

Instructions for Versioning

Important: Please do not include this slide in final presentation

Purpose: This presentation contains slides to train on how to complete the ADF and report packaging and shipment for apheresis centers and cell labs.

This slide highlights sections or slides that may differ depending on the CellChain™ login or dry vapor shipper used by the treatment center. Each treatment center will only use 1 of the 2 login methods presented, so please adjust the presentation accordingly. For ease of reference, amber text boxes indicating the CellChain™ login or dry vapor shipper have been added to the upper left corner of the respective slides/sections.

All amber text boxes and non-applicable slides should be removed prior to presentation.

Slide Number(s)	Slide Title(s)	Instruction
Slides 11-13	Initial Access to CellChain™; Initial Access to CellChain™ (cont); Logging into CellChain™	These slides should be used for treatment centers using the Microsoft Login option.
Slides 14-17	Initial Access to CellChain™; CellChain™ Account: Set Your Password on First Login; Logging into CellChain™; Logging into CellChain™ (cont)	These slides should be used for treatment centers using the SFDC Login option.
Slide 91	Review Dewar Tracking Information	This slide shows the tracking link for treatment centers using the Cryoport dry vapor shipper.
Slide 92	Review Dewar Tracking Information	This slide shows the tracking link for treatment centers using the evo® DV10 dry vapor shipper.
Slide 96	Access to Clinical Trial and Historical Orders in CellChain™ Classic	This slide shows how to access CellChain™ Classic for treatment centers with the Microsoft login.
Slide 97	Access to Clinical Trial and Historical Orders in CellChain™ Classic	This slide shows how to access CellChain™ Classic for treatment centers with the SFDC SSO login.

SFDC, Salesforce Dot Com; SSO, single sign-on.

Cell and Gene Therapy



How to Manage an ADF (Apheresis Data Form) and Report Packaging and Shipment

Doc No: CLLCHN_TM_491_LTA

Doc Version: 5.0

April 2022

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Approval

Author	Date and Signature
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Jamie Kutzer Regional Head, Chain of Identity & Supply Chain GSCM Planning	Digitally signed by Kutzer Jamie DN: dc=com, dc=novartis, ou=people, ou=TO, serialNumber=2067203, cn=Kutzer Jamie Reason: I am approving this document Date: 2022.04.08 07:24:45 -04'00' Kutzer Jamie
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Patrick Borer Project Quality Manager ISRM Governance & Risk Management	Digitally signed by Borer Patrick DN: dc=com, dc=novartis, ou=external-gold, serialNumber=1306776, cn=Borer Patrick Reason: I am approving this document Date: 2022.04.08 14:50:39 +02'00' Borer Patrick

Document History

Version	Date	Author	Comments
5.0	07-Apr-2022	Gašper Jordan	Slide 3: additional Document history slide added Slide 26: note on summer time zones constraint added

Document History

Version	Date	Author	Comments
4.0	10-Mar-2022	Gašper Jordan	<p>Slides 5, 7-10, 12, 19-21, 30, 31, 33, 35, 36, 51, 53, 54, 57, 59, 61, 63-66, 86, 88, 90, 91, 96: Editorial changes made to correct grammar and to ensure consistency of language/formatting throughout the presentation</p> <p>Slides 5, 9, 13, 44, 57, 62, 66, 93, 99, 102, 103: Added a new home button linking to the Agenda page; added a description of the button to slide 5</p> <p>Slide 5: Added a new section: "Editing an Approved ADF". Updated title of last Appendix</p> <p>Slides 11-13, 96: Added amber box identifying slides as using the Microsoft login</p> <p>Slide 13: Added a bracketed note about recommended browsers</p> <p>Slides 14-17: Added slides with the SFDC login process</p> <p>Slides 20, 46, 52, 55: Email screenshots were reworked to increase readability</p> <p>Slide 23: Added a note about infectious disease testing requirements</p> <p>Slides 25, 27, 31, 33, 37, 38, 41: Updated example cell counts to remove the decimal comma</p> <p>Slides 26, 27, 37, 38, 41: Updated units of measure in the screenshots</p> <p>Slide 31: Added note about cryobag ID</p> <p>Slide 34: Updated wording in 2nd note on excess apheresis material. Updated screenshot to reflect subtotals vs. grand totals</p> <p>Slide 47: Updated wording in step 2</p> <p>Slide 51: Corrected screenshot to read "ADF Approved"</p> <p>Slide 53: Updated the reason for ADF rejection in screenshot</p> <p>Slide 55: Updated note about timing of ADF correction, submission, and approval</p> <p>Slide 62: Updated screenshot to show the "Summary and Submission" page</p> <p>Slide 66: Added note about saving/printing new versions of the ADF</p> <p>Slides 67-85: Added new section: "Editing an Approved ADF"</p> <p>Slide 84: Slide had previously been in the "Printing" section. Moved to "Editing" section and enlarged email</p> <p>Slide 89: Added a new first instruction to verify patient data in the header section</p> <p>Slide 90: Updated wording on the timing of apheresis packaging in step 2. Updated number of sentinel vials in screenshot</p> <p>Slide 91: Updated wording in red bubble to reflect alternate tracking links. Added amber box identifying Cryoport shipper</p> <p>Slide 92: New slide added with evo® DV10 tracking link</p> <p>Slide 96: Bracketed screenshot</p> <p>Slide 97: Added new slide on CellChain™ Classic-CellChain™ PRO navigation with SFDC SSO login</p> <p>Slide 100: Updated Appendix Title</p> <p>Slide 101: Updated to have the ISBT 128 process slide presented first. Removed hyperlink to non-ISBT 128 slide</p> <p>Slide 102: Added additional language to the first box in the flow chart</p>

Document History (continued)

Version	Date	Author	Comments
3.0	12-Oct-2021	Divya Nambiar	<p>Slides 10-12: Updated the login process</p> <p>Slide 12: Note added about informing Novartis in case of personnel off-boarding</p> <p>Slide 23: Updated to include Document Upload steps</p> <p>Slide 26: Note about subtotals updated</p> <p>Slides 30-31: Updated to show warning message for high and low threshold respectively</p> <p>Slide 50: Note added about ADF update until Day 0 of Mfg</p> <p>Slides 51-52: Updated to show ADF re-submission</p> <p>Slides 54-56: Added note about Date format</p> <p>Slide 67: Updated to explain steps for entering Number of Sentinel Vials Shipped</p> <p>Slide 68: Text and Note updated for Dewar Tracking Information</p> <p>Slide 69: New slide added to show Document Upload</p> <p>Slides 72-73: Slides added for CellChain™ Classic-CellChain™ PRO navigation</p>
2.0	13-Jul-2021	Divya Nambiar	<p>Slides 6-7: Added Novartis CAR-T Order Process Overview</p> <p>Slides 10-13: Added new login process slides</p> <p>Old login process slides deleted</p> <p>Slides 70-71: New slides added to show navigation between 2.x and 4.x. Slides to be hidden while training new users.</p>
1.0	01-Jun-2021	Shombit Chatterjee	For Approval



Click this button to
return to Agenda page

Agenda

1. [Course Overview](#)
2. [Accessing CellChain™](#)
3. [Apheresis Data Form Submission](#)
4. [Apheresis Data Form Approval or Rejection](#)
5. [ADF List View](#)
6. [Printing an Approved Apheresis Data Form](#)
7. [Editing an Approved Apheresis Data Form](#)
8. [Entering Dewar Packaging and Apheresis Pickup Details](#)
9. [Appendix](#)
10. [Appendix: Apheresis Shipment Process Flow](#)

Course Overview

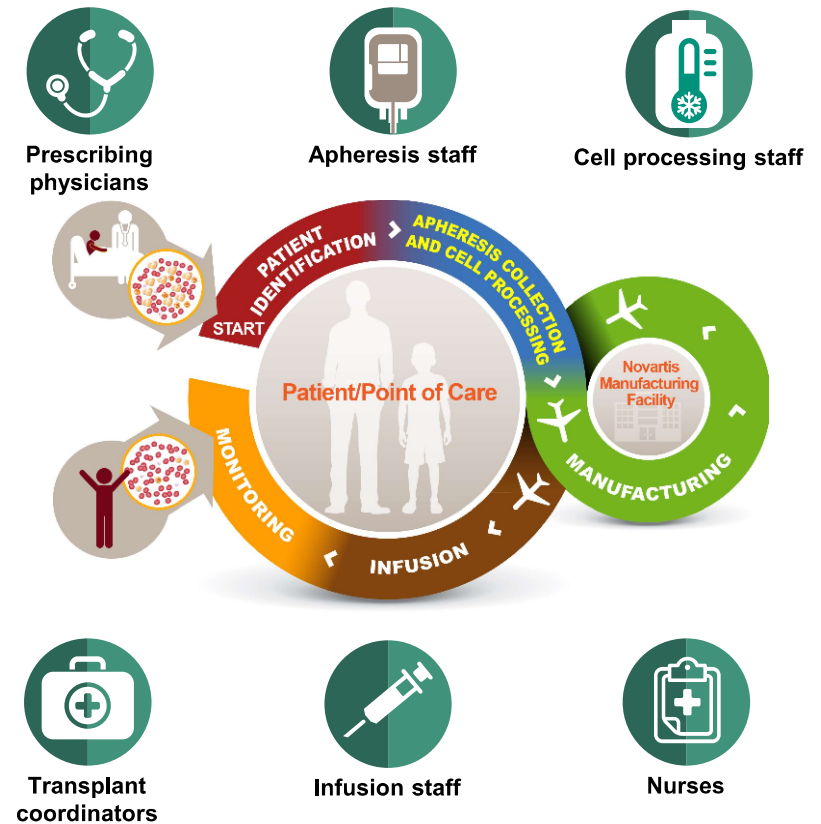
Prior to product manufacturing, information about the patient, the apheresis collection, apheresis material testing, and the cryopreservation procedure must be reported to Novartis on an Apheresis Data Form (ADF).

The ADF is completed in CellChain™, the Novartis Online Portal used to manage the CAR-T cell ordering process and coordinate manufacturing and logistics.

The purpose of this course is to provide apheresis/cell processing staff with the knowledge and skills required to submit, approve, and monitor the ADF in CellChain™. The course will also explain how to organize and report the shipment of apheresis material from your treatment center to Novartis Manufacturing Facilities.

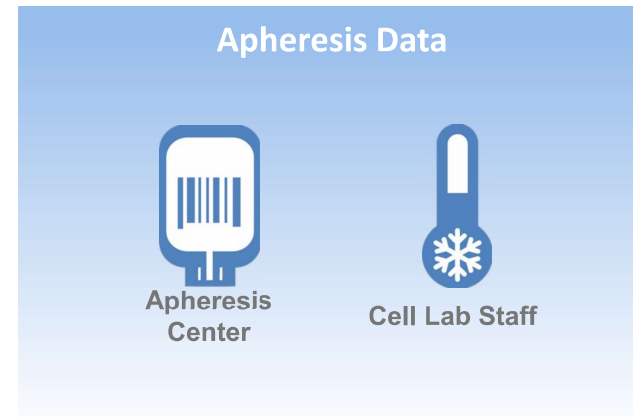
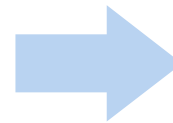
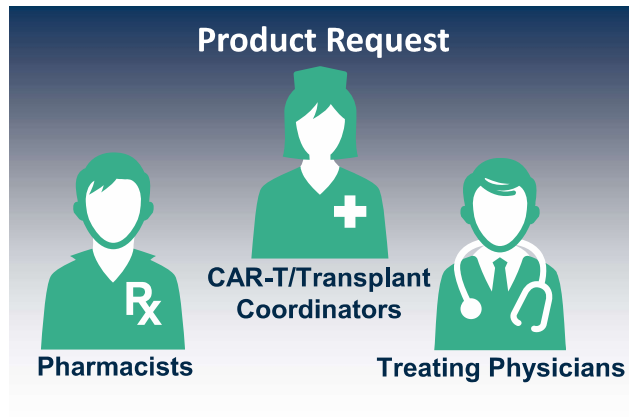
CAR, chimeric antigen receptor.

7 Business Use Only

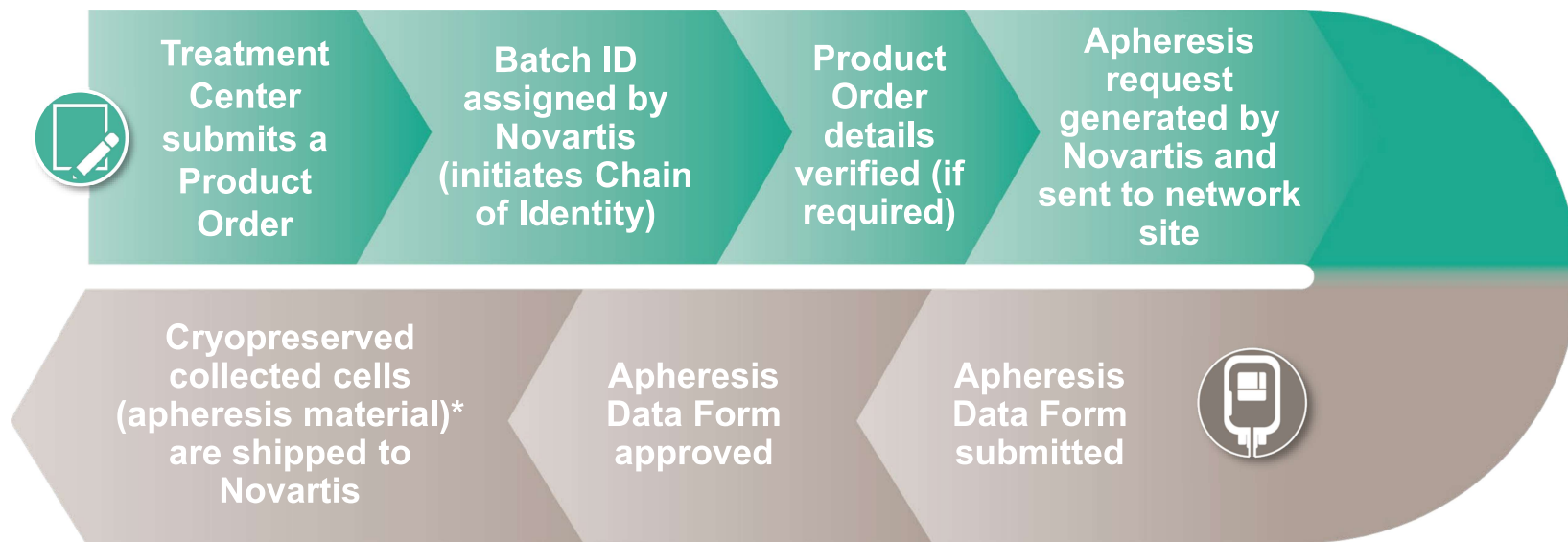


Novartis CAR-T Cell Order Process Overview

CellChain™ Online Ordering System



Novartis CAR-T Cell Order Process Overview (cont)



*The Apheresis Data Form (ADF) must be completed before apheresis material may be shipped to Novartis. Cryopreserved apheresis material may be collected up to 30 months before the start of manufacturing.



Key Guidelines For ADF Completion

- The submission and verification of the ADF signify the accuracy of the data representing apheresis material being submitted to Novartis
- CellChain™ provides screen and field-level validations throughout the ADF completion process to help ensure that the ADF is complete and accurate
- When completing the ADF, please be sure to adhere to the following requirements:
 - If there are multiple collections, you are required to individually report them
 - If there are multiple cryobags for the same collection, you are required to individually list them
 - The ADF **must be submitted and verified** before the apheresis material is shipped to the Novartis manufacturing facility
- If your center is not ISBT 128-compliant, you may be eligible to complete a waiver and not have hangtags sent to your center. Please notify your Novartis CTOM

CTOM, Cell Therapy Operations Manager; ISBT, International Society of Blood Transfusion.



Cell and Gene Therapy

Accessing CellChain™

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Initial Access to CellChain™

For enhanced security, Novartis is using Microsoft services to support CellChain™ access.

