ACE1831 Cell Therapy Manual

Version 3.0

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Sponsor	Acepodia Biotech, Inc. 1600 Harbor Bay Parkway; Suite 140 Alameda, CA 94502 USA
Title	A Phase 1 Multicenter Study Evaluating the Safety and Efficacy of ACE1831, an Allogeneic CD20-conjugated gamma delta T-cell therapy, in Adult Subjects with Relapsed/Refractory CD20-expressing B-cell Malignancies
Indication	Relapsed/refractory (r/r) non-Hodgkin lymphoma
Investigational Product	ACE1831
Product Description	Cryopreserved human allogeneic gamma delta T cells conjugated with anti -CD20 mAb
IND Number	27944

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ACEPODIA TEAM CONTACTS

1.a. The contract research organization (CRO [ICON]) clinical trial manager (CTM) is the primary contact for all study operational questions. If the CRO CTM is unavailable, contact the CRO's Clinical Research Associate or a member of the Acepodia clinical team. Please note that study contacts may change. Contact information for the study team can be found in the Investigator Site File (ISF).

Please contact your regional Medical Monitor for:

- All medical and urgent issues regarding ACE1831 administration
- All medical and urgent issues regarding subjects administered ACE1831

Consult the study protocol and ISF for contact details of the Medical Monitor.

1.b. If there is an issue with the ACE1831 Investigational Product (IP) pre-infusion (eg, visual appearance of the ACE1831 IP), or the vial has been compromised (eg, cracked vial, broken seal etc.), follow the steps listed below:

1. Quarantine the affected ACE1831 vial
2. Complete and submit the Product Complaint Reporting Form to **drugcomplaint@acepodiabio.com**. (Section 12)
3. Obtain another vial from your site inventory and proceed with product preparation process
4. Update the ACE1831 Investigational Product Master Accountability Form

1. TRAINING

Site staff delegated by the Principal Investigator responsible for the receipt, transfer, storage, preparation, administration, and disposal of ACE1831 will be required to train on the processes and procedures detailed within the ACE1831 Cell Therapy Manual.

Documentation of this training must be retained in the Investigator Site File (ISF).

2. ACE1831 INVESTIGATIONAL PRODUCT OVERVIEW

ACE1831 is an allogeneic gamma delta T cell therapy (gdT) under investigation for the treatment of CD20-expressing B-cell malignancies.

ACE1831 consists of human allogeneic gdT cells that are conjugated to an anti-CD20 monoclonal antibody (mAb) using short complementary strand DNA linkers. Using a novel selection and expansion technology, the gdT cells are enriched to express high levels of natural killer (NK)-activating receptors, such as CD56 and NKG2D, and low levels of inhibitory receptors

to enhance their potency. Gamma delta T cells have characteristics of both the innate and adaptive immune systems that make them an ideal platform for the development of cell therapies. This cell type can directly recognize and attack cancerous cells as well as coordinate a broad antitumor immune response by recruiting other accessory cells to the sites of disease and activating other immune factors. Gamma delta T cells do not recognize allogeneic major histocompatibility complex (MHC) restricted antigens, nor do they secrete excessive amounts of IL-6, a significant driver of cytokine release syndrome (CRS), providing a potential safety advantage over other cell therapies.

This ACE1831-001 is a first-in-human study designed to evaluate the safety and drug activity of ACE1831 as monotherapy and in combination with the FDA approved anti-CD20 mAb obinutuzumab (GAZYVA) in adult subjects with relapsed/refractory CD20-expressing B-cell malignancies.

A description of ACE1831 and its characteristics are provided in Table 1.

Table 1: ACE1831 Investigational Product Description and Characteristics

Cell Product and Appearance		
Acepodia cell product number	ACE1831, anti-CD20 monoclonal antibody conjugated gdT cells	
Cell product component	human allogeneic gamma delta T cells (gdT)	
Antibody conjugate	rituximab	
Appearance	Pale to milky-white suspension	
Release Test Specifications		
Item	**Method**	**Acceptance Criteria**
VCD	Cell Counting	1.25 ± 0.25 x10^8 cells/mL
Viability	Cell Counting	≥ 80%
Appearance	Visual Inspection	Pale to milky white suspension
Endotoxin	USP<85>	< 6 EU/mL
Sterility	USP<71>	No growth
Mycoplasma	NAT assay	Negative
CD20 binding	Flow cytometry	10 ug/mL CD20, MFI ≥ 2575
Biomarker (TCRvd2$^+$)	Flow cytometry	≥ 70%
Biomarker (TCRab$^+$)	Flow cytometry	< 0.25 %
HIV-1	NAT assay	Negative
HIV-2	NAT assay	Negative
HTLV-1	NAT assay	Negative
HTLV-2	NAT assay	Negative
HAV	NAT assay	Negative
HBV	NAT assay	Negative

HCV	NAT assay	Negative
HCMV	NAT assay	Negative
EBV	NAT assay	Negative
B19	NAT assay	Negative
HHV6	NAT assay	Negative
HHV7	NAT assay	Negative
HHV8	NAT assay	Negative
HPV16	NAT assay	Negative
HPV18	NAT assay	Negative
JCV	NAT assay	Negative
BKV	NAT assay	Negative

Abbreviations: HIV=human immunodeficiency virus; HTLV=human T lymphotropic virus; HAV=hepatitis viruses A; HBV=hepatitis viruses B; HCV=hepatitis viruses C; HCMV=cytomegalovirus; EBV=Epstein-Barr virus; B19=human parvovirus B19; HHV=human herpes virus; HPV=human papillomavirus; JCV=JC virus; and BKV=BK virus.

2.1 COMPOSITION AND FORMULATION

Each vial (bottle) contains 1×10^8 cells/mL of ACE1831 in cryopreservation media (10% DMSO) at a nominal volume of 10mL.

The ACE1831 Dose Assignment Form (ATTACHMENT A) will specify the total volume of ACE1831 to be administered for each subject.

3. PACKAGING AND LABELING

3.1 PACKAGING

ACE1831 is provided in 10 mL cycloolefin co-polymer (COC) vials (AT-vials®), as a pale to milky-white suspension solution intended for intravenous administration. The vials have a stopper with gray thermoplastic elastomer (TPE) and acrylonitrile butadiene styrene (ABS) top rings and sealed with yellow high-density polyethylene (HDPE) caps.

ACE1831 vials will be shipped to sites in vial-holder boxes.

3.2 LABELING

Each vial-holder box will have an individual label, as well as individual ACE1831 vials. Example labels are provided in Figure 1, Figure 2, and Figure 3.

