CELL THERAPY MANUAL

ALVR105 / POSOLEUCEL

PROTOCOL NUMBER	P-105-202
DATE:	20-Jan-2023
VERSION:	4.0
REGION:	Global (Replacing regional versions EU & APAC V1 18Feb 2022, and US V3 18Feb 2022)
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Version History

Date	Version Number	Summary of Changes
20 Jan 2023	4.0 (Global)	Original Global CTM replacing regional CTM versions 18Feb22 EU and APAC V1 and 18Feb22 US V3. 1) Updates related to change to single CTM for the trial using the new AlloVir Master CTM template: • Streamlined content to remove redundancy • Reorganized content sections and appendices • Incorporated all regions into single CTM and appendices • Removal of blinding/unblinding sections (reflected in study guide, protocol) • Removal of IRT instructions already reflected in study guide • Addition of clarification on CTM and appendices updates • Clarification of storage recommendations • Update of approver section • regional/country-specific updates/additions 2) Other changes • Change of 30 min thaw to end of infusion time to 45 min • IP shipment depot change for South Korea and related procedures (temperature monitoring and IP receipt) • Addition of Countries Australia, Canada and Turkey • IP shipment schedule change: single shipments for Australia, Canada, South Korea, Turkey and UK • US depot change of supplier name (Brooks to Azenta)
18 Feb 2022	US 3.0	• Implementation of updated cryovials (AT Closed Vials®) and AT-Adapt™ single-use needleless connection device • Updated labeling section with new US labels • Appendices updated: o Chain of Custody Form: remove cryoshipper label, add secondary label o Dose Worksheet: remove secondary label, remove lot number, add back signature lines for "verified by" on Dose Worksheet Moved shipping, handling, and packaging instructions to Appendix
20 Jul 2021	US 2.0	• Implementation of the JUDI system for submission of HLA reports • Removal of needleless connectors (eg, Clave™) • Designation of transport of the investigational product at room temperature • Priming of syringe filters at cell therapy lab or bedside • Change in extension tubing for use with peripheral intravenous catheters • Transition to new template and additional edits for clarity
16 Nov 2020	US 1.0	Original
18 Feb 2022	EU +APAC 1.0	Original (now superseded by Global Version 4 Jan 2023)

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1 CONTACTS

The parties involved in the processes outlined in this manual, and their corresponding roles, are listed in the table below.

Party Involved	Role
AlloVir	Sponsor
Azenta (formerly Brooks) for USA, Canada, and Australia	GMP Storage Facility
Cryoport for USA, Canada, and Australia	Cold Chain Logistics
Fisher BioServices for Europe (incl UK), South Korea, and Turkey	GMP Storage Facility Cold Chain Logistics
Charles River Laboratories, Inc. (formerly Cognate Bioservices)	Drug Product CDMO
ICON	Contract Research Organization (CRO) – CRO managing and operating CytoMatch

For issues which may arise during the conduct of this study, the appropriate contact is listed below.

Issue	Contact
General Issues	Primary: E-mail with Issue Reporting Form to Clinical Research Associate (CRA)
Dose preparation or dosing issues that require immediate attention	ICON Medical Monitor Team: Athena Kritharis, MD, (US) +1 (215) 616-4944 (US) Vladimir Shatrov, MD (Europe) +49 6103 904 1127 Vladimir.Shatrov@iconplc.com Michelle Xu, MD (APAC) +86 21 6129 3269 Michelle.Xu@iconplc.com AlloVir Medical Monitor: Dr Michelle Matzko +1 570 (594) 4424 Alternates: CRA, AlloVir

Issue	Contact
FlexAdvantage Interactive Response Technology (IRT) System technical issues	ICON Helpdesk Email: icophone@iconplc.com Phone: 1-888-426-8801 Country-specific phone numbers are available in current IRT Manual
Non urgent communication on IP	Assigned CRA & copy in ICON study email: study-icr-4690-0006@iconplc.com

Direct study team contact information is listed below. Please note that study contacts may change. Contact information for the study team can be found in the Site Regulatory Binder.

AlloVir Study Team	CRO Study Team
Dee Rodriguez Clinical Project Lead +1 (774) 266-5290 drodriguez@allovir.com	Terri Doolin (United States) Senior Clinical Trial Manager +1 (215) 616-3071 Terri.Doolin@inconplc.com
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Franklyn Valcarso, MD Clinical Operations Manager +1 (562) 746-1904 fvalcarso@allovir.com	Brian Bolinsky (Canada) Senior Clinical Trial Manager +1 (540) 761 7825 Brian.Bolinsky@iconplc.com

2 ABBREVIATIONS, TERMS, AND DEFINITIONS

Abbreviation	Definition
AT	Aseptic Technologies
CDMO	Contract development and manufacturing organization
COC	Chain of Custody
CRA	Clinical Research Associate (aka Clinical Site Monitor)
CRO	Contract research organization
CTL	Cell Therapy Laboratory
CTM	Cell Therapy Manual
FACT	Foundation for the Accreditation of Cellular Therapy
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HLA	Human leukocyte antigen
IP	Investigational product
IRT	Interactive response technology
ISF	Investigator Site File
IV	Intravenous, -ly
JACIE	The Joint Accreditation Committee International Society for Cellular Therapy - Europe & the European Society for Blood and Marrow Transplantation
LN2	Liquid nitrogen
mL	milliliter
PSL	Posoleucel (ALVR105)
SIW	Site Information Worksheet
SDS	Safety data sheet
SOP	Standard Operating Procedures
v/v	Volume per volume
VST	Virus-specific T cells

Term	Definition
Chain of Custody (COC)	A process that captures drug product handoff across various entities to ensure proper handling, including storage, and temperature conditions
Chain of Identity	A process used to link a specific drug product to a specific patient from enrollment to treatment
Chain of Identity Number	A unique number, used in concert with patient identifiers, to link a specific treatment to a specific patient throughout the process
Cryoport	Cold chain logistics service managing LN2 transport from Azenta depot to clinical sites in the US, Canada, and Australia
Depot	Entity responsible for dispatching of IP to study site
Shipper / Dewar	A specialized vacuum flask used to hold IP at cryogenic temperatures (</=-150C)
Expiry Date	The date before which IP must be administered to patients
Fisher	Refers to Fisher BioServices a subsidiary of Thermo-Fisher Scientific and Depot supporting Europe (incl UK), Turkey and South Korea

Term	Definition
Manufacturing Lot Number (MFG. #)	A unique identification number assigned to drug product and/or placebo for a single manufacturing run
Patient ID	A unique identification number that is linked to a patient for all study visits/treatments
Sendum.com	Portal website for Fisher BioServices LN2 Shipper temperature monitoring for shipments to Europe, Turkey, and South Korea
Thermo-Fisher	Refers to Thermo-Fisher Scientific: Depot shipping IP to European, Turkish, and South Korean sites

3 INTRODUCTION

3.1 Purpose

This Cell Therapy Manual (CTM) provides clinical sites and Investigator personnel with the standards for receipt, storage, preparation, dispensation, administration, return/destruction, and accountability of AlloVir investigational product (IP).

The CTM should be used in conjunction with and adherence to the industry requirements and standards, which includes:

- Applicable regulations
- Applicable Standard Operating Procedures (SOPs)
- Good Clinical Practices (GCP)
- Aseptic preparation techniques
- Cell therapy standards established by accreditation agencies, such as Foundation for the Accreditation of Cellular Therapy (FACT) and/or the Joint Accreditation Committee of the International Society for Cellular Therapy and the European Society for Blood and Marrow Transplantation (JACIE)

The CTM should be used in conjunction with associated study-specific clinical documents, such as but not limited to the approved Study Protocol, guides (including Interactive Response Technology guide), and study plans.

3.2 Updates, Version Control, and Corresponding Administrative letters

The CTM and its appendices may be updated and revised via updated CTM versions or corresponding administrative letters. All updated CTM versions and/or administrative letters should be shared with the relevant site personnel and filed accordingly in the site investigator file.

4 INVESTIGATIONAL PRODUCT DESCRIPTION

4.1 Composition

Investigational product refers to ALVR105 or placebo.

Posoleucel (AVLR105) is a biological product consisting of Posoleucel cells (third-party multivirus-specific T cells with specificity for adenovirus [AdV], BK virus [BKV], cytomegalovirus [CMV], Epstein-Barr virus [EBV], and human herpes virus 6 [HHV-6] in cryopreservation media. Based on substantial amino acid sequence homology between the BKV and JCV human polyomaviruses (including substantial homology with the immunogenic viral proteins large T and VP1 used in the production of Posoleucel), additional specificity is also expected for JCV.

ALVR105 will be supplied in 6.0 mL capacity AT-Closed Vials® (Aseptic Technologies) (formerly referred to as a cryovial) at a concentration of 1×10^7 virus-specific T cells (VSTs)/mL in a volume of approximately 2.5 mL. ALVR105 will be frozen in a cryopreservation media containing 50% volume per volume (v/v) of 25% human serum albumin, 40% (v/v) Hanks balanced salt solution, and 10% (v/v) dimethyl sulfoxide.

Cryopreservation media (without cells) will serve as the placebo. Placebo will be provided in the same 6.0 mL capacity AT-Closed Vials and filled to the same volume as posoleucel (AVLR105). Upon thaw, under normal light conditions without magnification, both posoleucel (AVLR105) and placebo

are clear straw-coloured liquids and are free of foreign particles and will be identical to Posoleucel (ALVR105) in volume and appearance. Packaging and Labeling

IP (active and/or placebo) is supplied in AT-Closed Vials packed in a cryobox shipped in an LN2 shipper.

4.2 Packaging

<table>
<tr><td rowspan="4">AT-Closed Vials® (Aseptic Technologies)
IP (posoleucel or placebo) will be supplied in 6 mL AT-Closed Vials at a concentration of 1×10^7 cells/mL in a volume of approximately 2.5 mL.

The vials are cryogenic, self-standing and capped with a snap-fit cap that protects the septum.</td><td colspan="2">  </td></tr>
<tr><td>AT-Closed Vial</td><td>6.0 mL</td></tr>
<tr><td>Height</td><td>40.3 mm including the cap, (-1 mm with cap removed)</td></tr>
<tr><td>External vial diameter</td><td>25.0 mm</td></tr>
<tr><td>Cryobox
(Europe, South Korea and Turkey will be sent the plastic box, other regions the cardboard box)
Dimensions: L 133 × W 133 × H 57 mm
Maximum Capacity: 25 vials
Each cryobox contains Investigational Product for only one patient. The Cryobox (5x5) 6mL can be used to store IP at the site; return to Depot is not required.

Each Cryobox will contain one (1) lot of IP.

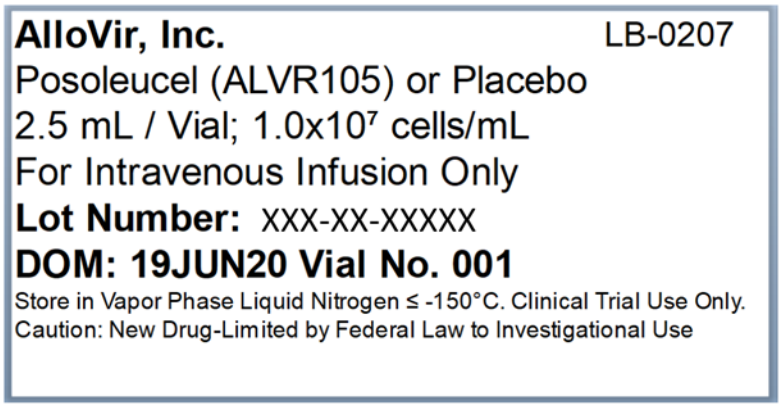
European site may be provided an alternative box for onsite storage when requested. Please refer to Appendix K for the details on the alternative cryobox.</td><td colspan="2"> 
Example of Carboard box</td></tr>
</table>

	AT-CryoBox™  Example of Plastic box
LN2 Shipper High Volume LN2 shipper will have a rack and may hold multiple cryoboxes. Carefully check the IRT Shipment Request Form (SRF) located with the shipper for IP details	  Examples of an LN2 shipper

4.3 Labeling

4.3.1 Primary Label

The IP will be labeled by the manufacturer. Representative examples of the primary and secondary labels have been included below. There may be minor differences between the representative examples and the actual labels currently in use; however, the main content/information contained on the labels should look similar to what is shown below.



