Apheresis, Local Cell Lab, & Dual

Version 6.0

Chain of Identity & Custody

Managing Chain of Identity & Chain of Custody (COI/C)
Across the Advanced Therapies Order Fulfillment Process

Johnson&Johnson

Audience: Commercial

Table of Contents

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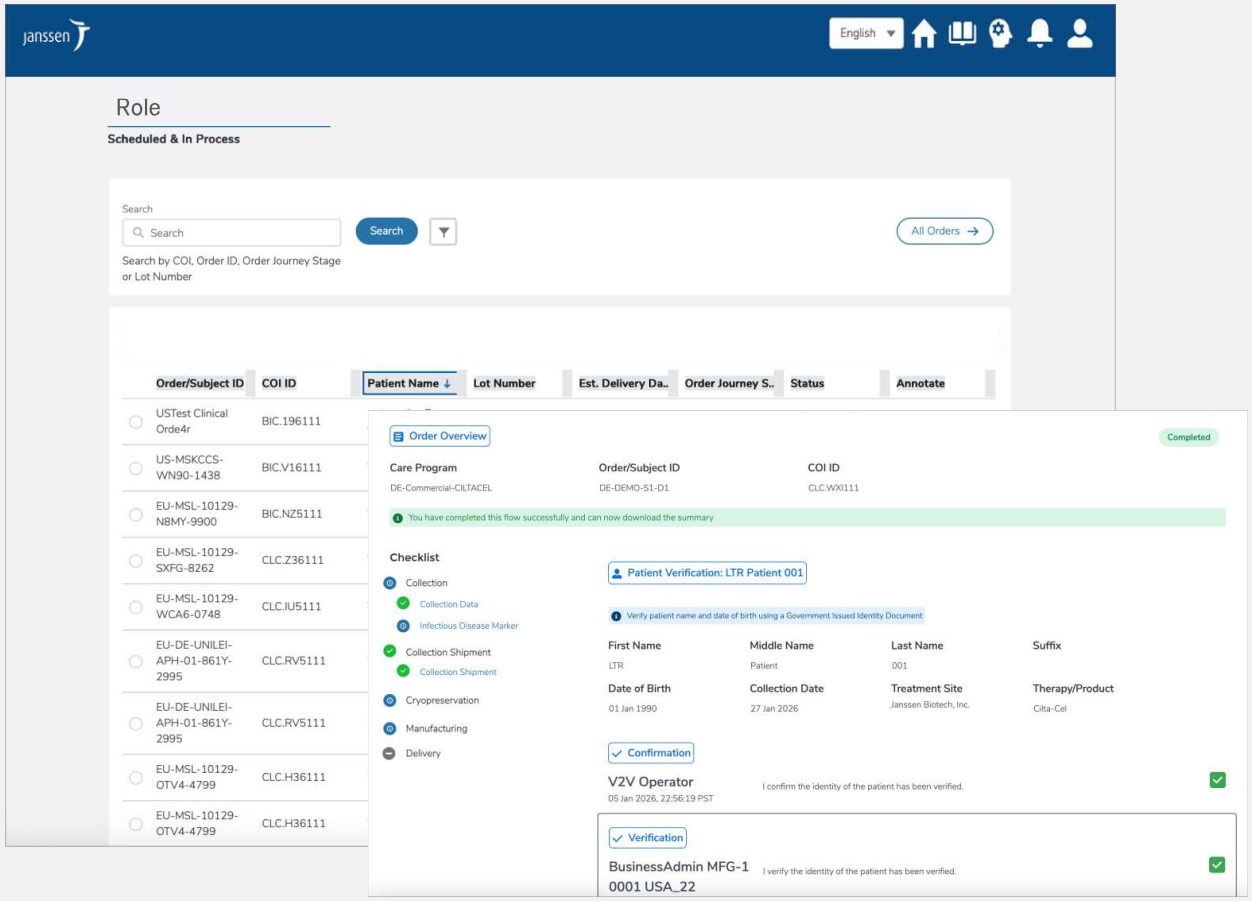
1. Overview

What is the Chain of Identity/ Custody portal?

The Chain of Identity/Custody (COI/C) portal tracks the chain of identity and chain of custody hand-offs throughout the order fulfillment process by managing and verifying proper handling of the drug product.



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Abbreviations

AWB	Airway Bill
COC	Chain of Custody *(not CoC, which is Certificate of Compliance)*
COI	Chain of Identity
COI/C	Chain of Identity/Custody
EQ	External Quality
DIN	Donor Identification Number
IDM	Infectious Disease Marker
NC	Non-Conformance
OKTA	(*Enterprise*) Identity Management Service
SEC-DIS	Single European Code Donor ID Sequence

Patient Identifier

In COI/C, you may be asked questions to enter in a patient identifier during your workflow. This is how the portal identifies if you have the correct order.

Different regions and countries use different identifiers. Please ensure that you refer to the most specific patient identifier for your country or region.

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Country/Region	PII Field 1	PII Field 2
Australia	DIN	Apheresis ID
Belgium	SEC-DIS	
Brazil	DIN	Apheresis ID
Canada	DIN	Apheresis ID
Czech Republic	SEC-DIS	
Denmark	SEC-DIS	
France	SEC-DIS	
Germany	SEC-DIS	
Greece	SEC-DIS	
Israel	DIN	Apheresis ID
Italy	SEC-DIS	DIN
Japan	Apheresis ID	
Korea	Apheresis ID	
Netherlands	SEC-DIS	
Norway	SEC-DIS	
Poland	SEC-DIS	
Spain	SEC-DIS	
Sweden	SEC-DIS	
Switzerland	DIN	
UK	DIN	SEC-DIS
US	DIN	Apheresis ID

The Privacy Policy for the use of the COI/C Portal is available at the following link: COI/C Privacy Policy.

Please read it carefully.

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2. Login

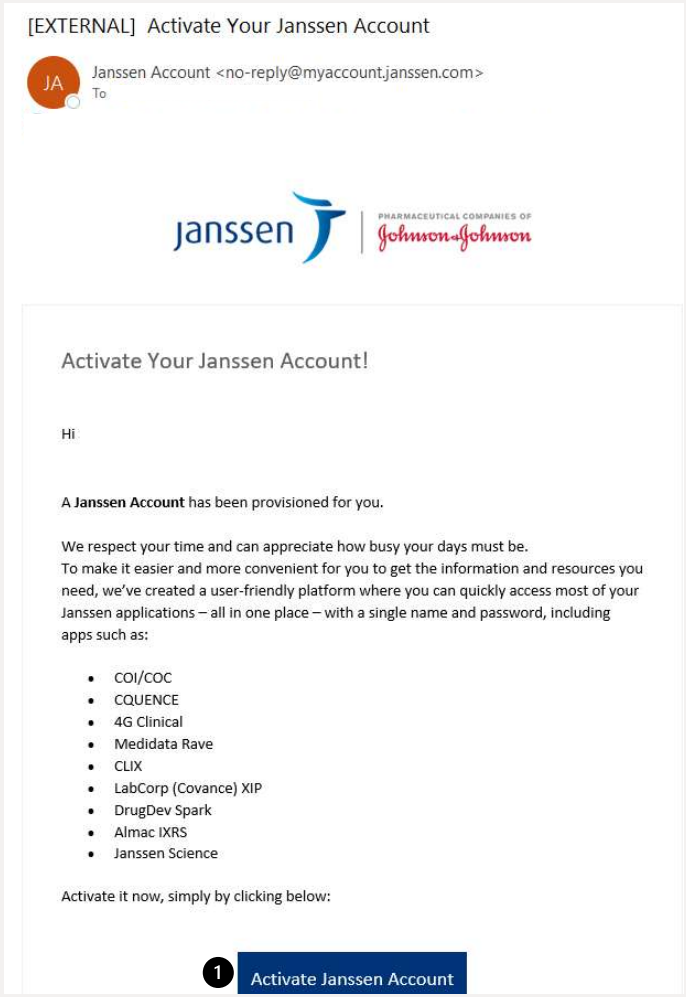
The following section has screenshots that may vary slightly for your role and region.

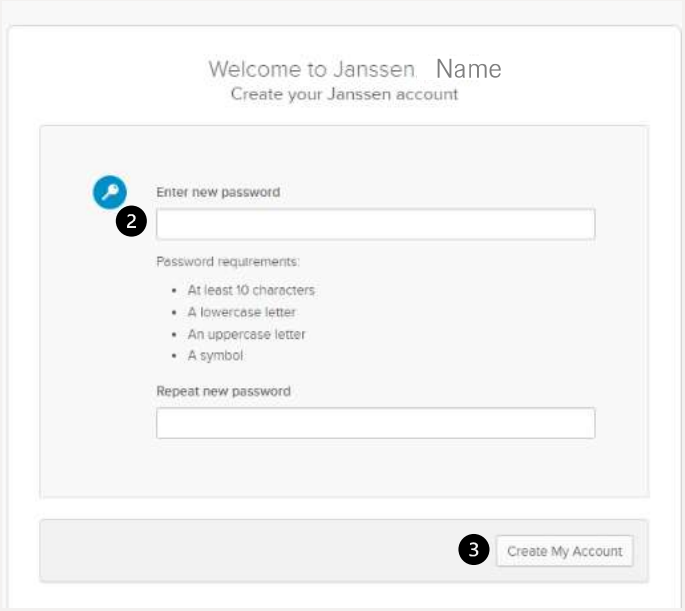
Activation

COI/C uses a sign-in software called OKTA. If you have an active OKTA account, you do not need to follow this process.

1. Within 30 days of receiving the activation email, press **“Activate Janssen Account”**.
2. Enter password twice.
3. Press **“Create My Account”**.

Note: If a user doesn't log into their account within 30 days, their account would be deactivated ; OKTA would then need to be contacted by your J&J representative





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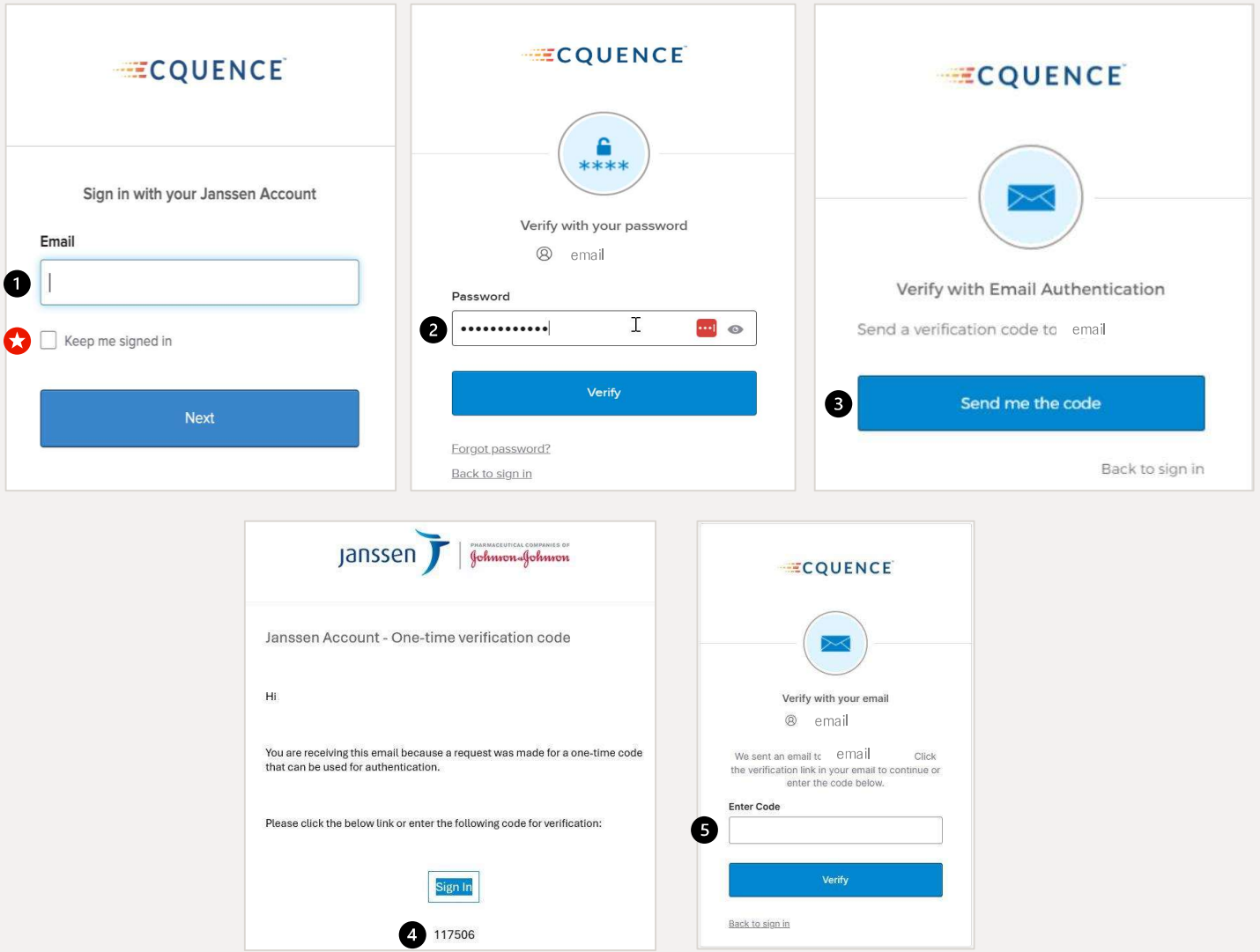
Login

1. Enter email and press **“Next”**.
   - If you click “Keep me signed in”, you won’t need a code for the next 7 days after verifying (Step 3).
2. Enter password and press **“Verify”**.
3. Press **“Send me the code”**.
4. Copy code from email.
5. Enter the code and press **“Verify”**.

