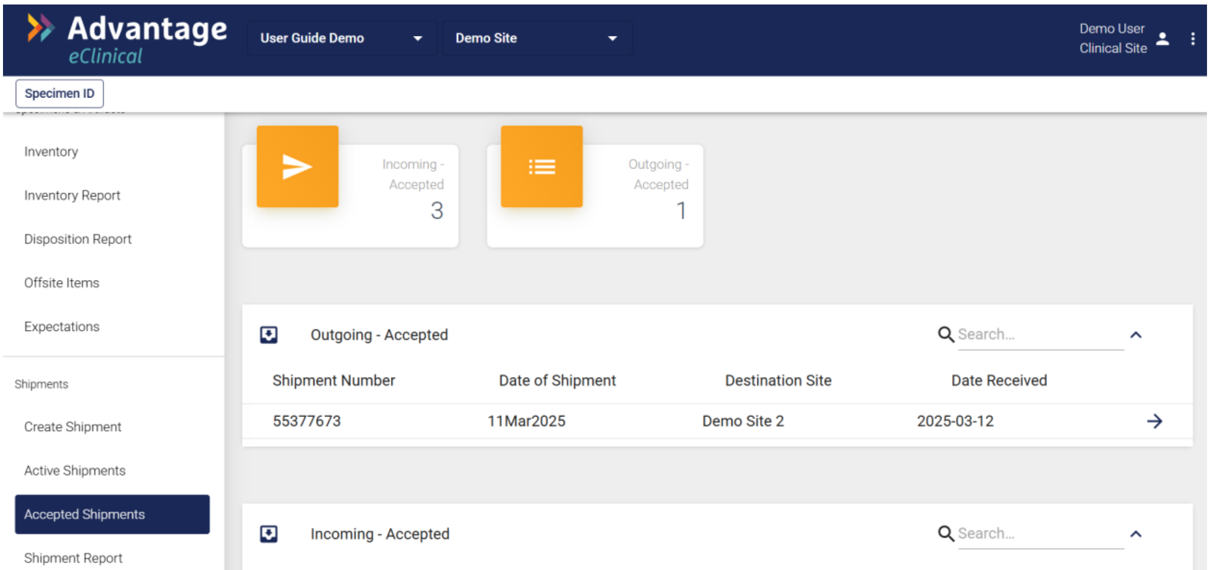
The **Accepted Shipments** page provides a record of all shipments that have been successfully received and accepted by your site or by another site when your site was the sender. This allows for easy tracking of completed shipments.

Viewing incoming accepted shipments

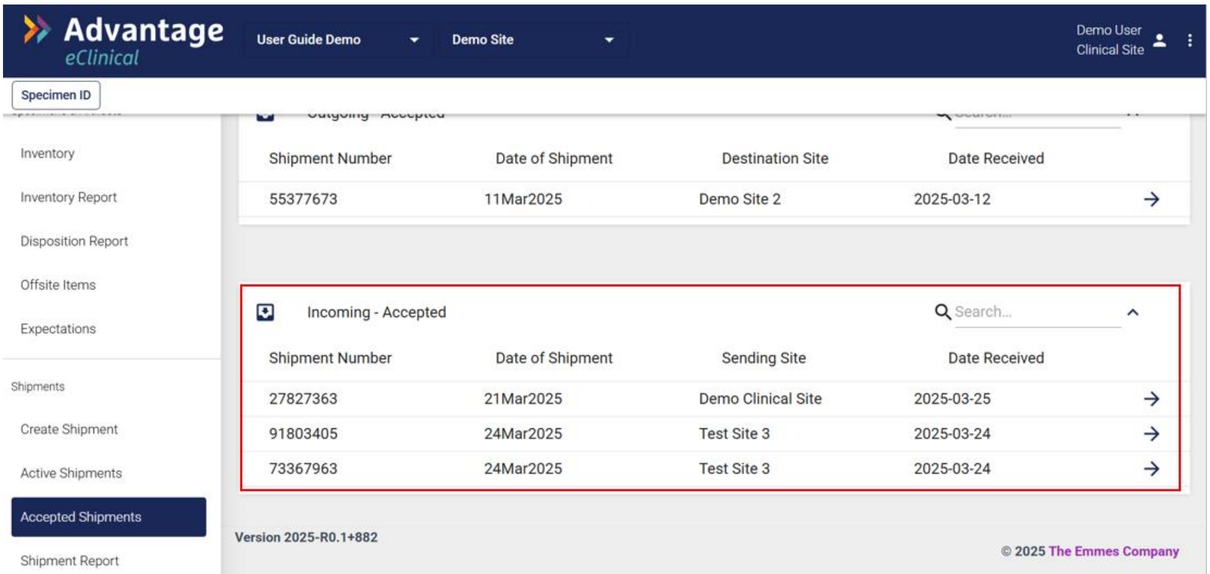
The **Incoming Accepted** table lists all shipments that your site has received and accepted.