4.3.2 Secondary Label

The Protocol Number and Lot Number will be pre-printed on each secondary label prior to shipment. Depending on your country:

- The secondary label may be a single panel or in booklet format containing several local languages.
- The table below details the expected secondary label format and fillable fields per region. For Australia, Canada and South Korea the expiry should be written onto the label by site staff and verified, based on information from the IRT system. The expiration date of each vial will be listed on the IRT Shipment Request Form (Appendix F).

Secondary labels per region	
USA	**Europe, Turkey, and South Korea**
The single panel secondary label(s) will be contained with the accompanying documentation of the shipper. Affix the corresponding secondary label on the applicable Chain of Custody (COC) form upon each dose dispensation and preparation. The number of secondary labels affixed onto the COC form will correspond to the number of vials prepared per dose (i.e., if 2 vials are prepared, affix 2 secondary labels to COC form)	The booklet secondary label(s) will be affixed to the lid of the Cryobox. Upon receipt of the shipment, the patient number, site/investigator and any other fillable fields should be written on the label. Note: For South Korea, the secondary label is a single panel secondary label.
Canada and Australia	
The secondary label(s) will be contained with the accompanying documentation of the shipper. Upon receipt of IP, expiry, patient number, site/investigator, and any other fillable fields present on the top of the secondary label should be filled in by the recipient, and the secondary label should then be adhered to the Cryobox.	

Representative Example of Secondary label booklet cover and example page:

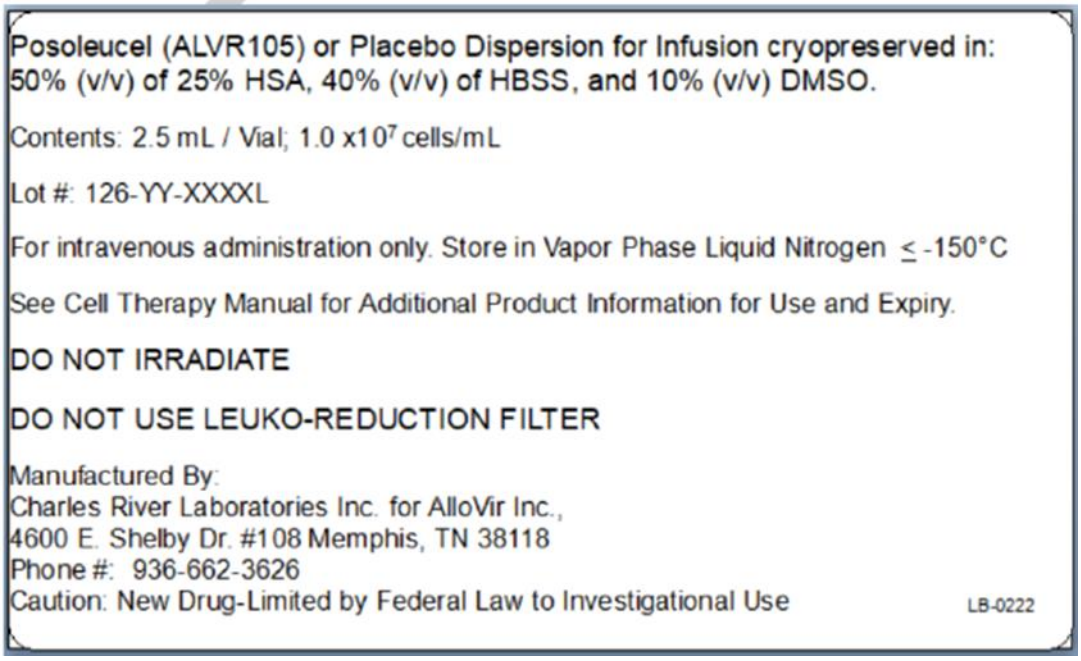
AlloVir
Posoleucel (ALVR105) or placebo

Belgium (Dutch).....3
Belgium (French).....4
Belgium (German).....5
France (French).....6
Italy (Italian).....7
Spain (Spanish).....8
Sweden (Swedish).....9
Turkey (Turkish).....10
United Kingdom (English).....11

ALV2507

I. Protocol Number:
II. Lot Number:
Patient Number: _____
Site/Investigator: _____
Each vial contains 2.5 mL Posoleucel (ALVR105) ($1.0x10^7$ cells/mL) or Placebo dispersion for infusion in 50% (v/v) of 25% human serum albumin, 40% (v/v) of Hanks balanced salt solution, and 10% (v/v) dimethyl sulfoxide. For intravenous administration only. Store in Vapor Phase Liquid Nitrogen at -150°C or below. See Cell Therapy Manual for Additional Product Information for Use and Expiry. The dosage instructions can be found in the cell therapy manual. Refer to cell therapy manual for disposing of unused or opened investigational medicinal product.
THE PACKAGE CONTAINS HUMAN TISSUES OR CELLS.
DO NOT IRRADIATE. DO NOT USE LEUKO-REDUCTION FILTER. CAUTION: For Clinical Trial Use Only.
Sponsor: AlloVir Inc., 1100 Winter Street, Waltham, MA 02451, USA. Telephone: +1 617-433-2605
Manufactured for AlloVir Inc. by: Charles River Laboratories Inc., 4600 E. Shelby #108 Memphis, TN 38118, USA.
⑪

Representative Example of Secondary label –Single Panel:



5 SHIPMENT, RECEIPT, STORAGE AND HANDLING PROCEDURES

5.1 Shipment of IP

Product will be shipped to the address that site provided to AlloVir prior to site activation.

All IP Shipments are initiated in accordance with the study protocol. Patient will be matched to a cell line after HLA reports are submitted and matching is completed in CytoMatch.

Depending on your country, you will receive a total of 1 or 2 shipments per patient:

Australia, Canada, South Korea, Turkey, and UK

The first (and only) shipment will be triggered by completing the randomization step in IRT. Please plan your day 1 treatment in accordance. Delivery will occur approximately 2 to 3 business days after completion of the randomization for Canada and UK and 3 to 7 business days after completion of the randomization for Australia, South Korea and Turkey. The shipment contains IP for all 7 administrations (Day 1, Week 2, Week 4; Week 6, Week 8, Week 10 and Week 12).

US and Europe (UK not included)

The first shipment will be triggered by completing the randomization step in IRT. Please plan your day 1 treatment in accordance. Delivery will occur approximately 2 to 3 business days after completion of the randomization. The first shipment contains IP for the first 3 administrations (Day 1, Week 2, and Week 4)

The second shipment will be triggered by completing the 3rd dose administration data in IRT. The Second shipment contains IP for 4 administrations (Week 6, Week 8, Week 10, and Week 12).

All Countries:

Once IP shipment has been initiated the designated CTL study team will receive an email notification with the following details:

USA, Australia, and Canada	Europe, Turkey, and South Korea
• Cryoport Shipment Order Number and Live View link for shipment tracking (including shipper location, temperature, etc.) • Expected delivery date and time of shipment • Expected pickup date and time for empty shipper	• Date of dispatch and estimated date of arrival • The link to access the temperature monitoring data • IRT request (Shipment Request Form)

5.2 Receipt of IP

5.2.1 External Inspection of LN2 Shipper

- Upon receipt of IP:
  - The LN2 shipper will arrive zip-tied. Inspect the LN2 shipper for any damage or disruption to seal or zip ties.
  - Use caution when cutting and removing zip ties
  - Document status of zip ties on Chain of Custody (COC) form (Appendix C)

IP temperature Verification Process overview	
USA, Australia, and Canada	Europe, Turkey, South Korea
CTL confirms LN2 shipment label matches shipment label received in the Cryoport email notification. CTL uses the link in the initial email from Cryoport to track the LN2 shipper location and temperature. Once IP is delivered, CTL receives an email from Cryoport which will include the Temperature Stability Report (Appendix B). CTL reviews Temperature Stability Report (Appendix B) and live view link to confirm if temperature excursions occurred from shipment to storage in long term LN2 freezer at site. If any excursions occur, follow the Issue Reporting Instructions. File the Temperature Stability Report and live view link printout in the site files accordingly. Please make sure to review and file the temperature stability report in your Study file.	Prior to removing IP from the shipper, the CTL will scan the QR code on the shipper which will redirect the user to the sendum.com site and the temperature monitoring for the LN2 shipper. Detailed instructions on how to document the receipt and confirm the end of cold chain monitoring of the LN2 shipper are clarified in Appendix A.

- IP should be unloaded and receipt registered in IRT on the day of receipt.
- Store the empty LN2 shipper in an area with an adequate cellular phone or mobile data signal (avoid areas like basement rooms or refrigeration where data transmission may be blocked). Not applicable for LN2 shippers sent by Fisher (Europe, South Korea and Turkey).

5.3 Storage and Handling of Investigation Product (IP)

- IP must be stored at <-150°C in a secure temperature monitored location.
- For Europe, Turkey, and South Korea only: Please follow the instructions on temperature monitoring and verification prior to opening the frozen Dewar compartment. (see Appendix A).
- IP should not be outside of the LN2 shipper and/or vapor phase LN2 freezer longer than one (1) minute.

The LN2 shipper will include the following documents, which should be completed (if applicable) and filed:

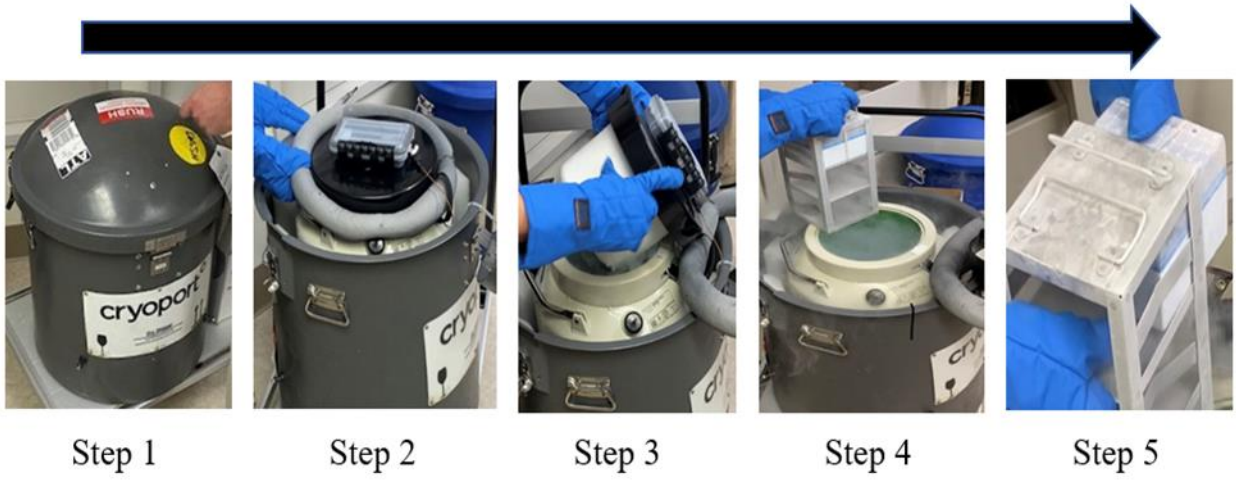
IP Shipment Accompanying Documentation	
USA, Australia, and Canada	**Europe, Turkey & South Korea**
– Azenta pack out slip (Appendix E) – IRT shipment request (Appendix F) – Secondary label(s) – One per vial (US) and one per lot (Australia and Canada) – Shipper return label – Safety Data Sheet (SDS) – Certificate of Conformance (for both PSL and placebo) – Customs invoice for Australia and Canada Note: For all non-US regions, the site will receive 1 cryobox per IP lot. The Secondary label will be attached to the lid of each cryobox or included in the pouch with the shipping documentation.	– Fisher BioServices Depot pack out slip – IRT shipment request (Appendix F) – Shipper return Air Waybill – Safety Data Sheet (SDS) – Certificates of Conformance (for both PSL and placebo) – Fisher EU/UK QP certificate of release (Not for South Korea or Turkey) – Fisher proforma invoice for shipper re-export (UK, Turkey, and South Korea only) Note: The site will receive 1 cryobox per IP lot. The Secondary label will be attached to the lid of each cryobox.