Important: After 30 minutes of inactivity, you will automatically be logged out



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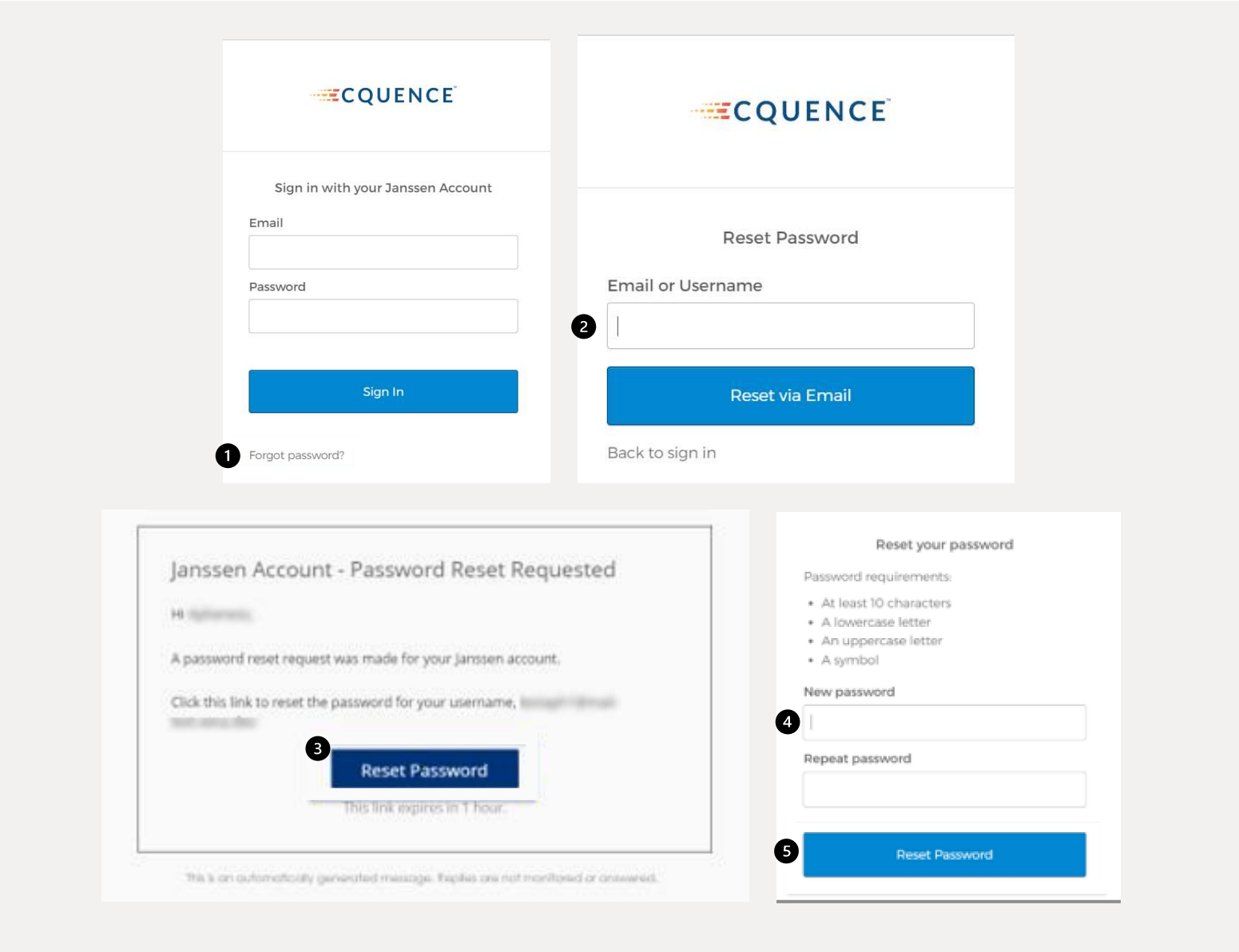
Reset Password

1. Press “**Forgot password?**”
2. Enter email or username.
3. Within 1 hour of receiving email, press “**Reset Password**”.
4. Enter new password twice.
5. Press “**Reset Password**”.



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3. Portal Layout

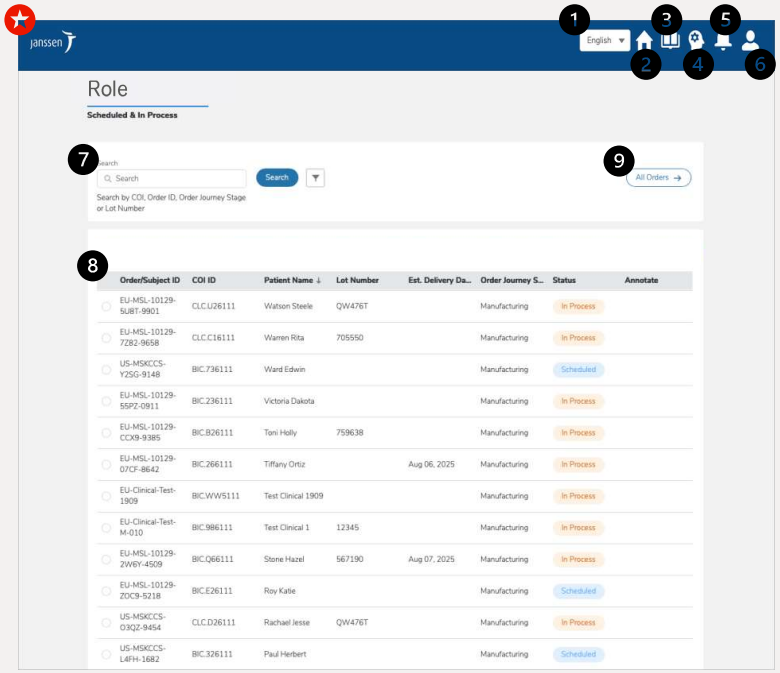
The following section has screenshots that may vary slightly for your role and region.

3.1 Home

Home

Homepage: The most recent 300 Scheduled & In Process records

1. Press and select your desired **language**.
2. Press to return to **home** page.
   ★ If you click the logo in the top left corner, it will also return you to home.
3. Press to view **reports**. The reports visible to you are dependent on your role and region.
4. Press to view **resource page**. The articles published related to your category will appear.
5. Press to view **notifications**. A red dot appears when a new notification is available.
6. Press to view your name or **log out**.
7. Enter desired order in **search** or **filter** by desired criteria before pressing “Apply All and Search”.
8. Your site’s in-progress and scheduled orders will appear here by default, unless you search or filter.
9. Press to view **all orders** for your site.
   All orders not visible on home page are accessible within the ‘All Orders’ page.



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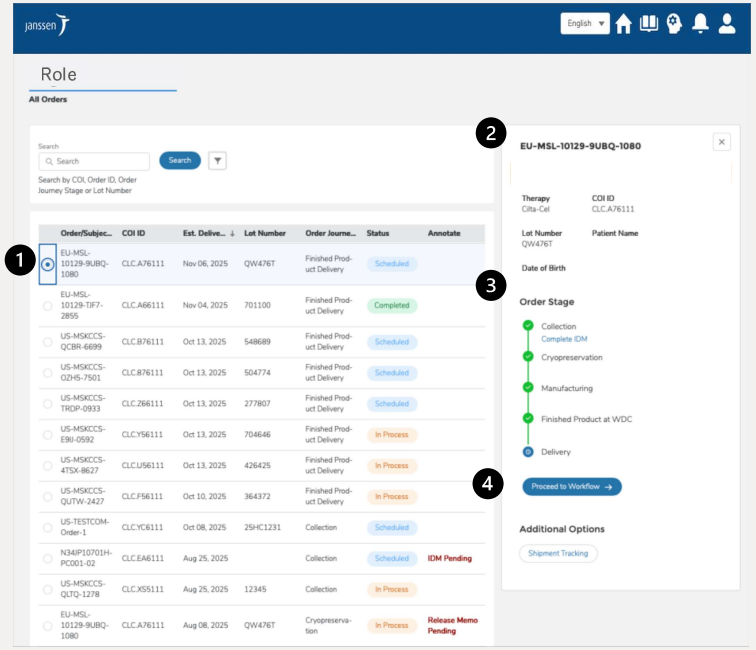
Side Panel

1. To **open** the side panel, select the circle radio button (on the left-hand side) for the order you'd like to view.
2. Review the **patient and product information** to ensure you have selected the correct order.
3. Order Stage shows the progression of the order through its milestones. Press **"Proceed to Workflow"** to see your workflow or previously completed pages in your order journey.
4. Additional buttons may be available to you such as **Shipment Tracking** for quick links to shipment links or **All Summaries** to view completed workflows.



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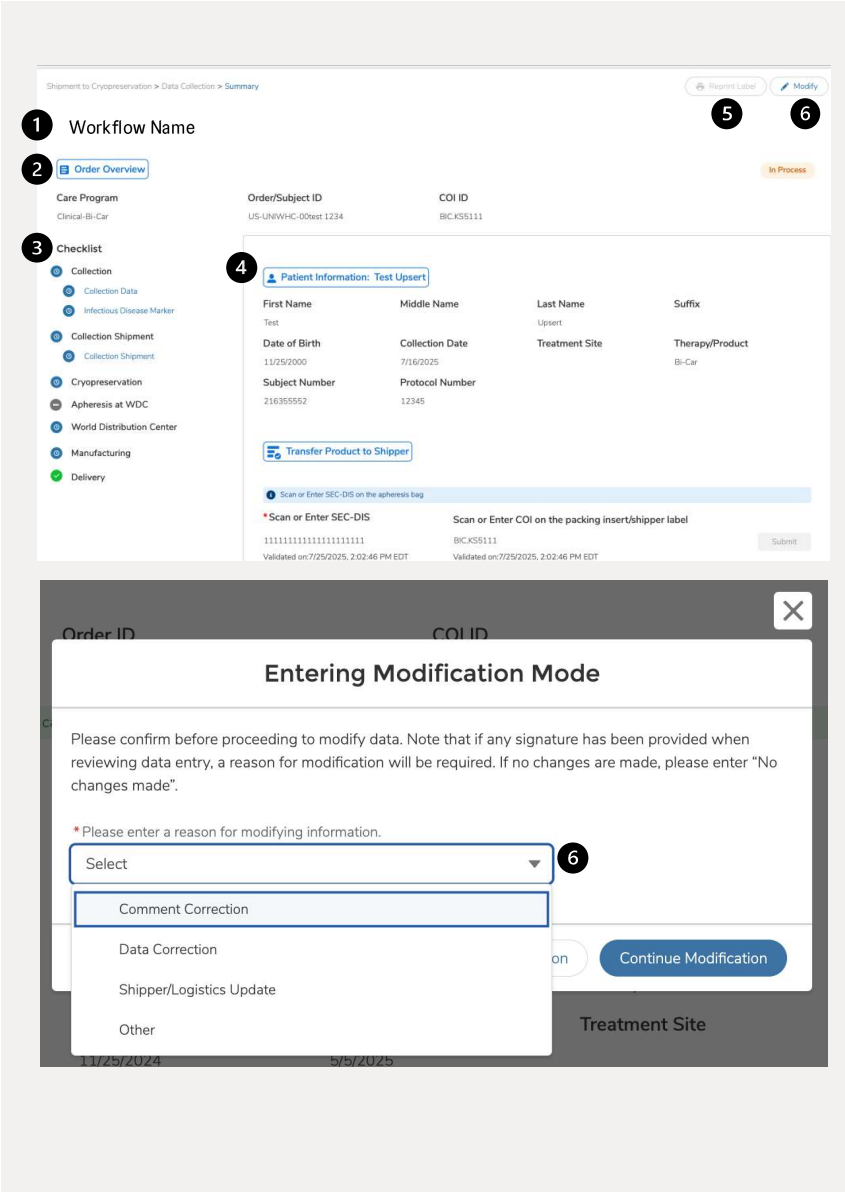
3.2 Navigation & Portal Functionality

Upper Page

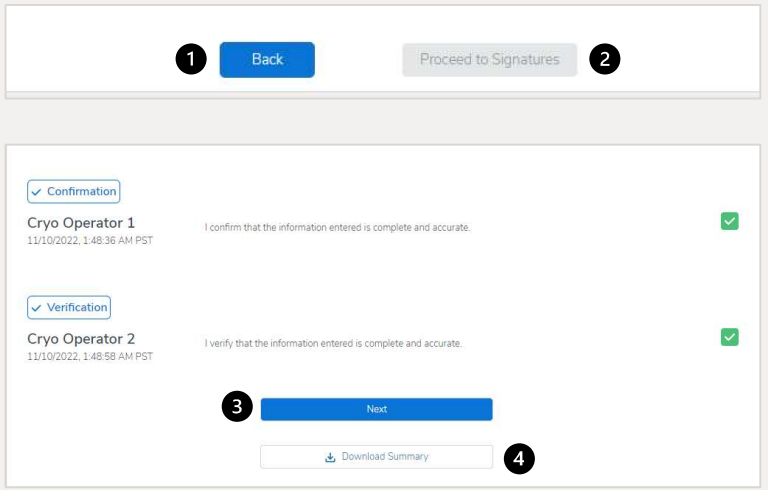
1. The **title** of the page.
   i. This is an example of the Collection Shipment page.
2. Review the **order overview** to confirm you have selected the correct order.
3. View the **checklist** to see the status of each section. Navigate to an available workflow page by pressing on its blue title.
4. Review the **patient and product information** to confirm that all information is correct. Contact your J&J representative if anything is incorrect.
5. Press **"Reprint Label"** to re-download a label that has been previously generated and signed for in a workflow.
6. Press **"Modify"** to edit a page. Select the reason for modification and press **"Continue Modification"**
   i. Modification abilities are dependent on access type.