Figure 1: Individual Vial Label

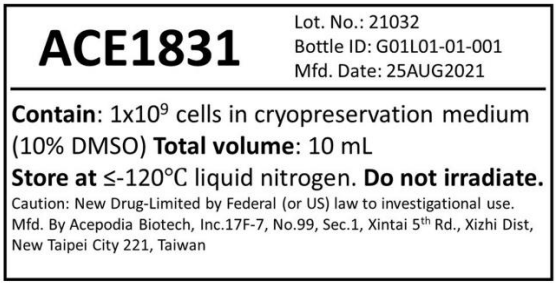


Figure 2: Vial-Holder Box Label

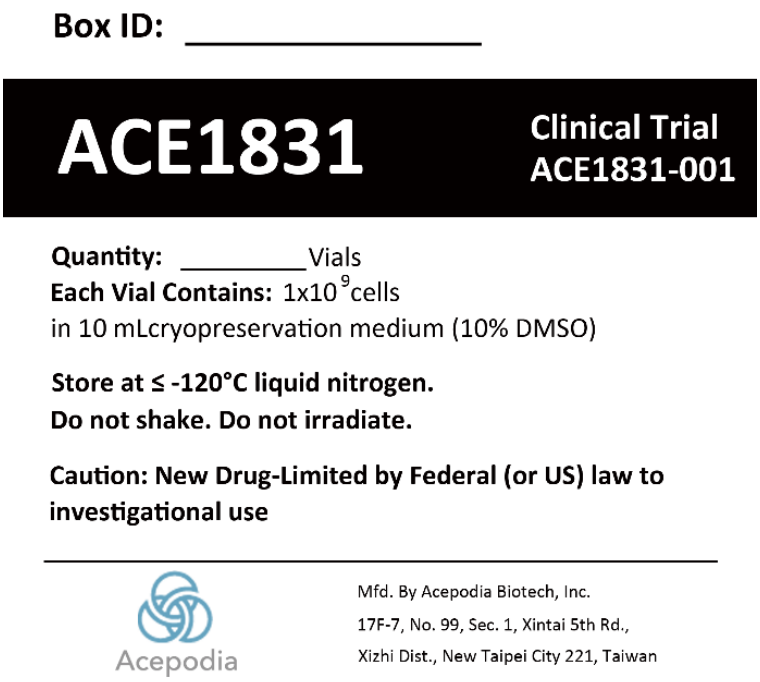
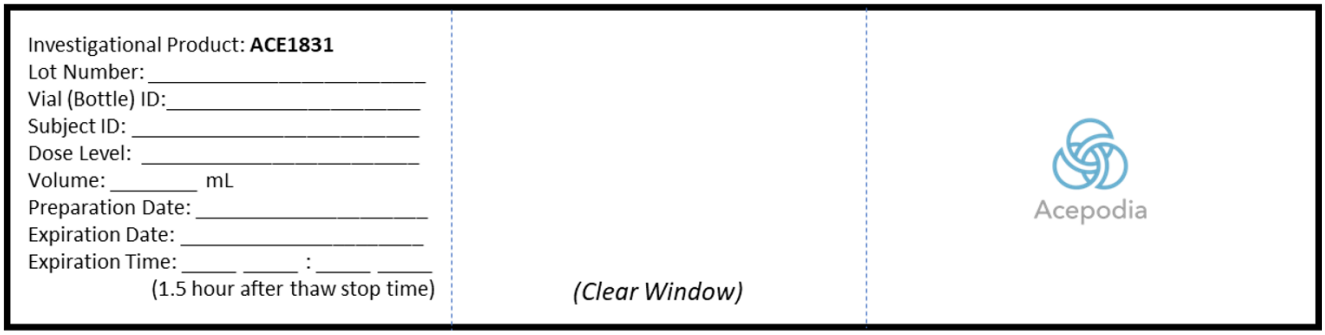


Figure 3: Syringe Label



4. PRODUCT REQUEST, SHIPMENT, RECEIPT AND STORAGE

Shipment and receipt of the ACE1831 investigational product (IP) to the investigative site's Pharmacy or Cellular Therapy Lab facility will occur after confirmation by the Sponsor that all the requirements to release IP to the investigative site have been met.

Procedures for the shipment, receipt, and storage of the ACE1831 IP requirements are provided in Sections 4.1 through 4.4.

4.1 INITIAL ACE1831 SHIPMENT TO CLINICAL SITE

1. The Sponsor will arrange for the ACE1831 vials to be shipped to the clinical site following confirmation of all necessary regulatory approvals and site activation.
2. ACE1831 vials will be delivered to clinical sites by a courier service, Cryoport.
3. ACE1831 vials will be shipped in a cryopreserved liquid nitrogen cold-chain storage shipper, referred to as the LN_2 Dry Vapor Shipper and temperature controlled to ≤-120°C.
4. ACE1831 vials will be supplied in a vial-holder box.
5. Cryoport will collect the LN_2 Dry Vapor Shipper and temperature tracking device after delivery of the ACE1831 investigational product at the clinical site.

4.2 RE-SUPPLY OF ACE1831

Subsequent supplies of ACE1831 will be auto-supplied by the Sponsor based on enrollment. If additional enrollment is anticipated, additional vials of ACE1831 can be requested by the site by

emailing the Investigational Product Order Form (ATTACHMENT B) to the Sponsor and cc'ing the CRO CTM. Refer to the study contact list for the relevant email address.

- Sponsor Contacts:
  - E-mail: drugsupply@acepodiabio.com

The Sponsor will send a confirmation email back to the clinical site within 48 business hours of receiving the Investigational Product Order Form. Prior to each shipment, Cryoport will send out a shipping confirmation email with a tracking number to the site. Five business days from receipt of IP request should be allowed for delivery of ACE1831.

4.3 RECEIPT OF LN_2 DRY VAPOR SHIPPER AND INVESTIGATIONAL PRODUCT AT CLINICAL SITE

After receipt of the LN_2 Dry Vapor Shipper, complete the following activities:

1. A trained site staff member is required to sign the Investigational Product Receipt Form (ATTACHMENT C) and Part III of Material Transfer Form (ATTACHMENT D) to confirm receipt of the LN_2 Dry Vapor Shipper.
2. A copy of the signed Investigational Product Receipt Form and Material Transfer Form are required to be filed in the sites' study file.
3. Inspect the LN_2 Dry Vapor Shipper for any damage or leaks. If any damages or leaks are identified, contact the Sponsor immediately at the email address drugcomplaint@acepodiabio.com , cc'ing the CRO CTM and wait for further instructions.
4. Open the shipper and inspect the ACE1831 vial-holder box for damage or leaks. The two box seals on the side of the vial-holder box should be intact upon receipt. If there is any damage or leaks or the box seals are not intact, follow the instructions listed on Section **1.b.**
5. Open the vial-holder box and check the number of ACE1831 vials listed on the Part I of the Material Transfer Form **(**ATTACHMENT D) matches the number of ACE1831 vials received.
6. Each ACE1831 vial is individually labeled.