- Open the shipper lid to access the accompanying IRT shipment request form and documentation. Transcribe the lot and vial numbers from the IRT shipment request form onto the Chain of Custody (COC) form (Appendix C) and file per site SOPs.
- Remove the vapor plug and remove the cryobox containing IP.
- Place the vapor plug back and allow it to settle completely.
- Do not tamper with monitoring system located at the top of the vapor plug.
- <u>USA, Australia, and Canada only</u>: Cryoport will continue to monitor the GPS location until delivery is complete. The temperature stability report will be emailed to your site once available. Temperature data can also be reviewed via the live view link in the initial delivery email and in the cryoportal.
- Conduct visual inspection of the IP as close as possible to the LN2 freezer, where the IP will be stored.
- Carefully remove the vials from the LN2 shipper by taking out the Cryobox from the metal rack. IP vials should always remain in an upright position.
- Inspect the Cryobox and vials for damage.

- Review IP vial labels and confirm lot and vial identification (ID) numbers match the accompanying IRT Shipment Request Form (SRF) to verify that the correct drug has been received.
- Review the secondary label and evaluate if any fillable fields are present. Please refer to section 4.3.2 Secondary Label, for information on how secondary labels are supplied and to be used in your region.
- Following delivery and inspection of the IP, transfer the IP rapidly from the LN2 shipper to a vapor phase LN2 freezer with continuous temperature monitoring until the day of infusion. It is recommended to limit the time that IP is outside of cryogenic conditions to ≤ approximately 1 minute.
- Review expiration dates on IRT SRF to verify that IP is not expired. If IP is expired, notify your CRA and complete an IP issue reporting form (Appendix H)
- Complete shipment receipt sections of the COC form (Appendix C) and file.

Refer to Figure 1 for a visual representation of required steps to unpack the LN2 shipper.

Figure 1 Steps outlining unpacking of the LN2 shipper



Upon completion of inspection, unpacking, and storage the site must register IP receipt in the IRT.

If you have unacknowledged shipments at your site, you may be blocked from performing certain actions within IRT.

5.4 Return of the Shipper

After unloading the IP, complete the return of the LN2 shipper the same day or the following business day after receipt of IP.

USA, Canada, and Australia	Europe, Turkey, and South Korea
Remove the old shipping documentation from outside of shipper. Return of the shipper is prearranged by Cryoport on the Cryoportal.	Preferred option is for site to hand back shipper to driver immediately **(Mandatory for Turkey and South Korea; driver to wait up to 1 hour.)**

USA, Canada, and Australia	Europe, Turkey, and South Korea
Please see Appendix B for detailed steps.	Alternative option (available for European sites only) is to return the shipper to the respective Fisher BioServices facility of origin via DHL. Please see Appendix A for detailed steps.

6 EQUIPMENT AND SUPPLIES

Equipment provided by CRO/AlloVir **must be used** for IP preparation and administration.

The supplies listed below will be used to support dosing:

6.1 Equipment Provided by ICON/AlloVir

Equipment provided by ICON/AlloVir	Used for
AT-Adapt™ (single-use needleless connection device)	IP preparation
5 mL Luer lock syringes	IP preparation and Administration
Syringe caps	IP preparation
Syringe labels (Please see Syringe Label Template Appendix D)	IP preparation
3-way stopcock	IP Administration
Hemo-Nate® syringe filter (also referred to as “Hemo-Nate filter”)	IP Administration

6.2 Equipment Provided by Site

Equipment provided by site	Used for
LN2 Transport shipper (If Applicable)	Transport to IP preparation location
Dry-Block heater or water bath	IP Preparation (Thaw)
Infusion tubing for intravenous (IV) injection	IP Administration
Bag of sterile normal saline (eg, 50 or 100 mL, but any volume is acceptable) for priming of IV line and flushing of line and syringe	IP Administration
5 or 10 mL normal saline flush for priming the Hemo-Nate filter	Hemo-Nate® Priming

6.3 Prohibited Equipment/Supplies

The only filter that should be used for the infusion is the Hemo-Nate filter provided by the Sponsor. **No in-line leuko-reduction filters should be placed between the syringe containing IP and the patient.**

7 DOSE CALCUALTION

The volume and quantity of IP required will be determined based on the patient's weight (at screening) according to Table 1.

Table 1 Posoleucel Dosing Schematic

Patient Weight	Dose (Cells)	Volume Drawn into Syringe(s)	IP Vials Required
<40 kg	2×10^7	2 mL	1
≥40 kg	4×10^7	4 mL	2

IMPORTANT: Maximum volume to be drawn out of a single IP vial is 2mL

8 HEMO-NATE FILTER PRIMING

The Hemo-Nate filter must be used as part of the IP administration infusion set-up.

Depending on your site logistics the Hemo-Nate filter can be primed in either the biological safety cabinet or at the patient's bedside.

Hemo-Nate priming instructions:

If the Hemo-Nate filter is to be primed in a biological safety cabinet, perform prior to thawing IP.

Option 1: Priming at patient bedside:

- Remove the Hemo-Nate filter from its packaging and attach a syringe containing sterile normal saline. It is acceptable to use whatever volume of normal saline syringe is available (eg, 5 or 10 mL). Prime the Hemo-Nate filter by injecting a minimum of 1 mL of normal saline through the filter (allowing the excess to spill into a sink or container). Leave the normal saline flush syringe attached to filter and attach the filter and flush to the 3-way stopcock (see setup below).

Option 2: Priming in the Biological Safety Cabinet

- Remove the Hemo-Nate filter from its packaging under aseptic conditions and attach a syringe containing sterile normal saline. Prime the Hemo-Nate filter by injecting a minimum of 1 mL of normal saline through the filter, allowing the excess to spill into a container. It is acceptable to prime with a larger volume if using a prefilled syringe (eg, 5 or 10 mL).
- Prepare the IP administration syringe per the instructions in Section 10 (Syringe Preparation), Option 2.
- Attach the primed Hemo-Nate filter to the syringe containing the IP and place the sterile syringe cap on the exposed end of the filter. Make sure that all three components are securely attached.

9 IP THAW – PREPARATION, OPTIONS, PROCEDURE

9.1 Preparation

Coordinate and verify the following critical checks with Study Coordinator/Infusion team prior to removing IP from LN2 conditions:

Critical Checks
Patient is in the infusion location and ready to receive the infusion
Peripheral or central IV access is in place
Remove any needleless connectors or claves from infusion line setup
Hemo-Nate filter has been primed (if being done in a biological safety cabinet) or ready to be primed (if being done at bedside)
3-Way Stopcock connected to infusion lines (Figure 4)
Normal Saline and IV lines have been set up and primed (Figure 4)

!	**The infusion of IP must be completed within 45 minutes following completion of IP thaw.** **To ensure this timeframe, the dose worksheet, COC form, and secondary labels (if applicable) should be prepared prior to IP removal from LN2 storage.**

9.2 IP dispensing and documentation preparation

Retrieve the Dose Worksheet (Appendix G), COC Form (Appendix C), and consult the Dosing Schematic in Table 1 to confirm the dose and number of cryovials and syringes needed to prepare the patient dose.

Register Dispensing Visit in the IRT to receive the appropriate IP lot and vial numbers.

Confirm the cryovials have not expired and remove dispensed vials from LN2 freezer/transport dewar.

9.3 Thawing of IP

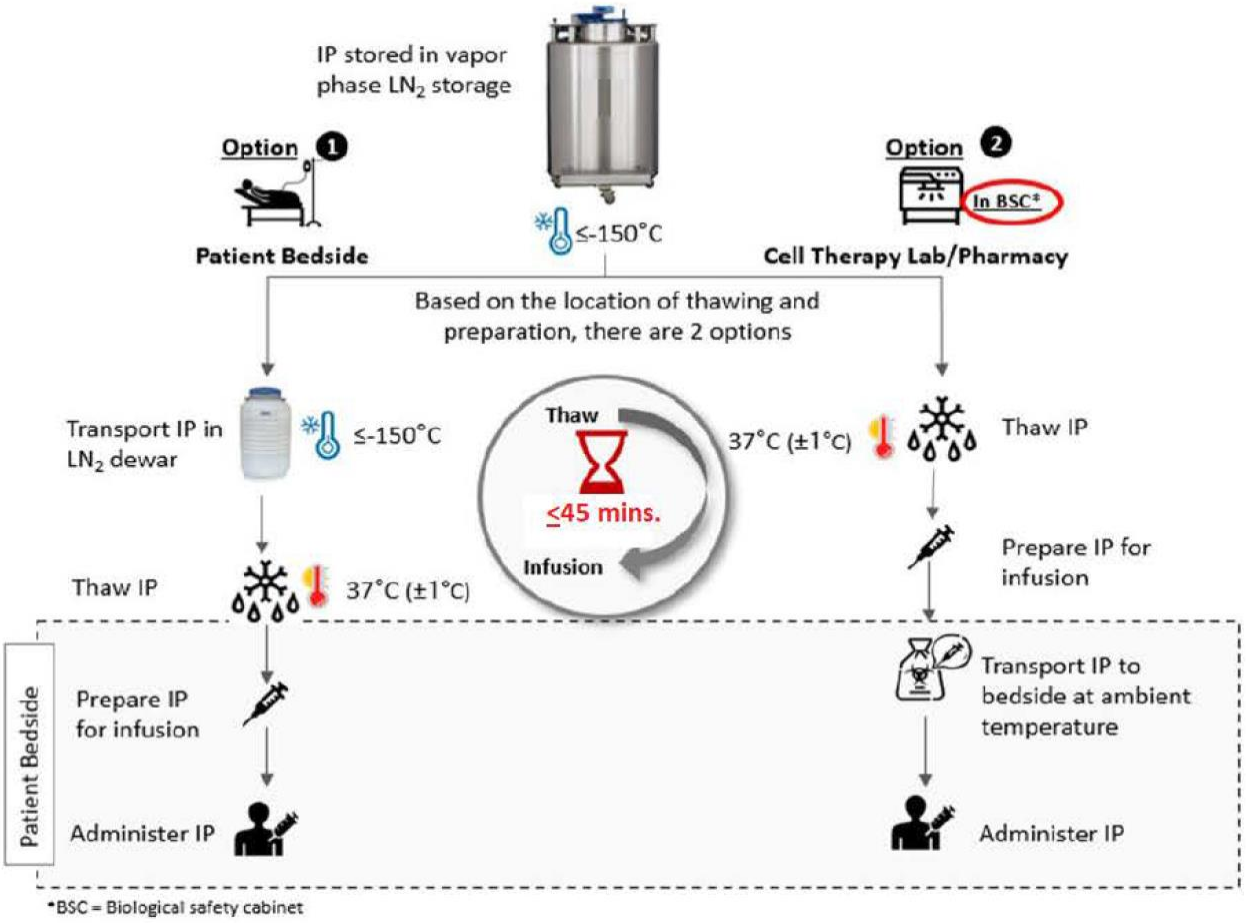
Take all necessary measures to avoid prolonged exposure of the cryopreserved vials to conditions outside of the LN2 shipper and/or vapor phase freezer. It is critical to minimize the time the IP is handled outside the LN2 shipper and/or vapor phase LN2 freezer to no more than approximately one (1) minute prior to initiation of thaw.