Lower Page

Scroll to the bottom of your workflow page
to find these buttons.

1. If you can access multiple workflow pages, you may have a **“Back”** button available at the bottom of the page. This will bring you to the previous page or to the Home page.
2. If the workflow needs signatures, press **“Proceed to Signatures”** to reveal where to sign.
3. If you can access multiple workflow pages, you may have a **“Next”** or **“Proceed to Collection Shipment”** button available at the bottom of the page. This will bring you to the next page to be completed. If you have this button, press it to ensure that your workflow is completed.
4. If workflow is complete, press **“Download Summary”** to create a PDF version of the page.



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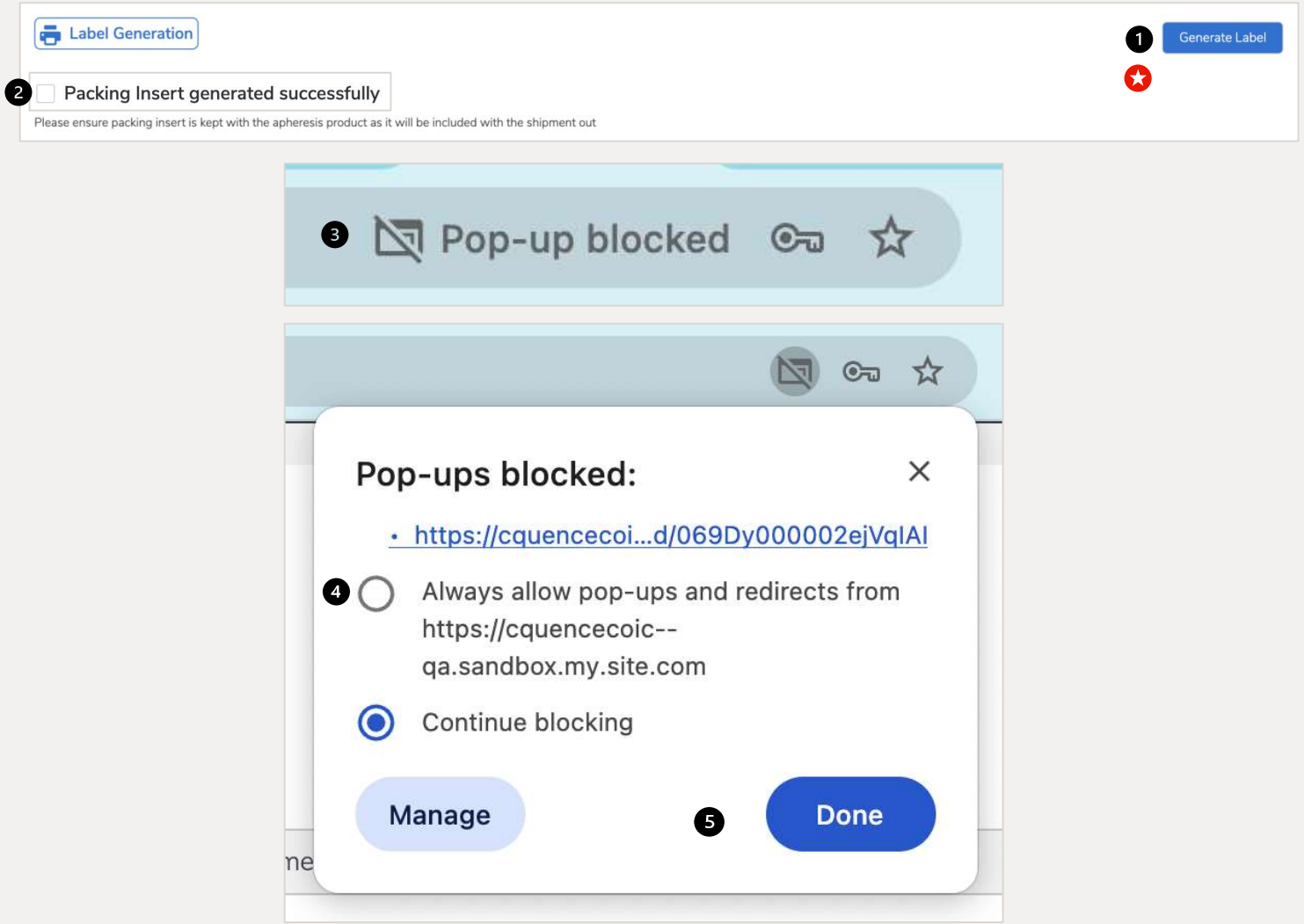
Label Generation

If the label did not generate as expected, follow Upper Page's instructions for "Reprint Label".

1. Press "**Generate Label**".
   - If it is blocked, you must enable pop-ups.
2. Press checkbox on.

If blocked on Chrome:

3. Press "Pop-up blocked".
4. Press first circle.
5. Press "Done".



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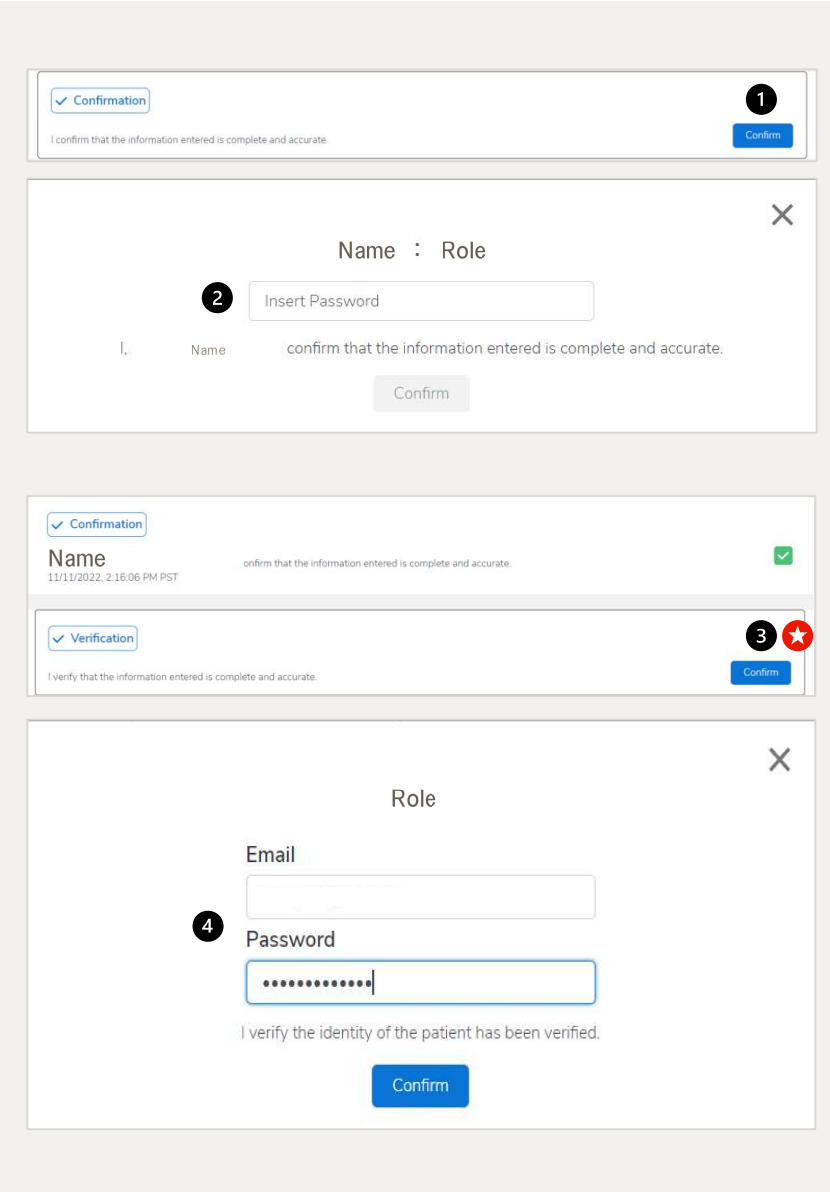
Signatures

1. Review all information entered on the page and press “**Confirm**”.
2. Enter your password and press “**Confirm**”.
3. A second person must review the information entered on the page. Once reviewed and confirmed that it is correct, press “**Confirm**”. It is important to confirm that the information is correct.

   ★ The second person may log in from another computer to verify the information if they prefer not to use the same computer.
4. The second person needs to enter their email and password associated with the portal before pressing “Confirm”.



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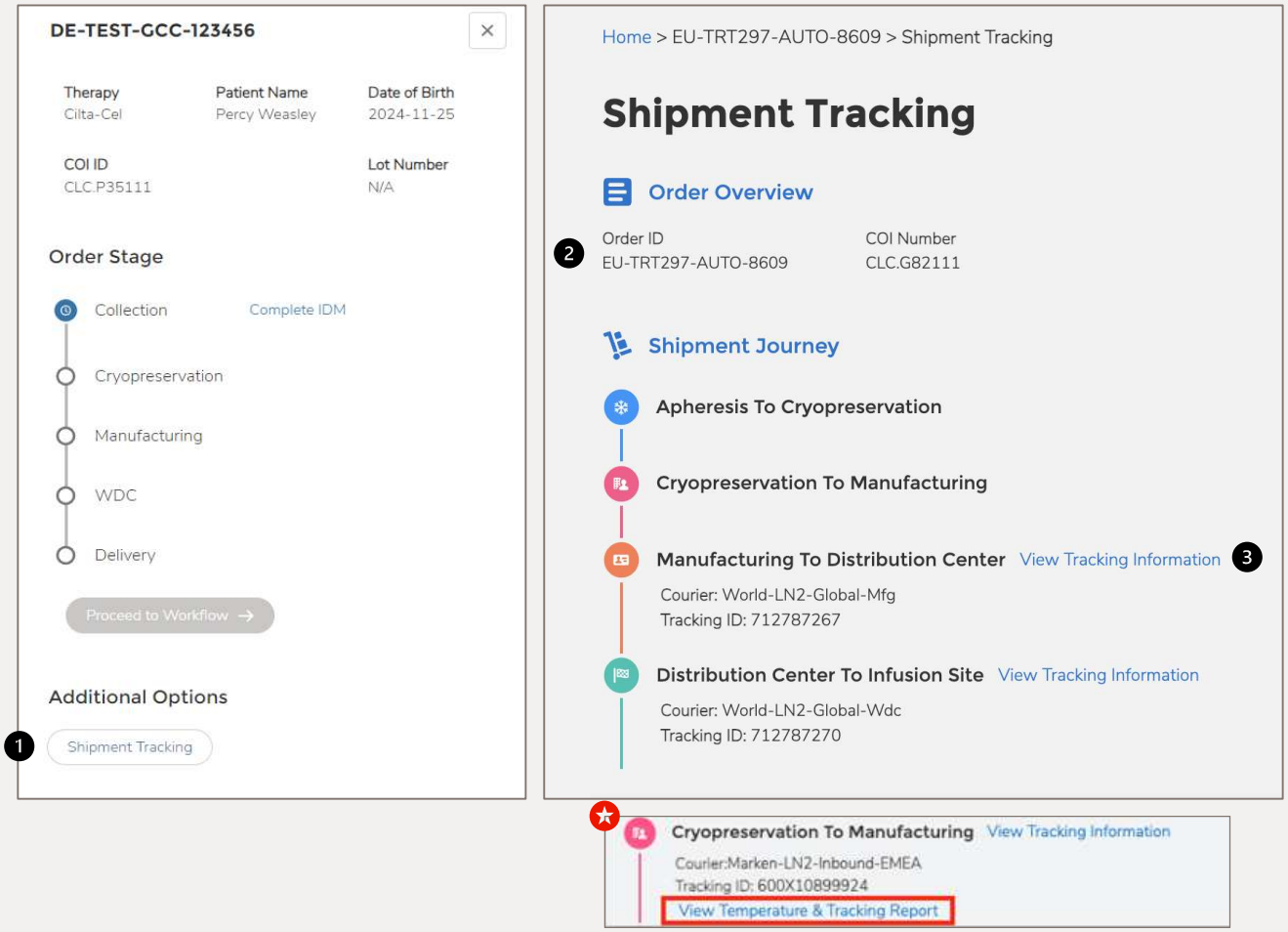
3.3 Shipment Tracking

Shipment Tracking

1. Press "**Shipment Tracking**" in the Side Panel.
2. Review the Order Overview to ensure that you are viewing your desired order.
3. Find the desired part of the shipment journey and select the corresponding link:
   - Click '**View Tracking Information**' to see standard tracking on the courier's website
   - Click '**View Temperature & Tracking Report**' (*for Marken LN2 shipments*) to view Temperature & Tracking Report.