   Check each individual ACE1831 vial (Figure 4) for labeling, damage, or leaks. The yellow vial cap should be secured with the center flap intact. If any ACE1831 vials are unlabeled, visually appear to be damaged, have leaks, or show signs of premature thawing, follow the instructions listed in Section **1.b.** \

Figure 4: A vial (bottle) of ACE1831

Bottle with a secure yellow vial cap


7. Record the number of ACE1831 vials received on the ACE1831 Investigational Drug Product Master Accountability Log (ATTACHMENT E).
8. Confirm that the ACE1831 IP lot(s) in the LN_2 Dry Vapor Shipper are within their shelf life, as provided on the ACE1831 Shelf Life Memo (ATTACHMENT F).

4.4 STORAGE AT CLINICAL SITE.

IP Transfer to On-Site Storage (On-Site Storage capabilities have been assessed by the CRO, as part of the site selection process):

1. ACE1831 IP will arrive at the site in a LN_2 Dry Vapor Shipper and will be transferred to an on-site, LN_2 storage tank.
2. Proper Personal Protective Equipment (PPE) should be worn as per institutional guidelines while handling liquid nitrogen.
3. The transfer of all ACE1831 IP vials from the LN_2 Dry Vapor Shipper to an On-Site LN_2 storage tank **must be completed within 2 minutes**.
4. Record the transfer time on the Investigational Product Receipt Form (ATTACHMENT C)
5. ACE1831 vials must be stored in the vial-holder box in LN_2 (≤ -120°C) upon receipt until use.
6. Vials should be kept upright during storage to avoid physical damage.

5. TEMPERATURE TRACKING, VERIFICATION, AND EXCURSIONS

5.1 TEMPERATURE TRACKING

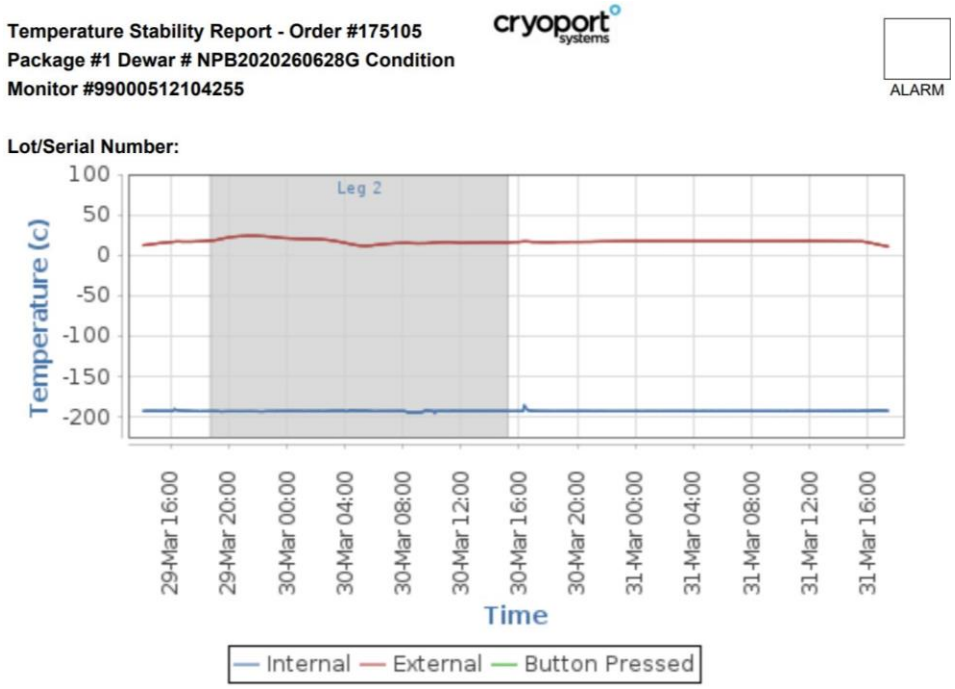
The Sponsor is responsible for monitoring of the LN_2 Dry Vapor shipper temperature from the time of IP packaging and shipping at the US storage facility until removal of IP from the LN_2 Dry Vapor shipper to local storage at the clinical site. The Sponsor will review the Cryoport temperature monitoring report to confirm that the LN_2 Dry Vapor Shipper maintained a temperature of –120°C or below.

Site staff will be provided with the Cryoport temperature monitoring report by the Sponsor. Sites will also be able to access temperature data and download reports via the Cryoport Live Link. The Cryoport Live Link will be provided via email from cs@cryoport.com or noreply@cryoport.com. Contact your CRO CTM if you have not received the Cryoport Live Link. An example of the Cryoport Live Link data and temperature monitoring report is provided in Figure 5 and Figure 6.

The clinical site is responsible for monitoring of storage temperatures from the point of storage at the clinical site.

Figure 5: Cryoport Data

Figure 6: Example of Cryoport Temperature Monitoring Report



Once ACE1831 is transferred to an on-site LN_2 storage tank, continuous temperature monitoring must be conducted per institutional policies and procedures up to the ACE1831 thaw start time.

The Cryoport temperature monitoring report provided by the Sponsor, together with all the site temperature records must be filed in the Investigator Site File (ISF) and made available to the site CRA for verification during monitoring visits.

6. TEMPERATURE EXCURSIONS

6.a Reporting Temperature Excursion Prior to Receipt of Shipper at the Clinical Site

In the event the Sponsor becomes aware of any temperature excursion that occurred during shipment of the ACE1831 IP to the clinical site, the Sponsor will immediately inform the site staff via email and instruct them to quarantine the ACE1831 IP. The Sponsor will provide the clinical site with instructions on how to proceed. A Product Complaint Reporting Form (ATTACHMENT G) will be completed by the Sponsor and provided to the clinical site for filing in the ISF.

6.b Reporting Temperature Excursions After Transfer to On-site Storage at the Clinical Site

In the event a temperature falls outside of ≤-120°C during storage at the site, the following steps must be followed:

1. Complete the Product Complaint Reporting Form (ATTACHMENT G) Part I and Part II-B Temperature Excursion Information, and submit the form immediately to the Sponsor at the email address drugcomplaint@acepodiabio.com, cc'ing the CRO CTM and wait for further instructions.
2. The Sponsor will provide the clinical site with instructions on how to proceed. Instructions to the site and all relevant communication will then be documented in Part III of the Product Complaint Reporting Form and shared with the site for filing. .

Temperature excursions that occur at the site will be evaluated on a case-by-case basis by the Sponsor.

7. IP PREPARATION

Preparation of ACE1831 IP will be conducted by trained site staff delegated by the Principal Investigator listed on the ICON Delegation of Authority Log.

7.1 DOSE ASSIGNMENT

The Sponsor Medical Monitor will assign the dose level and the intended total volume of ACE1831 cells to be withdrawn from the vial for each subject. ACE1831 will be administered at a dosage of 100×10^6, 300×10^6, 600×10^6, or 1000×10^6 cells via intravenous infusion (Table 2). The dose level (DL), lot number, and total volume of ACE1831 to be administered will be specified on the ACE1831 Dose Assignment Form (ATTACHMENT A). The treatment group (A or B) will also be specified on the ACE1831 Dose Assignment Form.