If thawing multiple IP vials (for the same patient), thaw all vials at the same time in the same manner.

9.3.1 Thaw Procedure Options

There are two options for the location of thawing and preparing IP (summarized in Figure 2):

Figure 2 Storage to Infusion Flowchart



Option 1: Bedside Thaw

- Place frozen vials in an LN2 shipper/dewar at ≤ -150°C. Transport the IP to the patient bedside or another suitable location.
- Proceed to thaw procedure.

Option 2: CTL or Pharmacy Thaw

- Remove IP from LN2 freezer
- Proceed to thaw procedure.

9.3.2 Thaw Procedure

- Immediately thaw designated vial(s) in a Dry-Block Heater at 37°C (±1°C) per site SOPs. A pre-heated 37°C (±1°C) water bath within a sealed bag consistent with clinical site's SOPs is also acceptable. Do not shake vials in water bath.
- If using a water bath, do not submerge top cap of the IP vial.
- Observe the designated vial(s) of IP carefully as the thaw time may vary.

- The IP can be considered fully thawed when there are no more ice crystals visible inside the vial. At this time, the vial(s) should be removed from the thawing device and thoroughly wiped with an alcohol swab.
- Record the time of thaw completion for the designated vial(s) on the Dose Worksheet (Appendix G).

10 SYRINGE PREPARATION

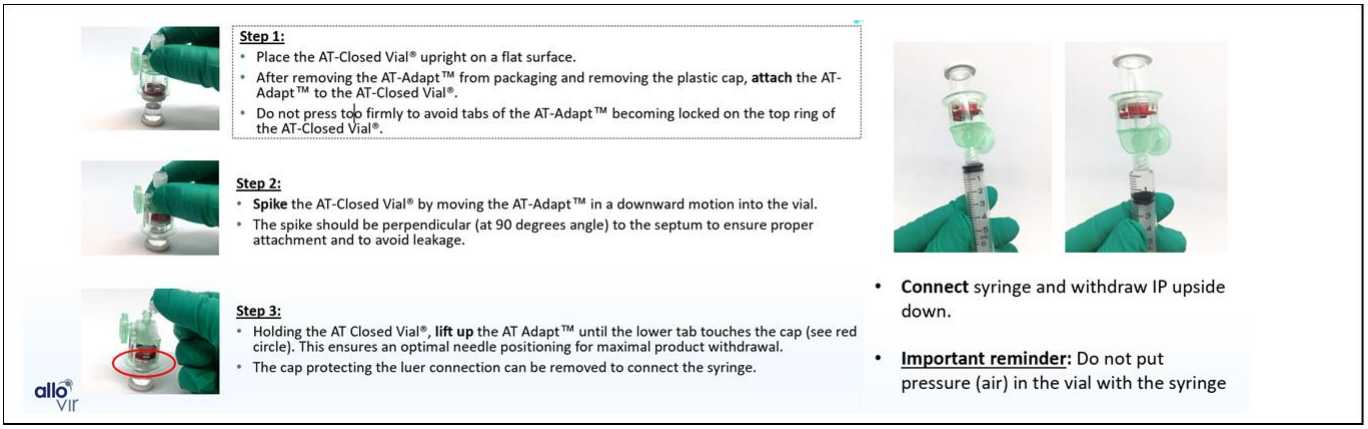
There are two different preparation processes for the IP, depending on whether you will prepare the IP syringes in a Biosafety cabinet or at the patient bedside. AT-Closed Vials® (IP cryovials) allow for a sterile aspiration of IP with/without use of a Biological Safety Cabinet. Preparation of IP can occur in either location; however, the sites should consider the ability to meet the post thaw dosing timeframe of **45 minutes**.

10.1 Checks and Documentation

Retrieve the Dose Worksheet (Appendix G), COC Form (Appendix C), and consult the Dosing Schematic in Table 1 to confirm the dose and number of cryovials and syringes needed to prepare the patient dose.

Prepare product per Option 1 or Option 2 immediately following thaw completion.

Accessing AT Vial via AT Adapt (Please refer to Appendix I User Guide AT-Adapt for the Full AT Adapt guide)



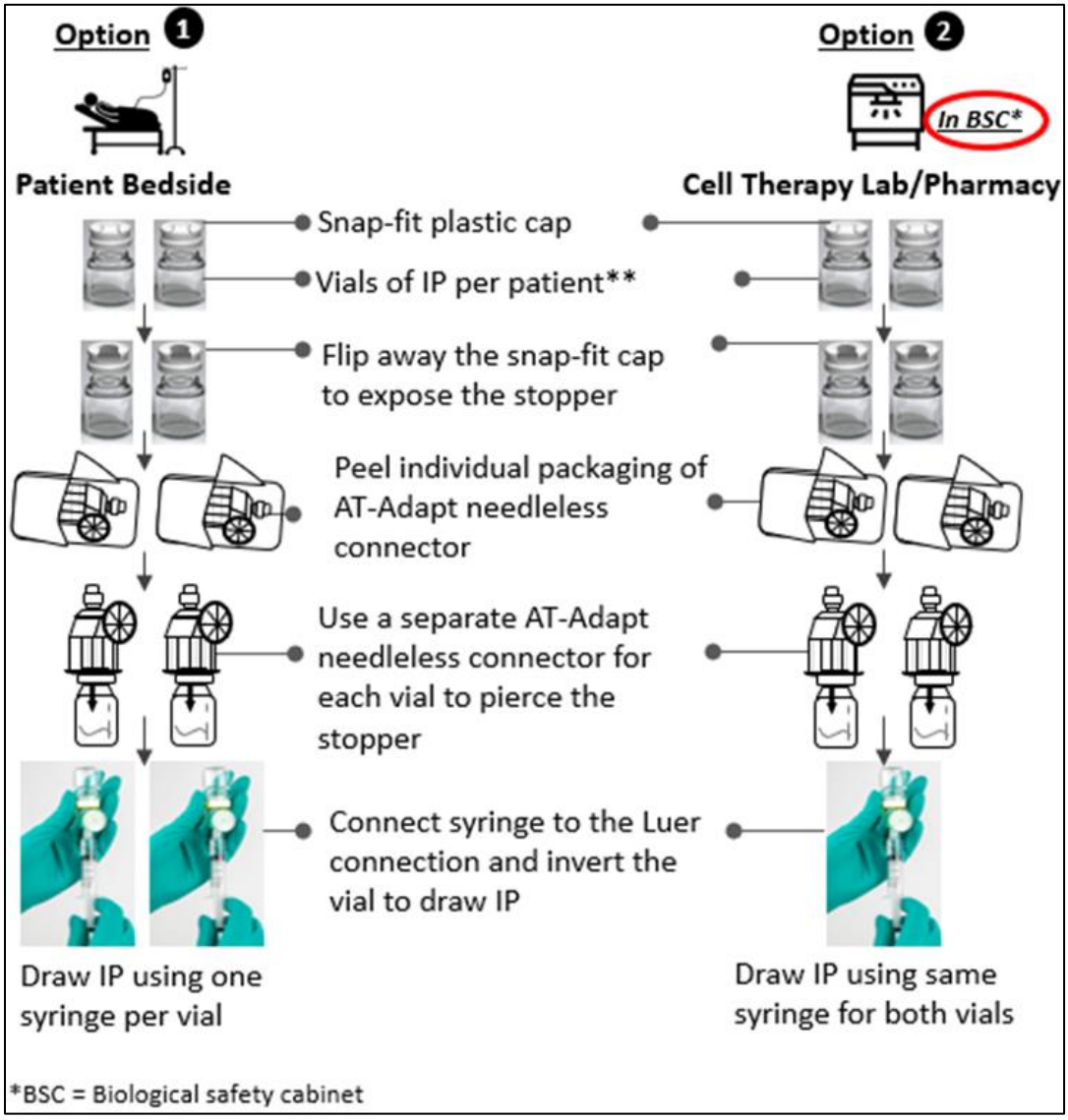
- **Option 1 (Figure 3): Preparation of IP at the patient's bedside or in a nearby area**
  - Prime the Hemo-Nate filter following the instruction is section 8 (Hemo-Nate Filter priming).
  - Use one syringe per IP vial. If there are multiple vials required to complete the full dose, draw the volume indicated for each vial into a separate syringe.
  - Use a new AT-Adapt™ needleless collection device for each individual syringe. Connect a labeled 5 mL Luer lock syringe to each AT-Closed Vial® via the AT-Adapt™.
  - Draw the prescribed dose into each labeled 5 mL Luer lock syringe. Draw a maximum of 2 mL out of a single vial.
  - Disconnect the syringe from the AT-Adapt™ and cap each dosing syringe with the AlloVir provided sterile syringe cap.
  - Affix the prepared label(s) to the/each 5 mL Luer lock syringe.
  - Proceed with Administration of IP per section 11.

- **Option 2 (Figure 3): Preparation in a biological safety cabinet**
  - **Critical Point**: For a biological safety cabinet prep, all IP can be consolidated into one 5 mL dosing syringe, i.e. 2 IP vials can be drawn into one dosing syringe.

For sites that prefer to prime the Hemo-Nate filter in a biological safety cabinet, follow the instructions immediately in section 8 (Hemo-Nate Filter priming)

- Follow instruction for syringe preparation as per Option 1 for the first AT-Closed Vial®
  - If a second AT-Closed Vial® is required for the dosing:
  - Use a new AT-Adapt™ for the second AT-Closed Vial®
  - Take the syringe (with volume of first vial) and connect it to the AT-Adapt™ on the second AT-Closed Vial®.
  - Draw the prescribed dose into the labeled 5 mL Luer lock syringe. Draw up a maximum of 2 mL out of a single vial.
- If the Hemo-Nate filter was primed in the biosafety cabinet, disconnect the syringe from the AT-Adapt™, attach the primed Hemo-Nate filter to the syringe, and cap the Hemo-Nate filter with the AlloVir provided sterile syringe cap.
- Otherwise disconnect the syringe from the AT-Adapt™ and cap with the AlloVir provided sterile syringe cap.
- Affix the prepared label to the 5 mL Luer lock syringe.