4. Workflows

Roles

Apheresis

Tasks
- Infectious Disease Marker (outside of North America)
- Collection

Local Cell Lab

Tasks
- Ship material
- Receive final product

For sites that also perform local cryopreservation:
- Cryopreservation
- Release Memo

Dual

Tasks
- Infectious Disease Marker (outside of North America)
- Collection
- Ship material
- Receive final product

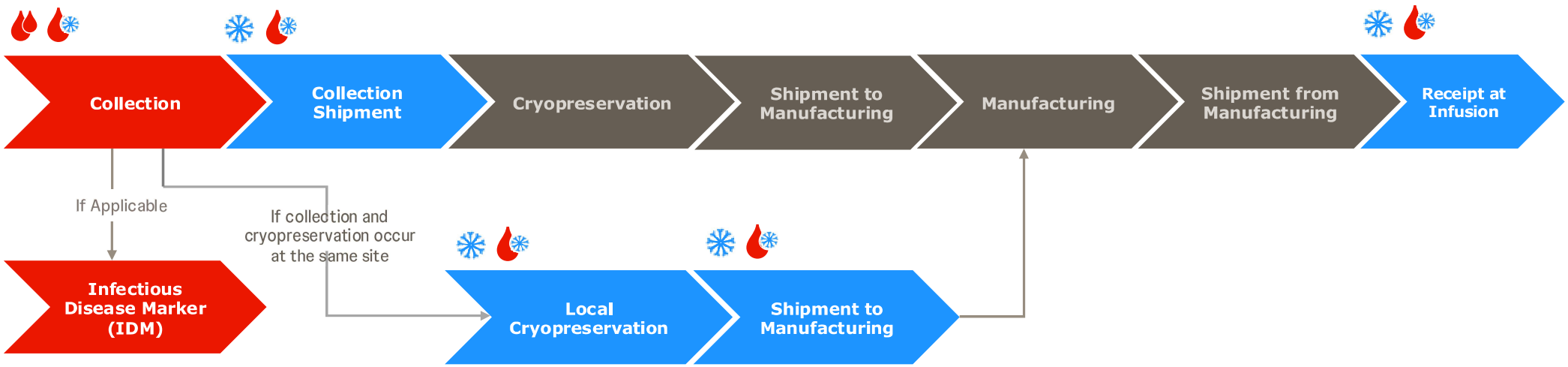
For sites that also perform local cryopreservation:
- Cryopreservation
- Release Memo

Process

Key

- Apheresis
- Local Cell Lab
- Other

Dual can complete both Apheresis & Local Cell Lab sections



4.1 Collection

Apheresis

Dual

Covers tasks related to patient apheresis.

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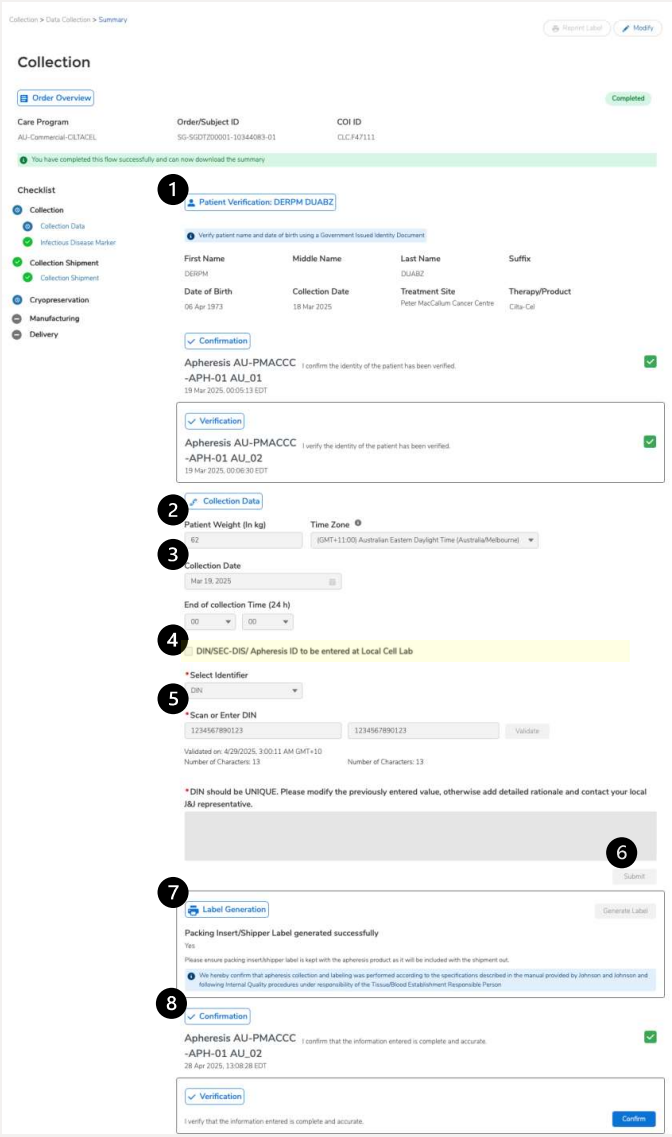
Collection

1. Follow 3.2's instructions for patient and product information as well as 3.2's instructions for signatures.
2. Enter the patient's weight in kilograms. Do not use commas.
3. Enter the collection date, its end time.

   Note: The time zone will be automatically populated. You will need to reach out to the J&J representative to get it changed.

4. If the final Unique identifier will be entered at the Cell Lab press the checkbox. Steps 5 and 7 will be hidden, if selected.
   - *(Applicable primarily to the EMEA market)* ☐ DIN/SEC-DIS/ Apheresis ID to be entered at Local Cell Lab
5. For sites with final unique identifier at collection, Enter your patient identifier twice and press "**Validate**".
6. "**Submit**" the Collection Data section.
7. Review 3.2's instructions for label generation.
8. Follow 3.2's instructions for signatures.



4.2 Infectious Disease Marker (IDM)

Apheresis

Dual

For sites outside of North America.\

Note: IDM is not Applicable to Japan orders, JCUU-34488

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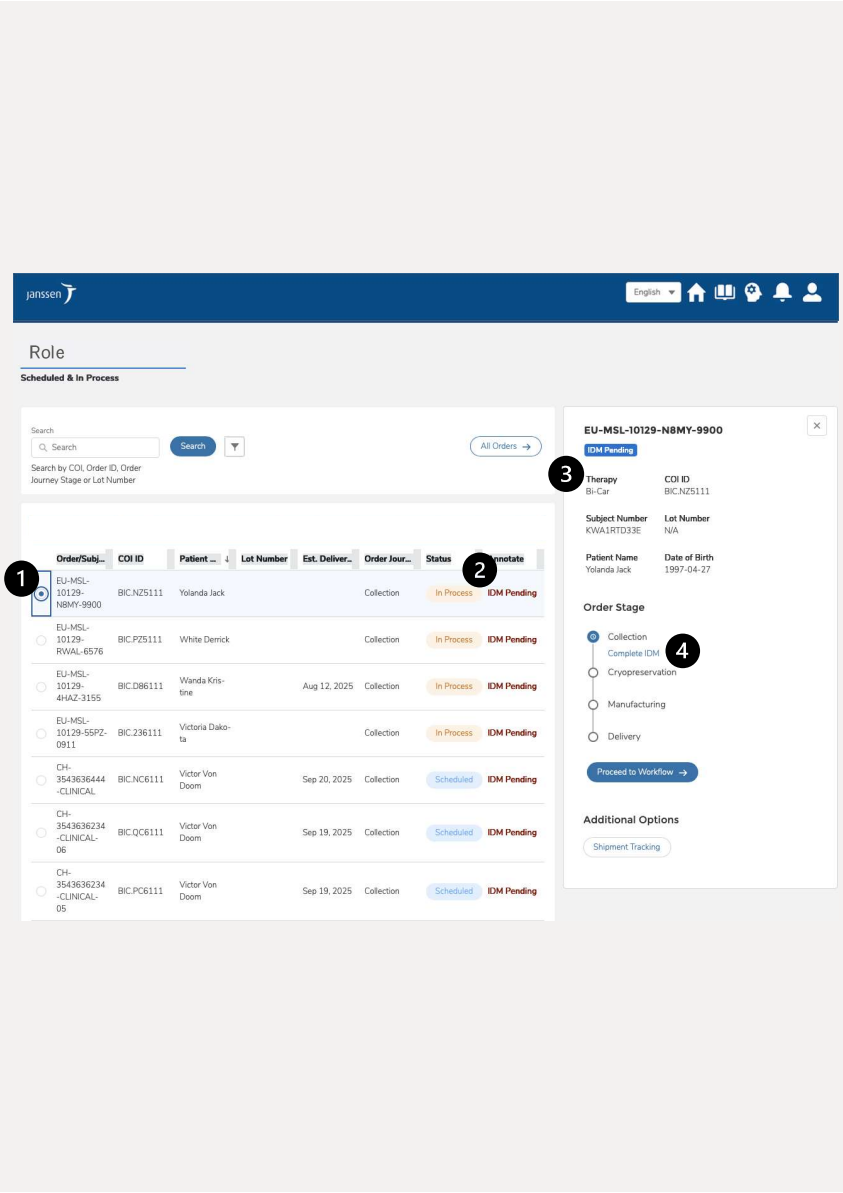
Open IDM Page

1. To open the side panel, select the circle radio button on the order you'd like to view.
2. For regions where IDMs are a requirement, view the Annotate column of the desired order and look for "**IDM Pending**".

   ***Note**: Regions where IDMs are not required will not see this option.*

3. Review the patient and product information to ensure you have selected the correct order.
4. Press "**Complete IDM**".



EMEA IDM

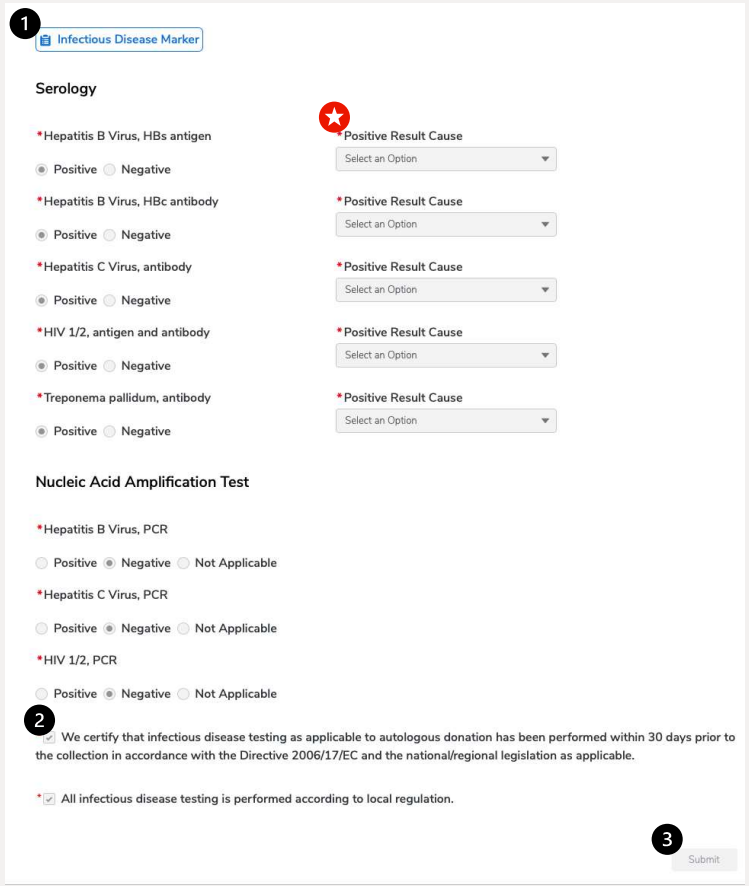
1. Select '**Positive**' or '**Negative**' for all required Hepatitis, HIV, and Syphilis markers under the Serology and Nucleic Acid sections.