To set up your account, you will receive an email from **Noreply, IamService (Gen)** (iamservice.noreply@novartis.com) with the subject line **“Novartis Communications: Invitation to access Novartis applications”**

- Click the **Accept Invitation** link in the email and proceed with the instructions on the screen to log in to your institution’s Microsoft account or to create an account

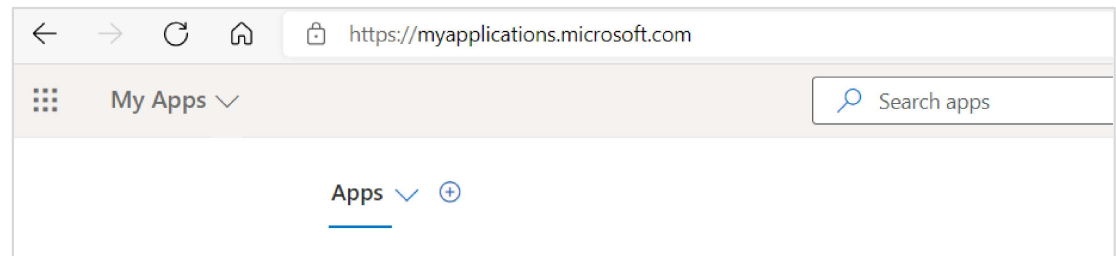
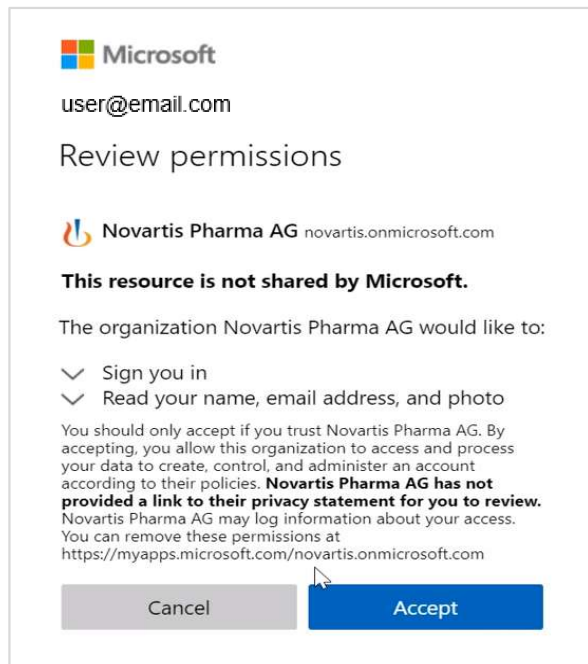


Note: If you are directed to your institution’s login page, please enter your institutional password. Novartis does not store or have access to your institutional password.

Initial Access to CellChain™ (cont)

After reviewing and accepting the access permissions, the **My Apps** page will appear.

This indicates that your account setup is complete.





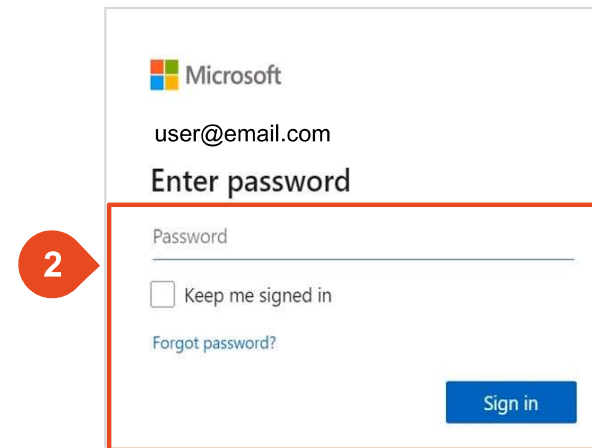
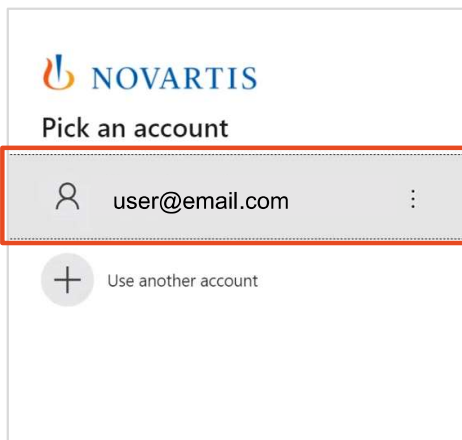
Logging in to CellChain™

After your account has been set up, you can go directly to www.cellchaincares.com/pro.

Novartis recommends that you use the latest version of Microsoft Edge or Google Chrome, as these are validated for the interface and functionalities of CellChain™.

Please bookmark the link for future access.

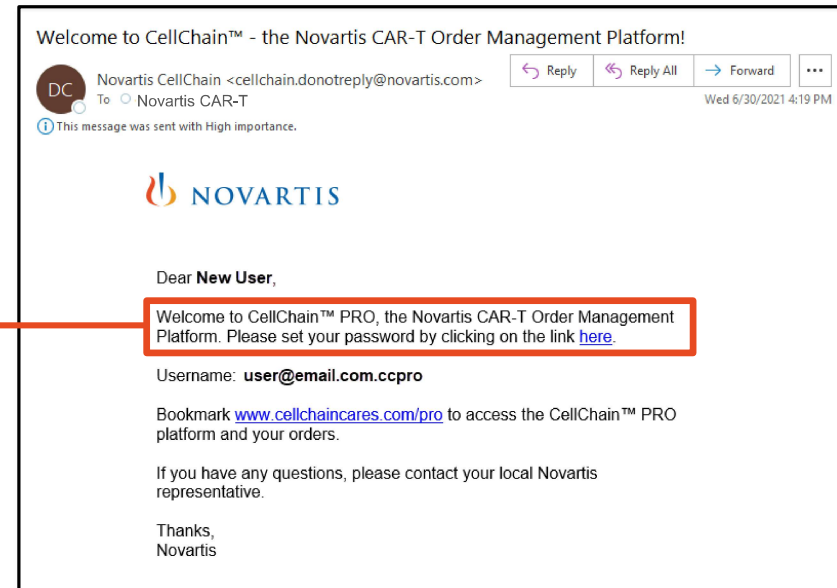
1. Select the work account you registered to use with CellChain™
2. Enter your password and click **Sign in**



Note: If a user is no longer with your institution, please inform your Novartis representative via email or in writing immediately. Their account will be deactivated to ensure data privacy and to protect information.

Initial Access to CellChain™

- To set up your CellChain™ account, you will receive an email from Novartis CAR-T [cellchain.donotreply@novartis.com] with the subject line “Welcome to CellChain™ - the Novartis CAR-T Order Management Platform!”
- Click the link in the email



CellChain™ Account: Set Your Password on First Login

The first time you log in to CellChain™, you will be prompted to change your password

Notice the specified password length and complexity requirements

Note: The system requires you to change your password every 3 months

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Change Your Password

Enter a new password for
user@email.com.

Make sure to include at least:

- 8 characters
- 1 uppercase letter
- 1 lowercase letter
- 1 number
- 1 special character ⓘ

* New Password

* Confirm New Password

Change Password

Password was last changed on 6/30/2021 10:18 PM.

Logging in to CellChain™

You will be redirected to www.cellchaincares.com/pro. You can bookmark the link for future access.

Novartis recommends that you use the latest version of Microsoft Edge or Google Chrome, as these are validated for the interface and functionalities of CellChain™.

Enter your username and password and click **Log In**.

Note: If a user is no longer with your institution, please inform your Novartis representative via email or in writing immediately. Their account will be deactivated to ensure data privacy and to protect information.



Logging in to CellChain™ (cont)

Please note:

- After five login attempts with an incorrect password, the system will lock you out for 30 minutes
- Your account must be activated within 7 days of receiving the CellChain welcome email from cellchain.donotreply@novartis.com
- If you forget your password, click the **Forgot Your Password?** link and you will receive an account recovery link which will be valid for 24 hours
- If you are locked out of the application, please contact your local Novartis Customer Service Center
- The system will automatically log out users after 15 idle minutes

NOVARTIS

Username

Password

Log In

[Forgot Your Password?](#)

Note: If a user is no longer with your institution, please inform your Novartis representative via email or in writing immediately. Their account will be deactivated to ensure data privacy and to protect information.



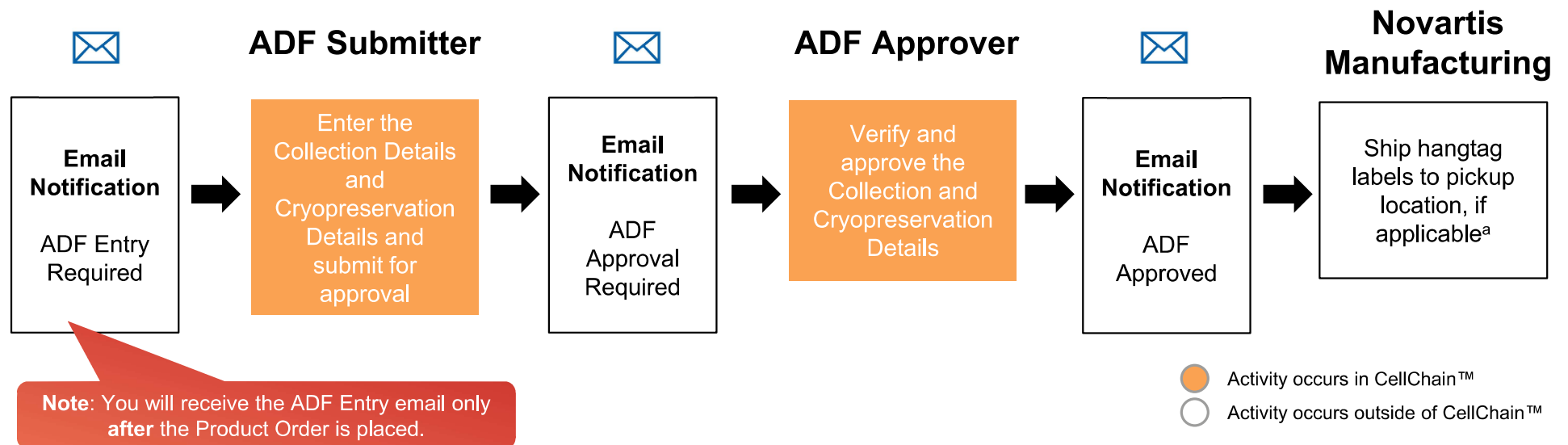
Cell and Gene Therapy

Apheresis Data Form Submission

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Process Flow

The process below depicts how the Collection and Cryopreservation Details in the ADF are submitted and verified by apheresis/cell processing staff.



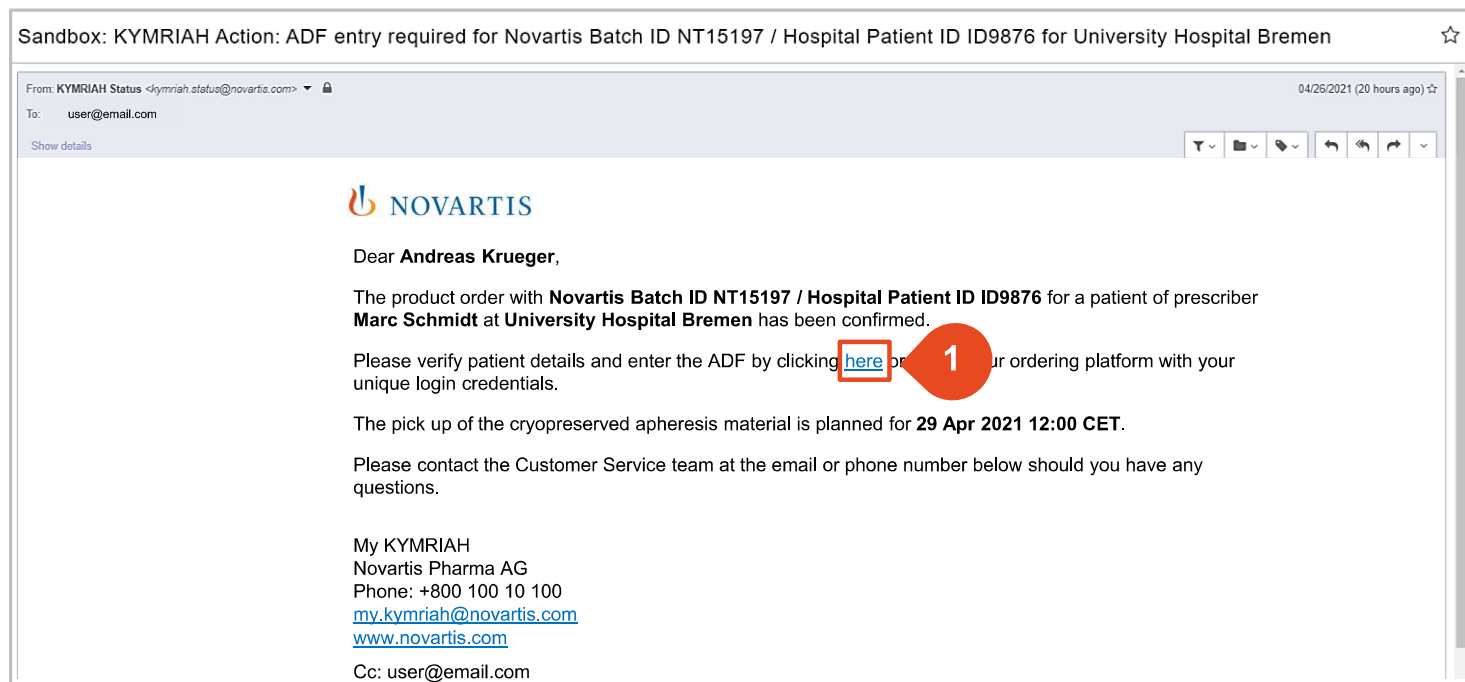
^aNovartis hangtag labels may be required for centers using non-ISBT 128 labeling. It may be possible for Novartis to review an institutional non-ISBT 128 label to determine if the requirement to use a Novartis hangtag label may be waived.

Receive Email

After the Product Order is placed, you will receive an email notification stating that ADF entry is required.

1. Click the link in the email to access CellChain™

Note: You can also log in to CellChain™ directly at www.cellchaincares.com/pro



Verify Patient Details

Verify that the patient data accurately match your most recent medical assessments/records and **collection bag labels**.

2. Select the check box to confirm that the patient data are accurate
3. Click **Next**

Note: If you are unable to confirm the patient details, please contact your Ordering Site before proceeding.

Patient Name Marie Plank					AWAITING ADF
Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Patient Weight (kg) 45	Novartis Batch ID NT15197	

[Back to Patient List](#)

Verify Patient Details

Please verify that the patient name (full name or initials) / Treatment Protocol Subject ID and date of birth above match exactly with your most recent medical assessments / records and Apheresis bag labels.

I confirm that the patient data is accurate

Andreas Krueger
26 Apr 2021 22:08 CET

2

3 [Next](#)

Verify Site and Scheduling Information

Verify the Site and Scheduling Information captured in the Product Order Summary section.

4. Click Next

Note: If any of the details are incorrect, please contact your Ordering Site before proceeding.

The screenshot displays a web interface for a 'Product Order Summary'. On the left, a vertical navigation menu includes: 'Back to Patient List', 'Verify Patient Details' (checked), 'Product Order Summary' (highlighted with a blue circle), 'Required Collection Details', 'Recommended Collection Details', 'Required Cryopreservation Details', 'Recommended Cryopreservation Details', and 'Summary and Submit'. The main content area is titled 'Product Order Summary' and contains a section 'Site and Scheduling Information' enclosed in a red border. This section is divided into two columns of information:

Site and Scheduling Information	
Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Cryopreserved Apheresis Pick Up 29 Apr 2021 12:00 CET	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

At the bottom right of the interface, there is a red circle with the number '4' and a blue 'Next' button, both highlighted with a red border.

Enter Required Collection Details

5. In the Infectious Disease Testing section, validate and check each box to confirm that the patient infectious disease testing results conform to requirements
6. Click **Next**

Note: If the patient does not meet the infectious disease testing requirements, contact your CTOM before proceeding.

[Back to patient list](#)

Required Collection Details

Infectious Disease Testing ⓘ

5

The patient does not have an active Hepatitis B (HBV) Infection. Do Results conform to requirement?
 Yes

The patient does not have an active Hepatitis C (HCV). Do Results conform to requirement?
 Yes

Patient does not have HIV Infection. Do Results conform to requirement?
 Yes

Any additional required autologous donor eligibility and / or infectious disease testing has been completed in compliance with Institutional and local Health Authority requirements, and is determined to be acceptable.
 Yes

Determination of the patient's HBV, HCV and HIV status was completed within 30 calendar days prior to collection or any date after collection. Note: Superseded by stricter local regulatory requirement if applies.
 Yes

6

Note: Click **Save for Later** to save partial entries and return to complete the ADF at a later date/time.