Figure 3 Preparation of IP



10.2 Transport after Syringe Preparation

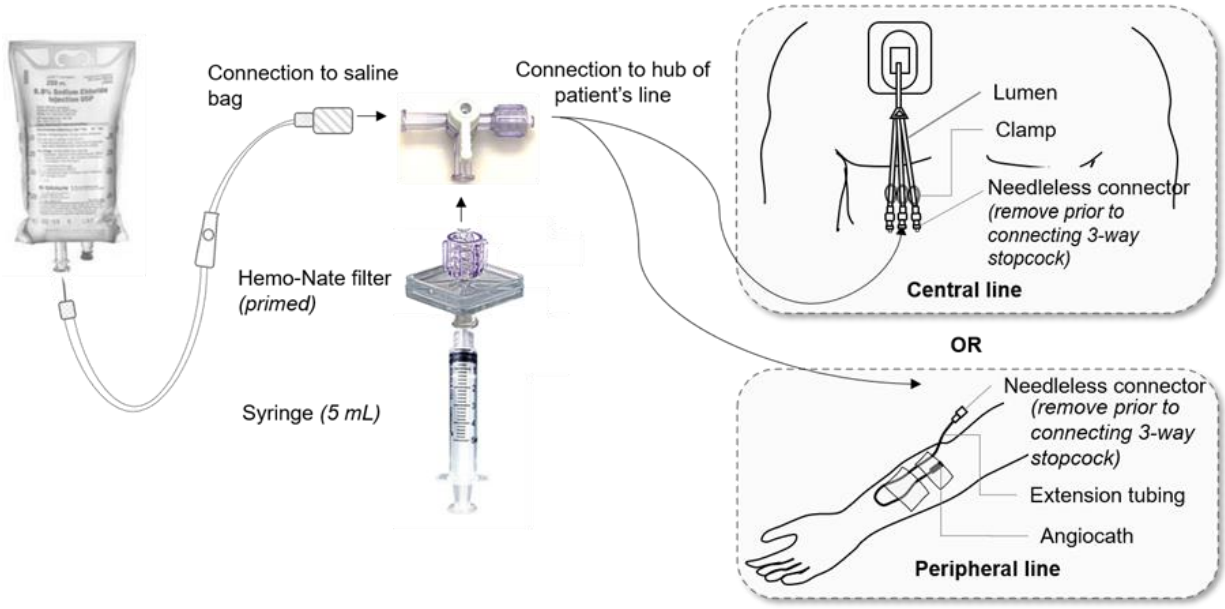
For IP Syringe transport after preparation:

- Place the syringe in a biohazard bag or equivalent, then place the bag into a suitable transport container at ambient temperature per site SOPs.
- Transport the container to the infusion location.
- Proceed to the administration instructions

11 ADMINISTRATION OF IP

A schematic of the IP administration set-up is pictured in Figure 4.

Figure 4 Set-Up for IP Administration



11.1 Premedication

Premedication is not required, except for patients with a prior history of reaction to blood products who will receive premedication with diphenhydramine 0.25 to 0.5 mg/kg IV or orally (maximum dose 25 mg) or a different antihistamine preferred by the study site and/or acetaminophen (paracetamol) 5 to 10 mg/kg IV or orally (maximum dose 1000 mg) prior to study treatment administration. Premedication with corticosteroids is prohibited. Any premedication required by a patient will be provided by the site. Any premedication administered to the patient must be recorded in the patient's concomitant medication log.

11.2 IP Administration Instructions

!	**Critical Checks** • Do not use Leukoreduction Filter. Only use the AlloVir supplied Hemo-Nate filter • Remove all needleless connectors and/or claves/microclaves from infusion line setup.

When the IP syringe(s) arrives at the dosing location, perform the following:

- Double verify that the syringe label information matches the patient intended to receive the infusion.
- **If Hemo-Nate filter was primed in the Biological Safety Cabinet**: Hemo-Nate Filter will arrive attached to the IP dosing syringe. Remove sterile syringe cap from Hemo-Nate filter and attach IP syringe with Hemo-Nate filter directly to the 3-way stopcock.
- **If Hemo-Nate Filter was primed at the Bedside:** Remove sterile normal saline flush from Hemo-Nate filter (Figure 4) and attach IP dosing syringe directly to the Hemo-Nate filter.

- Initiate infusion as a slow IV push. Total Infusion time should be 5 minutes regardless of the number of syringes infused (i.e. if infusing 2 syringes, 2.5 minutes per syringe, etc). Infusion time does not include the post-infusion flushes.
- **One-Syringe Post-Infusion Flush** - If you are administering all IP in one dosing syringe following the infusion, turn the 3-way stopcock, aspirate 5 mL of Normal Saline from the IV bag and flush it into the patient. Perform this procedure twice for a total of 10 mL of Normal Saline.
- **Multi-Syringe Post-Infusion Flush** - If you are administering IP in more than 1 syringe, following dosing with each syringe turn the 3-way stopcock, aspirate 5 mL of Normal Saline from the IV bag and flush it into the patient. Following the final dosing syringe, you will perform two (2) 5 mL flushes for a total of 10 mL.

!	**IV Line Priming Volume Guidance** • It is recommended to avoid using IV extension tubing between the inferior aspect of the 3-way stopcock and the patient's IV access. • If you must use IV extension tubing, please verify the priming volume of the tubing. If the priming volume of the patient's access (i.e., PICC line, central line +/- extension tubing) is greater than 10 mL's please increase the final flush volume to make sure all IP gets into the patient (i.e. final flush volume must be greater than priming volume of access lines +/- extension tubing.

11.3 Destruction of the Investigational Product

!	IP vials (used or unused) and all used infusion materials (syringes, infusion tubes, etc.) should be treated and disposed of as biohazard waste in accordance with local governing regulations and clinical site SOPs/written procedure.

11.3.1 Destruction of the Investigational Product (USA, Canada, Turkey, Australia and Europe)

Sites should dispose of used vials as biohazard waste in accordance with local governing regulations and clinical site SOPs/written procedures.

For unused vials, approval is required to destroy at the Site.

Prior to IP destruction, the site SOP or written procedure for destruction must be reviewed and approved by the sponsor and/or CRO. Email approval will be filed at the site. Approval is expected if the following criteria are met:

- Site must have a documented procedure for destroying IP
- Procedure must state that destruction will follow applicable laws and regulations
- Procedure must state that the destruction will be documented, including what was destroyed, how it was destroyed, and when it was destroyed

Once the site's IP destruction procedure is approved, the site can destroy specific vials of IP per their SOP/written procedure.

Destruction of unused IP must be documented on the COC form (Appendix C)

11.3.2 Destruction of the Investigational Product (South Korea)

Sites should send unused vials of IP to Fisher South Korea for destruction. The process for shipping unused IP to Fisher South Korea is described below:

1. Clinical site staff will contact their CRA and initiate a request for return of IP for destruction.
2. Clinical site staff will provide their CRA with the number of vials to be included in shipment for IP destruction as well as the desired date for collection/shipment. The minimum is 10 working days from the date of request.
3. CRA or ICON CTM will send an email attaching the return collection form (KR-FM-035.02 IP Drug Return Collection Request Form) in Appendix J to:
   - Fisher Germany team: HGHFBS@thermofisher.com,
   - Fisher South Korea person in charge: project.korea@thermofisher.com,
   - FCS South Korea e-mail address: returns.korea@thermofisher.com, and
   - ALVR-APAC: SupplyChain@allovir.com.
4. Fisher Germany PM will provide AlloVir Supply Chain with the return collection form which includes date and time of pick up at the clinical site.
5. Fisher's designated carrier will collect the IP at the clinical site and transport to the Fisher SK depot.

Unused IP sent to Fisher South Korea for destruction must be documented on the COC form (Appendix C).

12 ISSUE REPORTING

!	Report any issues with the IP immediately and quarantine and/or label (if possible) all IP and related supplies with potential issues until AlloVir or the CRO communicates on the usability of the IP and related supplies

Urgent Issues during dose preparation should be reported to the ICON Regional Medical Monitor (see contact in Section 1) or Dr. Michelle Matzko, AlloVir Medical Director by phone at +1 570 (594) 4424 and with an e-mail follow-up to mmatzko@allovir.com submitting the Issue Reporting Form (Appendix H). The CRA should also be contacted. See Section 1 for contact details. Non-Urgent issues should be reported to your CRA via the Issue Reporting Form.

Issues with IP may include, but are not limited to, the following:

- Issues with IP (e.g. leaks, cracks, damage)
- Reconciliation
- Destruction
- Temperature excursions (on site or in transit)

If there are any issues with IP, the site should:

- Quarantine and/or label (if possible) all IP and related supplies with potential issues (to prevent accidental use) until AlloVir or the CRO communicates on the usability of the IP and related supplies
- Report issues by completing the Issue Reporting Form (Appendix H) and submitting the form via email to the CRA
- Follow-up with CRO/Sponsor until resolution
- Upon resolution, the site will receive a completed Issue Reporting form to close the investigation
- File the completed Issue Reporting Forms and any related correspondence in the Investigator Site File (ISF)

13 LIST OF APPENDICES

Appendix A Fisher Bioservices LN2 Shipper Handling and Return (Europe, Turkey, and South Korea only)

Appendix B Receipt of Product at the Investigative Site US, Canada, Australia, and South Korea

Appendix C AlloVir Chain of Custody Forms, Version 4 (for all 4 regional forms)

Appendix D Example Syringe Label

Appendix E Example IP Pack Out Slip – Regional

Appendix F Example IRT Shipment Request

Appendix G Dose Worksheet, Version 4

Appendix H Issue Reporting Form, Version 4

Appendix I User Guide AT-Adapt

Appendix J Fisher IP Drug Return Collection Request Form (KR-FM-035.02) South Korea Only

Appendix K Alternative Storage Cryobox. Europe Only

APPENDIX A Fisher Bioservices LN2 Shipper Handling and Return - Europe, Turkey, and South Korea

Receipt / Unpacking of LN2 Shipper

!	Do Not unpack until ready to remove product! Complete the steps below on the day of IP receipt.

Step 1: Access shipper:

Cut Tamper seal spanning metal latches on outside of shipper and open blue protective case.

Remove paperwork and Return Air waybill from Shipping envelope.

Reminder: Do not cut tamper seals until day of removal

Step 2: Inspect contents

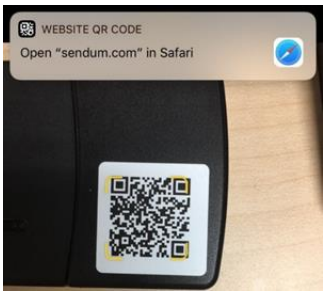
Check the shipment visually for potential damage. Document your inspection by completing the shipment receipt confirmation form and email the form to AlloVir supply chain (ALVR-EU-SupplyChain@allovir.com.). Do this immediately upon IP receipt and inspection.

Step 3: View Data

- Using a smartphone or tablet open the camera app
- Scan the code that appears on Sendum device.
- The Camera app will prompt you to open a web browser and redirect to sendum.com

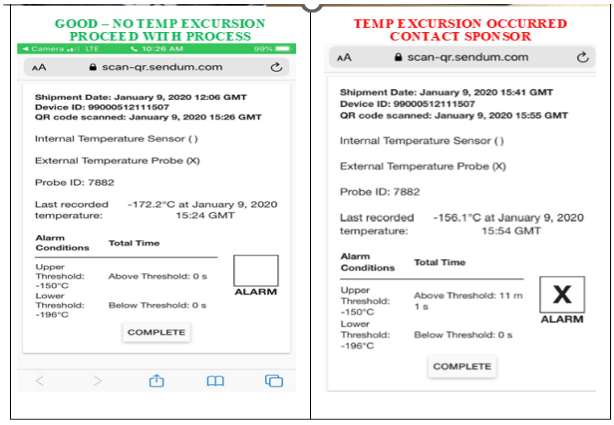
OR

using a QR code scanner, scan the QR code into an internet browser



Step 4a: Check last recorded temperature

- On sendum.com, check the 'Last recorded Temperature' and ensure it is within the acceptable range.
- The Alarm box should be empty. If there is an 'X' in the alarm box there has been a temperature excursion. Quarantine IP in IRT and contact AlloVir/CRA immediately



Step 4b: Finalize chain of temperature documentation

!	Do not open the inner shipper without first finalizing the temperature documentation as It will lead to an immediate temperature alarm.

– If temperature is within acceptable range press the 'Complete' button on the bottom of the page to finalize the chain of temperature documentation.

– Press 'Complete' button immediately before removing product from shipper.

Note: Once complete, the temperature will no longer be readable via QR code

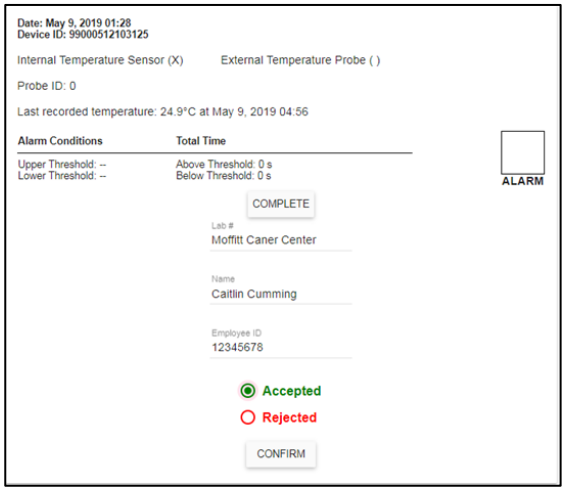
Step 5: Confirm parameters are accepted.