Results of tests that are required to release the IP are specific for each clinical lot of ACE1831. For each clinical lot of ACE1831, the volume to be administered for each dose level is calculated based on that lot's Viable Cell Density (VCD) release test result. Since the administration volume for each dose level is calculated based on each clinical lot's VCD, the sites **must** follow the Dose Assignment Form that has been signed by the Acepodia Medical Monitor and the

Acepodia Clinical Trial Manager for specific details on the total volume of ACE1831 to be administered.

The Sponsor signed and approved ACE1831 Dose Assignment Form will be provided to the Principal Investigator and other study site staff in advance of the subject's planned ACE1831 infusion date.

Full approval of ACE1831 Dose Assignment Form from Sponsor Medical Monitor and Sponsor CTM must be obtained before proceeding with ACE1831 administration.

A copy of the subject's signed Dose Assignment Form must be file in the Investigator Site File and subject's medical record.

Table 2: ACE1831 Dosing Levels

DOSE LEVELS	DOSE (CELLS)
3[a]	1000×10^6cells
2	600×10^6cells
1 (Starting Dose)	**300×10^6cells**
-1	100×10^6cells
[a] Dose level 3 only: subject must have a minimum weight of 55 kg or 120 lbs.	

7.2 EQUIPMENT AND SUPPLIES

Assemble the following supplies prior to retrieving the ACE1831 vial from the LN_2 storage tank:

- AT-vial Access Device AT-Adapt (AD) provided by CRO for ACE1831 vial withdraw
  - Alternatively, an 18-gauge blunt needle may be utilized for ACE1831 vial withdraw
- Appropriately sized sterile syringes with Luer-Lok tip should be used to withdraw and administer the required volume from each of the ACE1831 vial
- Cryogloves
- Alcohol pads
- Water bath
- Sterile bags for holding ACE1831 vial in water bath during thawing
- Weight or other device to hold down sterile bags with IP
- Prepared Syringe labels

7.3 SUBJECT PREPARATION

Prior to beginning the IP thaw, the subject should be prepared by starting an IV line primed with 0.9% (NaCl) normal saline. The IV line will be used to flush the infusion tubing prior to and after the completion of IP administration.

- The IV can be a peripheral line or central line
- Concurrent IV fluids and medications must be held during IP administration

NOTE: Inline filters, leukoreduction, or cell filters are **NOT** to be used for administration of ACE1831 IP

7.4 PREMEDICATION

To minimize the risk of infusion reactions, all subjects should be pre-medicated per the study protocol. All subjects will receive the following pre-medications approximately 30 to 60 minutes prior to ACE1831 infusion:

- Acetaminophen 500 to 1,000 mg given orally or equivalent
  and/or
- Diphenhydramine 12.5 to 25 mg intravenously (IV) or 25 mg given orally or equivalent

Once the subject is prepared and pre-medicated, site staff responsible for administering ACE1831 should notify the site staff responsible for preparing the ACE1831 IP to begin the thaw process.

8. THAW PREPARATION

General Instructions

- Review the continuous temperature monitoring records prior to the start of the product thaw.
- Two site staff will participate in the product thaw and preparation procedures. One staff member will complete the required procedures and one staff member will verify that the procedures were performed according to the instructions in this manual. Both staff members will sign and date the ACE1831 Preparation and Administration Form (ATTACHMENT H).
- In the event a temperature excursion or missed temperature reading is detected, while the ACE1831 IP has been stored in the on-site LN_2 storage tank, stop, and refer to **Section 6.b, Reporting Temperature Excursions After Transfer to On-site Storage at the Clinical Site**, as to next steps**.**

- It is important to coordinate the timing of ACE1831 thawing and infusion. Confirm subject's expected infusion time in advance, and adjust the start time of ACE1831 thawing accordingly, so that ACE1831 is infused within 1.5 hour from the thaw stop time.
- Do NOT begin the thaw and preparation of ACE1831 IP until just prior to administration.
- Check for any damage or cracks on the ACE1831 vial prior to thawing.
- If during the thawing or preparation of ACE1831, any of the vials appear to be compromised (eg, visual appearance of the product, or cracked vial, broken seal etc.), follow the steps listed below:
    - Quarantine the affected vial
    - Complete and submit the Product Complaint Reporting Form to **drugcomplaint@acepodiabio.com**.
    - Obtain another vial from your site inventory and proceed with product preparation process
    - Update the ACE1831 Investigational Product Master Accountability Form

THAW Procedure

Note: Personal Protective Equipment (PPE) must be used during ACE1831 preparation, per institutional guidelines.

1. Prepare and allow the water bath to reach 37°C (temperature range of 36.5°C to 37.5°C is acceptable) per institutional procedure. Ensure the water bath calibration and maintenance records follow the investigational sites SOPs.
2. Only remove one ACE1831 vial from the on-site LN_2 storage tank.
3. The remaining vials should continue to be stored at ≤ -120°C in the on-site LN_2 storage tank.
4. Once the ACE1831 vial is removed from the on-site LN_2 storage tank, thawing should start immediately. If thawing does not start immediately, ACE1831 must be held under refrigerated conditions (2 to 8°C) or on ice until thawing. Thawing must occur within 5 minutes from removal of the on-site LN_2 storage tank. **Note**: once the ACE1831 vial is removed from the on-site LN_2 storage tank, it is not to be put back into the LN_2 storage tank.
5. Once the vial is ready to be thawed, place the vial in a sterile Ziplock bag and squeeze out any excess air before sealing the bag.
6. If held on ice, ensure entire vial body is under ice, while vial cap is above ice level.
7. Record the water bath temperature prior to the start of the thaw on the ACE1831 Preparation and Administration Form (ATTACHMENT H).
8. Place bag into water bath and **record the THAW START TIME on the ACE1831 Preparation and Administration Form.**

9. The THAW START TIME is the time the vial is placed in the water bath.

Figure 7: Diagram of Thawing ACE1831 Vial

How to Thaw the ACE1831 Vials

10. Once submerged in the water bath, ensure the vial is standing upright, and the water level covers the height of the vial body. The bag's opening should be above water. Ensure vial is standing upright and firmly held down by a lead ring or other weight device (Figure 7).
11. Thaw for 10 minutes. **Do not** shake vial in the water bath. Do not leave the vial in the water bath unattended at any time. If upon inspection, ice crystals still remain in the vial after 10 minutes, continue to thaw the vial for a maximum of 2 additional minutes. The complete thaw process must not exceed 12 minutes. Do not shake the vial at any time during the thaw process.
12. Once thawed, ACE1831 vial must be removed from the water bath immediately.
13. RECORD the THAW STOP TIME on the ACE1831 Preparation and Administration Form.
14. The ACE1831 vial MUST be administered within 1.5 hours from the THAW STOP TIME.
15. To ensure this timeframe, ACE1831 should be thawed in a suitable facility near infusion location or at the subject's bedside.