   ***Note**: If any result is marked 'Positive', you must select a valid reason from the 'Positive Result Cause' dropdown menu to proceed*

2. Check the two mandatory boxes at the bottom of the form to certify that testing was performed in accordance with Directive 2006/17/EC and local regulations.

3. Click **Submit** to finalize the IDM record

   ***Note**: Electronic signatures will be prompted on the next screen.*



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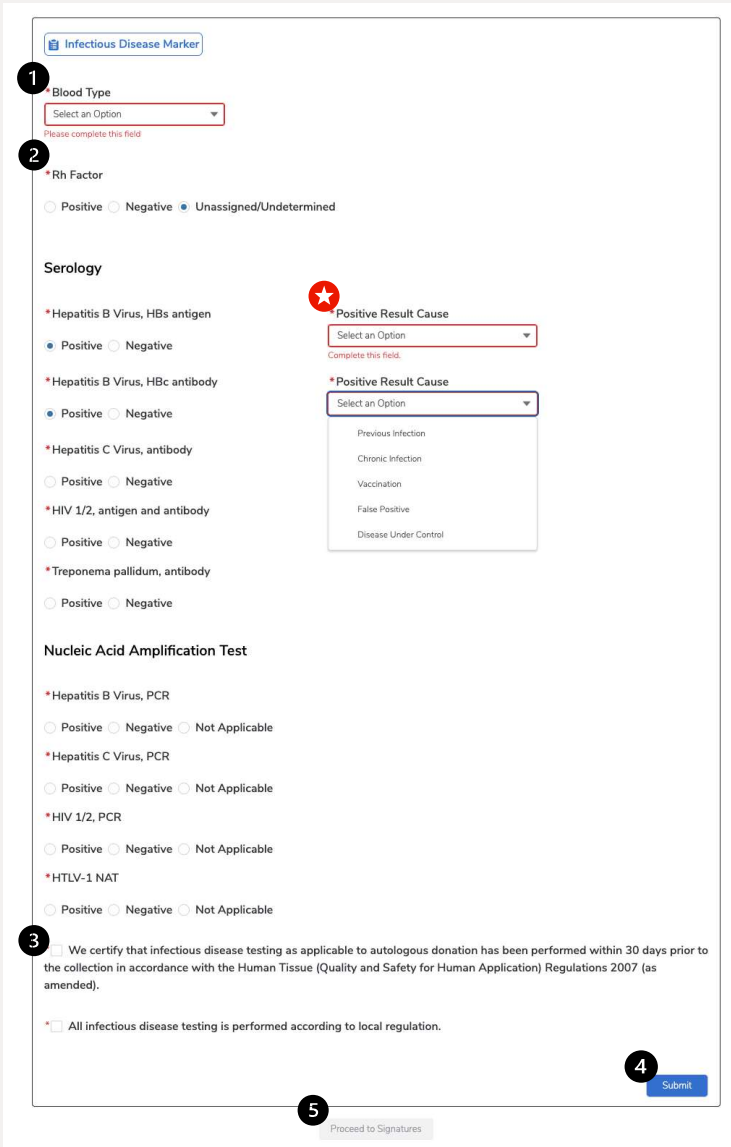
United Kingdom IDM

1. Select the patient's **Blood Type** from the dropdown menu and indicate the Rh Factor (Positive, Negative, or Unassigned).
2. Complete the Positive/Negative/Not Applicable radio buttons for all markers.

   ✪ ***Note**: If any result is marked 'Positive', you must select a valid reason from the 'Positive Result Cause' dropdown menu to proceed*

3. Check the mandatory boxes to certify compliance with the '*Human Tissue Regulations 2007' and local regulation.*
4. *Click **Submit** to save the record.*
5. Follow 3.2's instructions for signatures.



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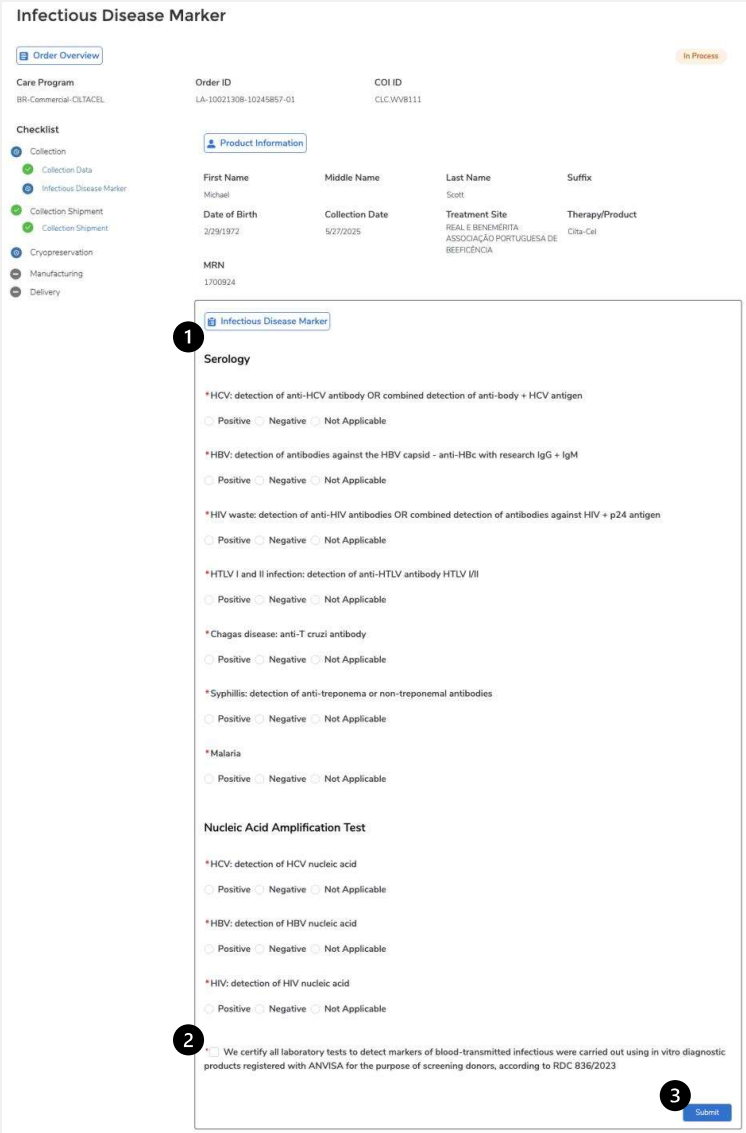
LATAM IDM

1. Select '**Positive**', '**Negative**', or **Not Applicable** for all required Hepatitis, HIV, and Syphilis markers under the Serology and Nucleic Acid sections.
2. Check the mandatory box at the bottom to certify that test were performed using products registered with ANVISA and in accordance with RDC 836/2023
3. Click **Submit** to finalize the record.



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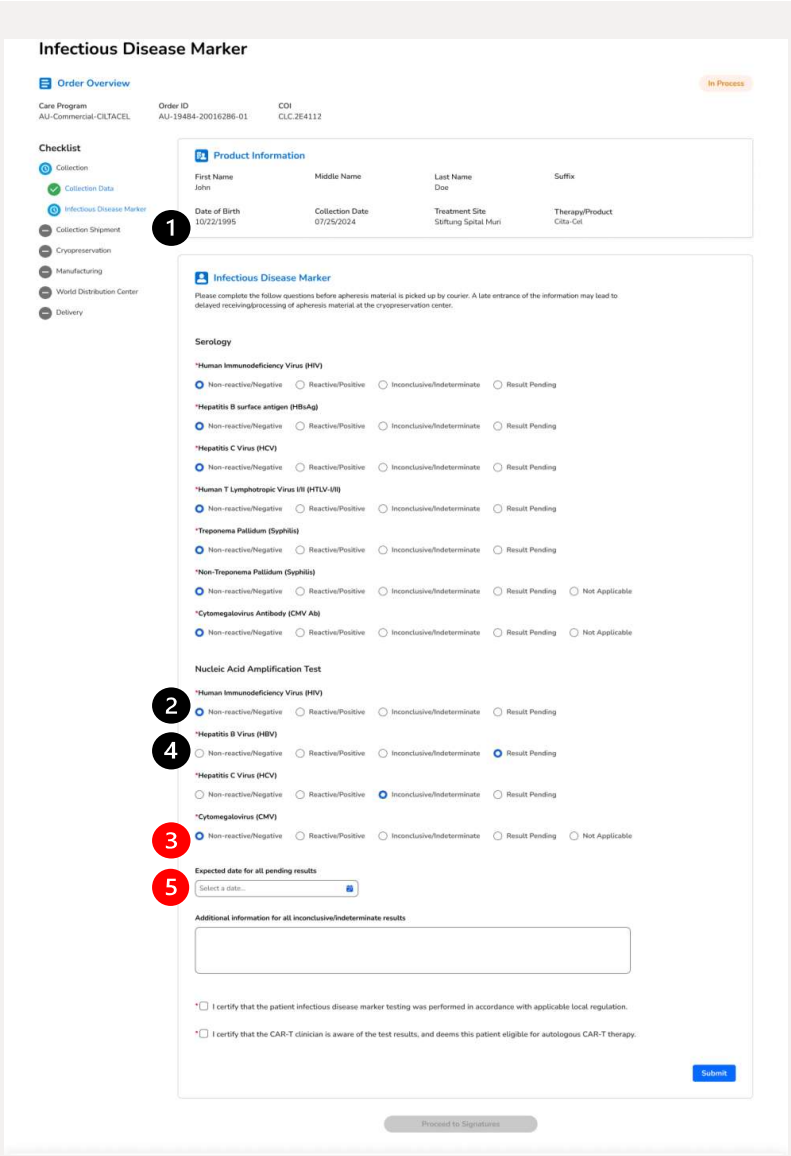
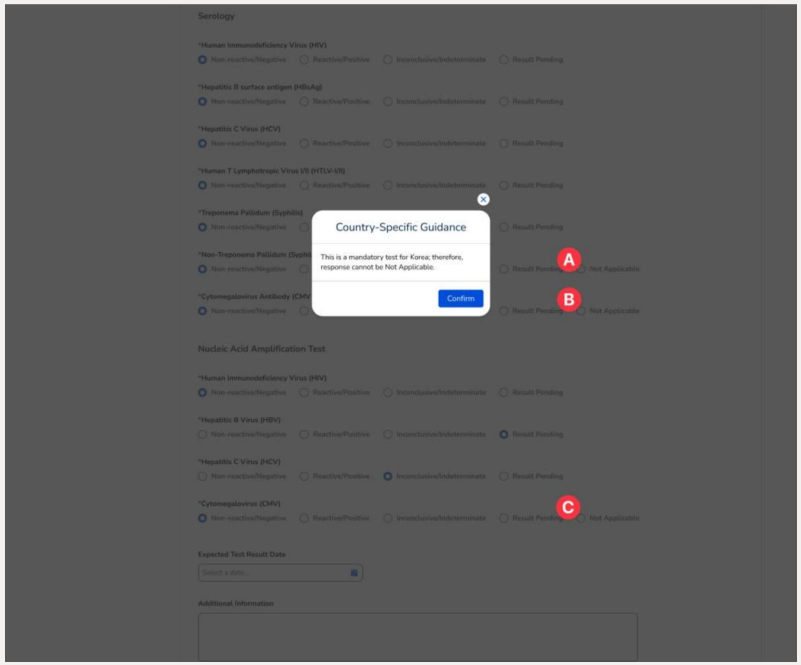
APAC IDM

1. Complete the questions:
2. If a particular test is selected as '**Result Pending**', the '**Expected Date for all pending results**' field (*#3*) will present itself.
4. If a particular test is selected as '**Inconclusive/Indeterminate**', you will see an '**Additional information for all inconclusive/indeterminate results**' field (*#5*) appear



