

This quick start guide (QSG) describes how to enter safety information into the HiLIT electronic system.

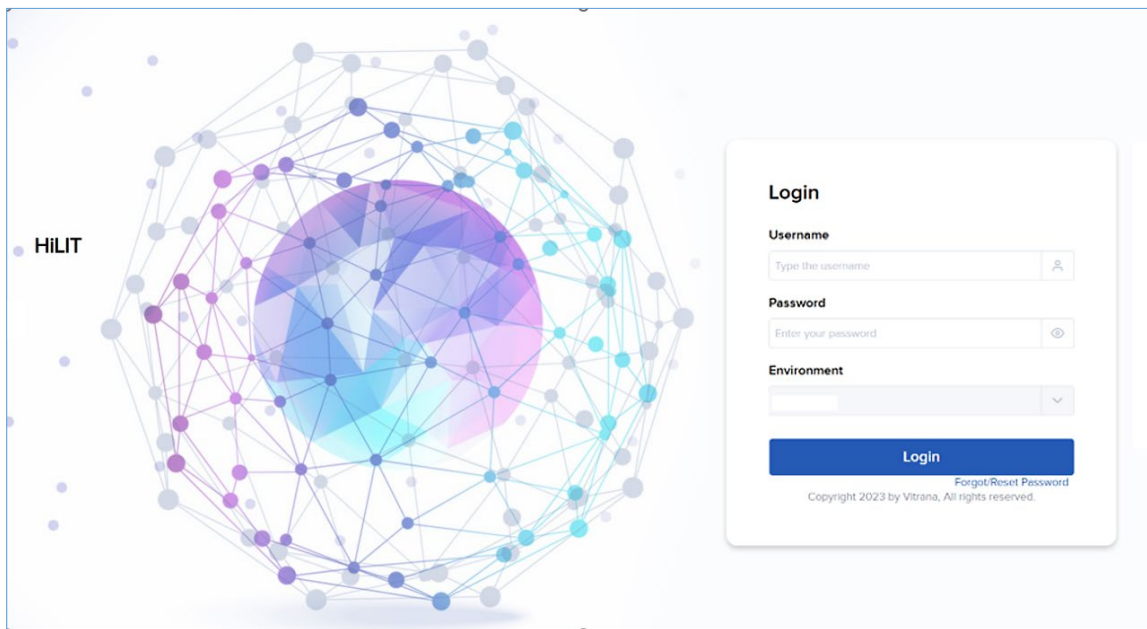
Click on the links below to learn how to perform the following tasks:

- [Logging into the DMID-CROMS HiLIT System](#)
- [Checking for Previously Submitted Cases](#)
- [Reporting an Event](#)
- [Entering Information](#)
- [Routing a Request](#)
- [Submitting a Request \(PI\)](#)
- [Contacting Staff for Assistance](#)

Reminder: When providing copies of medical records, redact all personal identifiers (i.e.: names, addresses, birthdates, etc.) and label each record with the Protocol # and Participant ID #.

Logging into the DMID HiLIT System

1. Open your web browser and navigate to <https://www.dmidcroms.com>. Please note that training is required for access to HiLIT. For training contact PVG@dmidcroms.com.
2. On the login screen enter your username and password.






3. HiLIT Login Credentials:
 - a. Username: [your site's Microsoft Office 365 Credential]
 - b. Password: [your site's Microsoft Office 365 Password]
 - c. Forgot/Reset Password. Click on this link to reset your password.


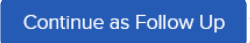
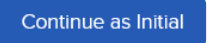
Checking for Previously Submitted Cases

Check for previously submitted cases:

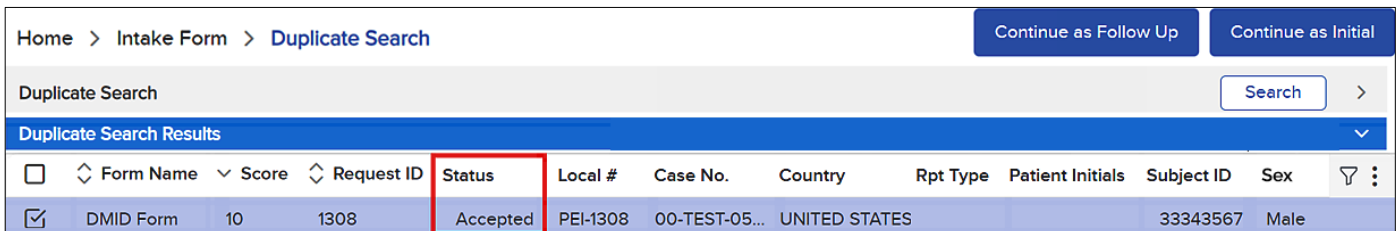
- Before entering a new request, to determine whether a case was previously reported; or
- When following up on an existing case or previously submitted case.