Thaw in Cellular Therapy Lab (or equivalent):

1. Remove the required number of vials from the on-site LN_2 storage tank.
2. Thaw the vial, in the water bath, and draw up the assigned ACE1831 dose in the syringe based on the Sponsor approved ACE1831 Dose Assignment Form (ATTACHMENT A).
3. Attach the prepared syringe label to the syringe and place the syringe in a sterile plastic Ziplock bag. Since the syringe labels are waterproof, write on the labels with a Sharpie pen.
4. Transport the syringe(s) to the subject's bedside in refrigerated conditions (2°C to 8°C) OR on ice until administration.

5. The syringe must be securely packed with ice to avoid shaking of the ACE1831 throughout the transport duration to the subject's bedside.

OR

Thaw at Subject's Bedside:

1. Transport on-site LN_2 storage tank (if applicable) directly to the infusion area near the subject's bedside.
2. Thaw the vial in the water bath and draw up the assigned ACE1831 dose level and volume in the syringe based on the Sponsor approved ACE1831 Dose Assignment Form.
3. Attach the prepared syringe label to the syringe. Since the syringe labels are waterproof, write on the labels with a Sharpie pen.

9. GENERAL INSTRUCTIONS

1. PPE should be worn used during ACE1831 administration, per institutional guidelines.
2. Coordinate with cellular therapy lab to infuse ACE1831 as soon as possible but within 1.5 hours of the THAW STOP TIME.
3. ACE1831 IP should only be administered by trained and qualified site staff using standard clinical practice for subjects receiving biological or cellular products.
4. Ensure a minimum of two vials of tocilizumab and emergency equipment and medications are available prior to infusion and during the recovery period.
5. The subject's institutional Drug Order, ACE1831 Dose Assignment Form and subject identity check MUST be confirmed prior to administration of ACE1831 per institutional policy for cellular products.
6. Subject safety and monitoring during the administration should follow institutional guidelines.
7. Vital signs pre- and post-ACE1831 infusion should be monitored per protocol.
8. **IV Infusion START and STOP time and Volume Administered** will be recorded on the ACE1831 Preparation and Administration Form (ATTACHMENT H).

ACE1831 Administration Procedure

1. On the day of ACE1831 infusion refer to the subject's institution Drug Order and ACE1831 Dose Assignment Form to confirm the ACE1831 dose level and volume to be administered.
2. IP will be administered at a dosage of either 100 x 10^6, 300 x 10^6, 600 x 10^6, or 1000x 10^6 cells via intravenous infusion **(**Table 3**)**. The dose level and total administration volume will be specified on the subject's ACE1831 Dose Assignment Form (ATTACHMENT A).

Table 3: ACE1831 Dosing Levels and Syringe Size

Dose Levels	Dose (cells)	Syringe Size
3	1000 x 10^6 cells	Up to 10 mL
2	600 x 10^6 cells	Up to 10 mL
1 (Starting Dose)	**300 x 10^6 cells**	**Up to 5 mL**
-1	100 x 10^6 cells	Up to 1 mL
There is no weight restriction for subjects enrolled in DL -1, DL1, or DL2. **Dose Level 3 only**: Subject must have a minimum weight of 55 kg or 120 lbs.		

3. Select syringe with luer lock. Do not use any syringe filters.
4. Take thawed ACE1831 vial and break the center flap of the yellow lid to expose grey stopper. Wipe top of vial with alcohol swab.
5. Do not shake, flick, or repeatedly invert ACE1831 vial.
6. **Vial Access**

   Vials can be accessed via Access Device AT-Adapt™ (AD) or blunt needle. A video demonstrating the Needleless Collection using the Access Device AT-Adapt™ (AD) is available at: https://youtu.be/8Te_qVSXP88.

   Vial access using AD (ATTACHMENT I)

   - Remove the AD from the individual package and remove protective cover of the spike.
   - Firmly press down the AD into the vial to break vial stopper.
   - Lift up the AD until lower tab touches the cap bead.
   - Remove protective cover of luer connector and connect syringe.
   - Gently invert vial and hold vial upside-down for 10 seconds.
   - Withdraw the required volume of ACE1831 specified on the approved Dose Assignment Form.

   Vial access using blunt needle.

   - Use a gauge 18 blunt needle for drawing ACE1831. Insert needle into rubber top and push air into vial.
   - Gently invert vial and hold vial upside-down for 10 seconds. Pull back plunger to withdraw the required volume of ACE1831. If ACE1831 becomes hard to draw, push more air into vial or slightly adjust position of needle tip.
   - Remove syringe from vial and remove additional air inside syringe. Clip-on needle cap and remove blunt needle safely.

7. Affix the correct prepared syringe label onto the syringe – DO NOT obscure the measurements on the syringe.
8. Prior to the ACE1831 administration two trained staff members must verify the subject's identity (subject's first and last name, date of birth) against the subject's institution Drug Order and ACE1831 Dose Assignment Form to confirm the ACE1831 dose level and volume to be administered.
9. Lock syringe into catheter/access line Y-side for infusion.
10. Administer the IP as an IV push at an infusion rate of 2-3 mL/min.
11. After the ACE1831 infusion, flush IV tubing with an adequate amount of normal saline (sodium chloride 0.9%) to ensure all product is delivered

Subject Monitoring

During and following the administration of IP, the subject must be monitored for infusion reactions per the study protocol.

NOTE: If the administration of ACE1831 is stopped or delayed due to an infusion reaction and not completed before the 1.5-hour expiration time post thawing, contact the Acepodia Medical Monitor immediately for further instruction.

10. DISPOSAL AND DESTRUCTION OF THE INVESTIGATIONAL PRODUCT

1. The Sponsor will notify the site if a specific lot/vial should be destroyed.
2. All used vials (bottles) should be destroyed on-site in accordance with institution's biohazard disposal policy.
3. Any unused or expired ACE1831 should be disposed of in accordance with the institution's biohazard disposal policy applicable for cellular products or returned to Sponsor.
4. If any unused ACE1831 product is required to be returned to the Sponsor, the site must obtain approval from the Sponsor and document approval on the ACE1831 Investigational Drug Master Accountability Form.
5. Final disposition of ACE1831 must be documented on the ACE1831 Investigational Drug Product Master Accountability Form (ATTACHMENT E), and a copy retained in the Investigator Site File.