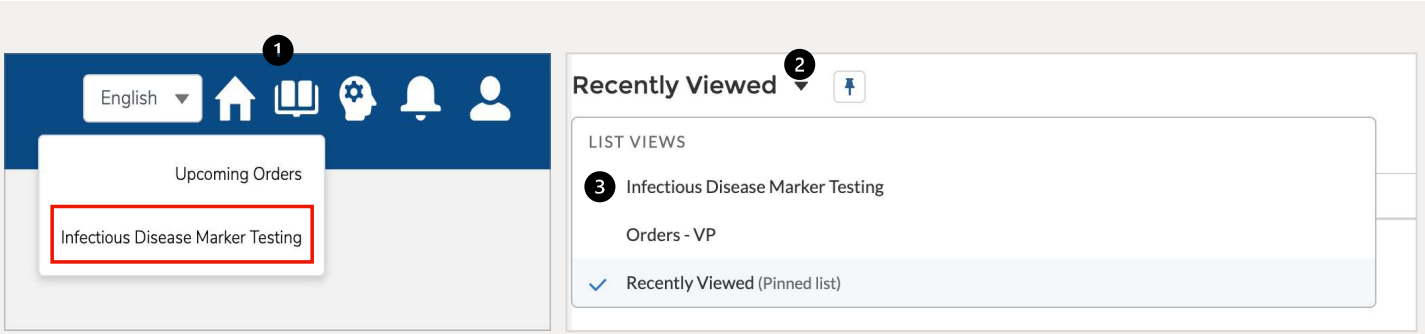
APAC IDM
(*Continued*)

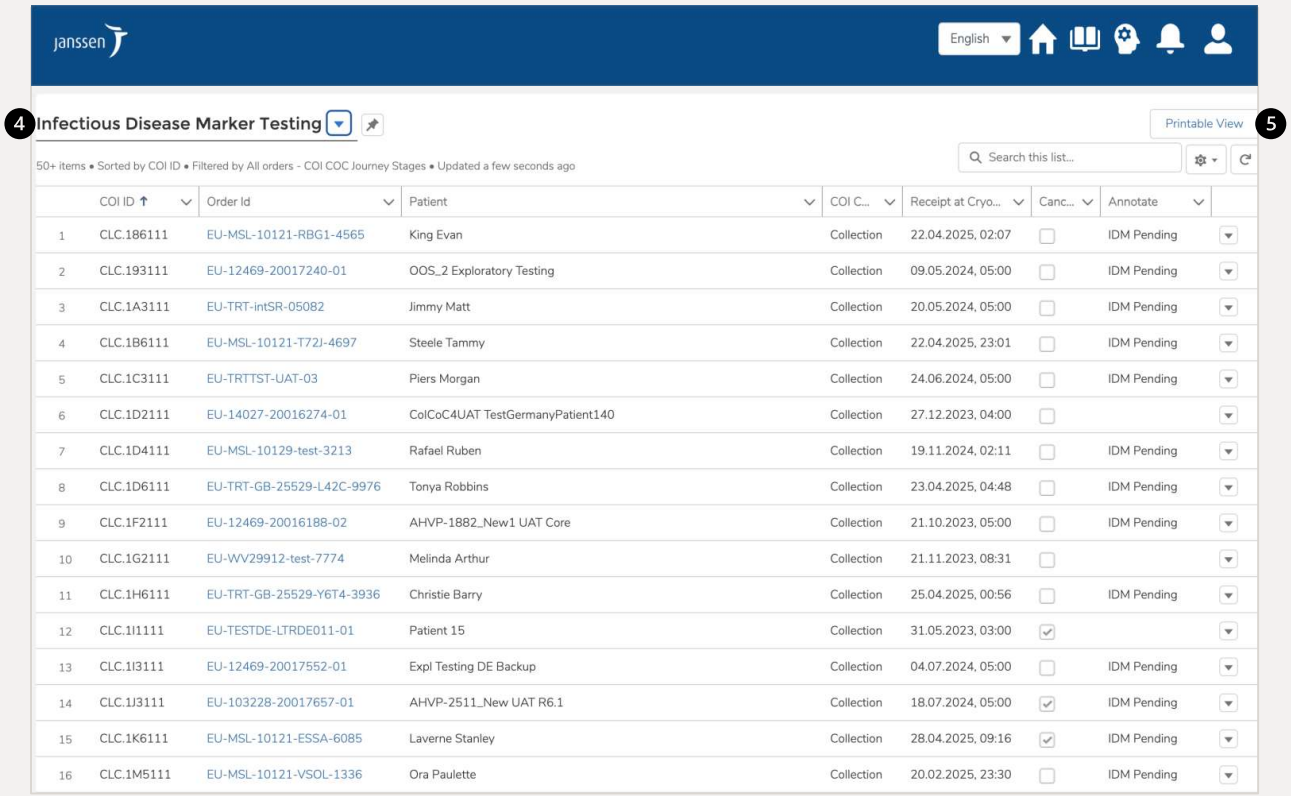
7. If a selection is marked as '**Not Applicable**' (*#A,B,C*), a warning will present itself, prompting a confirmation.
8. *Not Shown:* Follow prior 3.2's instructions for signatures.



IDM Report

1. To pull a report, press the book icon, and select “**Infectious Disease Marker Testing**”.
2. Press the down arrow.
3. Select “**Infectious Disease Marker Testing**”.
4. View report.
5. Press “**Printable View**” to print or download.





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4.3 Collection Shipment

Local Cell Lab

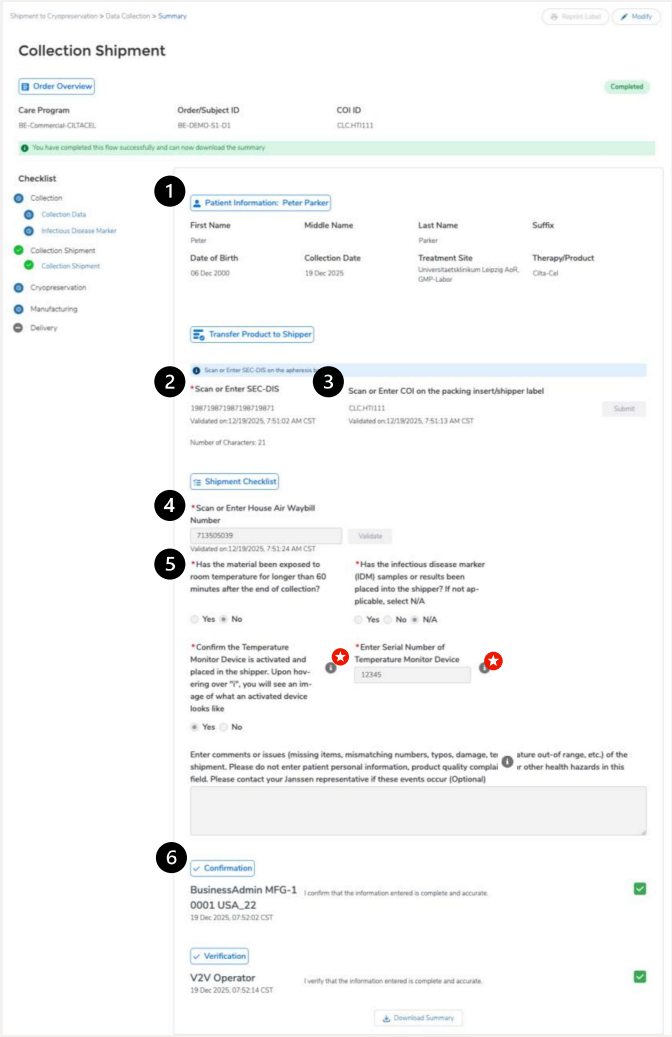
Dual

Covers tasks related to shipment if the order will be cryopreserved at a different location.

Collection Shipment

1. Follow 3.2's instructions for patient and product information.
2. For EMEA only, if entering the patient identifier was skipped in Collection, enter and validate your patient identifier.
3. Scan or enter the patient identifier and the COI on the packing insert. Press "**Validate**" and submit section.
4. Scan or enter the house air waybill (AWB) number.
5. Enter the shipping information. If an unfavorable answer is selected, you must answer the mandatory follow-up question that may appear on the screen.

   ✪ *Hovering above the 'i' icon will display the appropriate device for reference*
6. Follow 3.2's instructions for signatures.



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4.4 Local Cryopreservation

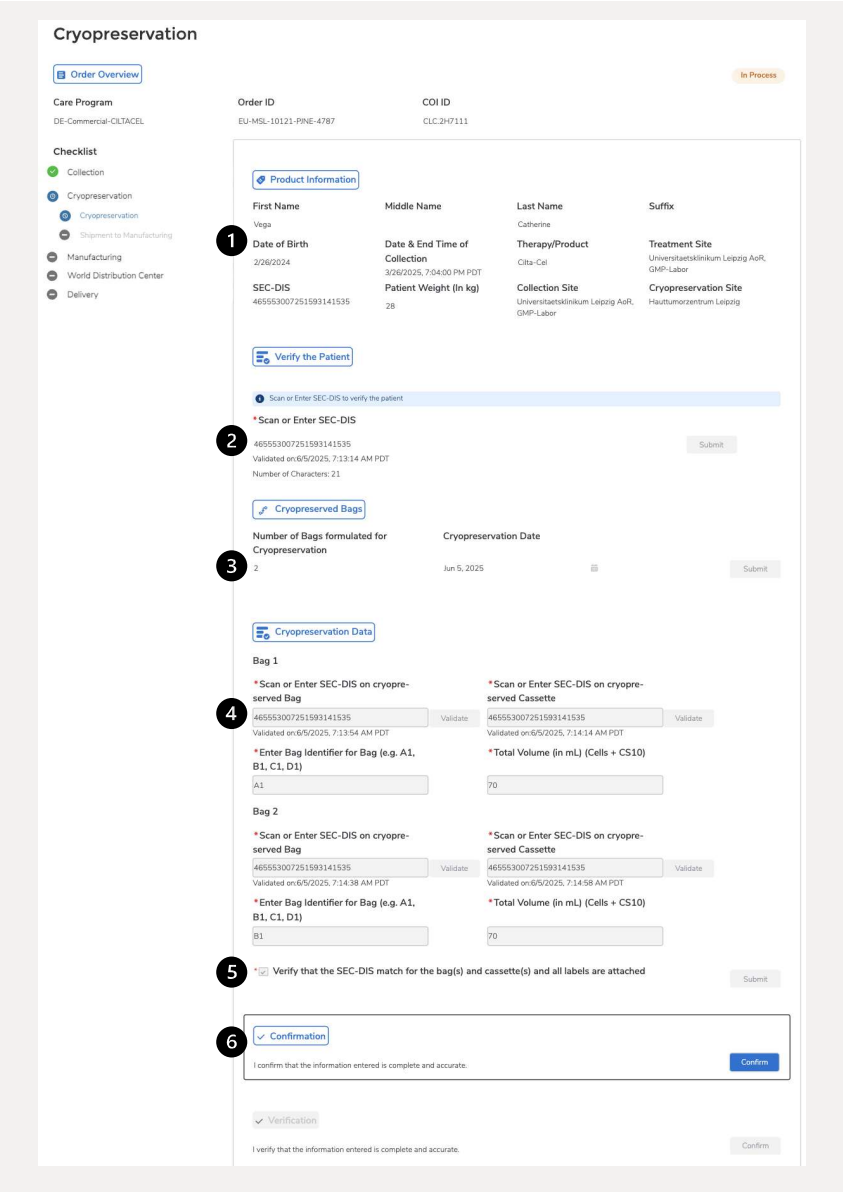
Local Cell Lab

Dual

Covers tasks related to cryopreservation when it occurs at the same site as collection. This section is not applicable outside of North America.

Local Cryopreservation

1. Follow 3.2's instructions for patient and product information.
2. Scan or enter patient identifier and press "**Submit**".
3. Enter number of bags and date cryopreserved. Press "**Submit**".
4. For each cryopreserved bag, scan or enter the patient identifier on the bag, patient identifier on the cassette, bag identifier, and the bag's total volume in milliliters (mL). Validate the patient identifier fields.
5. Review and verify the previously entered information before pressing the checkbox. Press "**Submit**".
6. Follow 3.2's instructions for signatures.



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4.5 Shipment from Cryopreservation

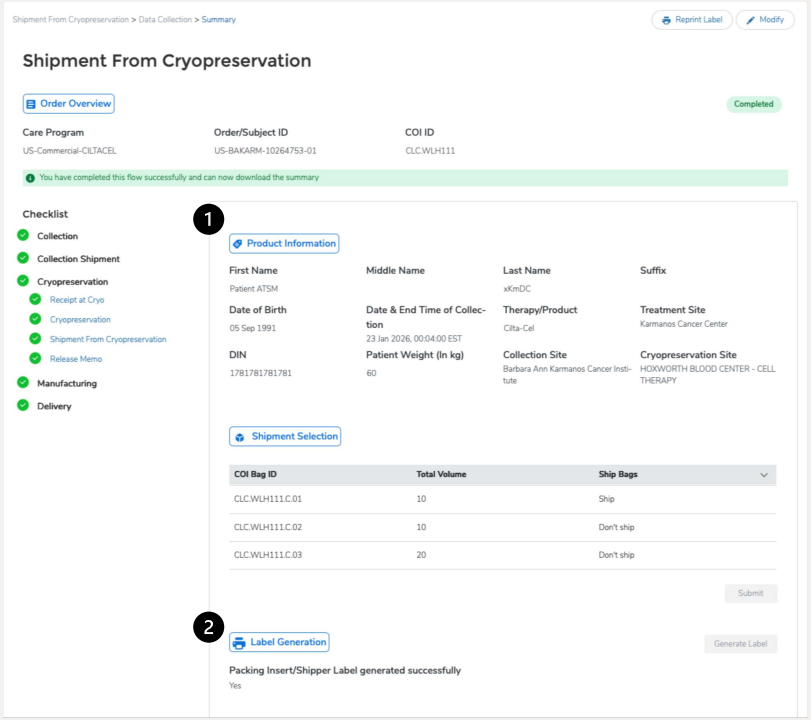
Local Cell Lab

Dual

Covers tasks related to the shipment of the cryopreserved material to a manufacturing site. This section is not applicable outside of North America.