1. Click the **Report an Event** () down arrow.
2. Select **DMID Form** to display a blank **Intake Form > DMID Form**.
3. From the intake form, click the **Duplicate Search** () button.
4. The **Duplicate Search** screen fields are displayed. Choose **Select All** or specific check boxes () to enter search criteria. Checked fields will be “required” data fields.

Note: The **E/P** option slider () searches for Exact or Partial matches for the Subject ID and DMID Protocol. In case of partial match, all the punctuation marks or special characters will be ignored.

5. Once you have entered the search criteria, click the **Search** () button.
6. Depending on the request status, select the desired action by clicking either:
Continue as Follow Up () or **Continue as Initial** ()

Only requests with a status **Accepted** have access to the **Continue as Follow Up** option. If selected, an intake form will display previously entered information in the database for the respective case, which can be updated as necessary.



The screenshot shows the 'Duplicate Search Results' table. The table has columns: Form Name, Score, Request ID, Status, Local #, Case No., Country, Rpt Type, Patient Initials, Subject ID, and Sex. A red box highlights the 'Status' column for the first row, which is 'Accepted'. The 'Continue as Follow Up' and 'Continue as Initial' buttons are visible at the top right of the interface.

<input type="checkbox"/>	Form Name	Score	Request ID	Status	Local #	Case No.	Country	Rpt Type	Patient Initials	Subject ID	Sex
<input checked="" type="checkbox"/>	DMID Form	10	1308	Accepted	PEI-1308	00-TEST-05...	UNITED STATES			33343567	Male

Only the **Continue as Initial** option is available for requests with status **Data Entry, QC Pending, Pending Acceptance, or Rejected**. Values entered for a duplicate search will be retained when continuing as an initial entry.

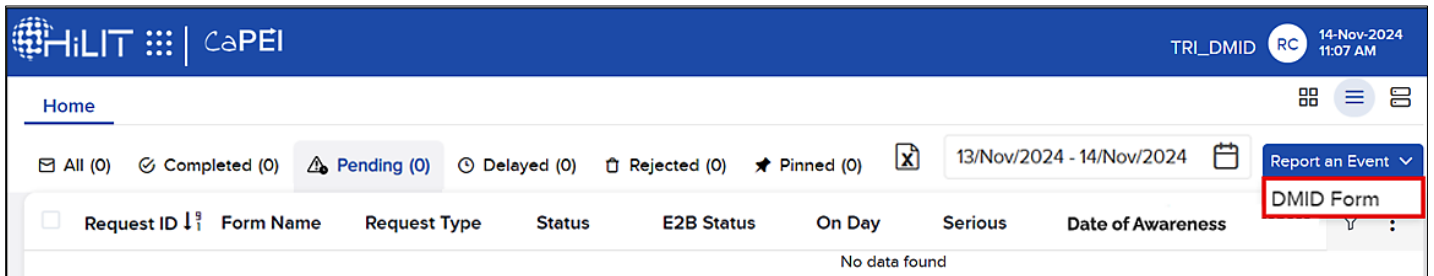
When submitting a new, different event for the same subject/participant, please proceed with an **Initial** request.

Reporting an Event

After login, the dashboard (or Home screen) is displayed. In HiLIT when you submit a safety event, they are called **Requests**.

Every new event for a subject/participant should be submitted as an initial report. Updates to initial reports are submitted as follow-up reports.

To create a new request for an initial report, click the **Report an Event** (**Report an Event**) down arrow. Select **DMID Form**. This initiates the process for entering information into the system.