11. INVESTIGATIONAL PRODUCT ACCOUNTABILITY

1. The investigator is responsible for ACE1831 IP accountability, reconciliation, and record maintenance during the study, including documentation of the receipt of ACE1831 vials and administration to the subject.
2. Records will be maintained indicating the receipt, transfer, storage, preparation, administration, and dispensation of all study ACE1831 IP shipments.
3. The CRO CRA will review the ACE1831 IP accountability records at regular intervals as part of the clinical site-monitoring visit.
4. The designated site staff at the investigational site must keep accurate records and inventory of ACE1831 receipt, transfer, storage, preparation, administration, and destruction.
5. A complete accountability inventory for all IP received, dispensed, administered, or destroyed must be documented throughout the course of the study.
6. ACE1831 **MUST NOT** be used for any purposes other than those outlined in the Sponsor's clinical protocol. Under no circumstances should the investigators, cellular therapy laboratory personnel, or other site staff use any of the ACE1831 supplies provided for any other purpose other than as directed by the protocol.

12. INVESTIGATIONAL PRODUCT COMPLAINT

For any issues that arise during the study related to quality, appearance, and/or other characteristics of the IP, the Product Complaint Reporting Form Part I and Part II- A Description of Product Complaint (ATTACHMENT G) should be completed and submitted to the Sponsor at **drugcomplaint@acepodiabio.com**.

A complaint should include any observation made by site personnel related to the IP itself. Study site personnel are responsible for reporting complaint information to the Sponsor.

The Sponsor will provide the clinical site with instructions on how to proceed. Instructions to the site and all relevant communication will then be documented in Part III of the Product Complaint Reporting Form and shared with the site for filing in the Investigator Site File.

13. RETURN OF THE LN_2 DRY VAPOR SHIPPER

The courier Cryoport-FedEx will be responsible to return the LN_2 Dry Vapor Shipper on the day of IP receipt.

If clinical site staff is not able to transfer IP to on-site LN_2 storage tank immediately, please arrange schedule pick-up for the LN_2 dry vapor shipper following the below options:

-Site call to schedule courier pick-up via 1800-463-3339
-Drop-off at regular FedEx pick-up location/ box

The LN_2 Dry Vapor Shipper **MUST BE returned within one week** of delivery of the ACE1831 at the site.

ATTACHMENT A: ACE1831 DOSE ASSIGNMENT FORM

Acepodia

DOSE ASSIGNMENT FORM | V3.0
ACEPODIA | ACE1831-001

INSTRUCTIONS:

- Site study staff will complete the Dose Assignment Form and submit to the Sponsor Medical Monitor for review and approval
- **No dosing will occur** until the subjects approved Dose Assignment form is returned from the Sponsor to the site
- Allow **24 hours** for review and return of this form.

Site Number _____	**Principal Investigator** _____
Prescreening ID _____	**ACE1831 Planned Dosing Date** (DD-MMM-YYYY) _____
Does the Subject continue to meet the eligibility criteria? ☐ Yes ☐ No (Please explain below) **Comments** _____	
Does the Subject weigh ≥ 55kg (120lbs)? ☐ Yes ☐ No	

Name of the person completing form: _____	**Signature of the person completing form:** _____	**Date** _____
Return Authorization form to Site Contact (Name, Email, or Fax)**:** _____		
By signing below, I am certifying the above subject meets all eligible criteria under the current IRB approved protocol. **Signature of PI or Sub-I only:** _____		**Date** _____

Dose Assignment Form | V3.0
Acepodia | ACE1831-001
Page 1 of 2

Acepodia

ACEPODIA Only Below This Line

ASSIGNED SUBJECT ID: _____

ASSIGNED TREATMENT GROUP AND DOSE LEVEL:

TREATMENT GROUP A (MONOTHERAPY)

- ☐ DL1A: 300×10^6
- ☐ DL2A: 600×10^6
- ☐ DL3A: 1000×10^6

TREATMENT GROUP B (COMBINATION WITH OBINUTUZUMAB)

- ☐ DL2B: 600×10^6 + obinutuzumab
- ☐ DL3B: 1000×10^6 + obinutuzumab

TOTAL VOLUME OF ACE1831 TO BE ADMINISTERED: _____ mL

ACE1831 LOT NUMBER: _____

Acepodia Medical Monitor Name	**Acepodia Medical Monitor Signature**	**Date**
_____	_____	_____
Acepodia Clinical Trial Manager Name	**Acepodia Clinical Trial Manager Signature**	**Date**
_____	_____	_____

ATTACHMENT B: INVESTIGATIONAL PRODUCT ORDER FORM

Acepodia

MM05-F03 Investigational Product Order Form	Version	v 1.0

Investigational Product Name: _____ Protocol No.: _____

Investigator Name: _____ Site No.: _____

Address for IP Shipment _____ Telephone No.: _____

_____ Fax No.: _____

_____ E-mail: _____

Order Request (Clinical Site or Sponsor / Sponsor Designee to Complete)

Date of Request: _____ , Requestor: ☐ Clinical Site, ☐ Sponsor

Type of Shipment: ☐ Initial shipment, ☐ Re-Supply shipment, Requested Quantity (# of vials):

_____

Reason of Re-supply: ☐ Anticipated enrollment, ☐ Low inventory, ☐ Other, specify: _____

_____

Requested[1, 2] by: _____, _____, _____

(Printed Name) (Title) (Signature)

Verified[3] by: ☐N/A, _____, _____, _____

(Printed Name) (Title) (Signature)

[1]: *Please email this form to drugsupply@acepodiabio.com*

[2] :*For the request from the clinical site, please copy your study CRA in the IP order email and file original form in the site study files. The Site CRA will verify the details recorded on this form during monitoring visits.*

[3] : *Acepodia will verify the order when the requestor is the clinical site.*

MM05-F03 Page 1 of 1

ATTACHMENT C: INVESTIGATIONAL PRODUCT RECEIPT FORM

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MM05-F04 Investigational Product Receipt Form	Version	v 2.0

Investigational Product Name: _____ Protocol No.: _____
Investigator Name: _____ Site No.: _____
Address for IP Shipment _____ Telephone No.: _____
_____ Fax No.: _____
_____ E-mail: _____

Investigational Product Shipment Receipt and Inspection Verification at Clinical Site (Clinical Site Designee to Complete)

Date and Time of LN_2 Dry Vapor Shipper Received: ____ - _____ - _____ (DD - MMM - YYYY) _ _:_ _ (24hr clock)

Is the **LN_2 Dry Vapor Shipper** intact free of damage?	☐ Yes ☐ No
Will the [Investigational Product Name (IP Name)] be transferred to On-Site Vapor-Phase LN_2 storage?	☐ Yes ☐ No

Date and Time of [IP Name] removed from the **LN_2 Dry Vapor Shipper** and transferred to **On-Site LN_2 storage:**

Box ID	Date	Time removed from the **LN_2 Dry Vapor Shipper**	Time transferred to **On-Site LN_2 storage**
	___ - _____ - _____ (DD - MMM - YYYY)		