Enter Required Collection Details (cont)

- From the drop-down menu, select the **Apheresis System** used for the collection
- Enter applicable comments in the **Collection and Cryopreservation Comments** field

[Back to Patient List](#)

Verify Patient Details

Product Order Summary

Required Collection Details

Recommended Collection Details

Required Cryopreservation Details

Recommended Cryopreservation Details

Required Collection Details

Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
--	---

Apheresis System Used

7

Other ⓘ

Collection and Cryopreservation Comments ⓘ

8

Apheresis Collections

Note: If you select **Other** as the **Apheresis System Used**, enter the name of the other Apheresis System used in this field.

Note: The Comments field has a 255-character limit. Any comments entered in this field will persist throughout the remainder of the ADF entry process.

Enter Required Collection Details (cont)

9. Enter the Apheresis Collection(s) details, using one row per collection

10. Click **Add another collection** to add rows

11. Click **Next**

Note: For countries where summer time is observed, all time zone labels displayed in the system will not change between summer time and standard time, however the time will be adjusted and displayed accurately.

The screenshot shows a web form titled 'Apheresis Collections'. On the left, a vertical navigation pane includes 'Recommended Cryopreservation Details' and 'Summary and Submit'. The main form area contains a table with the following columns: 'Collection', 'Apheresis ID', 'Volume of blood processed (litres)', 'End of Apheresis Collection Date', 'End of Apheresis Collection Time', and 'Time Zone'. Two rows of data are visible, each with a red 'X' in a box on the right. Below the table is a scroll bar, an 'Add another collection' button, a 'Back' button, a 'Save for Later' button, and a 'Next' button. Red callout boxes with numbers 9, 10, and 11 point to the first row, the 'Add another collection' button, and the 'Next' button respectively.

Collection	Apheresis ID	Volume of blood processed (litres)	End of Apheresis Collection Date	End of Apheresis Collection Time	Time Zone
1.	APH13132424	14.8	21 Apr 2021	12:30	CET
2.	APH56567878	14.2	23 Apr 2021	11:30	CET

Note: If your institution is ISBT 128-compliant, this column name will be **DIN** (Donation Identification Number). If your institution is not ISBT 128-compliant, then the column name will be **Apheresis ID**.

Enter Recommended Collection Details

12. For Collection 1, enter the **Preapheresis Peripheral Blood Testing** details

Back to Patient List

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details**
- Required Cryopreservation Details
- Recommended Cryopreservation Details

Recommended Collection Details

Collection 1 - Preapheresis Peripheral Blood Testing for Apheresis ID: APH13132424

Complete Blood Count (CBC) with Differential

Date Of Testing	<input type="text" value="21 Apr 2021"/>	Time	<input type="text" value="08:00"/>	Time Zone	<input type="text" value="CET"/>
Hemoglobin (g/dL)	<input type="text" value="13"/>	Platelets (x10⁹/L)	<input type="text" value="150"/>		

Absolute Counts

Date Of Testing	<input type="text" value="21 Apr 2021"/>	Time	<input type="text" value="08:00"/>	Time Zone	<input type="text" value="CET"/>
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Enter Recommended Collection Details (cont)

13. For Collection 1, continue to enter **Preapheresis Peripheral Blood Testing** details
14. In case of additional collections, click the next **Collection** and enter the **Preapheresis Peripheral Blood Testing** details

Recommended Cryopreservation Details

Summary and Submit

13

Absolute Counts

Date Of Testing 21 Apr 2021

Time 08:00

Time Zone CET

White Blood Cell Count (/µL) 5,000

Absolute Lymphocyte Count (/µL) 400

Flow Cytometry

Date Of Testing 21 Apr 2021

Time 08:00

Time Zone CET

Absolute CD3 Lymphocyte Count (/µL) 400

14

Collection 2 - Preapheresis Peripheral Blood Testing for Apheresis ID: APH56567878

Complete Blood Count (CBC) with Differential

Enter Recommended Collection Details (cont)

15. Enter applicable comments in the **Collection and Cryopreservation Comments** field
16. You may be requested by Novartis to upload relevant documents in the Additional Documentation section. After selecting your file(s) to upload from your computer, select the **Document Type**
17. Click **Save Documents** to ensure the document is uploaded successfully
18. Click **Next**

Collection and Cryopreservation Comments ⓘ

comments

Additional Documentation

Please upload files up to 5 MB in the following format: doc, docx, txt, pdf, xls,xlsx, csv, ppt, pptx, jpg, jpeg, png.

[Upload Files](#) Or drop files

! Select the Document Type for each uploaded file, then click the Save Documents button to submit the documents.

Document Name	Document Type*	Uploaded Date	Uploaded By
CBC Data.pdf	<div style="border: 1px solid black; padding: 2px;">Please Select Memorandum - Apheresis Material CBC Data Flow Cytometry Data Sterility Data Other Document - Apheresis Material</div>		

[Back](#) [Save Documents](#) [Save for Later](#) [Next](#)

Transfer to Cell Lab

At this stage, you can continue to enter the Cryopreservation Details yourself, or transfer the remainder of the ADF Entry and ADF Submission to a different user at your cell processing laboratory.

19. Click either **Transfer to Cell Lab** or **Enter Cryopreservation Details**, as applicable

The screenshot shows a software interface with a central white dialog box. At the top of the dialog is a green checkmark icon. Below it, the text reads 'Collection Details Completed by' followed by 'Andreas Krueger' and '26 Apr 2021 22:16 CET'. Below this, it says 'You can continue to enter the Cryopreservation Details or transfer that activity to a cell lab for entry'. At the bottom of the dialog are two buttons: 'Transfer to Cell Lab' and 'Enter Cryopreservation Details'. A red circle with the number '19' is positioned to the right of the 'Enter Cryopreservation Details' button. The background is a blurred view of a data entry form with fields for 'Time Zone' (set to CET) and 'Count (µl)'. The dialog box is titled 'Absolute Counts' at the top and 'Additional Information' at the bottom.

Enter Required Cryopreservation Details

At this stage, staff from either the cell processing laboratory or the apheresis collection unit can perform the subsequent tasks.

20. For Collection 1, enter the **Start of Cryopreservation Date and Time**

Back to Patient List

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details**
- Recommended Cryopreservation Details
- Summary and Submit

Required Cryopreservation Details

Collection 1 - Apheresis Material Cryobag Information for Apheresis ID: APH13132424

Apheresis ID
APH13132424

End of Apheresis Collection Date
21 Apr 2021

End of Apheresis Collection Time
12:30 CET

Start of Cryopreservation Date
21 Apr 2021

Start of Cryopreservation Time
16:00

Time Zone
CET

Collection and Cryopreservation Comments

Note: The DIN/Apheresis ID is carried over from the Collection Details and does not need to be reentered.

Note: The **Start of Cryopreservation Time** is the time at which the cryoprotectant (DMSO) is added to the apheresis material. This date and time should be within 24 hours of the End of Apheresis Collection Date and Time.

DMSO, dimethyl sulfoxide.

31 Business Use Only

Enter Required Cryopreservation Details (cont)

21. In the Cryobag Information section, enter the cryobag details, using one row per cryobag

Note: Use local procedure to determine the Cryobag ID

22. Click **Add another bag to this collection** to add rows

Summary and Submit

Collection and Cryopreservation Comments ⓘ

Cryobag Information
Number of Cryobags
1

Cryobag #	Cryobag ID ⓘ	Total Nucleated Cell Count	CD3+ Cell Count	Total Volume per Bag (mL)
1.	ID01	5.9 X 10 ⁹	3.6 X 10 ⁹	35

21

22 Add another bag to this collection Add up to 10 bags across all collection

Note: The subtotals for the collection will be calculated and displayed here. The CD3% of TNC will be automatically calculated by CellChain™

Subtotals

Total Nucleated Cell Count 5.90 x 10 ⁹ TNC	Total CD3+ Cell Count 3.60 x 10 ⁹ CD3+
WBC concentration 1.68 x 10 ⁸ cell/ml	CD3+/TNC X100 61.01 %

Enter Required Cryopreservation Details (cont)

23. In case of additional collections, click the next **Collection** and enter the required details

23 **Collection 2 - Apheresis Material Cryobag Information for Apheresis ID: APH56567878**

Apheresis ID
APH56567878

End of Apheresis Collection Date
23 Apr 2021

End of Apheresis Collection Time
11:30

Time Zone ⓘ
CET

Start of Cryopreservation Date

Start of Cryopreservation Time

Time Zone ⓘ
CET

Collection and Cryopreservation Comments ⓘ

Cryobag Information
Number of Cryobags
1

Enter Required Cryopreservation Details (cont)

24. Continue to enter cryobag details for the additional collection
25. After the cryobag details across all collections have been entered, click **Finished Adding Bags**. This will calculate the grand total number of cells for all cryobags across all collections

Cryobag Information
Number of Cryobags
1

Cryobag #	Cryobag ID	Total Nucleated Cell Count	CD3+ Cell Count	Total Volume per Bag (mL)
1.	ID02	4.1 X 10 ⁹	1.7 X 10 ⁹	40

[Add another bag to this collection](#) Add up to 10 bags across all collection

Finished Adding Bags

Subtotals

Total Nucleated Cell Count 4.10 x 10 ⁹ TNC	Total CD3+ Cell Count 1.70 x 10 ⁹ CD3+
WBC concentration 1.02 x 10 ⁸ cell/ml	CD3+/TNC X100 41.46 %

Note: After clicking **Finished Adding Bags**, subtotals for that particular collection are listed below. The grand totals across all bags and collections will be calculated and displayed at the end of the screen.

Enter Required Cryopreservation Details (cont)

26. Select **Yes** or **No** to specify if excess apheresis material has been retained at your site

Note: If Yes, scroll up to the Comments field to enter how much excess material is stored at your site

Note: Cryobag information for excess apheresis material stored at your site is **not to be entered** into the ADF

[Add another bag to this collection](#) Add up to 10 bags across all collection

Finished Adding Bags

Subtotals

Total Nucleated Cell Count 4.10 x 10 ⁹ TNC	Total CD3+ Cell Count 1.70 x 10 ⁹ CD3+
WBC concentration 1.02 x 10 ⁸ cell/ml	CD3+/TNC X100 41.46 %

Excess Apheresis material retained at your site


Excess Apheresis material retained at your site

Yes
 No

Enter Required Cryopreservation Details (cont)

Review the grand totals across all cryobags and collections. In case of a **high** threshold, a warning will appear at the top of the screen as well as on all submission and approval screens.

27a. Click Next

 The collection for this batch has resulted in specifications that may be considered "excess material". Please contact your Cell Therapy Operation Manager for guidance.

Required Cryopreservation Details

▼ Collection 1 - Apheresis Material Cryobag Information for Apheresis ID : APH13132424

Note: The grand totals across all cryobags and collections will be calculated and displayed here. The high threshold warning will **not** be displayed in the printed ADF.

Grand totals across all bags and collection days

The collection for this batch has resulted in specifications that may be considered "excess material". Please contact your Cell Therapy Operation Manager for guidance.

<p>Total Nucleated Cell Count (Threshold: Min:2x10⁹) 10.00 x 10⁹ TNC</p> <p>CD3+/TNC X100 (Threshold: Min:3%) 53.00 %</p>	<p>Total CD3+ Cell Count (Threshold: Min:1x10⁹ Max:4x10⁹) 5.30 x 10⁹ CD3+</p> <p>Novartis Apheresis Expiration Date / Time 21 Mar 2024 13:00 CET</p>
---	---


27a

BackSave for LaterNext

Enter Required Cryopreservation Details (cont)

Review the grand totals across all cryobags and collections. In case of a **low** threshold, a warning will appear at the top of the screen as well as on all submission and approval screens.

27b. Click Next

 Total cell counts are below optimal manufacturing requirements. Your Novartis Operations Expert was notified to contact the prescriber to evaluate risks of proceeding with this order. Please wait for further instructions before requesting the Dewar.

Required Cryopreservation Details

▼ Collection 1 - Apheresis Material Cryobag Information for Apheresis ID : APH13132424

Note: The grand totals across all cryobags and collections will be calculated and displayed here. The low threshold warning will be displayed in the printed ADF.

Grand totals across all bags and collection days

Total cell counts are below optimal manufacturing requirements. Your Novartis Operations Expert was notified to contact the prescriber to evaluate risks of proceeding with this order. Please wait for further instructions before requesting the Dewar.

Total Nucleated Cell Count (Threshold: Min: 2×10^9) 1.00 x 10^9 TNC	Total CD3+ Cell Count (Threshold: Min: 1×10^9 Max: 4×10^9) 1.00 x 10^9 CD3+
CD3+/TNC X100 (Threshold: Min: 3%) 100.00 %	Novartis Apheresis Expiration Date / Time 15 Mar 2024 12:45 CET

BackSave for LaterNext

27b

Enter Recommended Cryopreservation Details

28. For Collection 1, enter the Apheresis Material Testing Information

[Back to Patient List](#)

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details
- Recommended Cryopreservation Details**

Recommended Cryopreservation Details

28

Collection 1 - Apheresis Material Testing Information for Apheresis ID : APH13132424

Date Of Testing	<input type="text" value="22 Apr 2021"/>	Time	<input type="text" value="08:00"/>	Time Zone	<input type="text" value="CET"/>
Complete Blood Count (CBC) with Differential					
Differential Performed			Hematocrit (%)		
<input checked="" type="radio"/> Manual <input type="radio"/> Automatic			<input type="text" value="9.0"/>		
Hemoglobin (g/dL)			Platelets (x10⁹/L)		
<input type="text" value="3"/>			<input type="text" value="200"/>		

Enter Recommended Cryopreservation Details (cont)

29. For Collection 1, continue to enter the **Apheresis Material Testing Information**

Summary and Submit

29

Absolute Counts	
White Blood Cell Count (/μL)	Absolute Lymphocyte Count (/μL)
<input type="text" value="50,000"/>	<input type="text" value="30,000"/>
Percentages	
Monocytes (%)	Neutrophils (%)
<input type="text" value="10"/>	<input type="text" value="55"/>
Lymphocytes (%)	Blasts (%)
<input type="text" value="25"/>	<input type="text" value="5"/>
Others (%)	
<input type="text" value="5"/>	
Cell Viability	
Viability(%)	
<input type="text" value="95"/>	

Enter Recommended Cryopreservation Details (cont)

30. In case of additional collections, click the next **Collection** and enter the testing details

31. Click **Next**

Note: You can enter additional comments. Any information that you previously entered will be displayed.

Note: You can upload related documents in the **Additional Documentation** section. Any documents that you previously uploaded will be displayed.

> Collection 2 - Apheresis Material Testing Information for Apheresis ID : APH56567878

Additional Information

Collection and Cryopreservation Comments ⓘ

Comments

Additional Documentation

Please upload files up to 5 MB in the following format: doc, docx, txt, pdf, xls, xlsx, csv, ppt, pptx, jpg, jpeg, png.

[Upload Files](#) Or drop files

Document Name	Document Type*	Uploaded Date	Uploaded By
CBC Data.pdf	CBC Data	22 Apr 2021	Andreas Krueger ×

[Back](#) [Save for Later](#) [Next](#)

Review ADF

The Summary and Submission screen is displayed.

32. Scroll through the form and review the information you entered

Note: This is a scrollable form that displays all the details entered in the ADF.

[Back to Patient List](#)
[Go to Shipment Details](#)

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details
- Recommended Cryopreservation Details
- Summary and Submit

Summary and Submission

Print ADF

Product Order Summary

Site and Scheduling Information

Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Cryopreserved Apheresis Pick Up 29 Apr 2021 12:00 CET	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

Edit ADF

33. If you should need to update any information, click **Edit** next to the relevant section to access the editable fields

Recommended Collection Details Edit

Collection 1 - Preapheresis Peripheral Blood Testing for Apheresis ID : 12345

Complete Blood Count (CBC) with Differential

Date Of Testing	Time	Time Zone
21 Apr 2021	08:00	CET

Hemoglobin (g/dL)
13

Platelets (x10⁹/L)
150

Absolute Counts

Date Of Testing	Time	Time Zone
23 Apr 2021	08:00	CET

White Blood Cell Count (/μL)
5,000

Absolute Lymphocyte Count (/μL)
400

Flow Cytometry

Date Of Testing	Time	Time Zone
-----------------	------	-----------

Submit ADF

After reviewing all the information, scroll to the bottom of the form.

34. Click **Submit**

Note: This is a scrollable form that displays all the details entered in the ADF.