Entering Information

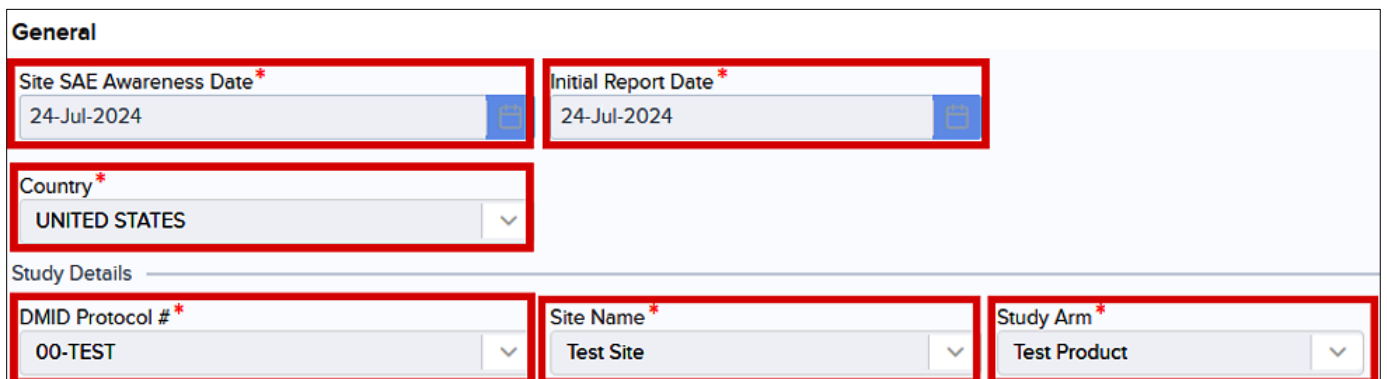
There are nine sections in the HiLIT system for entering safety information. It is mandatory to complete the required fields marked with the red asterisk (*). For each section, fill in the fields and provide complete and accurate information if available.

To navigate to a different section either scroll down the screen or click on an icon on the left side of the screen. Examples of completed screen shots are provided below for each section.

Information you entered in these sections will not save automatically. It can be saved at any time during data entry. Click the **Save** button (**Save**). The system will alert you of any missing mandatory fields but will not stop the save process. The system assigns and displays your Request ID number when the request has been successfully saved. For example, "Request ID: 1308 – Save Successful!"

1. General Section

Enter the **Site SAE Awareness Date**, **Initial Report Date**, **Country**, and the **Study Details** (DMID Protocol #, Site Name, Study Arm).

A screenshot of the 'General' section of the HiLIT system. The section is titled 'General' and contains several input fields, all of which are highlighted with a red border. The fields are: 'Site SAE Awareness Date*' with the value '24-Jul-2024'; 'Initial Report Date*' with the value '24-Jul-2024'; 'Country*' with the value 'UNITED STATES'; 'DMID Protocol #*' with the value '00-TEST'; 'Site Name*' with the value 'Test Site'; and 'Study Arm*' with the value 'Test Product'. The asterisk (*) indicates that these fields are mandatory.

2. Patient (Participant/Subject) Section

Enter the **Subject ID**, **Sex**, **Ethnicity**, **Race**, **Age**, **Age Unit**, **Weight**, and **Weight Unit**.

Patient			
Subject ID *	Sex	Ethnicity	Race
33343567	Male	Unknown	Asian
Age	Age Unit	Weight	Weight Unit
40	Years	63	Kilograms
If SAE occurred in an infant: Subject ID refers to:			
<input type="text"/>			
Pregnancy Information			
Neonate - Gestational Age	Neonate - Gestational age unit	Neonate - Birth Weight	Neonate - Birth Weight Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Neonate - APGAR Score - 1 min	Neonate - APGAR Score - 5 min	Neonate - APGAR Score - 10 min	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

3. Reporter Section

This section is auto populated from the login credentials.

Note: Data Entry and Investigator information is also auto populated from the login credentials once the case is routed to Quality Control (QC).

Reporter 1			
Investigator First Name	Investigator Last Name		
<input type="text"/>	<input type="text"/>		
Reporter Name *	Reporter Phone	Reporter Country *	Reporter Email *
KS	1112223333	UNITED STATES	ks@tech-res.com

4. Product Section

When entering a study product, check the box next to **Is Study Product** and select the appropriate study product from the **Product Name** dropdown.

Next, select the most appropriate **Action Taken With Study Product** from the dropdown menu and enter the **Date Last Taken Prior To SAE Onset**.

Select the **Product Type**. **Note: Suspect** displays as the default for Product Type.

When entering a Treatment Administered or Concomitant Medication, leave **Is Study Product** unchecked, select the appropriate **Product Type** from the dropdown, and write in the name of the product under **Product Name**.

Enter the **Dosage Regimen** for each product and provide the requested dates.

Additional **Study Product**, **Treatment** and **Concomitant** product can be added by clicking the plus icon (+) in the top right corner of the product section.