Steps to view incoming accepted shipments:

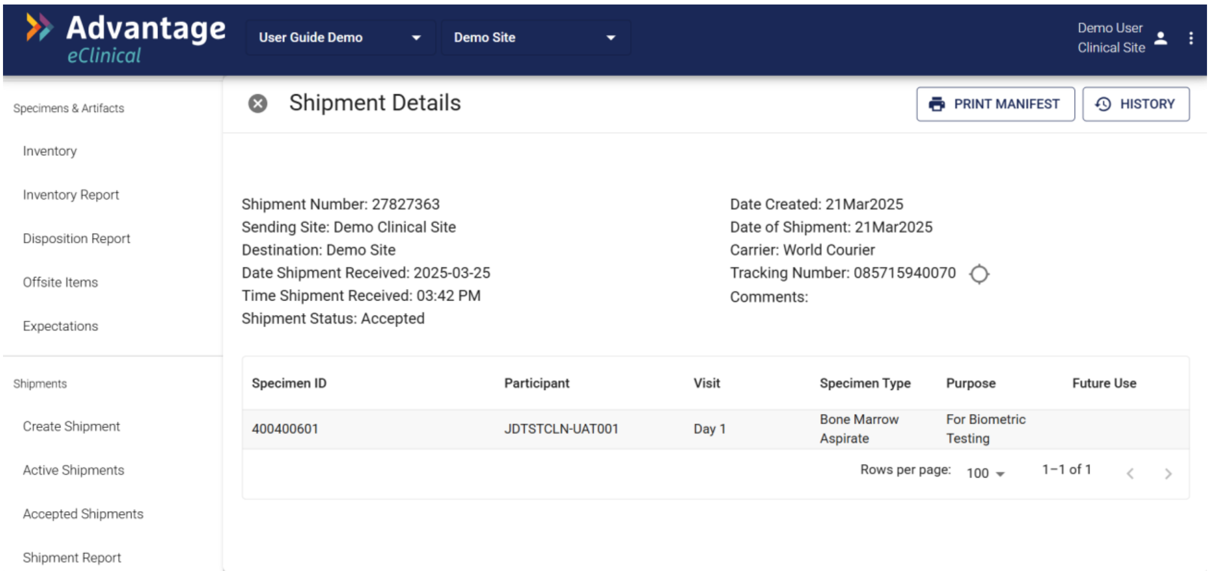
1. Go to the **Accepted Shipments** page from the 'Shipments' section.



2. Under 'Incoming – Accepted', review the list of shipments.



3. Select a shipment row to open the **Shipment Details** page.



4. On the **Shipment Details** page, review:
   - Shipment Number
   - Date of Shipment
   - Sending or Receiving Site
   - Date Received
5. If additional information is needed, refer to the shipment's history or associated records.