!	**If there has been a temperature excursion contact your CRA immediately**

– To accept the shipment, enter details in the field shown.
  - LAB #: Clinical site Location name
  - Name: First and Surname
  - Employee ID: Enter employee email
  - Address or Employee ID number

– Select Accepted

– Click CONFIRM.



Step 6: Remove Materials

Using Appropriate PPE, carefully remove the canister that holds the rack of IP box and pull up canister hook to remove the rack of the IP box.

Step 7: Return cannister and rack to shipper:

– Place the canister and rack back into the shipper.

– Ensure that the canister hook and wire are both in the wedge of the shipper

– Close the shipper by lining the groove of the lid's pink cord with the canister hook and probe wire.

Step 8: Secure latch and the plastic snap tag

– Secure the metal latch of the outer protective case.

– Close and secure the metal latches of the protective case with the provided zip ties.

– Place the pre-printed DHL airway bill provided on the handle. If the site does not have a regularly scheduled DHL pickup, you must call to schedule one as soon as possible. See next page for more details on empty shipper return.

Empty Shipper Return

There are 2 options to return the shipper:

Option 1: Empty shipper returned by Courier delivering Shipper (same day) :

- Option 1 is applicable to all sites in South Korea and Turkey and an option for sites in Europe that have indicated that they want a pick-up of the empty shipper at the time of IP delivery.
- The courier delivering the IP will wait up to 1 hour after the time of delivery, to collect the empty shipper after the IP has been transferred to the site's LN2 storage tanks.

Option 2: Empty shipper returned by DHL (Next day)

- After unloading the IP, the LN2 shipper must be returned the following day; to the respective Fisher BioServices facility of origin via DHL.
- Contact the DHL number above and provide the DHL representative the information found on the airway bill.
- Ensure the metal rack has been placed back into the LN2 shipper for return.
- The empty LN2 shipper should be stored at ambient temperature until ready for pickup.

If the site has any issues regarding return of the empty shipper (including changes to the pickup date, time, or location) contact DHL and the CRA.

For South Korea and Turkey: There is no DHL return option (2): The courier delivering the IP shipper will wait at site (for up to 1 hour) and collect the empty shipper. For European sites that prefer option 1, please inform your CRA to get confirmation whether this is possible.

See below for local DHL customer service contact numbers:

Austria	0820 / 55 05 05
Belgium	+32 2 715 50 50
Denmark	(+45) 70 345 345
Finland	+358 (0)30 45 345
France	0825 10 00 80
Germany	0049 1806 345 300
Italy	+39 199 199 345
Netherlands	+31 (0) 88 - 0552 000
Portugal	707 505 606
Spain	+34 902 12 24 24
Sweden	0771 345 345
Switzerland	0848 711 711
England	0844 248 0828

APPENDIX B Receipt of Product at the Investigative Site US, Canada, and Australia

This document describes the regional specific additional details to the IP receipt and IP empty shipper return.

Receipt of Product at the Investigative Site

The site will receive an email notification with an accompanying Temperature stability report (.pdf file) from Cryoport when the IP is delivered. The Cryoport Live View Link provided in the initial order notification email must be used to verify that no excursions have occurred between delivery and unpacking

Prior to placing the IP into long-term LN2 storage, site should compare the lot and vial #'s on the primary vial label with the lot and vial #'s listed in the IRT Shipment Request form that accompanies each shipment to verify the correct IP has been received.

Inspection of Shipment

External Inspection of the LN2 Shipper

- Described in main CTM, below are regional specific details.

Temperature

- Review the Cryoport Temperature Stability Report to confirm there were no temperature excursions during transit. If the report notes a temperature excursion during transit, follow the instructions in the Issue Reporting section.
- The Cryoport Live View Link provided in the initial order notification email can be used to view the shipper's location and temperature.

Additional Cryoport shipper handling details

- Unlatch the LN2 shipper in one of two ways:
  - If the shipper has Silver Metal Latches, unlock the latches by turning the key to the left. The latch will unhook from the top of the metal hardware.
  - If the shipper has Black Rubber Latches, pull the black handle down and away from the shipper.
- Open the lid to expose the dewar.
- Remove the vapor plug to retrieve and remove the Patient-labeled IP packaging from the dewar.
- Replace the vapor plug and allow it to settle down completely.

Note: Do not tamper with the Smartpak II® Conditioning Monitoring system located at the top of the vapor plug. Cryoport will continue to monitor the GPS location until the pick-up of the empty delivery is completed, and the collected temperature information for the delivery of the shipper will automatically be compiled and sent to all parties once available.

- Visual inspection of the IP should be conducted as close to the LN2 freezer where the IP will be stored as possible.
- Review vial labels and check received lot and vial identification (ID) numbers on the IRT Shipment Request Form. Upon completion of inspection, unpacking, and storage at the site (see inspection instructions below), the site reports the following information in IRT:
  - Shipment Order ID
  - Shipment condition at receipt
  - Date received and date and time of removal of cell product from the LN2 shipper
- At the conclusion of the action, site will print the transaction confirmation from IRT and file it.

Note: If you have unacknowledged shipments at your site, you may be blocked from performing certain actions within IRT.

Return of empty shipper

- Return should be completed the day following receipt of IP and as prearranged by Azenta and Cryoport on the Cryoportal.
- Ensure the metal rack has been put into the LN2 for return.
- Remove the original delivery shipment label, the clean shipping pouch and "Empty" adhesive label from the hanging sleeve attached to the handle of the dewar inside the enclosure.
- Attach the clean shipping pouch and the return airway bill to the metal rectangle on the side of the shipper, where the original shipping documents were.
- Unpeel/remove any final product labels from the side of the shipper as cleanly as possible.
- The adhesive "Empty" label should be removed from its backing and fully pasted onto the metal diamond on the site of the shipper.
- Secure the LN2 shipper with two (2) provided zip ties on each of the latches:
  - Silver Metal Latch:
    - Insert the zip tie down through the lid catch
    - Thread the zip tie through the body latch spring loop.
    - Thread the zip tie up through the body latch turn-buckle hole.
    - Bring the zip tie end up to the buckle.
    - Insert zip tie through the lid buckle and tighten.
  - Black Rubber Latch
    - Insert the zip tie through one of the holes on the metal latch hardware.
    - Thread the zip tie horizontally through the hole on the other side of the metal hardware.
    - Insert zip tie through the lid buckle and tighten.
- The empty LN2 shipper may be stored at ambient temperature until ready for pickup by Cryoport (usually the next day). As a reminder, the storage location should be in an area with an adequate cell signal.
- Contact Your CRA with any issues or questions regarding the return of the empty LN2 shipper.

APPENDIX C AlloVir Chain of Custody Form

REGION: US -Version 4.0

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 1 (Dose 1 + 2 + 3)				
Order ID:	*Listed on IRT Shipment Request:*			
Check Documentation Received:	☐ Azenta Pack-Out Slip ☐ IRT Shipment Request (Flexadvantage) ☐ Certificate(s) of Conformance ☐ Shipper return label ☐ Safety Data Sheet (SDS) ☐ Secondary label booklets (1 per vial)		Were there intact zip ties present on the cryoshipper upon delivery?	☐ Y ☐ N
			Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N
Vial Removal from shipper:	___ / _____ / _____ DD MMM YYYY	_____ HH:MM	Were there any temperature alarms in transit?	☐ Y ☐ N
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY	_____ HH:MM

❗	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 2 (Dose 4 + 5 + 6 + 7)			
Order ID: *Listed on IRT Shipment Request*			
Check Documentation Received:	☐ Azenta Pack-Out Slip ☐ IRT Shipment Request (Flexadvantage) ☐ Certificate(s) of Conformance ☐ Shipper return label ☐ Safety Data Sheet (SDS) ☐ Secondary label booklets (1 per vial)	Were there intact zip ties present on the cryoshipper upon delivery?	☐ Y ☐ N
		Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N
		Were there any temperature alarms in transit?	☐ Y ☐ N
Vial Removal from shipper:	_____ / _____ / _____ DD MMM YYYY _____ HH:MM		
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY _____ HH:MM

!	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

DOSE 1 (Secondary Label)
Attach secondary label below (one for each vial that you prepare for infusion)

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

DOSE 2 (Secondary Label)
Attach secondary label below (one for each vial that you prepare for infusion)

Patient and Information			
Patient ID:	________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			Dispensing			Destruction		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______ ; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

!	It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

REGION: Europe (UK not included) Version 4

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 1 / Dose 1 + 2 + 3				
Order ID:	*Listed on IRT Shipment Request:*			
Check Documentation Received:	☐ Fisher BioServices Depot pack out slip ☐ IRT Shipment Request ☐ Certificate(s) of Conformance (for both PSL and placebo) ☐ Shipper return Air Waybill ☐ Safety Data Sheet (SDS) ☐ Fisher EU QP certificate of release		Were there intact zip ties present on the cryoshipper upon delivery?	☐ Y ☐ N
			Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N
Vial Removal from shipper:	___ / _____ / _____ DD MMM YYYY	_____ HH:MM	Were there any temperature alarms in transit?	☐ Y ☐ N
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	
❗	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.			

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 2 (Dose 4 + 5 + 6 + 7)			
Order ID: *Listed on IRT Shipment Request*			
Check Documentation Received:	☐ Fisher BioServices Depot pack out slip ☐ IRT Shipment Request ☐ Certificate(s) of Conformance (for both PSL and placebo) ☐ Shipper return Air Waybill ☐ Safety Data Sheet (SDS) ☐ Fisher EU QP certificate of release	Were there intact zip ties present on the cryoshipper upon delivery?	☐ Y ☐ N
		Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N
		Were there any temperature alarms in transit?	☐ Y ☐ N
Vial Removal from shipper:	_____ / _____ / _____ DD MMM YYYY _____ HH:MM		
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY _____ HH:MM

!	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.

Patient and Information			
Patient ID:	________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			**Dispensing**			**Destruction**		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

! It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

REGION: South Korea, Turkey, and UK - Version 4

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 1 / Dose 1 through 7 (all 7 doses)				
Order ID:	*Listed on IRT Shipment Request:*			
Check Documentation Received:	☐ Fisher BioServices Depot pack out slip ☐ IRT Shipment Request ☐ Certificate(s) of Conformance (for both PSL and placebo) ☐ Shipper return Air Waybill ☐ Safety Data Sheet (SDS) ☐ Fisher UK QP certificate of release (Not for South Korea or Turkey) ☐ Fisher proforma invoice for shipper re-export		Were there intact zip ties present on the cryoshipper upon delivery? Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N ☐ Y ☐ N
Vial Removal from shipper:	___ / _____ / _____ DD MMM YYYY	_____ HH:MM	Were there any temperature alarms in transit?	☐ Y ☐ N
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	
!	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.			

Patient and Information			
Patient ID:	__________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			Dispensing			Destruction		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

!	It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

Patient and Information			
Patient ID:	________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			Dispensing			Destruction		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

❗	It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

REGION: Australia and Canada - Version 4

Patient and Information			
Patient ID:	_____ (Ex. Site#-Patient#)	Investigator Name:	

Shipment information: Shipment 1 / Dose 1 through 7 (all 7 doses)				
Order ID:	*Listed on IRT Shipment Request:*			
Check Documentation Received:	☐ Azenta Pack-Out Slip ☐ IRT Shipment Request (Flexadvantage) ☐ Certificate(s) of Conformance ☐ Shipper return label ☐ Safety Data Sheet (SDS) ☐ Secondary label booklets (1 per vial) ☐ Customs invoice for Australia or Canada		Were there intact zip ties present on the cryoshipper upon delivery? Were all contents listed on the IRT Shipment Request Form received?	☐ Y ☐ N ☐ Y ☐ N
Vial Removal from shipper:	___ / _____ / _____ DD MMM YYYY	_____ HH:MM	Were there any temperature alarms in transit?	☐ Y ☐ N
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ _____ DD MMM YYYY HH:MM	
❗	If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual.			