Shipment from Cryopreservation

1. Follow prior 3.2's instructions for patient and product information.
2. Follow prior 3.2's instructions for generating a label.



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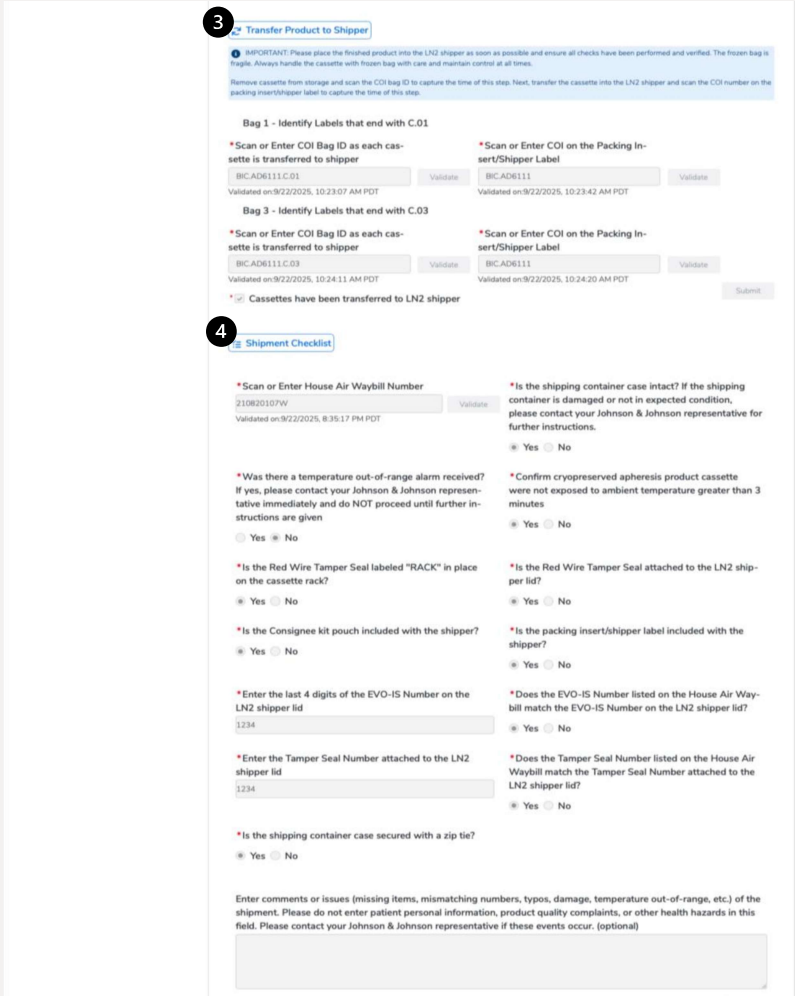
Shipment from Cryopreservation *(Continued)*

3. Enter and **Validate** the Transfer to Product Shipper information.
4. Enter the Shipment Checkless information and complete and mandatory follow-up questions prompted by your selection.
5. *Not Shown:* Follow prior 3.2 instructions for signatures.



4.6 Release Memo

Local Cell Lab

Dual

(Only for sites trained by J&J to perform cryopreservation)

Covers tasks related to Certificate of Compliance and Authorization for Further Processing of Cryopreserved Apheresis Material through the verification of process parameters and batch disposition. This section is not applicable outside of North America.

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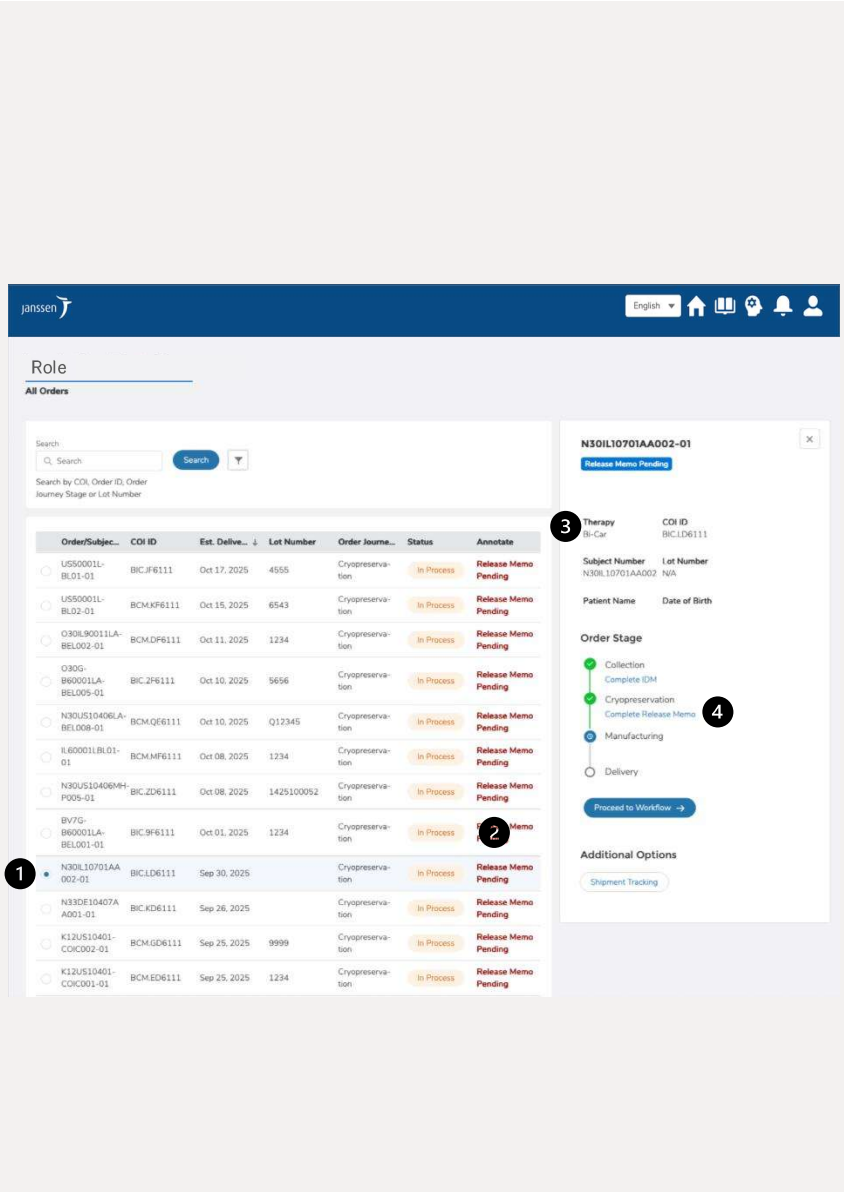
Open Release Memo Page

1. To open the side panel, select the circle radio button on the order you'd like to view.
2. To identify an order with an incomplete Release Memo, view the Annotate column of the desired order and look for "**Release Memo Pending**".
3. Review the patient and product information to ensure you have selected the correct order.
4. Press "**Complete Release Memo**".



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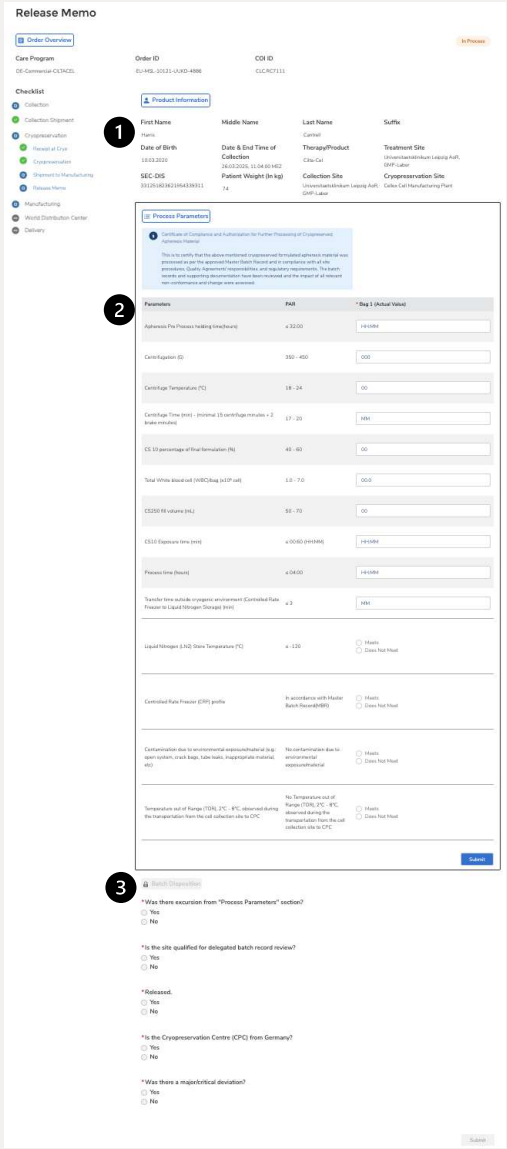
Release Memo

1. Follow 3.2's instructions for patient and product information.
2. Enter all parameters for each bag, ensuring you match the requested format, to certify the compliance of the cryopreserved apheresis. Press "**Submit**".
3. Enter the answers associated with the Batch Disposition and press "**Submit**".
4. *Not Shown:* Follow 3.2's instructions for signatures.



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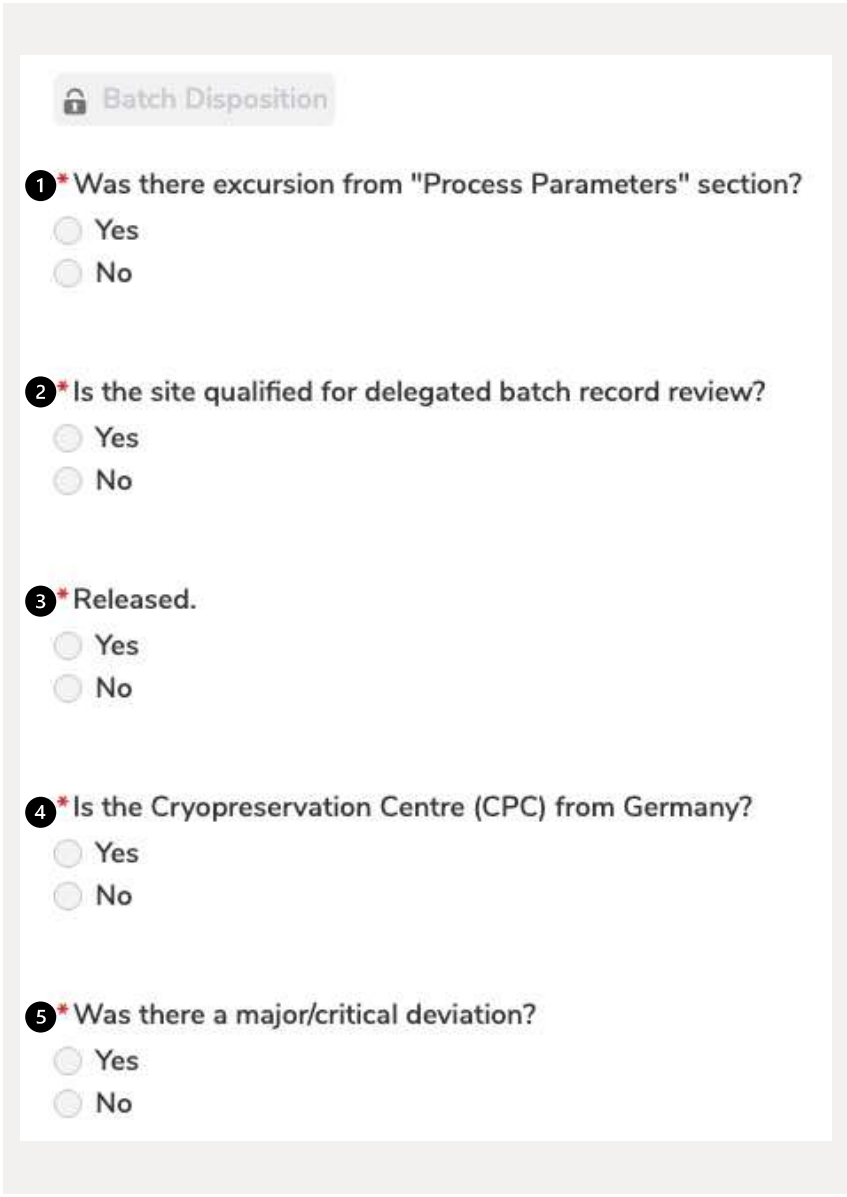
Batch Disposition