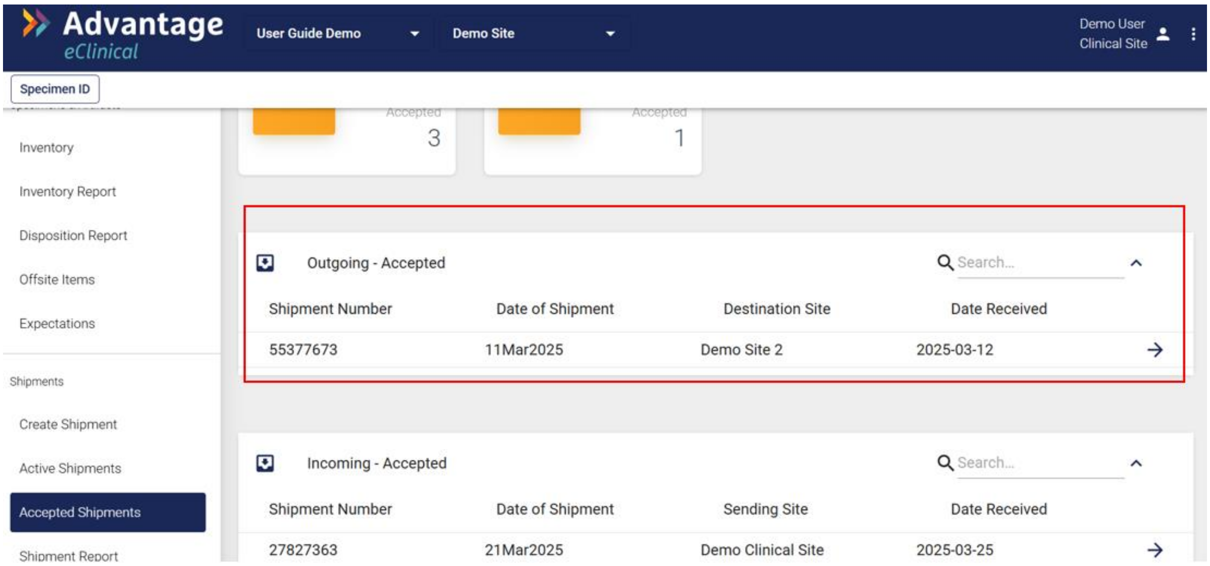
NOTE: Accepted shipments cannot be modified but remain accessible for auditing and tracking purposes.

Viewing outgoing accepted shipments

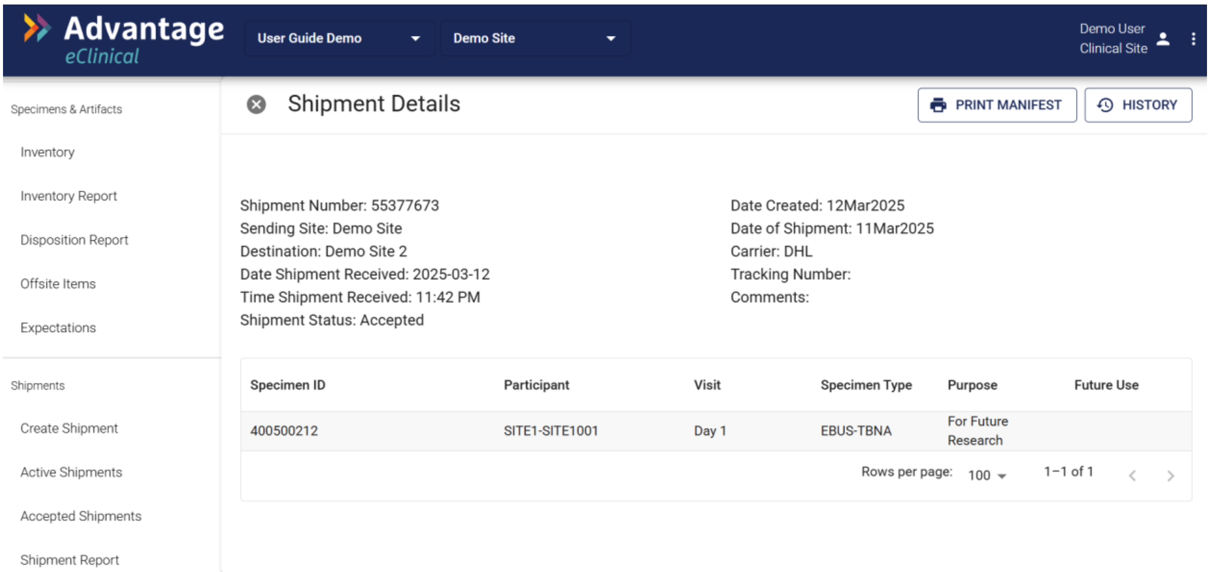
The **Outgoing Accepted** table lists all shipments sent from your site that have been received and accepted by the recipient site.