ADF Submission and Approval

Collection Details Completed by Andreas Krueger	Collection Details Completed Date/Time 26 Apr 2021 22:16 CET
ADF Submitted By	ADF Submitted Date/Time
ADF Approved By	ADF Approved Date/Time

34

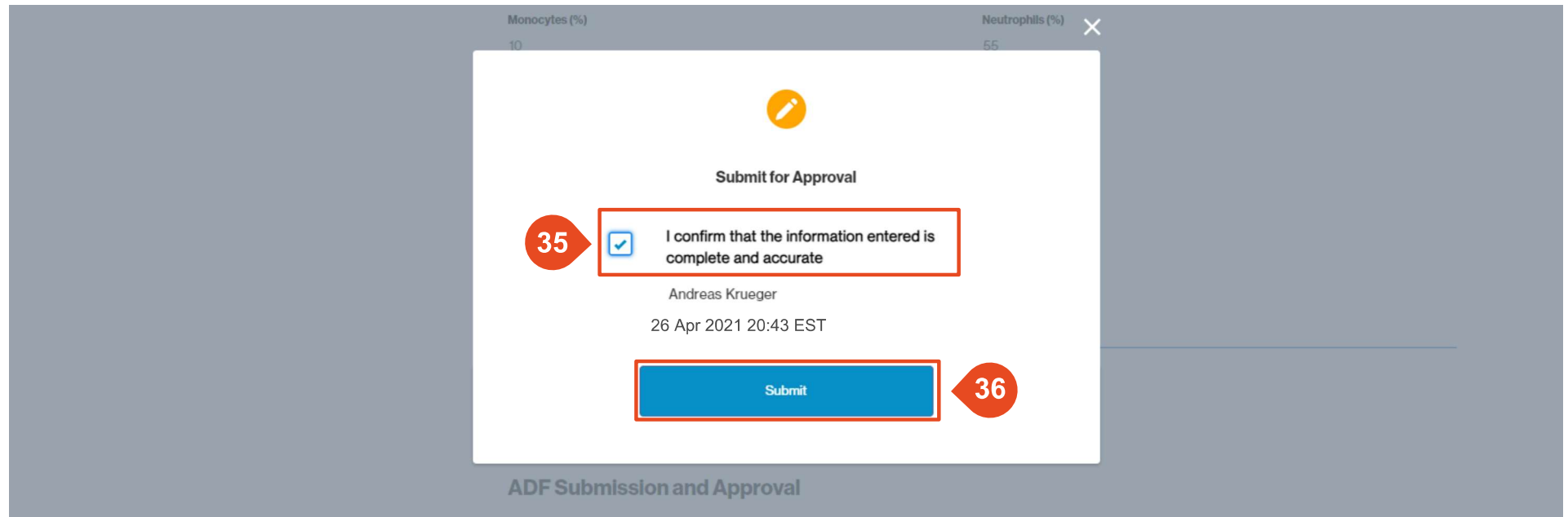
Submit

Confirm and Submit ADF

A **Submit for Approval** prompt will be displayed.

35. Check the box to confirm that the information entered is complete and accurate

36. Click **Submit**





Confirm and Submit ADF (cont)


A confirmation message will be displayed.

Patient Name ADF PENDING APPROVAL
Marie Plank

Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Patient Weight (kg) 45	Novartis Batch ID NT15197
-------------------------------------	---	--------------------------------------	------------------------------------	-------------------------------------

[Back to Patient List](#)
[Go to Shipment Details](#)

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details
- Recommended Cryopreservation Details
- Summary and Submit


Collection and Cryopreservation Submitted
Thank you, the Apheresis Data Form has now been submitted
[Back to Patient List](#)



Cell and Gene Therapy

Apheresis Data Form Approval or Rejection

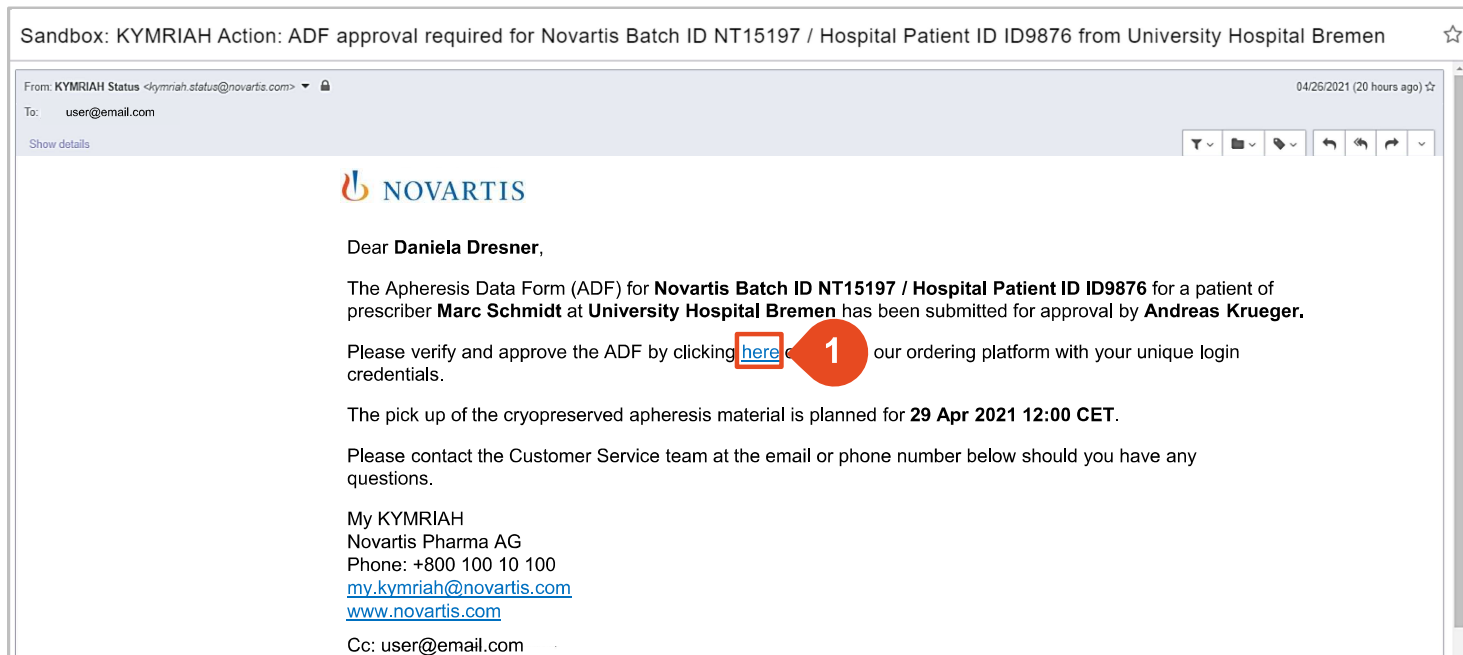
 **NOVARTIS** | Reimagining Medicine

Receive Email

You will receive an email notification stating that ADF approval is required.

1. Click the link in the email to access the CellChain™ login page

Note: Only a second apheresis or cell processing user (who is different from the first user who submitted the ADF) can verify and approve (or reject) the ADF.



Verify Patient Data and Enter DIN/Aph ID

Verify that the patient data accurately match your most recent medical assessments/records and cryobag labels.

2. Enter the **DIN** or **Apheresis ID** associated with the collection. If there were multiple collections, enter the DIN or Apheresis ID for any collection
3. Click **Enter**

Patient Name Marie Plank				ADF PENDING APPROVAL	
Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Patient Weight (kg) 45	Novartis Batch ID NT15197	

[Back to Patient List](#)
[Go to Shipment Details](#)

Summary and Approval

Please enter the Apheresis ID associated with this collection to proceed.

2

Daniela Dresner
25 Apr 2021 22:45 CET

3

Note: Enter the **DIN** (Donation Identification Number) if your institution is ISBT 128-compliant. If your institution is not ISBT 128-compliant, enter the **Apheresis ID**.

Verify ADF Information

The ADF will display in a read-only format, with relevant information captured in the sections listed below:

- **Product Order Summary**
- **Infectious Disease Testing**
- **Required Collection Details**
- **Recommended Collection Details**
- **Required Cryopreservation Details**
- **Recommended Cryopreservation Details**
- **Additional Information**
- **ADF Submission and Approval**

4. Verify the information in the different sections of the ADF

Patient Name **Marie Plank** ADF PENDING APPROVAL

Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Patient Weight (kg) 45	Novartis Batch ID NT15197
------------------------------	--	-------------------------------	---------------------------	------------------------------

[Back to Patient List](#) [Go to Shipment Details](#)

Summary and Approval

[Print ADF](#)

Product Order Summary

Site and Scheduling Information

Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Cryopreserved Apheresis Pick Up 29 Apr 2021 12:00 CET	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

Approve or Reject ADF

After verifying the information in the ADF, scroll to the bottom of the form.

5. If the information in the ADF is accurate, click **Approve**
6. If you should find inaccurate information in the ADF, click **Reject**

ADF Submission and Approval

Collection Details Completed by Andreas Krueger	Collection Details Completed Date/Time 26 Apr 2021 22:16 CET
ADF Submitted By Andreas Krueger	ADF Submitted Date/Time 26 Apr 2021 22:35 CET
ADF Approved By	ADF Approved Date/Time

Note: If you do not wish to decide at this time, you can safely log out and return at a later date/time to complete the process.

The screenshot shows a form titled "ADF Submission and Approval" with a table of submission details. Below the table are two buttons: "Reject" and "Approve". A red callout bubble with the number "6" points to the "Reject" button, and another red callout bubble with the number "5" points to the "Approve" button. A red note box is positioned below the "Reject" button, containing the text: "Note: If you do not wish to decide at this time, you can safely log out and return at a later date/time to complete the process."

Confirm Approval

If you click the Approve button, the following scenario covers the Approval flow.

- 7a. Check the box to confirm that the information in the ADF is complete and accurate
- 7b. Click **Approve**

Note: Click **Cancel** to return to the previous screen without approving the ADF.

Confirm Approval (continued)


7c. A confirmation message will be displayed

Patient Name **Marie Plank** ADF APPROVED

Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
11 Apr 1988	Diffuse Large B-Cell Lymphoma	ID9876	45	NT15197

[Back to Patient List](#)
[Go to Shipment Details](#)

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details
- Recommended Cryopreservation Details
- Summary and Submit



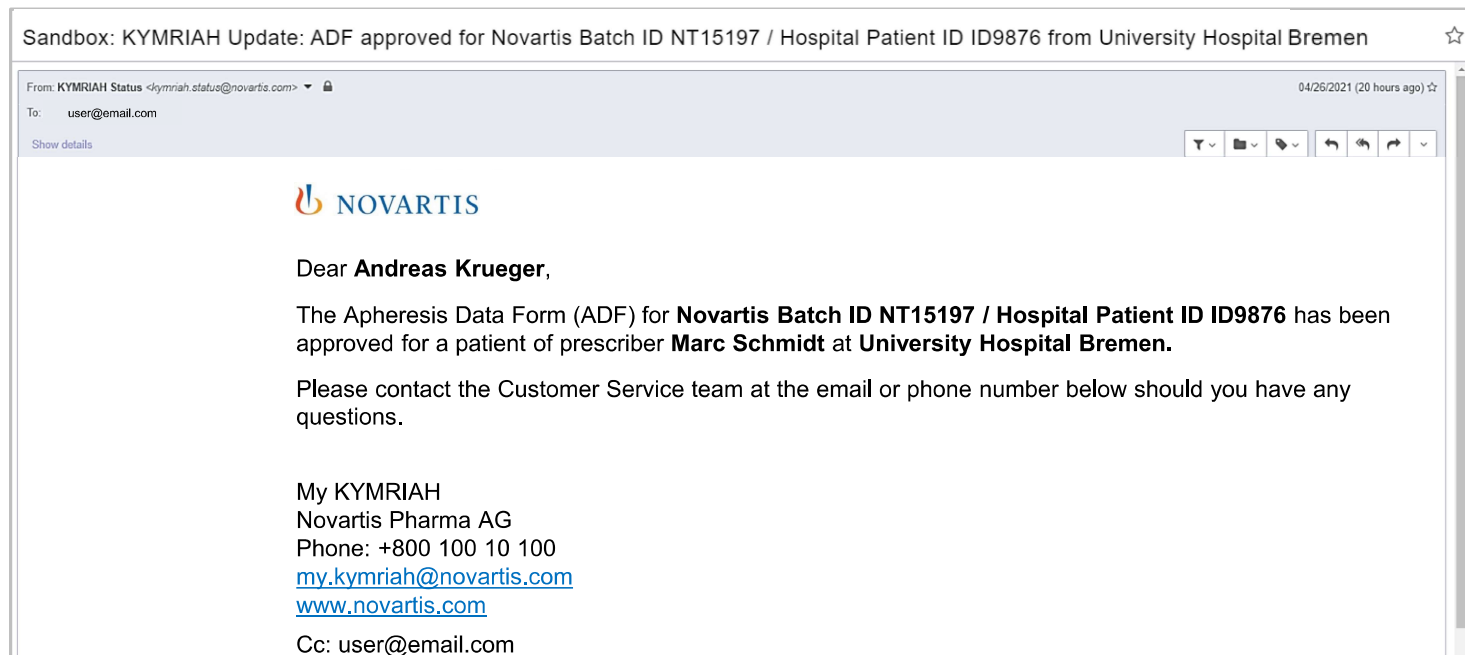
Collection and Cryopreservation Approved

Thank you, the Apheresis Data Form has now been submitted and approved

[Back to patient list](#)

Receive Email

7d. The ADF Submitter will receive an email notification stating that the ADF has been approved



Confirm Rejection

The following scenario covers the Rejection flow, using a different order as the example.

- 8a. Enter a reason for rejecting the ADF. This reason will be sent to the ADF submitter, who will need to make corrections and resubmit for approval
- 8b. Click **Reject**

Collection and Cryopreservation Comments

Reject Apheresis Data Form

Please enter a reason for rejecting the ADF. This will be sent to the submitter

Volume of blood processed needs to be corrected

Cancel Reject

Confirm Rejection (continued)

8c. A confirmation message will be displayed

The screenshot displays the Novartis Collection & Cryopreservation interface. At the top left is the Novartis logo, and the page title is "Collection & Cryopreservation". On the top right, there is a search icon and the user name "Daniela Dresner". The main content area shows patient information for "Lukas Weber" (Patient Name), "09 Jun 1991" (Date of Birth), "Diffuse Large B-Cell Lymphoma" (Indication / Clinical Trial), "ID54321" (Hospital Patient ID), "55" (Patient Weight (kg)), and "NT30531" (Novartis Batch ID). A red "ADF REJECTED" status is visible in the top right corner. Below the patient information, there are two links: "Back to Patient List" and "Go to Shipment Details". A red callout bubble labeled "8c" points to a modal dialog box. The dialog box has a red "X" icon at the top and contains the text "Collection and Cryopreservation Rejected" and "Thank you, the Apheresis Data Form has now been Rejected". A "Back to Patient List" button is located at the bottom of the dialog box.

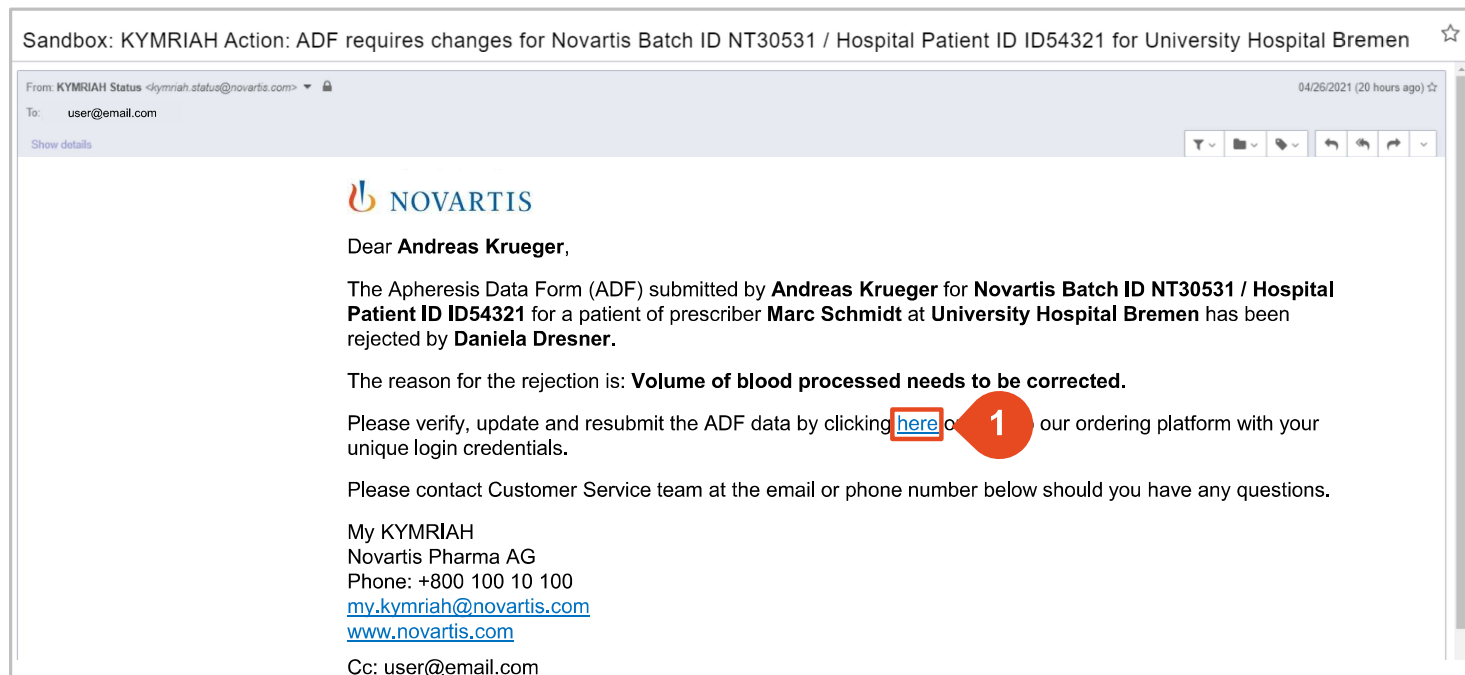
Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
09 Jun 1991	Diffuse Large B-Cell Lymphoma	ID54321	55	NT30531

Receive Email

The ADF Submitter will receive an email notification stating that the ADF has been rejected and requires changes.