The screenshot shows a form titled "Test Product 1 <Capsule>". The form contains several sections with red boxes highlighting specific fields:

- Is Study Product:** A checked checkbox.
- Product Type:** A dropdown menu with "Suspect" selected.
- Product Name:** A dropdown menu with "Test Product 1 <Capsul" selected.
- Action Taken With Study Product:** A dropdown menu with "Not Applicable" selected.
- Action Taken With Study Product (Comments):** A text input field with "Not Applicable" entered.
- Date Last Taken Prior to SAE Onset:** A date picker with "20-Dec-2022" selected.
- Event Abated After Use Stopped or Dose Reduced?:** A dropdown menu.
- Text for Dechallenge Comment:** A text input field.
- Event Reappeared After Reintroduction?:** A dropdown menu.
- Text for Rechallenge Comment:** A text input field.
- Concomitant Medication - Suspect?:** An unchecked checkbox.
- Total Daily Dose Unknown:** An unchecked checkbox.
- Dosage Regimen 1:** A section containing:
 - Date Started:** A date picker with "18 Oct 2022" selected.
 - Stop Date:** A date picker with "20 Oct 2022" selected.
 - Dosage:** A text input field with "100" entered.
 - Units:** A dropdown menu with "mg" selected.
 - Route of Administration:** A dropdown menu with "Oral use" selected.
 - Administration Schedule:** A dropdown menu with "Monthly" selected.
 - Dosage Description:** A text input field.

5. Test Attached Section

Check the box to indicate which tests are attached. The three options are **Lab Results Attached**, **Diagnostic Results Attached**, and **No relevant laboratory tests**. The respective tests can be attached in the **Attaching Files Section**.

The screenshot shows a form titled "Test Attached". The form contains three checkboxes, each highlighted with a red box:

- Lab Results Attached
- Diagnostic Results Attached
- No relevant laboratory tests

6. Events Section

Do not submit multiple events for the same subject. Please submit a new request for each event (see **Reporting an Event** and the **Checking for Previously Submitted Cases** sections).

Enter the **SAE Term** (Safety Event Term), **Onset Date**, **Severity**, **Outcome**, **Recovered/Resolved Date** (if resolved).

Check the **Seriousness Criteria** if the event meets serious criteria per protocol.

Enter **Death Information** (for fatal events).

Check any **Other Requirement** if the event meets other protocol-required reporting criteria.

Check an alternate etiology under **If not related to Study Product, then Related to?** if the event is **not related** to the study product. Write in the alternate etiology in the comment box.

Provide **Causality Information** for each study product.

SAE Term * Cerebrovascular Accident ✓	Onset Date 15 x Jun x 2023 x	Severity Severe x
Outcome Recovering/resolving x	Recovered/resolved (with or without sequelae) x	State Sequelae x
Seriousness Criteria		
<input type="checkbox"/> Death	<input type="checkbox"/> Important medical event	<input checked="" type="checkbox"/> Hospitalization/ Prolongation of existing hospitalization
<input type="checkbox"/> Life-threatening (immediate risk of death)	<input type="checkbox"/> Persistent or significant incapacity	<input type="checkbox"/> Required intervention to prevent permanent impairment/damage
<input type="checkbox"/> Congenital anomaly/birth defect	<input type="checkbox"/> Other Seriousness	Other Medically Seriousness Comment
Death Information		
Death Date x x x	Autopsy x	Death Certificate x
Other Requirement		
<input type="checkbox"/> AESI	<input type="checkbox"/> MAAE	<input type="checkbox"/> NOCMC
<input type="checkbox"/> PIMMC	<input type="checkbox"/> UP	<input type="checkbox"/> Others
If not related to Study Product, then Related to?		
<input type="checkbox"/> Study procedure	Study procedure: Comment x	<input type="checkbox"/> Other condition/illness x
<input checked="" type="checkbox"/> Other	Other Comment Cerebrovascular Accident	<input type="checkbox"/> Another Drug x
Causality Information		
Relation to Study Product or Intervention (Study Product Name) Test Product 1 <Capsule> x	Relation to Study Product or Intervention (Relatedness) Not Related x	

7. Lab Test Section

Enter the information requested for each test. Add any pertinent information in the **Notes** field.

Brain CT

 NR
 UNK

+

Test Name Brain CT ✓	Baseline Date 01-May-2022 ✕ 📅	Baseline Result Negative
Site Normal Range – Low 	Site Normal Range – High 	Result units activity ✕ ▾

Add Lab Result Date _____ +

Test Date 15 ✕ ▾ Jun ✕ ▾ 2023 ✕ ▾	Results Positive	Assessment Positive ✕ ▾
---	----------------------------	-----------------------------------

Pending Lab Test
 Pending Diagnostic Test

Notes
 The CT scan show hypoattenuation throughout the right-sided white matter and sulcal effacement in the distribution of the middle cerebral artery. This was assessed to be consistent with a cerebrovascular accident.

8. Summary Section

Enter a summary of the events or provide any additional information about the event in this section, for example:

- Chronological order of clinical course surrounding the event.
- Associated signs and symptoms.
- Participant's past relevant medical history, family history, social history, and allergies (for newborn and pregnant participant also include maternal history (obstetric and prenatal)).
- Reactogenicity records, current and past (FOR VACCINES ONLY). Provide local and systemic solicited adverse event records (i.e.: erythema, induration, fever, headache, etc.) for the participant.