Are the [IP Name] vial-holder box(es) and box seals intact without any damage?	☐ Yes ☐ No
Is the quantity of [IP Name] vials documented on the Part I of Material Transfer Form correct?	☐ Yes ☐ No
Is the individual [IP Name] vial and each label intact without any damage, e.g., breaks or leaks?	☐ Yes ☐ No
Was the Transfer completed within 2 minutes?	☐ Yes ☐ No
Have you recorded the number of vials, vial numbers and LOT Numbers on the [IP Name] Clinical Site Investigational Drug Product Master Accountability Log?	☐ Yes ☐ No

Comments: (If any questions are checked NO, please provide comments. If there are no comments, please indicate "N/A"):

Checked and received by: _____, _____
(Printed Name) (Title)

_____, _____
(Signature) (Date, DD-MMM-YYYY)

** Please file a copy of this competed form in the site study files. The Site CRA will verify the details recorded on this form during monitoring visits.*

MM05-F04 Page 1 of 1

ATTACHMENT D: MATERIAL TRANSFER FORM

Acepodia

MM05-F01 Material Transfer Form	Version	1.0

Part I. Transfer Request **MTF No.: _____**

Requestor (Print Name): _____, Date of Request: _____

Ship From:	Ship To:
Address:	Address:
Attn.:	Attn.:
Tel:	Tel:
E-mail:	E-mail:

☐ Packing List for Material Shipment

Part No.:	Lot No.:	Quantity (UOM[1]):

☐ Packing List for Product shipment, Product Name: _____, Total Quantity: _____ vial(s)

Vial-holder Box ID:	Vial ID:

Request type: ☐Return ☐Transfer ☐Scrap ☐Other: _____	Temperature Monitor (Logger): ☐Required ☐Not required	Shipping Container:
Shipping Condition:	Storage Condition:	
Requested Ship by Date:	Requested Delivery by Date:	
Comments:		

Request Approval (Sign and Date)

Supply Chain/ Date:	QA[2]/ Date: ☐ N/A,

[1]: Unit of Measurement. [2]: If it is to transfer material, it only needs approval from Supply Chain.

MM05-F01 Page 1 of 2

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MM05-F01 Material Transfer Form	Version	1.0

Part II. Transfer Acknowledgement (Completed by Shipping Site) MTF No.: _____		
Part No.:	Lot No.:	
Quantity (UOM[1]) Shipped:	Shipped From:	
Courier:	Shipping Reference. No.:	
Airwaybill No.:	Expected Delivery Date:	
Shipping Container:	Shipping Condition:	
Temperature Monitor (Logger) included in the shipment (Yes/No): _____, Serial No.: _____		
Shipped by: (Printed Name)	Signature:	Date: Time:
Verified by: (Printed Name)	Signature:	Date: Time:

[1]: *Unit of Measurement.*

**Please attach this form to the shipment and send a copy of it to Supply Chain of Acepodia via emailing to drugsupply@Acepodiabio.com*

Part III. Receipt Acknowledgement (Completed by Receipt Site)		
Received by: (Printed Name)	Signature:	Date: Time:
Material Condition: ☐ Good ☐ Damaged ☐ Other, _____		

**Please send a copy of completed form to Supply Chain of Acepodia via emailing to drugsupply@Acepodiabio.com*
**Please contact Supply Chain via emailing to drugsupply@Acepodiabio.com immediately if indication of damage, missing quantities and excursions are discovered during the receiving process.*

ATTACHMENT E: ACE1831 INVESTIGATIONAL DRUG PRODUCT MASTER ACCOUNTABILITY FORM

Acepodia

ACE1831 INVESTIGATIONAL PRODUCT MASTER ACCOUNTABILITY FORM | V3.0
ACEPODIA | ACE1831-001

Site # Principal Investigator

RECEIPT					DISPENSATION			RETURN/ DISPOSAL/ DESTRUCTION		
Box ID #	Vial (Bottle) ID#*	Lot Number	Received dd-MMM-yyyy	Initials	Dispensed dd-MMM-yyyy	Dispensed By	To Subject ID	Returned or Destructed (R/D) / dd-MMM-yyyy	Staff Initials/ Date	CRA Initials/ Date

*Each Vial (Bottle) within each box should be listed out separately.

Principal Investigator's Signature **Date**

ACE1831 Investigational Product Master Accountability Form | V3.0
Acepodia | ACE1831-001

Page ___ of ___

ATTACHMENT F: SAMPLE MEMO FROM SPONSOR - ACE1831 SHELF LIFE MEMO

Acepodia

Memorandum No. #####

Memorandum No. #####

Date: ddMMMyyyy
To: Clinical Trial Study Sites and Storage Depot
From: Acepodia Biotech, Inc.
Subject: Shelf Life of the Investigational Product ACE1831 Lots ######

This is to notify you that Acepodia Quality has established the shelf life of the following lots of Investigational Product ACE1831:

Lot No.:[######]

For Acepodia's Investigational Product ACE1831, the stability study conducted up to date has demonstrated that the Investigational Product ACE1831, if properly stored according to the storage conditions specified in the vial label (≤ -120°C liquid Nitrogen), can continue to be used up to the shelf life specified in the Certificate of Compliance, Attachment 1.

A separate memo will be provided if further stability test time point is reached, and the shelf life is extended.

If you have further questions, please contact Acepodia at qa_d@acepodiabio.com.

Name: Sophia Su
Title: Director of CMC and Quality

Signature: _____

Date: _____

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Memorandum No. ##### Attachment 1

Certificate of Compliance

Product Name	ACE1831	
Lot No.	######	######
Manufacturing Date	ddMMMyyyy	ddMMMyyyy
Shelf Life	## months	## months
Expiration Date	ddMMMyyyy	ddMMMyyyy

This is to certify that the above-mentioned clinical product lots are manufactured in accordance with current Good Manufacturing Practice (cGMPs) and conform to all regulatory regulations. Additionally, manufacturing and analytical records for each product lot are reviewed by the appropriate quality unit and determined to comply with master production documentation, test procedures, and specification prior to their release for clinical use.

Investigational Product ACE1831 has been evaluated through ongoing stability study testing. All testing records generated from the stability study have been reviewed and approved, and the results of the tests are in compliance with the product specification. The stability study results support the shelf life extension as indicated above from the date of manufacturing.

Name: Sophia Su
Title: Director of CMC and Quality

Signature: _____

Date: _____

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ATTACHMENT G: PRODUCT COMPLAINT REPORTING FORM

Refer to GLB-SOP-0054 QS-Product Complaint Management

Part I. Source of Product Complaint
(Reporter to complete)

Product Name		Date of Event	
Institution (Site) Name		Site No.	
Investigator Name		Protocol No.	
Contact Person		Contact Email	
Contact Phone No.		Contact Fax No.	
Receiving way	☐ Phone ☐ e-Mail ☐ Fax ☐ Other:		

If this complaint is due to a temperature excursion, please proceed with Part II-B after completing Part I Source of product complaint and the Part II-A doesn't need to be filled out.