1. Click the link in the email to log in to CellChain™

Note: The ADF must be corrected, submitted, and approved before manufacturing begins.



Update ADF

Open the Rejected ADF and verify the patient details.

2. Scroll to section which requires correction and click the **Edit** button



Required Collection Details

[Edit](#)

Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Apheresis System Used Fenwal Amicus®	Other

Collection and Cryopreservation Comments

Required Collection Details

Collection	Apheresis ID	Volume of blood processed (litres)	End of Apheresis Collection Date	End of Apheresis Collection Time ⓘ	Time Zone ⓘ
1.	APH0987	14.8	22 Apr 2021	11:00	CET



Update ADF (continued)

3. Make the required correction(s)
4. Click **Next** to proceed with the ADF re-submission

Apheresis Collections

Collection	Apheresis ID ¹	Volume of blood processed (litres) ¹	End of Apheresis Collection Date	End of Apheresis Collection Time ¹	Time Zone ¹
1.	APH0987	4.8	22 Apr 2021	11:00	CET

[Add another collection](#)

[Back](#) [Save for Later](#) [Next](#)



Cell and Gene Therapy

ADF List View

ADF List View

If you log in to CellChain™ without using the email links, the ADF list view is displayed.

By default, this list displays all active ADFs for your site. You can use the available filtering options to filter the list view per your requirements.

1. Click the **Active ADF** drop-down to view the available filtering options

NOVARTIS Collection & Cryopreservation Gabriele Fruehauf

Active ADF 1

3 items • Sorted by Patient • Filtered by All collection & cryopreservations - Status • Updated a few seconds ago

Search this list... ⚙️ 📄 🔄 ⏴

Patient ↑	Date of Birth	Novartis Batch ID	Hospital Patient ID/Protocol Subject ID	Indication / Clinical Trial	Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick up	Status
		NTT7611	ID14478	Diffuse Large B-Cell Lymphoma	22.04.2021 00:00		Awaiting ADF
		NT28236	23455	Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF
		NT32751	ID56678	Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF

Note: All dates, except Date of Birth, in the List Views will appear in your local date format (eg, DD/MM/YYYY), and are chronologically sortable.

Filtering and Search Options

2. These are the available list view filtering options

Apart from the list view filtering options, you can also filter using the Novartis Batch ID or Patient Name.

3. In the **Search** field, enter the **Novartis Batch ID** or **Patient Name** to filter the list view

The screenshot shows the Novartis CellChain interface. At the top left is the Novartis logo. A search bar and user profile (Gabriele Fruehauf) are at the top right. A dropdown menu for 'Active ADF' is open, showing a list of views: 'Active ADF (Pinned list)', 'ADF Pending Approval', 'All ADF', 'Approved ADF', 'Cancelled Order', 'Recently Viewed', and 'Rejected ADF'. A red callout box with a '2' points to the 'Active ADF (Pinned list)' option, and another red callout box with a '3' points to the search bar. A table of data is visible on the right side of the interface.

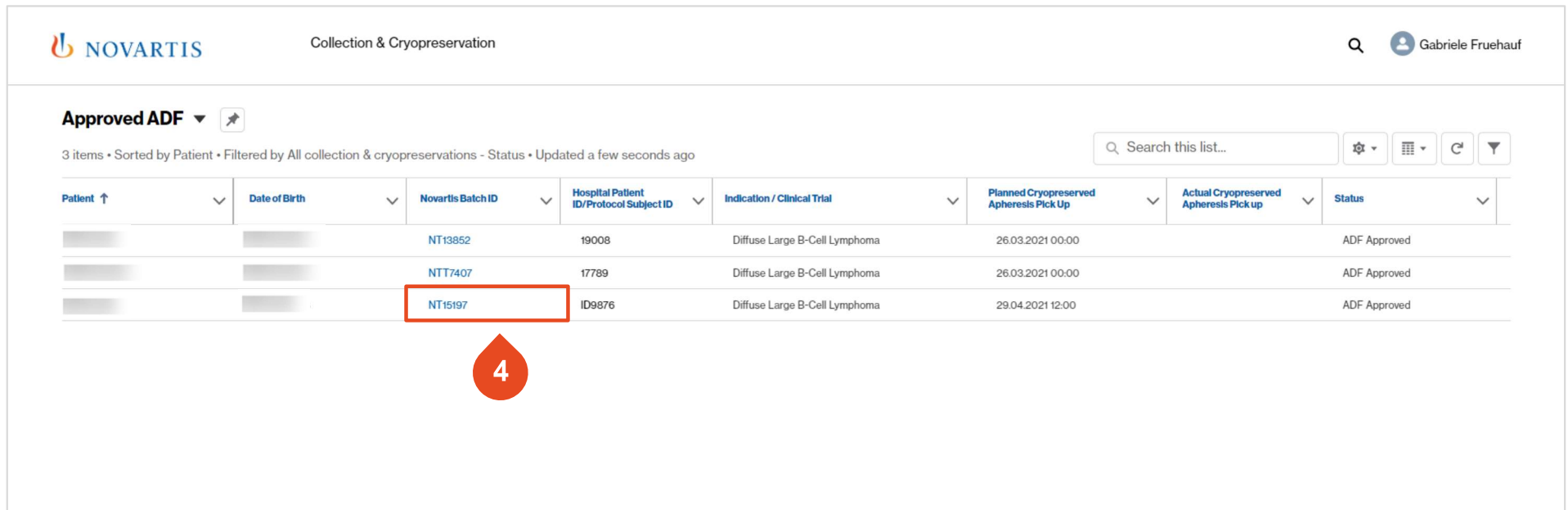
Note: You can click the pin icon to pin the selected list view as your default. The pinned view will then be displayed every time you log in to CellChain™.

Indication / Clinical Trial	Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick up	Status
Diffuse Large B-Cell Lymphoma	22.04.2021 00:00		Awaiting ADF
Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF
Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF

Note: All dates, except Date of Birth, in the List Views will appear in your local date format (eg, DD/MM/YYYY), and are chronologically sortable.

Filtered View/Search Results

4. In the filtered list view, click the **Novartis Batch ID** in a record to open the relevant ADF



NOVARTIS Collection & Cryopreservation

Approved ADF

3 items • Sorted by Patient • Filtered by All collection & cryopreservations - Status • Updated a few seconds ago

Patient ↑	Date of Birth	Novartis Batch ID	Hospital Patient ID/Protocol Subject ID	Indication / Clinical Trial	Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick up	Status
		NT13852	19008	Diffuse Large B-Cell Lymphoma	26.03.2021 00:00		ADF Approved
		NTT7407	17789	Diffuse Large B-Cell Lymphoma	26.03.2021 00:00		ADF Approved
		NT15197	ID9876	Diffuse Large B-Cell Lymphoma	29.04.2021 12:00		ADF Approved

Note: All dates, except Date of Birth, in the List Views will appear in your local date format (e.g. DD/MM/YYYY), and are chronologically sortable.



View ADF

5. Review the patient details in the header section of the ADF
6. Scroll to review the information in the different sections of the ADF

The screenshot displays the ADF interface for patient Marie Plank. The header section includes the patient name and 'ADF APPROVED' status. Below this, a table lists patient details: Date of Birth (11 Apr 1988), Indication / Clinical Trial (Diffuse Large B-Cell Lymphoma), Hospital Patient ID (ID9876), Patient Weight (45 kg), and Novartis Batch ID (NT15197). A navigation menu on the left lists steps from 'Verify Patient Details' to 'Summary and Submit', with a red callout '5' pointing to 'Verify Patient Details' and '6' pointing to 'Required Collection Details'. The main content area is titled 'Summary and Submission' and contains a 'Product Order Summary' section with 'Site and Scheduling Information'. This section is divided into two columns: 'Ordering Hospital Name' (University Hospital Bremen) and 'Prescriber' (Marc Schmidt); 'Apheresis Collection Center' (Cell Lab Bremen-X, Musterstrasse 1, Building A 62, 28001 BREMEN, GERMANY) and 'Apheresis Pick Up Location' (Cell Lab Bremen-X, Musterstrasse 1, Building A 62, 28001 BREMEN, GERMANY); 'Planned Cryopreserved Apheresis Pick Up' (26 Jan 2022 13:00 CET) and 'Manufacturing Plant' (PharmOps Plant Stein, Schaffhauserstrasse 101, 43322 Stein, Aargau, Switzerland). A 'Print ADF' button is located in the top right of the summary section. Below the summary is an 'Infectious Disease Testing' section with an 'Edit' button.

Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
11 Apr 1988	Diffuse Large B-Cell Lymphoma	ID9876	45	NT15197

Summary and Submission

Product Order Summary

Site and Scheduling Information

Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Cryopreserved Apheresis Pick Up 26 Jan 2022 13:00 CET	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

Infectious Disease Testing

Printing an Approved Apheresis Data Form

Printing an Approved ADF

Access the approved ADF.

1. In the ADF Summary View, click **Print ADF**. (Please follow institutional guidelines related to saving and printing patient information)

Patient Name **Marie Plank** ADF APPROVED

Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Patient Weight (kg) 45	Novartis Batch ID NT15197
------------------------------	--	-------------------------------	---------------------------	------------------------------

[Back to Patient List](#) **Print ADF**
[Go to Shipment Details](#)

ADF Summary View

Product Order Summary

Site and Scheduling Information

Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY

Printing an Approved ADF (continued)

The ADF opens in a new browser tab. Depending on the browser you use, the available options may be different.

2. Click the **Printer** icon to print the ADF
3. Click the **Save** icon to download a PDF copy of the ADF

1 of 5

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Page 1 of 5

Apheresis Data Form (ADF)

[Product Request Summary for Novartis Batch ID: NT15197](#)

Hospital Patient ID:	ID9876	Indication:	KYMRIAH - DLBCL EU
Prescriber:	Marc Schmidt		



Printing an Approved ADF (continued)

The footer of the document will display the version of the ADF. Confirm that the correct version is saved/printed for your center records.

In case there is a change to the ADF, and a new version is issued, you will be notified via email. In this case, ensure that you retrieve and save the latest version and archive or delete any prior version(s) you may have printed or saved.

Infectious Disease Testing		
Item	Requirement	Do results conform to requirement?
Hepatitis B (HBV)	No Active Infection	<input checked="" type="checkbox"/> Yes
Hepatitis C (HCV)	No Infection	<input checked="" type="checkbox"/> Yes
HIV	No Infection	<input checked="" type="checkbox"/> Yes
Any additional required autologous donor eligibility and/or infectious disease testing has been completed in compliance with institutional and local Health Authority requirements, and is determined to acceptable.	Additional Tests Completed	<input checked="" type="checkbox"/> Yes
Determination of the patient's HBV, HCV, and HIV status was completed within 30 calendar days prior to collection or any date after collection. Note: Superseded by stricter local regulatory requirement if applies.	Completed Within 30 days	<input checked="" type="checkbox"/> Yes

Note: the bottom of every page will display the Novartis Batch ID-ADF-Version Number

NT15197-ADF-V01

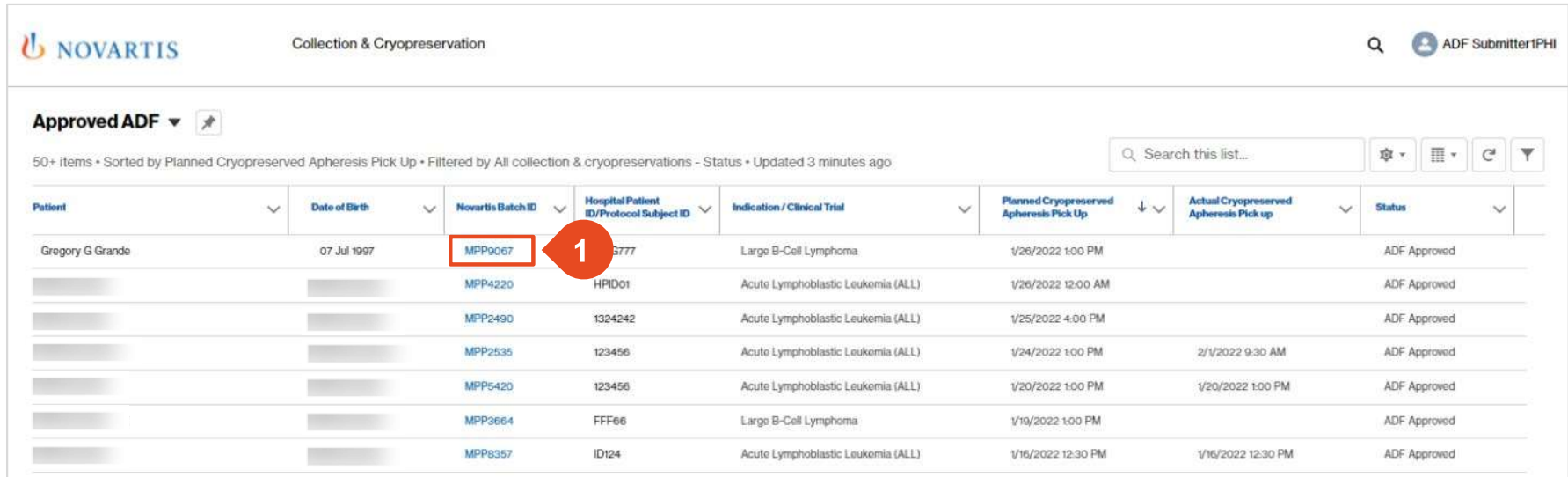
Editing an Approved Apheresis Data Form

How to Edit an Approved ADF

In the ADF List View, search for the approved ADF you would like to edit.

Note: The edited ADF must be resubmitted and reapproved before manufacturing begins.

1. Click the **Novartis Batch ID** to open the ADF



The screenshot shows the 'Collection & Cryopreservation' interface. At the top left is the Novartis logo. The page title is 'Collection & Cryopreservation'. On the right, there is a search icon and a user profile icon labeled 'ADF Submitter1PHI'. Below the header, there is a section for 'Approved ADF' with a dropdown arrow and a plus icon. Below this, it says '50+ items • Sorted by Planned Cryopreserved Apheresis Pick Up • Filtered by All collection & cryopreservations - Status • Updated 3 minutes ago'. There is a search bar 'Search this list...' and several filter icons. The main table has the following columns: Patient, Date of Birth, Novartis Batch ID, Hospital Patient ID/Protocol Subject ID, Indication / Clinical Trial, Planned Cryopreserved Apheresis Pick Up, Actual Cryopreserved Apheresis Pick up, and Status. The first row is for Gregory G Grande, born 07 Jul 1997, with Novartis Batch ID MPP9067, Hospital Patient ID HPID01, Indication Large B-Cell Lymphoma, Planned Pick Up 1/26/2022 1:00 PM, Actual Pick Up 2/1/2022 9:30 AM, and Status ADF Approved. A red box highlights the 'MPP9067' cell, and a red circle with the number '1' points to it.