9. Attachments Section

Click the **plus** icon (**+**) on the upper right corner to select the appropriate files to attach from your file folder. The number of attachments is displayed beside the word "Attachments" (e.g., **Attachments 1**). Attached documents are displayed at the bottom of the screen.

Note: When providing medical records, redact all personal identifiers and label with Protocol # and Participant ID #.

Check **Send to Safety** to submit to the safety database upon HiLIT case submission.


Attachments 1

S.No.	File Name ^	Date	Size	Source	Send to Safety
1	CT Scan.docx		(12.87KB)	Intake ✕ ▾	<input checked="" type="checkbox"/>

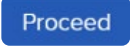

Routing a Request

Once all the required fields have been entered, the request can be routed to the Principal Investigator (PI) for review and approval. If the Reporter is also a PI, the Reporter can self-assign the request.

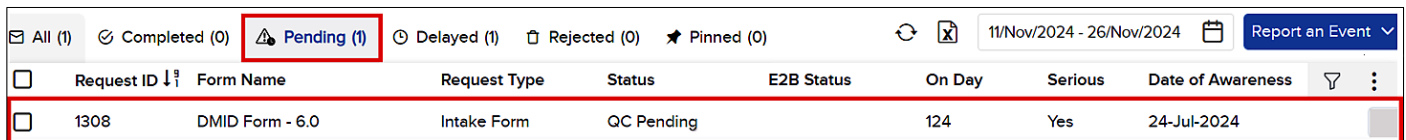
Note: The system will alert you of any missing mandatory and optional fields. The user will not be able to route the request for review if mandatory fields are missing. Optional fields will not restrict the user from routing the request.

1. Click the **Route** button () to forward the request to a reviewer.
2. **Select a reviewer from the drop-down list** or assign the request to yourself. Provide any comments for the reviewer, as applicable.

Note: An authorized Study Investigator or Sub-Investigator listed on Form 1572 must review all submitted safety events. If an authorized investigator is not available, users may submit safety events to avoid delays. DMID-CROMS PVG will query for an authorized user to review and approve the request.

3. Click **Proceed** () to complete the routing. The system displays your **Request ID** number and a message that the request has been submitted successfully. You can keep the **Request ID** number to do a search for the report.
4. Click **OK** () to complete the routing. The request should appear on the **Pending** tab of the dashboard/Home screen.

Note: Make sure to select the correct date range to view the desired requests.

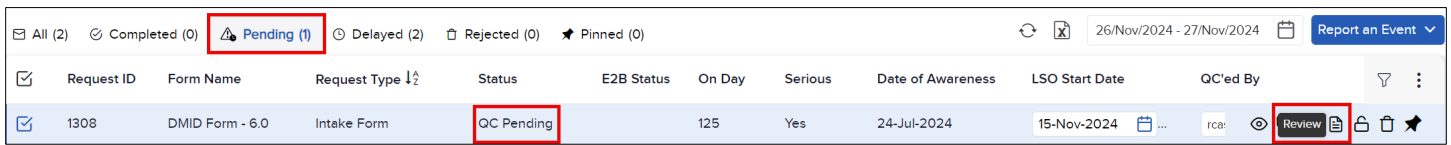


<input type="checkbox"/>	Request ID ↓↑	Form Name	Request Type	Status	E2B Status	On Day	Serious	Date of Awareness	⌵
<input type="checkbox"/>	1308	DMID Form - 6.0	Intake Form	QC Pending		124	Yes	24-Jul-2024	

Submitting a Request (PI)

After the PI reviews a request and determines the content is valid, the PI can submit the request to the safety database.