Patient and Information			
Patient ID:	__________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			**Dispensing**			**Destruction**		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

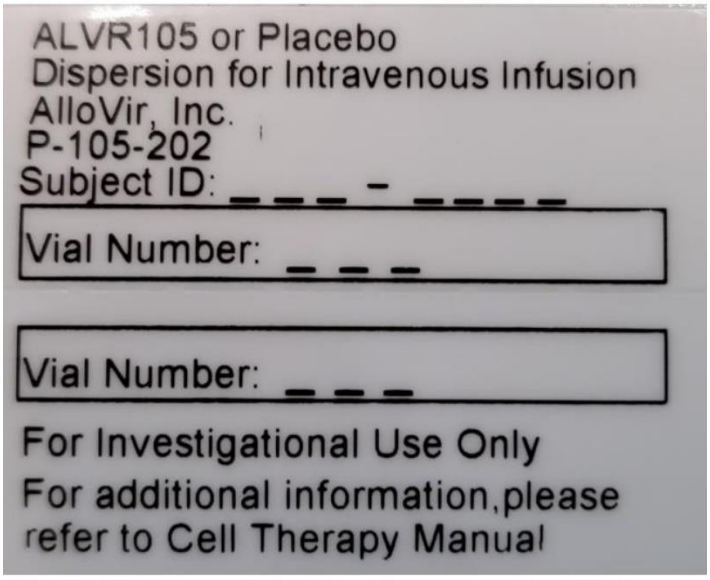
!	It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

Patient and Information			
Patient ID:	_________________ (Ex. Site#-Patient#)	Investigator Name:	

	Receipt			**Dispensing**			**Destruction**		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Dispensed to Patient**	**Date Dispensed** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date of Destruction** *(dd-MON-yyyy)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(Initials/ dd-MON-yyyy)*
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - _ _ - _ _ _ _ _ _ ; _ _ _	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

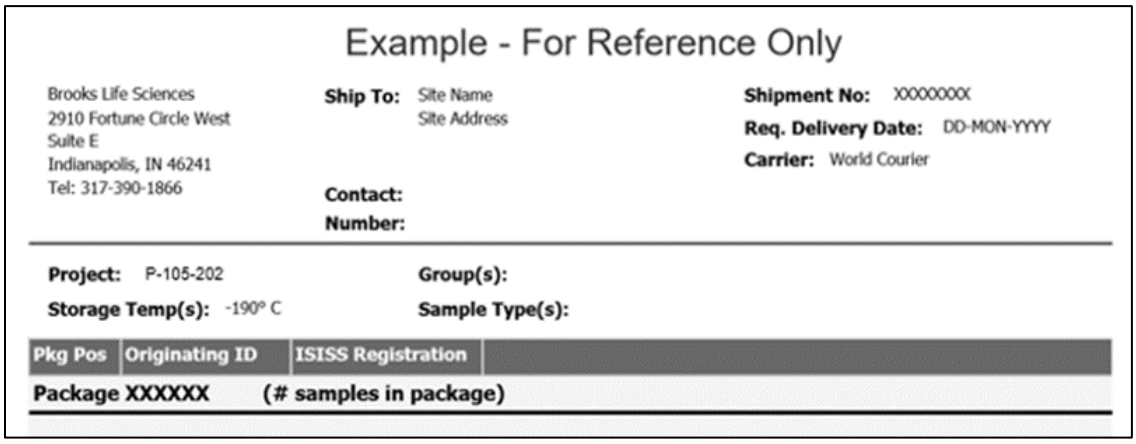
!	It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

APPENDIX D Example Syringe Label (Global)



APPENDIX E Example IP Pack Out Slip – Regional –

Example for Australia, Canada, and US



Example - For Reference Only

Brooks Life Sciences
2910 Fortune Circle West
Suite E
Indianapolis, IN 46241
Tel: 317-390-1866

Ship To: Site Name
Site Address

Contact:
Number:

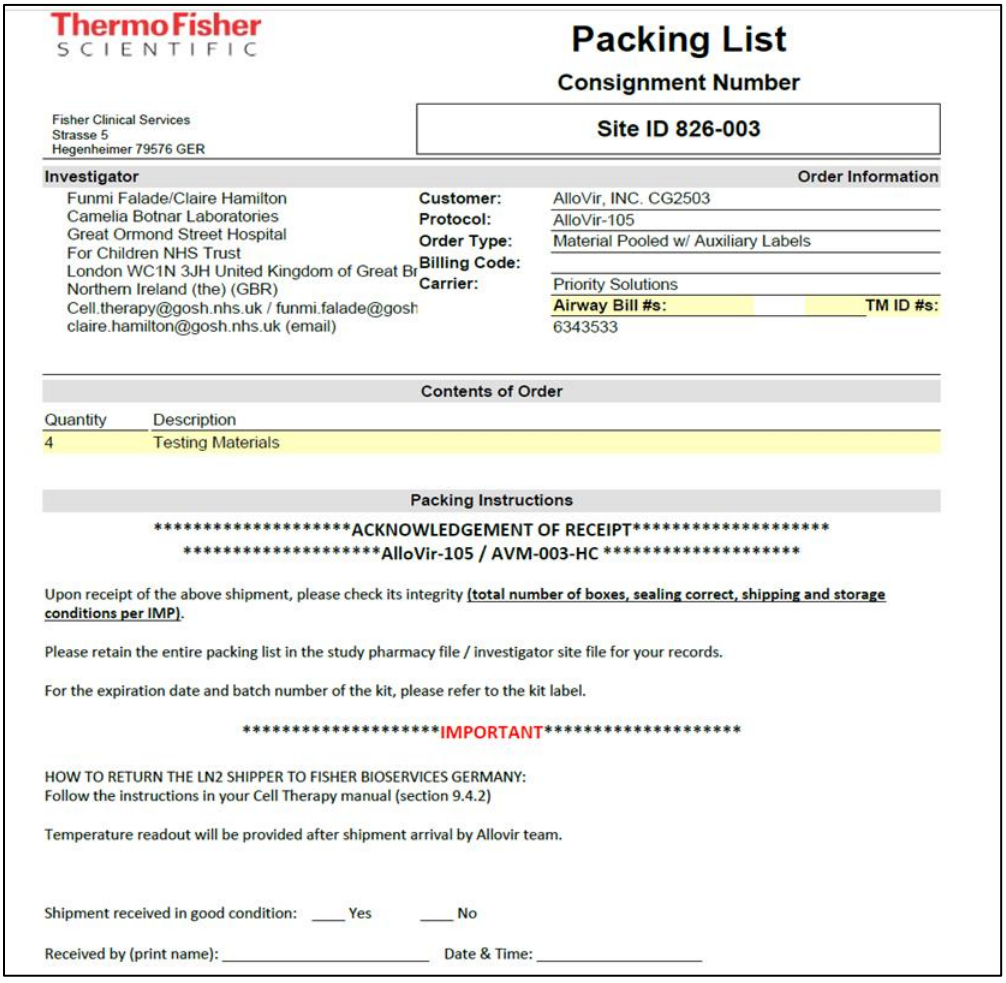
Shipment No: XXXXXXXX
Req. Delivery Date: DD-MON-YYYY
Carrier: World Courier

Project: P-105-202
Storage Temp(s): -190° C

Group(s):
Sample Type(s):

Pkg Pos	Originating ID	ISISS Registration
Package XXXXXX	**(# samples in package)**	

Example for Europe, Turkey, and South Korea



ThermoFisher SCIENTIFIC

Packing List

Consignment Number

Site ID 826-003

Fisher Clinical Services
Strasse 5
Hegenheimer 79576 GER

Investigator

Funmi Falade/Claire Hamilton
Camelia Botnar Laboratories
Great Ormond Street Hospital
For Children NHS Trust
London WC1N 3JH United Kingdom of Great Br
Northern Ireland (the) (GBR)
Cell.therapy@gosh.nhs.uk / funmi.falade@gosh
claire.hamilton@gosh.nhs.uk (email)

Order Information

Customer: AlloVir, INC. CG2503
Protocol: AlloVir-105
Order Type: Material Pooled w/ Auxiliary Labels
Billing Code:
Carrier: Priority Solutions
Airway Bill #s: 6343533 **TM ID #s:**

Contents of Order

Quantity	Description
4	Testing Materials

Packing Instructions

**********ACKNOWLEDGEMENT OF RECEIPT**********
**********AlloVir-105 / AVM-003-HC **********

Upon receipt of the above shipment, please check its integrity **(total number of boxes, sealing correct, shipping and storage conditions per IMP)**.

Please retain the entire packing list in the study pharmacy file / investigator site file for your records.

For the expiration date and batch number of the kit, please refer to the kit label.

**********IMPORTANT**********

HOW TO RETURN THE LN2 SHIPPER TO FISHER BIOSERVICES GERMANY:
Follow the instructions in your Cell Therapy manual (section 9.4.2)

Temperature readout will be provided after shipment arrival by Allovir team.

Shipment received in good condition: ____ Yes ____ No

Received by (print name): _____ Date & Time: _____

APPENDIX F Example IRT Shipment Request

Allovir
P-105-202
Unblinded Shipment Request

Shipment ID	S-3-89-1308	Shipment Type	MANUAL
Date Requested	01-Jun-2021	Fill Type	FULL
Supplying Warehouse	Brooks	Site Phone Number	123-123-1234
Destination Site Number	123	Site Shipping Address	ICON 1234 Dairy Ashford Sugar Land, TX, 77479 United States
Site Investigator	Nausheen Siddiqui		
Drug Contact Name	MS. Nausheen ..... Siddiqui		
Drug Contact Email	test@test.com		
Patient Number	123-1122		

Please ship the following:

Lot Number + Vial No	Expiration Date
128-ZZ-23TSTB-113	31-Jan-2025
128-ZZ-23TSTB-114	31-Jan-2025
128-ZZ-23TSTB-115	31-Jan-2025
128-ZZ-23TSTB-116	31-Jan-2025
128-ZZ-23TSTB-117	31-Jan-2025
128-ZZ-23TSTB-118	31-Jan-2025
128-ZZ-23TSTB-119	31-Jan-2025
128-ZZ-23TSTB-120	31-Jan-2025
128-ZZ-23TSTB-121	31-Jan-2025
128-ZZ-23TSTB-122	31-Jan-2025

APPENDIX G Dose Worksheet - Version 4

ALLOVIR | P105-202

Dose Worksheet
Site Instructions: Complete this worksheet for **each dose** of Investigational Product prepared and administered to the patient. Prior to preparation for dosing, the patient must be randomized in IRT for dose 1 by completing the action "Randomize a Patient" OR IRT must assign doses 2 through 7 by completing the action "Vial Assignment." Completing these actions will assign the cryovials for the dose Report issues via the issue reporting instructions in the Cell Therapy Manual (section 12).