Patient	Date of Birth	Novartis Batch ID	Hospital Patient ID/Protocol Subject ID	Indication / Clinical Trial	Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick up	Status
Gregory G Grande	07 Jul 1997	MPP9067	HPID01	Large B-Cell Lymphoma	1/26/2022 1:00 PM	2/1/2022 9:30 AM	ADF Approved
		MPP4220	HPID01	Acute Lymphoblastic Leukemia (ALL)	1/26/2022 12:00 AM		ADF Approved
		MPP2490	1324242	Acute Lymphoblastic Leukemia (ALL)	1/25/2022 4:00 PM		ADF Approved
		MPP2535	123456	Acute Lymphoblastic Leukemia (ALL)	1/24/2022 1:00 PM	2/1/2022 9:30 AM	ADF Approved
		MPP5420	123456	Acute Lymphoblastic Leukemia (ALL)	1/20/2022 1:00 PM	1/20/2022 1:00 PM	ADF Approved
		MPP3664	FFF66	Large B-Cell Lymphoma	1/19/2022 1:00 PM		ADF Approved
		MPP8357	ID124	Acute Lymphoblastic Leukemia (ALL)	1/16/2022 12:30 PM	1/16/2022 12:30 PM	ADF Approved

How to Edit an Approved ADF (continued)

Verify that the patient details in the header section are correct.

2. Scroll through the ADF to the section that requires editing

The screenshot displays the Novartis ADF interface for 'Collection & Cryopreservation'. The top header includes the Novartis logo, the text 'Collection & Cryopreservation', a search icon, and the user 'ADF SubmitterPH'. The patient name 'Gregory G Grande' is highlighted with a red box. Below the name, a table lists patient details: Date of Birth (07 Jul 1997), Indication / Clinical Trial (Large B-Cell Lymphoma), Hospital Patient ID (GGG777), Patient Weight (kg) (77), and Novartis Batch ID (MPP9067). A green 'ADF APPROVED' status is visible in the top right. A navigation menu on the left includes 'Back to Patient List', 'Go to Shipment Details', and a vertical list of steps: 'Verify Patient Details', 'Product Order Summary', 'Required Collection Details', 'Recommended Collection Details', 'Required Cryopreservation Details', 'Recommended Cryopreservation Details', and 'Summary and Submit'. The 'Summary and Submission' section is highlighted with a red box and contains a 'Print ADF' button. This section includes a 'Product Order Summary' and 'Site and Scheduling Information' with details for 'Ordering Hospital Name' (University Hospital Bremen), 'Prescriber' (Marc Schmidt), 'Apheresis Collection Center' (Cell Lab Bremen-X, Musterstrasse 1, Building A 62, 28001 BREMEN, GERMANY), 'Planned Cryopreserved Apheresis Pick Up' (26 Jan 2022 13:00 CET), 'Apheresis Pick Up Location' (Cell Lab Bremen-X, Musterstrasse 1, Building A 62, 28001 BREMEN, GERMANY), and 'Manufacturing Plant' (PharmOps Plant Stein, Schaffhauserstrasse 101, 43322 Stein, Aargau, Switzerland). An 'Infectious Disease Testing' section with an 'Edit' button is visible at the bottom of the summary area. A red circle with the number '2' is positioned to the right of the summary section.

Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
07 Jul 1997	Large B-Cell Lymphoma	GGG777	77	MPP9067

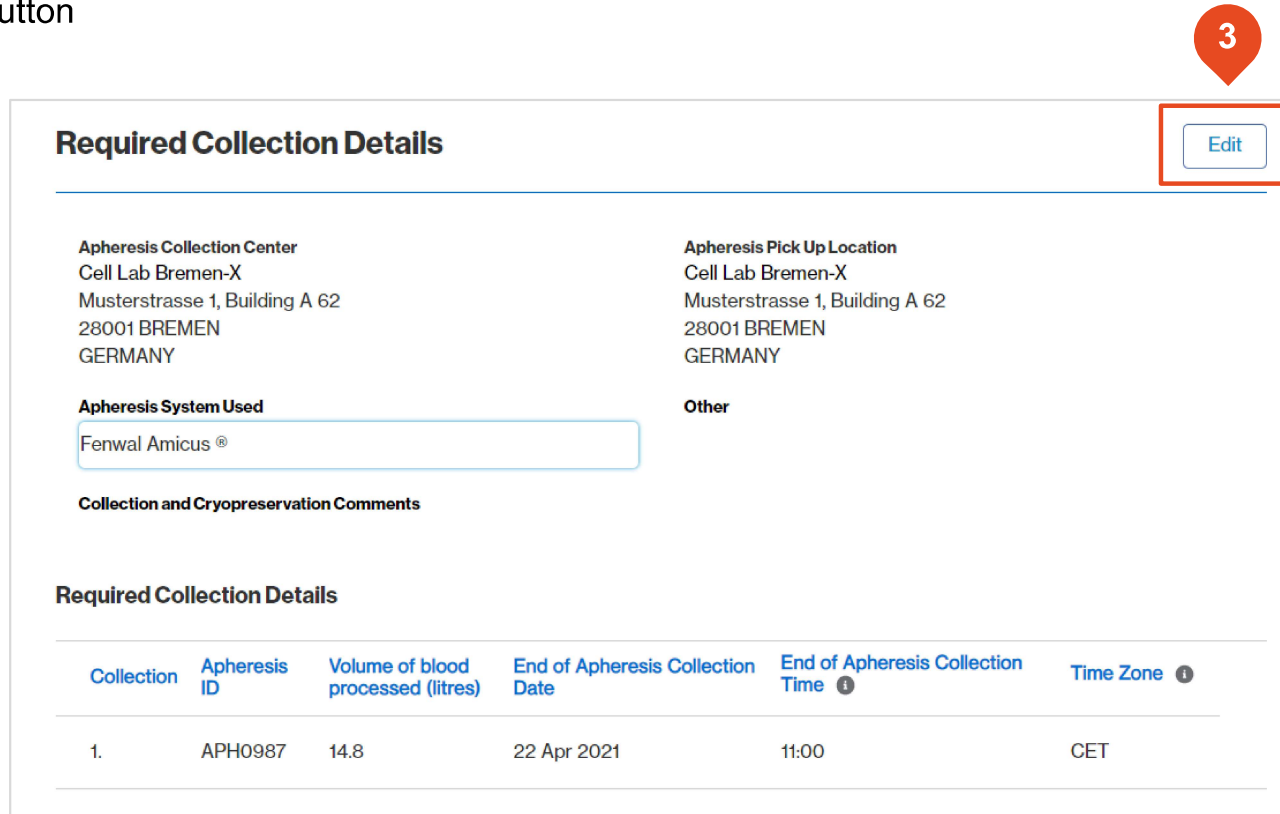
Ordering Hospital Name	Prescriber
University Hospital Bremen	Marc Schmidt

Apheresis Collection Center	Apheresis Pick Up Location
Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY

Planned Cryopreserved Apheresis Pick Up	Manufacturing Plant
26 Jan 2022 13:00 CET	PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

How to Edit an Approved ADF (continued)

3. Click the **Edit** button



Required Collection Details

Apheresis Collection Center
Cell Lab Bremen-X
Musterstrasse 1, Building A 62
28001 BREMEN
GERMANY

Apheresis Pick Up Location
Cell Lab Bremen-X
Musterstrasse 1, Building A 62
28001 BREMEN
GERMANY

Apheresis System Used
Fenwal Amicus ®

Other

Collection and Cryopreservation Comments

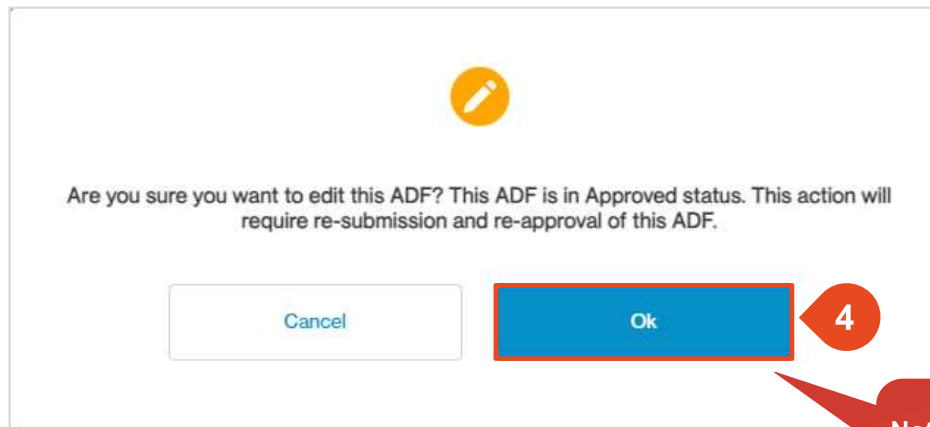
Required Collection Details

Collection	Apheresis ID	Volume of blood processed (litres)	End of Apheresis Collection Date	End of Apheresis Collection Time ⓘ	Time Zone ⓘ
1.	APH0987	14.8	22 Apr 2021	11:00	CET

How to Edit an Approved ADF (continued)

A pop-up window will appear, confirming that you wish to edit the approved ADF.

4. Click **OK** to proceed



Note: After clicking OK, the ADF status will change to ADF PENDING SUBMISSION.

How to Edit an Approved ADF (continued)

5. After clicking OK, the ADF status will change to **ADF PENDING SUBMISSION**
6. Make the required edit
7. Click **Next** to proceed with the ADF re-submission

The screenshot displays the 'Collection & Cryopreservation' interface for patient Gregory G Grande. The status is 'ADF PENDING SUBMISSION'. The patient's details include Date of Birth (07 Jul 1997), Indication (Large B-Cell Lymphoma), Hospital Patient ID (GGG777), Patient Weight (77 kg), and Novartis Batch ID (MPP9067). The 'Required Collection Details' section shows the Apheresis Collection Center and Apheresis Pick Up Location, both at Cell Lab Bremen-X, Musterstrasse 1, Building A 62, 28001 BREMEN, GERMANY. The Apheresis System Used is Fenwal Amicus. The 'Apheresis Collections' table has one entry with Apheresis ID APH0987, Volume of blood processed (liters) 4.0, End of Apheresis Collection Date 22 Apr 2021, End of Apheresis Collection Time 11:00, and Time Zone CET. The interface includes a 'Next' button and a 'Save for Later' button.

Collection	Apheresis ID	Volume of blood processed (liters)	End of Apheresis Collection Date	End of Apheresis Collection Time	Time Zone
1.	APH0987	4.0	22 Apr 2021	11:00	CET

How to Edit an Approved ADF (continued)

A pop-up window will appear.

8. Confirm the changes by providing details in the **Reason for data update** text field
9. Click **Save Changes** to proceed with the ADF re-submission

Confirm Changes

Please confirm your request to amend collection and cryopreservation details and please provide some comments on why this update is necessary.

Reason for data update ⓘ

Volume of blood processed was previously incorrect.

Back Save Changes

How to Edit an Approved ADF (continued)

10. Click **Next** in each subsequent screen to navigate through further sections of the ADF

The screenshot displays the 'Recommended Collection Details' screen for patient Gregory G Grande. The interface includes a sidebar with navigation steps: Verify Patient Details, Product Order Summary, Required Collection Details (highlighted), Required Cryopreservation Details, Recommended Cryopreservation Details, and Summary and Submit. The main form area contains the following sections:

- Collection 1 - Preapheresis Peripheral Blood Testing for Apheresis ID: APH0987**
 - Complete Blood Count (CBC) with Differential**
 - Date of Testing: [Please select date]
 - Time: HHMM (dropdown)
 - Time Zone: CET (dropdown)
 - Hemoglobin (g/dL): [XXXXXX]
 - Platelets (x10⁹/L): []
 - Absolute Counts**
 - Date of Testing: [Please select date]
 - Time: HHMM (dropdown)
 - Time Zone: CET (dropdown)
 - White Blood Cell Count (/µL): [XXXXXXXXXX]
 - Absolute Lymphocyte Count (/µL): [XXXXXXXXXX]
 - Flow Cytometry**
 - Date of Testing: [Please select date]
 - Time: HHMM (dropdown)
 - Time Zone: CET (dropdown)
 - Absolute CD3 Lymphocyte Count (/µL): [XXXXXXXXXX]
- Additional Information**
 - Collection and Cryopreservation Comments: []
- Additional Documentation**
 - Please upload files up to 5 MB in the following format: doc, docx, txt, pdf, xls,xlsx, csv, ppt, pptx, jpg, jpeg, png.
 - Upload Files | Or drop files
 - Table with columns: Document Name, Document Type*, Uploaded Date, Uploaded By

At the bottom of the form, there are three buttons: 'Back', 'Save for Later', and 'Next'. The 'Next' button is highlighted with a red circle containing the number 10.

How to Edit an Approved ADF (continued)

11. In the final **Summary and Submission** screen, scroll through and review the sections of the ADF

Note: This is a scrollable form that displays all the details entered in the ADF.

[Back to Patient List](#)
[Go to Shipment Details](#)

- Verify Patient Details
- Product Order Summary
- Required Collection Details
- Recommended Collection Details
- Required Cryopreservation Details
- Recommended Cryopreservation Details
- Summary and Submit

Summary and Submission

Product Order Summary

Site and Scheduling Information

Ordering Hospital Name University Hospital Bremen	Prescriber Marc Schmidt
Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Cryopreserved Apheresis Pick Up 26 Jan 2022 13:00 CET	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

[Print ADF](#)

How to Edit an Approved ADF (continued)

12. After reviewing the form, scroll to the bottom and click **Submit**

Note: This is a scrollable form that displays all the details entered in the ADF.

ADF Submission and Approval

Collection Details Completed by Andreas Krueger	Collection Details Completed Date/Time 18 Jan 2022 15:00 CET
ADF Submitted By	ADF Submitted Date/Time
ADF Approved By	ADF Approved Date/Time

12

Submit

How to Edit an Approved ADF (continued)

A **Submit for Approval** prompt will be displayed.

13. Check the box to confirm that the information entered is complete and accurate
14. Click **Submit** to submit the edited ADF and begin the re-approval process

Submit for Approval

13 I confirm that the information entered is complete and accurate

ADF Submitter1PHI
26 Jan 2022 08:18

Submit 14

Note: The 2-person process for submission and approval remains the same. Only an authorized approver (other than the individual who edited the ADF) can approve the resubmitted ADF. After approval, a new version of the ADF will be created and users will be notified.

How to Edit an Approved ADF (continued)

A confirmation message will be displayed and the status updated to **ADF PENDING APPROVAL**.

The screenshot displays the Novartis Collection & Cryopreservation interface. At the top left is the Novartis logo and the text "Collection & Cryopreservation". At the top right is a search icon and the text "ADF Submitter|PHI". Below the header, the patient name "Gregory G Grande" is displayed in blue. To the right of the patient name, the status "ADF PENDING APPROVAL" is shown in a red-bordered box. Below the patient name, a table lists patient details:

Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
07 Jul 1997	Large B-Cell Lymphoma	GGG777	77	MPP9067

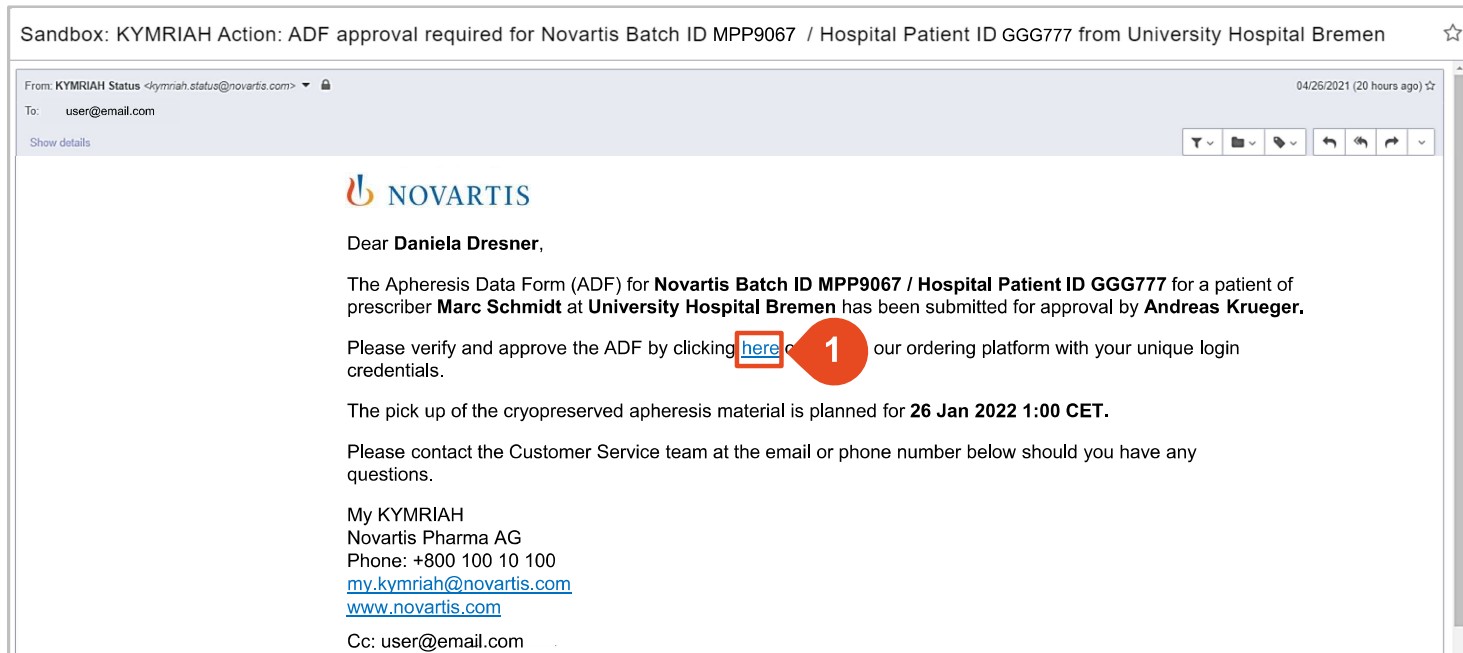
Below the table, there are two links: "Back to Patient List" and "Go to Shipment Details". On the left side, there is a vertical progress bar with eight steps: "Verify Patient Details", "Product Order Summary", "Required Collection Details", "Recommended Collection Details", "Required Cryopreservation Details", "Recommended Cryopreservation Details", and "Summary and Submit". The "Required Collection Details" step is currently selected. In the center of the page, a large red-bordered box contains a confirmation message: "Collection and Cryopreservation Submitted" with a green checkmark icon, followed by "Thank you, the Apheresis Data Form has now been submitted" and a "Back to Patient List" button.