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Effective Date: 2022-11-23 01:13 PMCST Revision Number: 2.0

Acepodia	FORM **QS- Product Complaint Reporting Form** Uncontrolled copies of this document will expire 24 hours from Exported Time. Forms that are in use prior to expiration remain valid.		
	Document No. **GLB-FRM-0022**	Revision No. 2.0	Effective Date: See Signature Page

Part II-A. Description of Product Complaint

(Reporter to complete)

Product Complaint Information:

Lot No		Impacted Quantity of Vial(s)	
Vial (Bottle) ID (s)			

Description of Product Complaint

- **If applicable, please take photo(s) and submit the photo(s) with this form)**
- **Please describe the detail of the product complaint below (If applicable, please take photo(s) and submit the photo(s) with this form):**

Was affected investigational drug product dispensed?

☐ **Yes, the date and time of administration:**

☐ **No**

If yes, were any adverse effects observed in the recipient?

☐ **No**

☐ **Yes, please describe:**

Reported by (Print Name/Title)		**Signature/Date**	

*** Please quarantine the product in doubt as soon as possible until you receive the sponsor's instruction.**

*** Email this form to Sponsor: drugcomplaint@acepodiabio.com and a copy to the CRO CRA.**

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Acepodia	Effective Date: 2022-11-23 01:13 PMCST Revision Number: 2.0 **FORM** **QS- Product Complaint Reporting Form** Uncontrolled copies of this document will expire 24 hours from Exported Time. Forms that are in use prior to expiration remain valid.		
	Document No. **GLB-FRM-0022**	Revision No. 2.0	Effective Date: See Signature Page

Part II-B. Temperature Excursion Information **(Reporter to complete, only applies to complaints for temperature excursion)**			
Excursion Type	☐ Storage ☐ Upon Receipt		
Lot No(s).		Affected Vial ID	
Shipping/Storage Condition	≤ -120°C		
Site LN2 Storage Equipment ID:			
Excursion START Date	dd-mmm-yyyy	Duration of Excursion (HH, MM or days) Please specify	
Excursion END Date	dd-mmm-yyyy		
Date of Discovery	dd-mmm-yyyy		
Maximum temperature reached during excursion	_____°C	Minimum temperature reached during excursion	_____°C
Note: A copy of the temperature log capturing the temperature excursion must be attached with this completed form.			
Description of Excursion			
Has the above listed product experienced a previous excursion? If yes, please specify vials and provide previous Clinical Site Investigational Product Temperature Excursion Form and associated temperature logs.			☐ Yes ☐ No
Reported by (Print Name and Title)		Signature/Date	
Verified by (Print Name and Title)		Signature/Date	
Pending a response from the Sponsor, please separate the Investigational Product listed above from other study drug supply and keep appropriate storage conditions per label instructions. Do not use the affected Investigational Product until this form is completed and returned indicating it is safe to do so. ***Please send a completed form and a copy of the temperature log to drugcomplaint@acepodiabio.com and wait for further instructions.*** **** If the site CRA is not reporting this excursion remember to copy the site CRA.***			

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Acepodia	FORM **QS- Product Complaint Reporting Form** Uncontrolled copies of this document will expire 24 hours from Exported Time. Forms that are in use prior to expiration remain valid.		
	Document No. **GLB-FRM-0022**	Revision No. 2.0	Effective Date: See Signature Page

Part III. Communication record between Sponsor and Clinical Sites or Appropriate Party*(completed by Acepodia staff)			
(should include contact time, contact person, contact content/instructions)			
Reported by (Print Name/Title)		**Signature/Date**	

* The form can be increased as needed, and can also be written on a separate sheet of paper or attached with an attachment

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ATTACHMENT H: ACE1831 PREPARATION AND ADMINISTRATION FORM

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ACE1831 PREPARATION AND ADMINISTRATION FORM | V2.0

ACEPODIA | ACE1831-001

Subject Number: __ __ __ - __ __ __ **Principal Investigator Name:** _____

ACE1831 PREPARATION:	
Date of Preparation (DD-MMM-YYYY):	__ __ - __ __ __ - __ __ __ __
Assigned ACE1831 Dose Level & Corresponding Volume: (As documented on the Institutions Subjects Drug Order and Sponsor's Subjects Dose Assignment Form)	Dose Level : _____ Volume: __ . __ mL
Number of Vials (bottles) to Thaw:	____ Vial(s)
REMOVAL of ACE1831 VIALS FROM the Site's LN_2 Storage Tank (Temperature & Time)	
Temperature of LN_2 Storage Tank at the time vials removed	Temperature : _____ *°C*
Time Vial(s) Removed from LN_2 Storage tank (HH:MM)	__ __ : __ __
WATER BATH TEMPERATURE AND THAW OF ACE1831 VIAL	
Water bath temperature prior to thawing the vials *ACE1831 vials must be thawed in a 37°C water bath per your institutional standard operating procedure. (The temperature range of the water should be between 36.5 and 37.5 °C)*	Water bath Temperature : _____ *°C*
THAW START TIME * (HH:MM):	__ __ : __ __
THAW STOP TIME * (HH:MM):	__ __ : __ __

*** Thaw start time is the time vial is placed within the water bath/ Thaw stop time is the time vial is removed from the water bath.**

ACE1831 IP Vials Thawed	Vial ID Expiration (DD-MMM-YYYY)	Site Staff	(CRA initials & date)
Bottle ID:	DD-MMM-YYYY:		
Bottle ID:	DD-MMM-YYYY:		

Comments:

_____

_____

Preparer:
(Print):_____**Signature:**_____**Date:**_____

Verifier:
(Print):_____**Signature:**_____**Date:**_____

SYRINGE PREPARATION	
Date of ACE1831 Infusion (DD-MMM-YYYY):	__ __ - __ __ __ - __ __ __ __
Volume of ACE1831 documented on the approved, ACE1831 Dose Assignment Form	__ __ . __ mL
Volume of ACE1831 Drawn into Syringe	__ __ . __ mL
ACE1831 INFUSION	
START TIME OF IV INFUSION:(HH:MM): __ __ : __ __	**STOP TIME OF IV INFUSION:** (HH:MM): __ __ : __ __
ACE1831 INFUSION RATE:	_____ml/min
ENTER THE VOLUME OF ACE1831 ADMINISTERED *(If the actual volume administered was less than the assigned volume select the reason why)*	__ __ . __ mL ☐ Adverse event ☐ Dosing error ☐ NA
WAS THE ACE1831 INFUSION INTERRUPTED? ☐ YES ☐ NO. If yes, indicate the action taken. ☐ Restarted ☐ Terminated	

*For any details unable to be captured in table above, please add details to the comments section

Comments:

_____

_____

Personnel Responsible for Administering the ACE1831 Infusion:

(Print): _____ **Signature:** _____ **Date:** _____

Verifier:

(Print): _____ **Signature:** _____ **Date:** _____

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ATTACHMENT I: ACESS DEVICE (AD) IMAGE

Anatomy of the Access Device