1. From the dashboard **Pending** tab, click the **Review** icon (📄) of the case with status **QC Pending**.



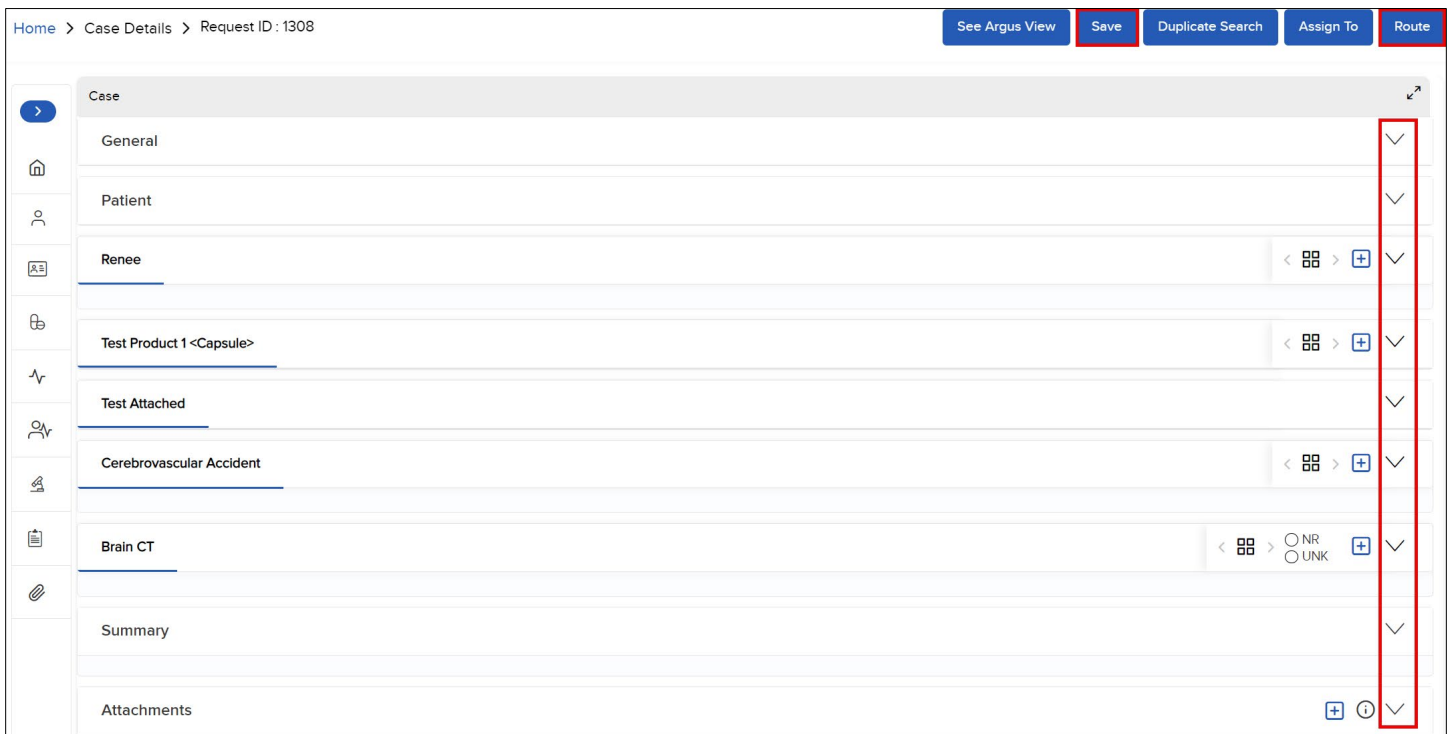
Request ID	Form Name	Request Type	Status	E2B Status	On Day	Serious	Date of Awareness	LSO Start Date	QC'ed By
1308	DMID Form - 6.0	Intake Form	QC Pending		125	Yes	24-Jul-2024	15-Nov-2024	rcb

2. Click the **down arrow** (∨) to expand the desired section(s) in the **Case** to review and edit as needed.

Note: A **Case Details** summary screen gives the PI access to all the data fields entered for the case.

3. If any edits were made, click the **Save** button (Save) to update the request.

4. Click the **Route** button (Route).



Home > Case Details > Request ID: 1308

See Argus View Save Duplicate Search Assign To Route

Case

- General
- Patient
- Renee
- Test Product 1 <Capsule>
- Test Attached
- Cerebrovascular Accident
- Brain CT
- Summary
- Attachments