How to Edit an Approved ADF (continued)

You will receive an email notification stating that ADF approval is required.

1. Click the link in the email to access the CellChain™ PRO login page

Note: Only a second apheresis or cell processing user (who is different from the first user who submitted the ADF) can verify and approve (or reject) the ADF.



How to Edit an Approved ADF (continued)

Verify that the patient data in the header section are accurate.

2. Enter the **DIN** or **Apheresis ID** associated with the collection. If there were multiple collections, enter the DIN or Apheresis ID for any collection
3. Click **Enter**

The screenshot displays the Novartis Collection & Cryopreservation interface. At the top, the patient name is **Gregory G Grande**. Below this, a table lists patient details:

Date of Birth	Indication / Clinical Trial	Hospital Patient ID	Patient Weight (kg)	Novartis Batch ID
07 Jul 1997	Large B-Cell Lymphoma	GGG777	77	MPP9067

The interface includes a sidebar with navigation options: Verify Patient Details, Product Order Summary, Required Collection Details, Recommended Collection Details, Required Cryopreservation Details, Recommended Cryopreservation Details, and Summary and Submit. The main content area is titled "Summary and Approval" and contains a text input field with the prompt "Please enter the DIN associated with this collection to proceed." and a blue "Enter" button. Red boxes and callouts highlight the input field (labeled '2') and the "Enter" button (labeled '3'). A status indicator "ADF PENDING APPROVAL" is visible in the top right corner.

How to Edit an Approved ADF (continued)

Review all details in the different sections of the ADF and scroll to the bottom of the page.

4. If the information in the ADF is accurate, click **Approve** to proceed

Note: If information is inaccurate, click **Reject** and follow the [rejection process flow](#)

ADF Submission and Approval

Collection Details Completed by ADF Submitter1PHI	Collection Details Completed Date/Time 18 Jan 2022 15:00 CET
ADF Submitted By ADF Submitter1PHI	ADF Submitted Date/Time 26 Jan 2022 08:18 CET
ADF Approved By	ADF Approved Date/Time

4

How to Edit an Approved ADF (continued)

A pop-up window will appear.

5. Check the box to confirm that the information in the ADF is complete and accurate
6. Click **Approve** to approve the edited ADF

Approve Apheresis Data Form

5 I confirm that the information entered is complete and accurate

ADF Approver/Submitter1PHI
26 Jan 2022 08:53 EST

Cancel Approve 6

How to Edit an Approved ADF (continued)

A confirmation message will be displayed and the status updated to **ADF APPROVED**.

The screenshot displays the Novartis Collection & Cryopreservation interface. At the top left is the Novartis logo. The page title is "Collection & Cryopreservation". On the top right, there is a search icon and a user profile icon labeled "ADF Approver/Submi...".

The patient information section shows:

- Patient Name: **Gregory G Grande**
- Date of Birth: 07 Jul 1997
- Indication / Clinical Trial: Large B-Cell Lymphoma
- Hospital Patient ID: GGG777
- Patient Weight (kg): 77
- Novartis Batch ID: MPP9067

On the right side of the patient information section, a red-bordered box highlights the text "ADF APPROVED".

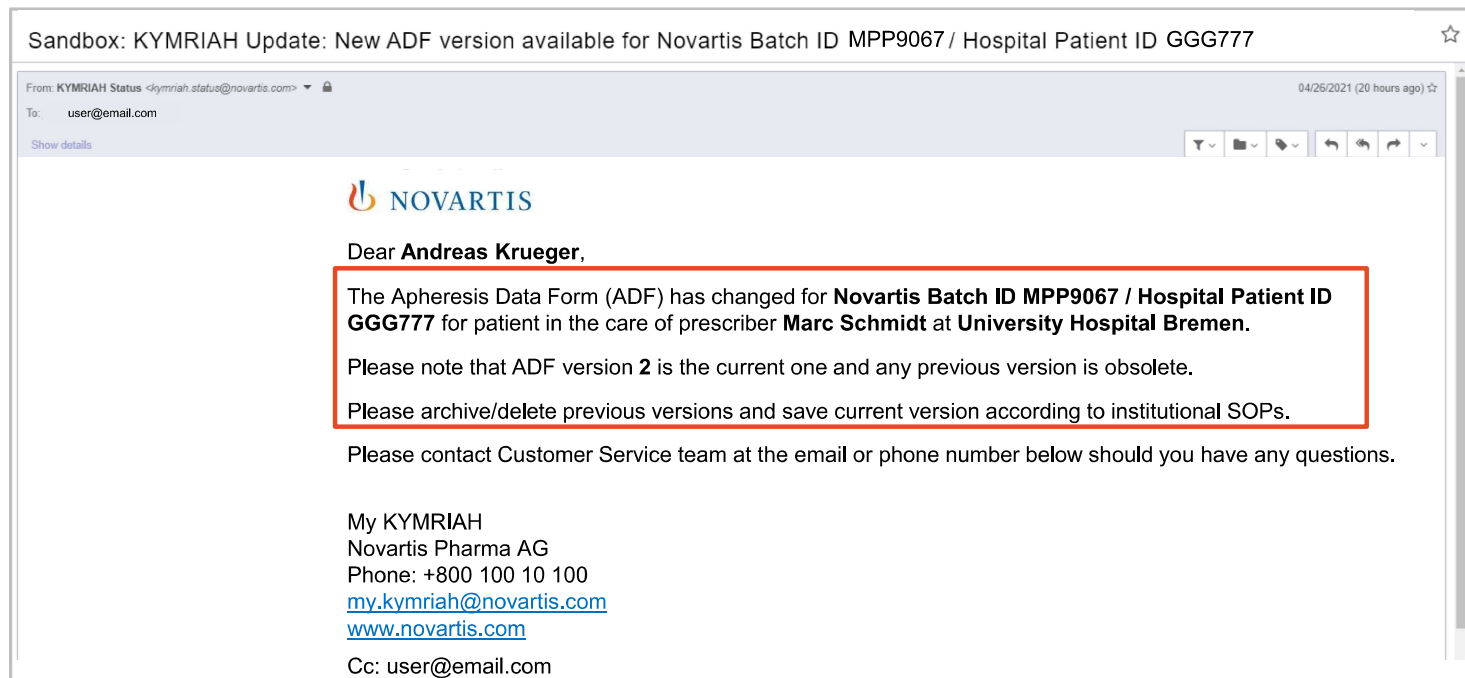
Below the patient information, there are two links: "Back to Patient List" and "Go to Shipment Details".

In the center of the page, a large red-bordered box contains a confirmation message:

- A green checkmark icon.
- Collection and Cryopreservation Approved**
- Thank you, the Apheresis Data Form has now been submitted and approved
- A button labeled "Back to Patient List".

How to Edit an Approved ADF (continued)

In case there is a change to the ADF, and a new version is issued, you will be notified via email. In this case, ensure that you retrieve and save the latest version and archive or delete any prior version(s) you may have printed or saved.





How to Edit an Approved ADF (continued)

If a new Lab version of the ADF is issued, the updated version number will be visible in the bottom right corner of the document: Novartis Batch ID-ADF-Version Number.

NOVARTIS | Reimagining Medicine Page 1 of 3

Apheresis Data Form (ADF)

[Product Request Summary for Novartis Batch ID: MPP9067](#)

Hospital Patient ID:	GGG777	Indication:	KYMRIAH - DLBCL
Prescriber:	Marc Schmidt		
Patient Identity Confirmed By:	ADF Submitter1PHI		
Apheresis Collection Center:	Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location:	Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Patient Weight:	77.00 kg		
Replacement Order Statement:	N/A		
ISBT 128 Status:	<input checked="" type="checkbox"/> ISBT 128 <input type="checkbox"/> Non-ISBT 128 <input type="checkbox"/> Exempt from Aph Label Shipment		
Manufacturing Plant:	To be determined		

[Required Collection Details for Novartis Batch ID: MPP9067](#)

Item	Requirement	Do results conform to requirement?
Hepatitis B (HBV)	No Active Infection	<input checked="" type="checkbox"/> Yes
Hepatitis C (HCV)	No Infection	<input checked="" type="checkbox"/> Yes
HIV	No Infection	<input checked="" type="checkbox"/> Yes
Any additional required autologous donor eligibility and/or infectious disease testing has been completed in compliance with institutional and local Health Authority requirements, and is determined to be acceptable.	Additional Tests Completed	<input checked="" type="checkbox"/> Yes
Determination of the patient's HBV, HCV, and HIV status was completed within 30 calendar days prior to collection or any date after collection. Note: Superseded by stricter local regulatory requirement if applies.	Completed Within 30 days	<input checked="" type="checkbox"/> Yes

MPP9067-ADF-V02

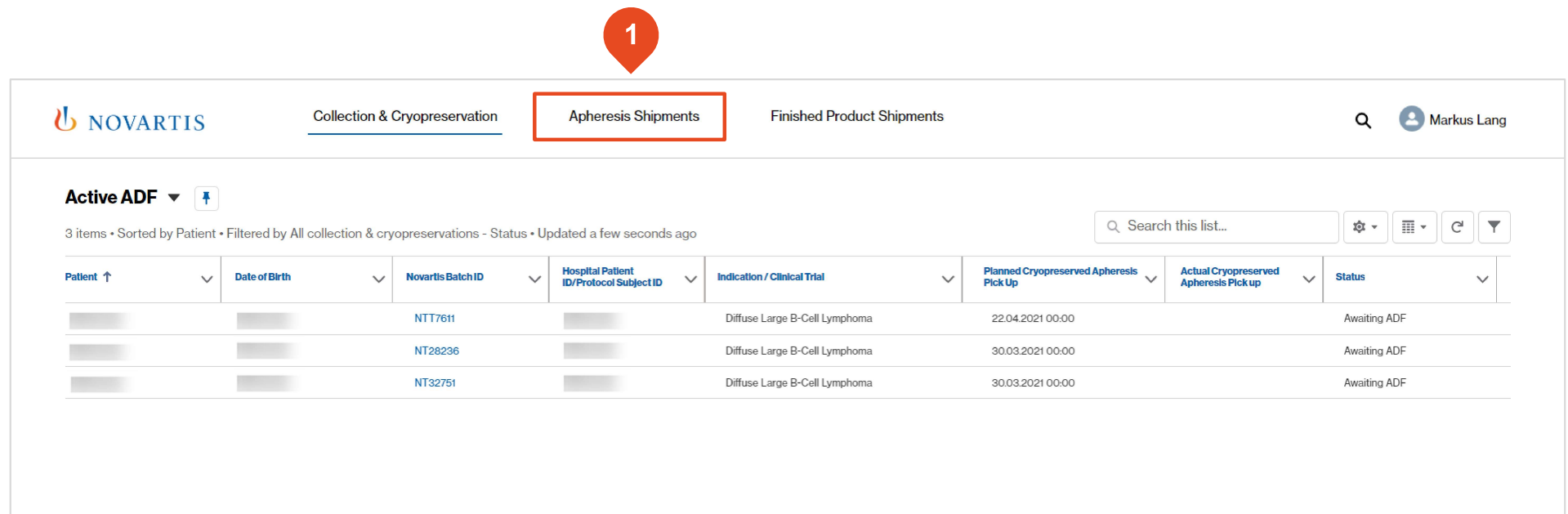
MPP9067-ADF-V02

Entering Dewar Packaging and Apheresis Pickup Details

View an Apheresis Shipment

Log in to CellChain™. By default, the Active ADF list view will be displayed.

1. Click Apheresis Shipments



The screenshot shows the CellChain interface with the 'Apheresis Shipments' tab selected. A red callout bubble with the number '1' points to the 'Apheresis Shipments' tab. The interface displays a table of active ADFs with columns for Patient, Date of Birth, Novartis Batch ID, Hospital Patient ID/Protocol Subject ID, Indication / Clinical Trial, Planned Cryopreserved Apheresis Pick Up, Actual Cryopreserved Apheresis Pick up, and Status.

Patient ↑	Date of Birth	Novartis Batch ID	Hospital Patient ID/Protocol Subject ID	Indication / Clinical Trial	Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick up	Status
		NTT7611		Diffuse Large B-Cell Lymphoma	22.04.2021 00:00		Awaiting ADF
		NT28236		Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF
		NT32751		Diffuse Large B-Cell Lymphoma	30.03.2021 00:00		Awaiting ADF

View an Apheresis Shipment (continued)

The Apheresis Shipments list view is displayed. By default, this list displays all Active Apheresis Shipments. You can use the available filtering options to filter the list view per your requirements.

2. Click a Shipment ID

Note: In a list view, you can search for a particular order using the Novartis Batch ID or Patient Name.

Active Apheresis Shipments

6 items • Sorted by Planned Cryopreserved Apheresis Pick Up • Filtered by All shipments - Status, Record Type, Actual Apheresis Received Date/Time • Updated a few seconds ago

Planned Cryopreserved Apheresis Pick Up	Actual Cryopreserved Apheresis Pick Up	Shipment ID	Patient	Date of Birth	Novartis Batch ID	Hospital Patient ID/Protocol Subject ID	Status
26.03.2021 00:00		AP00004993			NTT7407		Apheresis Pick Up Planned
26.03.2021 00:00		AP00005387			NT13852		Apheresis Pick Up Planned
30.03.2021 00:00		AP00005391			NT28236		Apheresis Pick Up Planned
30.03.2021 00:00		AP00005391			NT32751		Apheresis Pick Up Planned
22.04.2021 00:00		AP00007172			NTT7611		Apheresis Pick Up Planned
29.04.2021 12:00		AP00007485			NT15197		Apheresis Pick Up Planned

Review Shipment Information

Review and confirm the patient details in the CellChain™ header section of the ADF.