1. Select "**Yes**" if any of the Process Parameters are out-of-range or “Does not Meet” was selected, otherwise select "**No**".
2. Select **"Yes"** if site is qualified for delegate batch record review, otherwise select "**No**".
3. Select **"No"** if site answered “Yes” to #1 or “No” to #2 due to any major or critical deviation requiring an external quality assessment, otherwise select **"Yes"** if site is comfortable to release the material.
4. Select **"Yes"** if site is in Germany, otherwise select **"No"**.
5. *For EMEA only:* Select **“Yes”** if there was a major or critical deviation during the process, otherwise select **“No”.**



4.7 Receipt at Infusion Site

Local Cell Lab

Dual

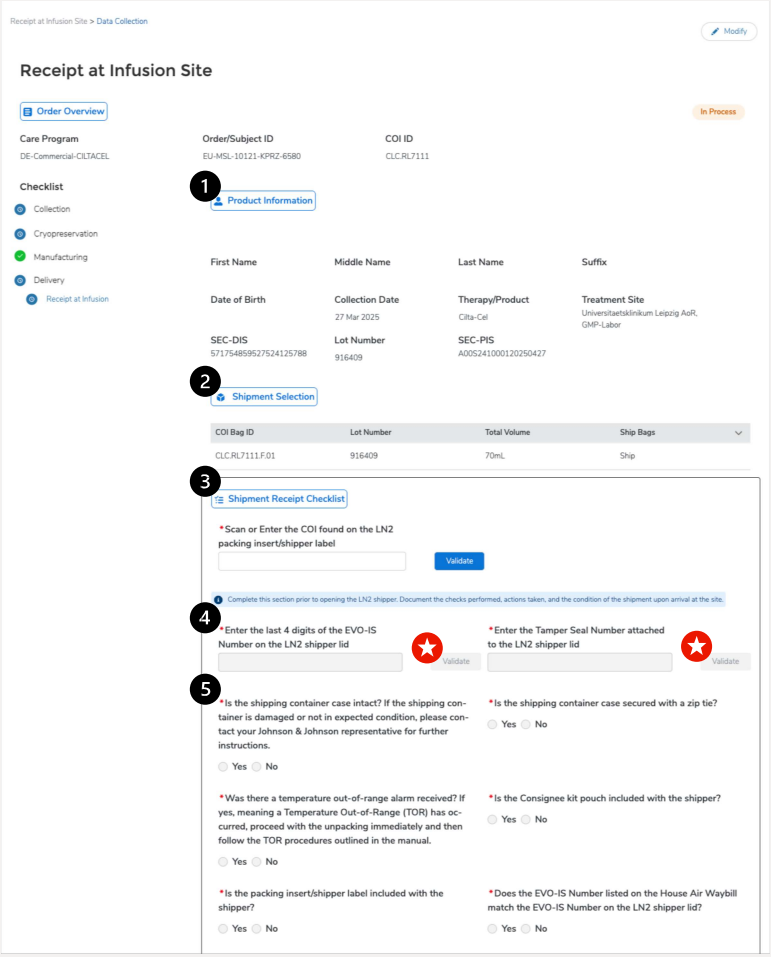
Covers tasks related to receiving the final product at the infusion site.

Receipt at Infusion Site

1. Follow 3.2's instructions for patient and product information.
2. Verify that the bags shipped match what was selected from the previous site and press "**Submit**".
3. Scan or enter the COI on the packing insert.
4. Enter the shipping information. If an unfavorable answer is selected, you must answer a mandatory follow-up question.

- **Important**: You must click the '**validate**' button. This captures a critical timestamp that is used to verify temperature data.
- **Important**: If the EVO-IS or Tamper Seal Number do not match what is expected from the previous site, you must reach out to a J&J representative.

5. Enter the correct shipping information and submit section.



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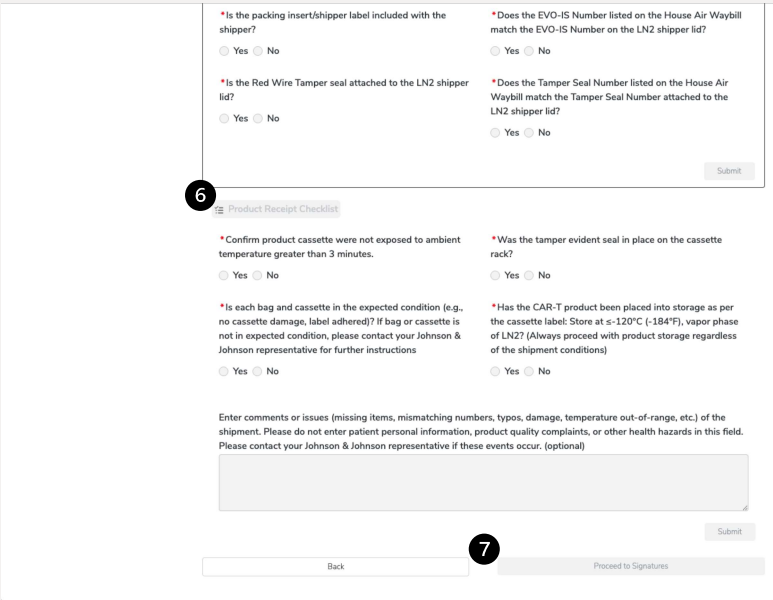
Receipt at Infusion Site
(Continued)

6. Enter the correct product information and submit section.
7. Follow 3.2's instructions for signatures.

- Canada-Only: Once Local QA completes the local quality decision workflow, Local Cell Lab Operators associated to the treatment site will be notified of the decision via email.



5. Exceptional Scenarios

5.1 Paper Processes

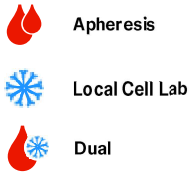

Apheresis


Local Cell Lab


Dual

Covers tasks related to completing your work on paper.

Paper Processes



Why?

Moving to a paper process when errors occur allows you to continue your work while minimizing potential delays to guarantee chain of identity/custody.

When?

- Inaccurate patient information has been identified and is past the stage to edit it.
- Portal is malfunctioning and not working as you expect it to.
- Previous workflow is paper-based.

How?

1. Contact your J&J Representative immediately when initiating the paper-based process.
2. Open your file sharing tool. Johnson & Johnson users will use TruVault. External users will use MBOX.
3. Download the corresponding form on the file sharing tool.
4. Complete the form and upload it to the file sharing tool on the same day.

5.2 Second Bag Delivery

Local Cell Lab

Dual

Covers tasks related to when an additional final product bag is needed after the initial shipment to the infusion site has been completed.

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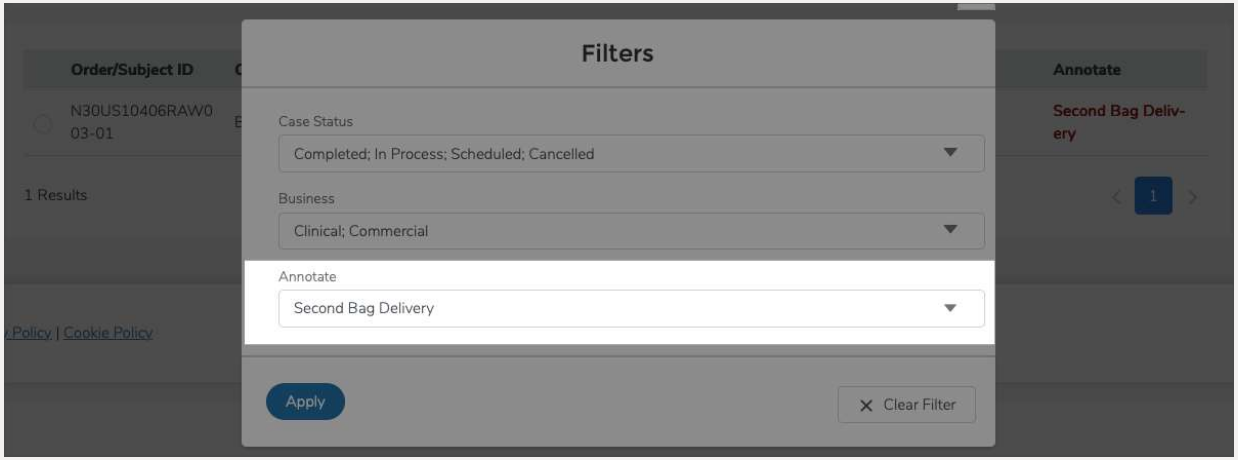
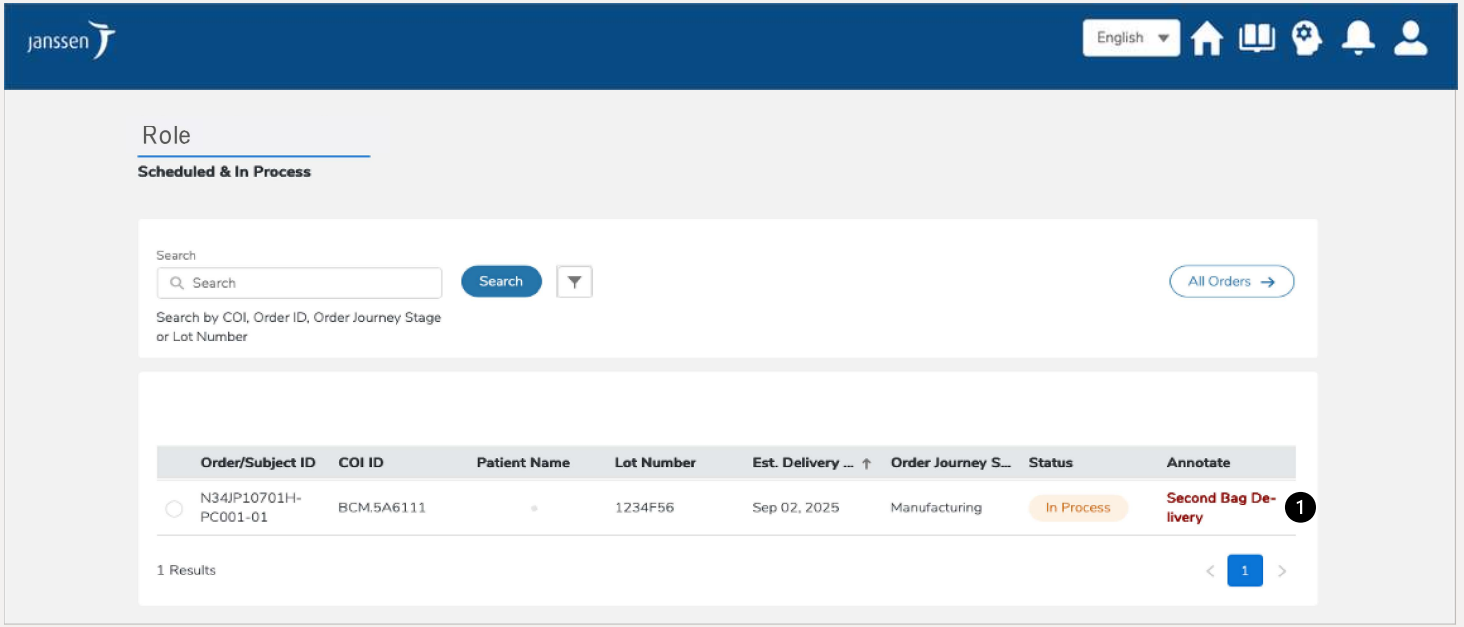
Second Bag Delivery

1. Identify the order with the tag “**Second Bag Delivery**” in the Annotate column.
   Can leverage filters to search for Second Bag Delivery.
2. Complete a second Receipt at Infusion workflow page.



Local Cell Lab

Dual



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6. Change Log

End of Document

Johnson&Johnson

(Document Revision History)			
Version Number	**Section**	**Description of Change**	**Justification of Change**
9.0	10	Added portal timeout information	CQUENCE Cell Management Release 6.0
	27	Updated Collection page to reflect time zone as read-only and included screenshot of new view	
	4, 14, 15, 29, 43, 52	Updated landing page screenshots	
	24	Changed the design for the role slide	
	27	Updated time zone comment	
	30	Updated screenshot for EMEA IDM questions	
	34	Updated screenshot for APAC IDM	
	32	Updated screenshot for UK IDM questions	
	31	Updated Step Verbiage in EMEA IDM	