5. Click **Submit** from the drop menu.



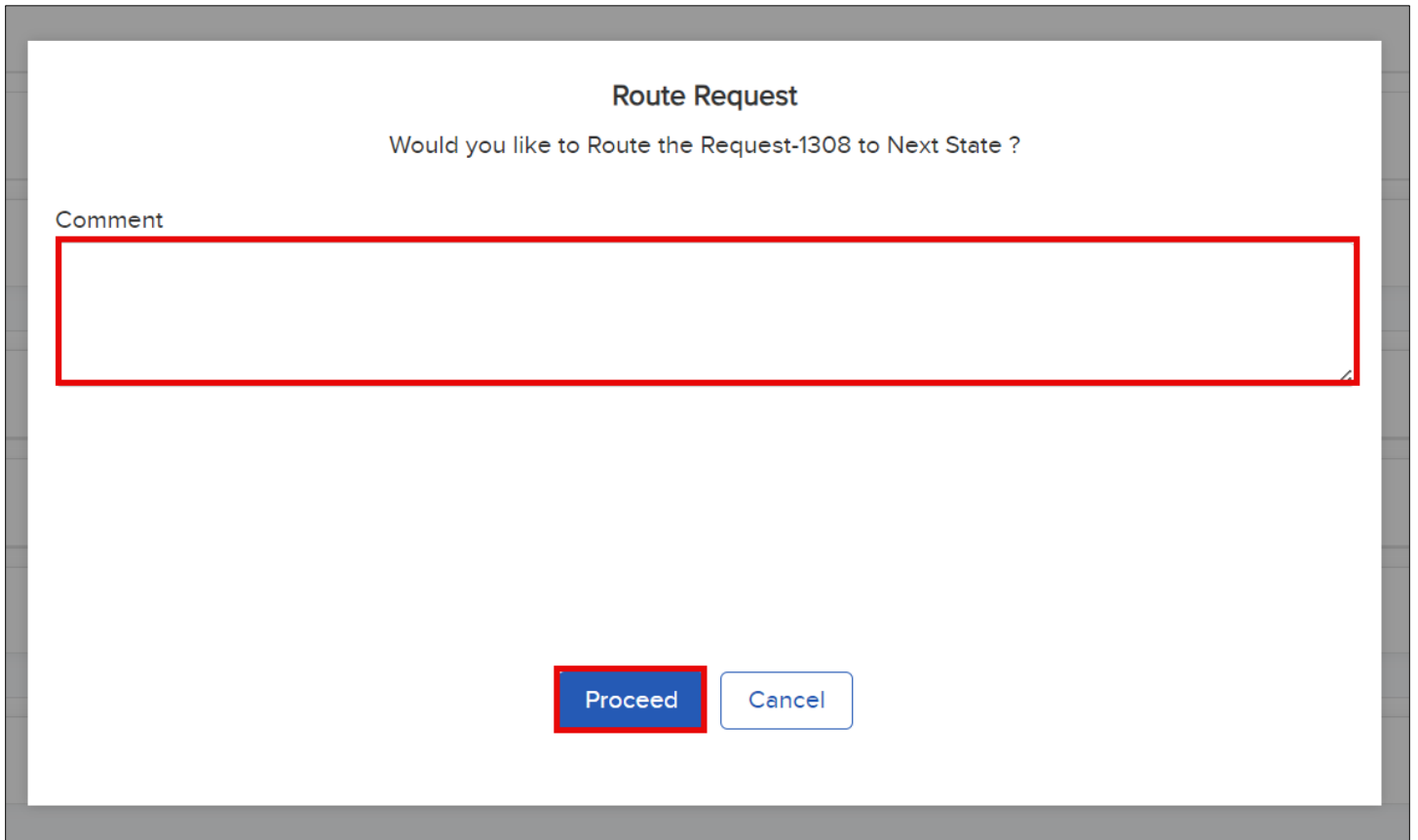
Home > Case Details > Request ID: 1308

See Argus View Save Duplicate Search Assign To Route


Submit

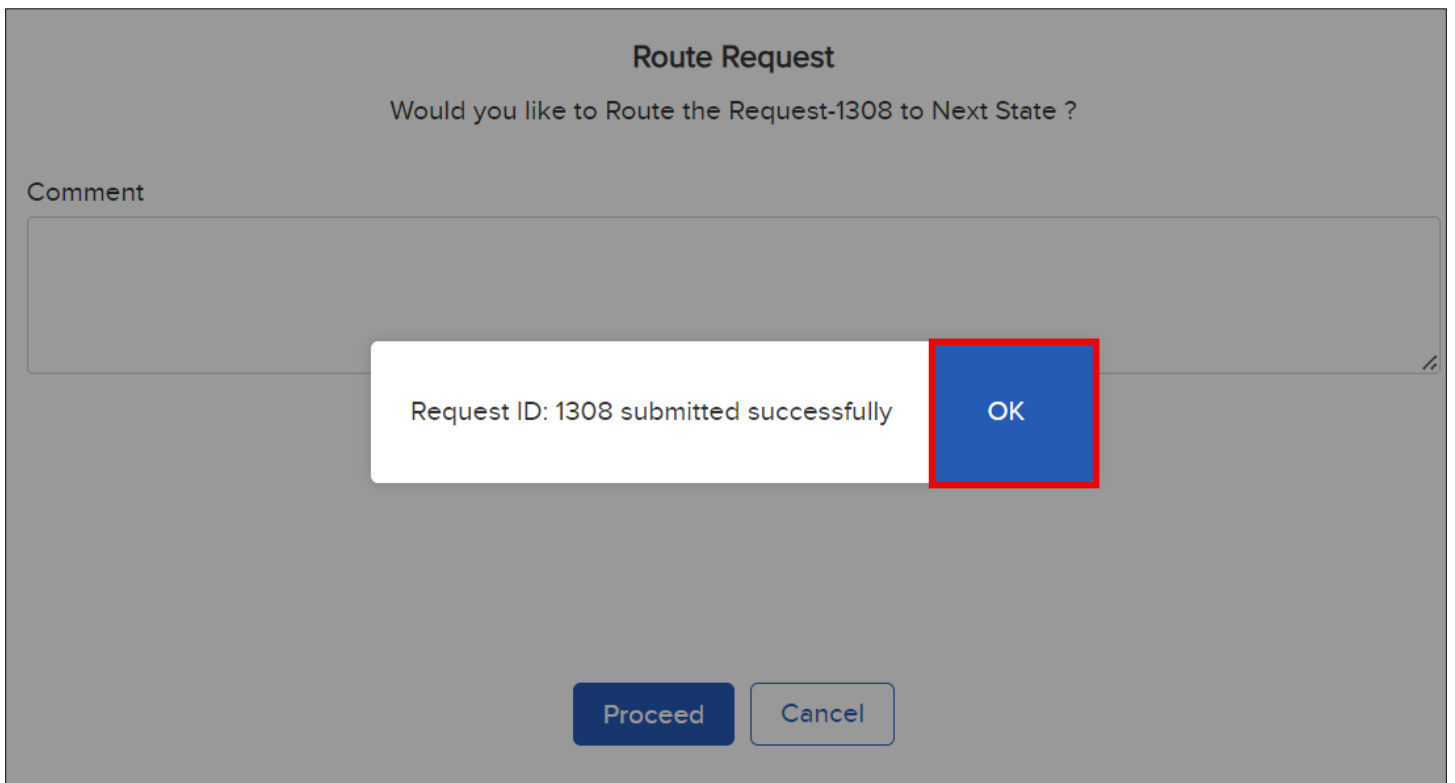
Send Back

6. Enter any appropriate comments and then click **Proceed** () to route to the next state.



The dialog box is titled "Route Request" and contains the text "Would you like to Route the Request-1308 to Next State ?". Below this text is a text input field labeled "Comment" with a red border. At the bottom of the dialog, there are two buttons: "Proceed" (highlighted with a red border) and "Cancel".

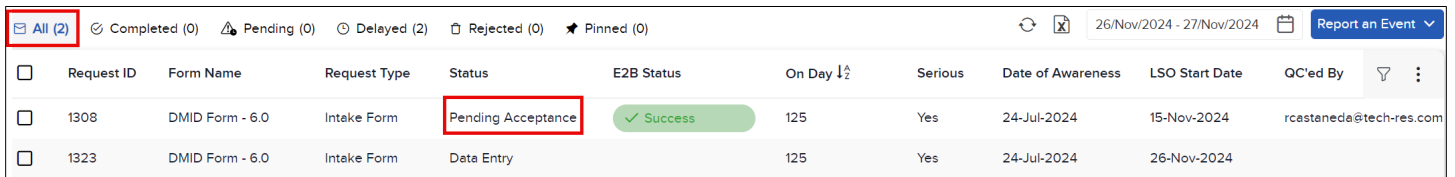
7. Click **OK** () to complete the routing.



The dialog box is titled "Route Request" and contains the text "Would you like to Route the Request-1308 to Next State ?". Below this text is a text input field labeled "Comment". A white message box is overlaid on the dialog, containing the text "Request ID: 1308 submitted successfully" and an "OK" button (highlighted with a red border). At the bottom of the dialog, there are two buttons: "Proceed" and "Cancel".

8. Return to the **dashboard** (Home) and click the **All** tab.

Note: The submitted case appears with the status **Pending Acceptance**.



<input type="checkbox"/>	Request ID	Form Name	Request Type	Status	E2B Status	On Day ↓↑	Serious	Date of Awareness	LSO Start Date	QC'ed By	
<input type="checkbox"/>	1308	DMID Form - 6.0	Intake Form	Pending Acceptance	✓ Success	125	Yes	24-Jul-2024	15-Nov-2024	rcastaneda@tech-res.com	
<input type="checkbox"/>	1323	DMID Form - 6.0	Intake Form	Data Entry		125	Yes	24-Jul-2024	26-Nov-2024		

Note: Only the PI will receive email notifications when the status of a report changes. PIs will be recipients of automated notifications when a case is ready for their review, has been reviewed, has been submitted to DMID-CROMS PVG or transmission to DMID-CROMS PVG has failed.

Contacting Staff for Assistance

- For HiLIT technical questions contact: ITsupport@dmidcroms.com.
- For all other questions related to the report submission process contact: PVG@dmidcroms.com.