1. Review the Shipment Information

Patient Name
Marie Plank

APHERESIS PICK UP PLANNED

Date of Birth 11 Apr 1988	Indication / Clinical Trial Diffuse Large B-Cell Lymphoma	Hospital Patient ID ID9876	Prescriber Marc Schmidt	Ordering Hospital University Hospital Bremen	Novartis Batch ID NT15197
------------------------------	--	-------------------------------	----------------------------	---	------------------------------

[Back to Shipment List](#)

Apheresis Shipment Details

[Print ADF](#)

Shipment Information

[View Order Summary](#)

Status
Apheresis Pick Up Planned

Apheresis Collection Center Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY	Apheresis Pick Up Location Cell Lab Bremen-X Musterstrasse 1, Building A 62 28001 BREMEN GERMANY
Planned Charged Dewar Arrival Date/Time 29 Apr 2021 08:11 CET	Planned Cryopreserved Apheresis Pick Up 29 Apr 2021 12:00 CET

Enter Details

2. Select the **Actual Dewar Packaging Date** and **Time**. This is the time the apheresis material was loaded into the dewar
3. Select the **Actual Cryopreserved Apheresis Pickup Date** and **Time**
4. In the Cryobag/Batch Information section, enter the **Number of Sentinel Vials Shipped**
5. Check the box to confirm that all the listed cryobags and sentinel vials have been packed for this shipment

The screenshot shows a form with four main sections, each highlighted with a red callout bubble containing a number:

- 2**: **Actual Dewar Packaging Date** (calendar icon, 29 Apr 2021, close icon), **Time** (clock icon, 11:00), and **Time Zone** (dropdown, CET).
- 3**: **Actual Cryopreserved Apheresis Pick Up** (calendar icon, 29 Apr 2021, close icon), **Time** (clock icon, 12:00), and **Time Zone** (dropdown, CET).
- 4**: **Cryobag/Batch Information** section with a **Number of Sentinel Vials Shipped** input field containing the value 4.
- 5**: A confirmation checkbox checked, with the text: "Please select to confirm that all of the cryobags listed below and sentinel vials have been packed for this shipment." Below this is a table with three columns: Cryobag #, Apheresis ID, and Cryobag ID.

Cryobag #	Apheresis ID	Cryobag ID
1.	APH56567878	ID02
2.	APH13132424	ID01

Review Dewar Tracking Information

- Review the **Dewar Tracking Information**. If the Dewar Tracking Link is not working, please contact the **Novartis Customer Service Center**

2.	APH13132424	ID01
----	-------------	------

6	Dewar Tracking Information
	Waybill Number WB12354
	Dewar Tracking Link 1 https://www.cryoport.com/
	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

Note: You can click this link to check the shipment status on the courier's website. This link will take you to an alternate external website. The link and website may vary, depending on which dry vapor shipper/courier is used for the shipment.

Review Dewar Tracking Information

- Review the **Dewar Tracking Information**. If the Dewar Tracking Link is not working, please contact the **Novartis Customer Service Center**

2.	APH13132424	ID01
----	-------------	------

6	Dewar Tracking Information
	Waybill Number WB12354
	Dewar Tracking Link 1 https://evois.savsu.com/evois/quicklook/xxxxxxx
	Manufacturing Plant PharmOps Plant Stein Schaffhauserstrasse 101 43322 Stein, Aargau Switzerland

Note: You can click this link to check the shipment status on the courier's website. This link will take you to an alternate external website. The link and website may vary, depending on which dry vapor shipper/courier is used for the shipment.

Upload Additional Documents

7. Upload relevant documents in the Additional Documentation section and select the **Document Type**
8. Click **Save Documents** to ensure the document is uploaded successfully
9. Click **Save**

Additional Documentation

Please upload files up to 5 MB in the following format: doc, docx, txt, pdf, xls, xlsx, csv, ppt, pptx, jpg, jpeg, png.

[Upload Files](#) Or drop files

Select the Document Type for each uploaded file, then click the Save Documents button to submit the documents.

Document Name	Document Type*	Uploaded Date	Uploaded By
Do Not X-Ray.pdf	Do NOT X-Ray Document		

7 (points to the table row)

8 (points to the Save Documents button)

9 (points to the Save button)

Cancel Save



View Confirmation

10. The **Apheresis Shipment Details** are saved. The status is updated to **Apheresis Picked Up**

Patient Name **Marie Plank**

Date of Birth: 11 Apr 1988 Indication / Clinical Trial: Diffuse Large B-Cell Lymphoma Hospital Patient ID: ID9876 Prescriber: Marc Schmidt Ordering Hospital: University Hospital Bremen Novartis Batch ID: NT15197

10 APHERESIS PICKED UP

✓ Apheresis Shipment Details Saved

[Back to Shipment List](#)

Apheresis Shipment Details

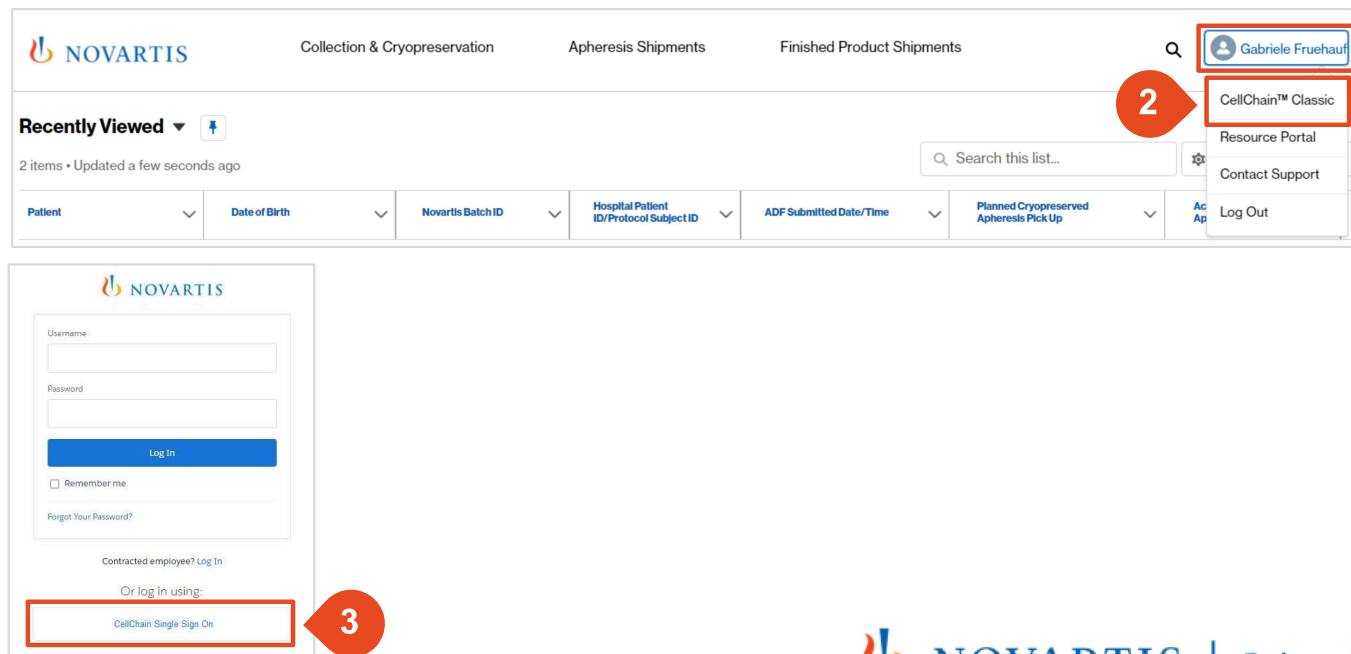
Shipment Information

Print ADF

Appendix

Access to Clinical Trial and Historical Orders in CellChain™ Classic

1. Click the **User** icon to view additional options
2. Click **CellChain™ Classic** to view clinical trial or historical orders placed in **CellChain™ Classic**. The orders will open in a new tab in your browser
3. When you see the **CellChain™ Classic** login screen, click the **CellChain Single Sign On** button to log in using the Microsoft service.

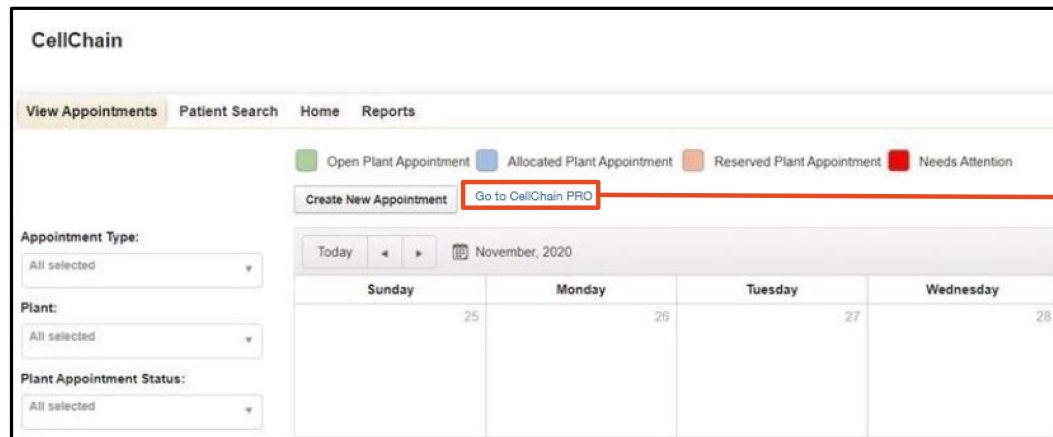


Access to Clinical Trial and Historical Orders in CellChain™ Classic

1. Click the **User** icon to view additional options
2. Click **CellChain™ Classic** to view clinical trial or historical orders placed in **CellChain™ Classic**. The orders will open in a new tab in your browser
3. [When you see the **CellChain™ Classic** login screen, click the **I have a CellChain™ PRO login** button and sign in with your **CellChain™ PRO** credentials]

The screenshot displays the Novartis CellChain™ Classic user interface. At the top, there are navigation tabs for 'Collection & Cryopreservation', 'Apheresis Shipments', and 'Finished Product Shipments'. A user profile icon for 'Gabriele Fruehauf' is highlighted with a red box and labeled '1'. A dropdown menu is open, showing options: 'CellChain™ Classic' (highlighted with a red box and labeled '2'), 'Resource Portal', 'Contact Support', and 'Log Out'. Below the navigation is a 'Recently Viewed' section with a search bar and a table of items. On the right, the login screen is shown, featuring a 'Log In to Sandbox' button, a 'Forgot Your Password?' link, and an 'Or log in using:' section with a 'CellChain Single Sign On' button. A red box highlights the 'I have a CellChain™ PRO login' link, labeled '3'.

Navigating from CellChain™ Classic to CellChain™ PRO



To navigate from **CellChain™ Classic** to **CellChain™ PRO**, you can click this link





Key Terms

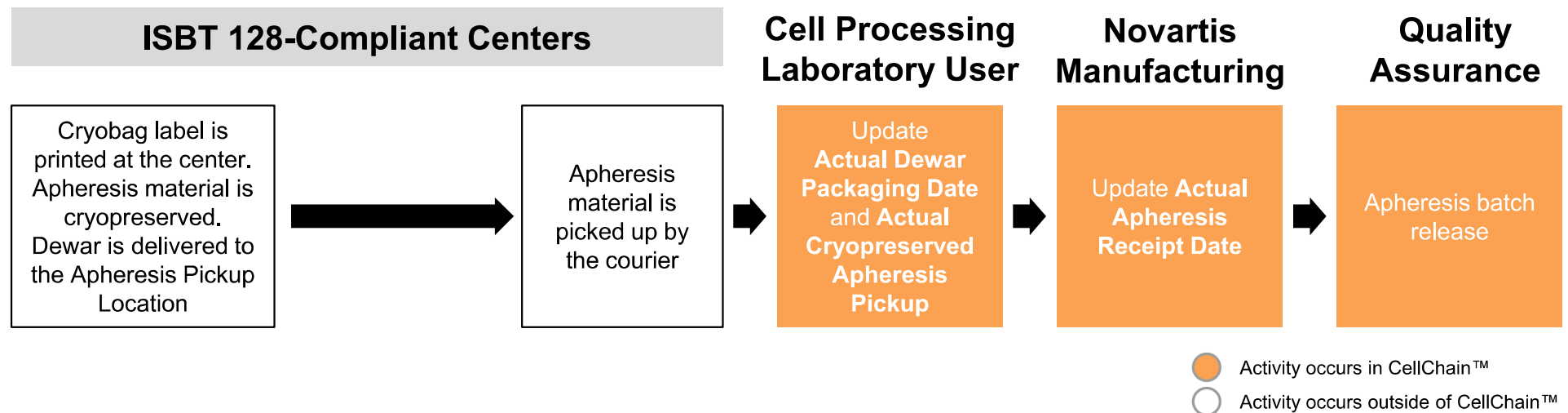
Terms	Description
ADF	The Apheresis Data Form (ADF) collects information about the patient, the apheresis collection, apheresis material testing, and the cryopreservation procedure
CellChain™	The Novartis online system used to manage the CAR-T cell ordering process and coordinate manufacturing and logistics. Also referred to as CellChain Application, Novartis Online Portal
Center/Site	An institution where a Commercial Indication treatment or Clinical Trial treatment is provided
DIN	The Donation Identification Number (DIN) is a unique identification number assigned by the ISBT 128 labeling process for each collection event
Novartis Batch ID	A unique system-generated identifier for each order
Product Order	The Product Order (previously Product Request Form [PRF]) is submitted by a certified prescriber or authorized individual at the treatment center

Appendix: Apheresis Shipment Process Flow

Apheresis Shipment Process Flow

After the ADF is completed, the apheresis material is picked up from the cell processing laboratory and shipped to the Novartis manufacturing facility. The process flow for ISBT 128-compliant centers is shown below.

Note: ISBT 128-compliant centers may use their own labels, per their own SOPs.



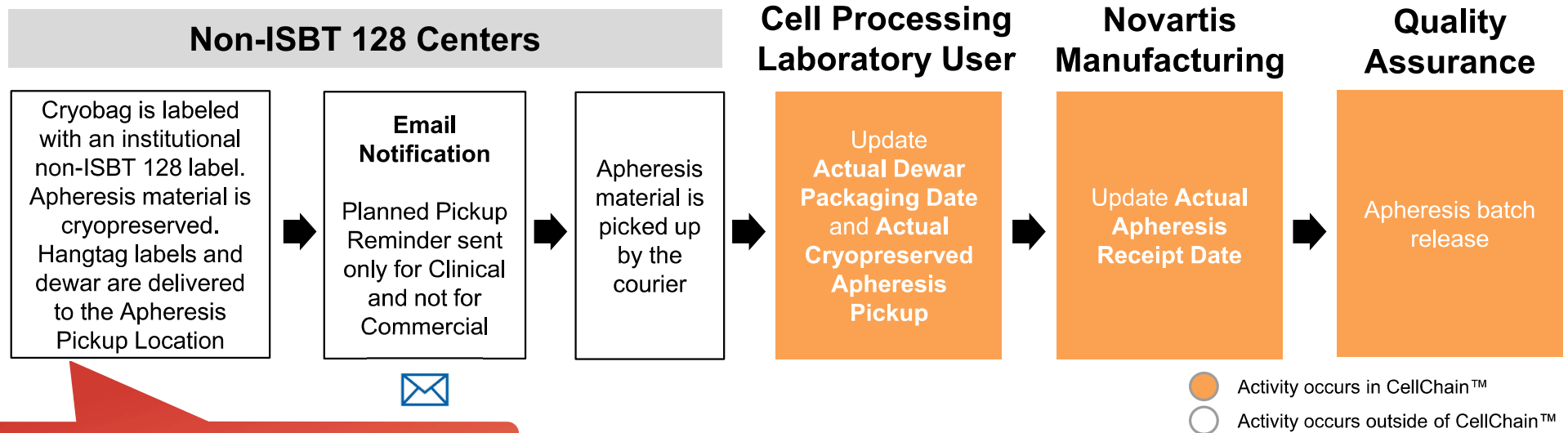
SOPs, standard operating procedures.



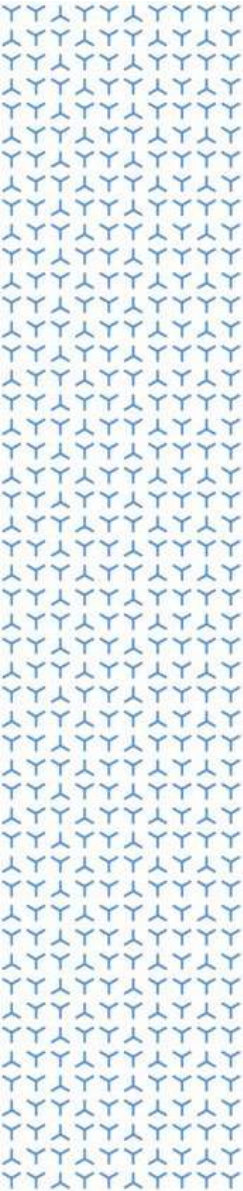
Apheresis Shipment Process Flow: Non-ISBT 128 Centers

Novartis hangtags may be required for centers using non-ISBT 128 labeling. It may be possible for Novartis to review an institutional non-ISBT 128 label to determine if the requirement to use a Novartis hangtag label may be waived.

If a waiver is approved, follow the shipment process for ISBT 128-compliant centers. If a waiver is not approved, Novartis will ship the hangtag labels to the pickup location after the ADF has been submitted and approved.



Note: For hangtag labels to be created and shipped, the ADF must be submitted and approved.



Thank you