POSOLEUCEL DOSING SCHEMATIC			
Patient Weight	Dose (Cells) (Each Dose)	Volume Drawn into Syringe	IP Vials Required
<40 kg	2×10^7	2 mL	1
≥40 kg	4×10^7	4 mL	2

PART A: PATIENT AND VIAL INFORMATION Part A to be completed by CTL/pharmacy or responsible party for retrieving the IP.			
Site Number:	_____	Investigator Name:	_____
Patient ID #:	_____ (Ex. Site#-Patient#)		
Patient Weight (Measured at screening)	_ _ . _ kg		
Visit #:	☐ Day 0 (Dose 1) ☐ Week 2 (Dose 2) ☐ Week 4 (Dose 3) ☐ Week 6 (Dose 4) ☐ Week 8 (Dose 5) ☐ Week 10 (Dose 6) ☐ Week 12 (Dose 7)		

Please add information for all the vials needed for this dosing visit:			
IRT assigned Vial 1: Vial #	_____	Vial 1 Expiration Date	___ / _____ / _____ DD MMM YYYY
Mark if not applicable ☐ IRT assigned Vial 2: Vial #	_____	Vial 2 Expiration Date	___ / _____ / _____ DD MMM YYYY

Confirm Expiry date is in future per the Shipment Request Form (SRF) or the IRT transaction confirmation	☐ YES ☐ NO

Was as LN_2 shipper used to transport the IP between the LN_2 long term storage tank and IP preparation location

☐ Yes (complete time of removal from LN_2 storage and time placed in LN_2 Shipper)

☐ No, Skip to signature section of Part A

Vial removal from storage tank:	___ / _____ / _____ DD MMM YYYY	_____ HH:MM	
Was the transfer time out of Cryogenic conditions within the recommended 1 minute?	☐ Y ☐ N	If No, Vial placement back in cryogenic conditions	_____ / _____ / _____ DD MMM YYYY _____ HH:MM

Completed By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY

PART B: INVESTIGATIONAL PRODUCT THAW AND PREPARATION OF ADMINISTRATION SYRINGE

Part B to be completed by CTL/pharmacy or the party responsible for thawing and preparing the syringe. After completing Part B, provide the entire form to infusion team with the prepared syringe.

Patient ID #:	_____ (Ex. Site#-Patient#)

!	**Administration of Investigational Product is to be completed within 45 minutes of thaw completion.** **If thawing multiple cryovials, thaw all vials at the same time in the same manner.**		
Prior to thaw, were the lot and vial numbers listed on the vials double verified against the IRT assignment?			☐ Yes ☐ No
Removal of Vials from LN_2 Cryogenic condition immediately prior to start of IP Thaw	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	Was the vial / Were the vials intact, sealed, and frozen?	☐ Yes ☐ No
Placement in water bath /thawing device (= Start of thaw)	_____ / _____ / _____ _____ DD MMM YYYY HH:MM		
Thaw Completion	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	Indicate method of thawing and thawing temperature:	☐ Water bath ☐ Dry-Block Temperature: _____ºC
Dose Volume to prepare (refer to dosing table above or latest study correspondence)	_____ mL	Actual volume prepared:	_____ mL

!	**NOTE: The maximum volume to be drawn up out of a single vial is 2 ml**
When IP was drawn into the syringe(s), were the vial numbers listed on the vials verified against the vial numbers listed on the syringe label?	☐ YES ☐ NO
Was the patient ID listed on the syringe label verified against the IRT assignment?	☐ YES ☐ NO

Completed By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY

Part C: Administration of investigational product (To be completed by the infusion team.)			
Patient ID #:	_____ (Ex. Site#-Patient#)		
!	**Follow instructions in Cell Therapy Manual Section 11 Administration of IP.**		
If the team administering the IP is different from the team preparing the IP syringe(s): Were the vial numbers listed on the syringe label double verified against the IRT assignment?	☐ YES ☐ NO ☐ N/A (same team preparing IP as administering IP)		
Was patient Identity appropriately confirmed prior to dosing per site process?	☐ YES ☐ NO		
Administration Start	____ / _____ / _____ DD MMM YYYY _____ HH:MM	Administration Completion *(not including post-infusion flush)*	____ / _____ / _____ DD MMM YYYY _____ HH:MM
Total Volume administered	_____mL		
Was administration completed within 45 minutes of thaw completion?	☐ YES ☐ NO		
Confirm that the Hemo-Nate syringe filter was utilized:	☐ YES ☐ NO		
Completed By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY

!	**The following fields are to be completed only if the dose was interrupted or the entire volume was not administered.**

If the dose was interrupted, reason for dose interruption			
Administration Pause	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	Administration Re-start	_____ / _____ / _____ DD MMM YYYY _____ HH:MM
Total volume administered	_____ mL	Estimated remaining volume after administration completion: *(Complete only if the entire volume was not administered)*	_____ mL

PART D: Flush (To be completed by the infusion team.)			
!	**Follow instructions in Cell Therapy Manual Section 11 – Administration of IP.** **IP vials and all infusion materials (syringes, infusion tubes, etc.) containing IP should be treated and disposed of as biohazard waste in accordance with local governing regulations and clinical site SOPs.**		
Flush Start	_____ / _____ / _____ DD MMM YYYY _____ HH:MM	Flush Completion	_____ / _____ / _____ DD MMM YYYY _____ HH:MM
Saline Flush Volume	_____ mL		
Completed By:	Print Name:	Signature:	_____ ___ / _____ / _____ DD MMM YYYY

APPENDIX H Issue Reporting Form, Version 4

ALLOVIR | P-105-202

Site Instructions: In the event of an issue regarding investigational product (IP) for Posoleucel or Placebo, please follow the reporting instructions in the Cell Therapy Manual section 12 Issue Reporting and email this completed form with section A and section B or section C your unblinded CRA.

Once a decision has been made, CRO or the Sponsor will communicate the decision to the site via email and include the completed form. Please file the completed form.

SECTION A: Site and Issue Information			
Site Name / Number		Institution	
PI Name			
Reported by *Print name and title*		Signature/Date	
Email		Telephone	
Please check appropriate box:	☐ IP temperature excursion *(please complete section B)* ☐ Product complaint or other issue *(please complete section C)*		
Was this an urgent issue?	☐ Yes *(If yes, please complete the box below)* ☐ No		
Please describe the actions taken at the time the urgent issue was discovered.			

SECTION B: IP Temperature Excursion			
Product Name *Storage Condition is vapor phase liquid nitrogen (LN2) at ≤ -150°C*	Posoleucel / placebo	Affected Lot + Vial #s:	126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _
Did the excursion occur during shipment of IP to the site?	☐ Yes *If yes, please attached the Cryoport temperature stability report and submit the signed form. Do not complete the remainder of section B.* ☐ No		
Start Date of Excursion (dd-MMM-yyyy)		Duration of Excursion (HH:MM)	
Start Time of Excursion (24H HH:MM)			
Date of Discovery (dd-MMM-yyyy)		Maximum temperature reached during excursion	
Description and Cause of Excursion			

Section C: Product Complaint Or Other Issue Information	
Affected Lot + Vial #s:	126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A
Please describe the issue(s) identified:	

Section D: AlloVIR/CRO Use Only			
Assessment	☐ Acceptable for use ☐ NOT acceptable for use. Site to destroy affected vials. ☐ Other - see notes.		
Notes			
Name and Title (Print)		Signature:	_____ ___ / _____ / _____ DD MMM YYYY

APPENDIX I User Guide AT-Adapt

AT-Adapt™

Overview

The AT-Adapt™ is a stand-alone, single-use, disposable device which permits access to an AT-Closed Vial® (2, 6, 10, 20 and 50mL format) without the use of a needle.

The device is intended for use by healthcare professionals in a wide variety of healthcare environments, including hospitals, healthcare facilities and pharmacies.

Together always one step ahead **www.aseptictech.com** 3

AT-Adapt™

Material

A processed (filled and capped) AT-Closed Vial®;
An AT-Adapt™;
A syringe with luer connection.

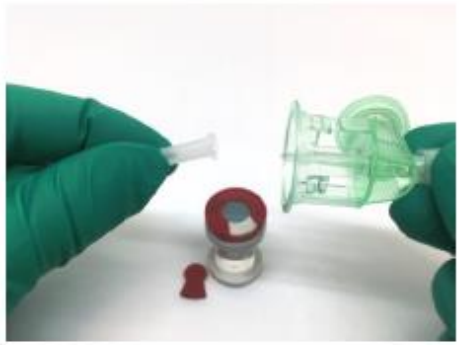
Together always one step ahead **www.aseptictech.com** 4

AT-Adapt™

Process

The individual packaging of the AT-Adapt™ is peeled

The flip-off cap protecting the AT-Closed Vial® stopper is removed



The protection of the spike of the AT-Adapt™ is removed

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AT-Adapt™

Process

Attaching the AT-Adapt™ to the AT-Closed Vial® is a 3 step process:

Step 1: **ATTACH** the AT-Adapt™ to the AT-Closed Vial®.

Do not press too firmly to avoid tabs of the AT-Adapt™ to be locked on the top ring of the AT-Closed Vial®.

Step 2: **SPIKE** the AT-Closed Vial® by moving the AT-Adapt™ in a downward motion into the vial. Spike should be perpendicular to stopper. Do not insert at an angle.

Step 3: Holding the AT-Closed Vial®, **the AT-Adapt™ shall be lifted up until the lower tab touches the cap (see yellow circle). This ensures an optimal needle positioning for maximal product withdrawal.**

The cap protecting the luer connection can be removed.

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AT-Adapt™

Process

A syringe is connected and the product is withdrawn from the AT-Closed Vial® , upside down.

Do not put pressure (air) in the vial with the syringe (prior retrieving)

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APPENDIX J Fisher IP Drug Return Collection Request Form (KR-FM-035.02) South Korea Only

Fisher Clinical Services **IMP Drug Return Collection Request Form**

Please fill in all areas marked in grey as appropriate.	
SECTION I:	**CLIENT CONTACT DETAILS**
Protocol	[
Date of request sent (DD/MM/YYYY)	[
Site No	[
Country of Export	[
STUDY SPECIFIC INSTRUCTION	[
SECTION II:	**IMP PICKUP DETAILS**
Hospital Name	[
Hospital Address	[
Site Contact Name	[
Site Contact Number and Alternative Number	[
Site Contact Email	[
Total number of shipping cartons to return (All products must be packed into the number of cartons declared)	[
Date of pickup (Minimum 5 days from date of sending completed form to Fisher)	[
SPECIAL INSTRUCTION FOR FISHER (e.g.: Day/date and time which courier should avoid returns collection)	[
SECTION III:	**FISHER CONTACT DETAILS**
Deliver to	**Return Team** 서울 강서구 금낭화로 16 길 32(방화동) 우편번호 : 07517 (Banghwa-dong) 32, Geumnanghwa-ro, 160gil, Gangseo-gu, Seoul, Korea
Contact Department	Return Team
Telephone	070-4418-0211
Fax	02-2666-7955
Email	returns.korea@thermofisher.com

KR-FM-035.02 FISHER CLINICAL SERVICES KOREA

APPENDIX K Alternative Storage Cryobox. Europe Only

For sites that cannot store the IP in the AT-CryoBox (5x5), an alternative size box can be supplied.

All shipments of IP to sites will still come in the AT-CryoBox (5x5). Upon receipt of an IP shipment sites may transfer the IP to the alternative Cryobox. When transferring the IP from the LN2 Shipper to their LN2 storage tanks, please follow all transfer requirements per the Cell Therapy Manual Section 9. The Cryobox should be stored in the upright position in the storage tank.

Sites may also use the alternative Cryobox in their LN2 transport shippers for the transport between site locations on the day of the IP preparation. The vials must remain in an upright position during transport.

Upon receipt of the alternative Cryobox sites need to reconfigure the subdivider configuration per the image provided below.

Alternative Cryobox **Dimensions:** L 75 × W 75 × H 51 mm **Maximum Capacity:** 4 vials (one vial in each conner of the box) **Note:** The Cryobox can be used to store IP at the site; return to Depot is not required. **Product reference:** VWR SKU: 89128-202	VWR PolarSafe™, Argos Technologies  Box subdivider reconfiguration 

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