Steps to view outgoing accepted shipments:

1. Go to **Accepted Shipments** page from the 'Shipments' section.
2. Under 'Outgoing – Accepted', review the list of shipments.



3. Select on a shipment row to open the **Shipment Details** page.



4. On the **Shipment Details** page, review:
   - Shipment Number
   - Date of Shipment
   - Sending or Receiving Site
   - Date Received
5. If additional information is needed, refer to the shipment's history or associated records.

NOTE: Accepted shipments cannot be modified but remain accessible for auditing and tracking purposes.

Viewing Shipment Report

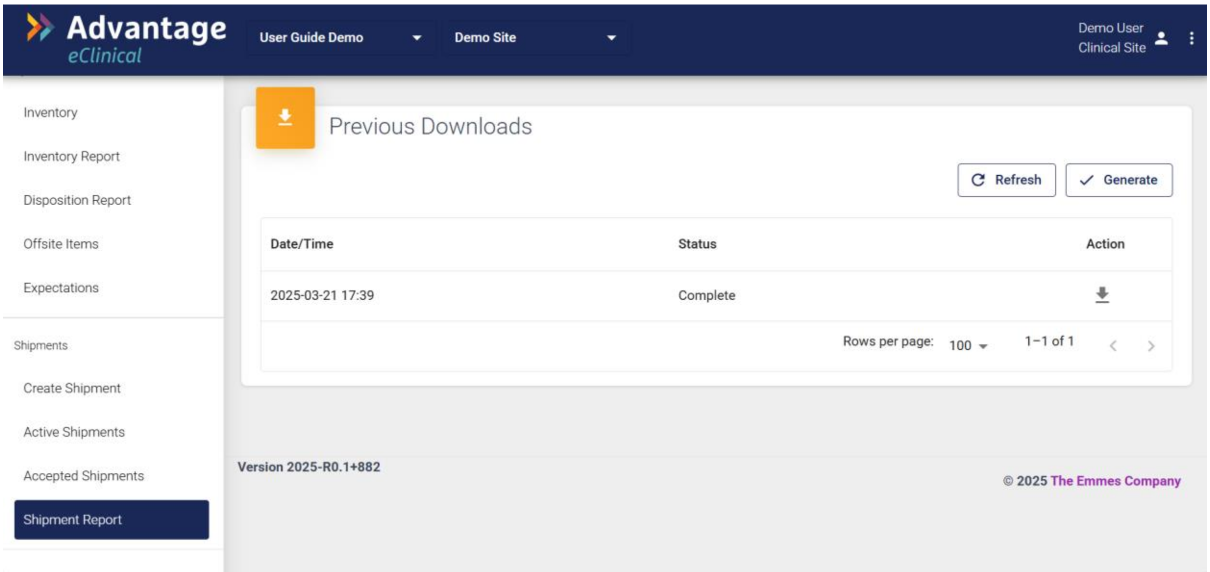
You can generate and download reports containing shipment details in the **Shipment Report** page to get visibility into shipment activity and auditing needs.

Generating and downloading a shipment report

You can track previously generated reports, check their status, and download them for review.

Steps to generate and download a shipment report:

1. Go to the **Shipment Report** page and select **Generate** to generate the report.
   The system processes the request and lists the report under 'Previous Downloads' with a timestamp.



2. Select **Refresh** to update the report status.
3. If the report status changes to 'Complete', click the **Download** icon under the 'Action' column.
   The report downloads as an Excel file (.xlsx).

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