Investigational Product Manual

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A PHASE 1B, OPEN-LABEL STUDY OF ELRANATAMAB IN COMBINATION WITH IBERDOMIDE IN PARTICIPANTS WITH RELAPSED REFRACTORY MULTIPLE MYELOMA

ATTENTION: Iberdomide risk of embryo-fetal toxicity

Iberdomide has pregnancy risk mitigations plans in place to ensure that unborn babies are not exposed to Iberdomide.

- **All sites must follow the Iberdomide Pregnancy Prevention Program (PPP) which applies to all participants receiving iberdomide within the clinical trial.**
- **Each site must also have two PPP trained counselors.**

Worldwide Research & Development

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Revision History

Version	Version Date	Summary of Changes
2.0	08MAR2024	**Source Documents:** • Updated DAI to its latest version **Section 3. Study Overview** • Formatted treatment period text to table **Section 3.1. Pfizer Supplied Investigational Products** • Added picture of Iberdomide 0.6 mg, 0.75 mg, 1 mg, 1.3 mg, and 1.6 mg capsules • Updated pictures of Elranatamab carton and vial label • Updated pictures of Iberdomide 0.6 mg, 0.75 mg, 1 mg, 1.3 mg, and 1.6 mg bottle labels **Section 6.3. Special Handling of IP** • Added additional handling information for participants **Section 7. Dosage and Administration Instructions** • Added additional dose modification information **Section 7.1. Drug Dispensing Per Visit** • Updated information on iberdomide dose on study visit days **Section 7.2. General Preparation Guidelines:** • Updated preparation guidelines based on the latest DAI **Section 7.3. In-Use Shelf Life and Storage Requirements of IP** • Added information regarding the in-use shelf life of elranatamab when prepared outside of an aseptic environment **Section 7.4.2. Preparation and Administration Instructions** • Removed information to track injection site on diagram with red pen **Appendix 2. Example Site Temperature Excursion Report Form** • Updated representative photos to its latest version **Appendix 3. Example Pfizer Investigational Product Accountability Log (IPAL)** • Updated representative photos to its latest version **Appendix 4: Preparation Record for Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)** • Added in-use stability for preparations done outside the hood **Investigational Product Manual** • Updated study contact from Study Monitor to primary point of contact

Version	Version Date	Summary of Changes
		• Updated “Pregnancy Prevention Plan” to “Pregnancy Prevention Program”
1.0	31OCT2023	Not applicable – first version

Source Documents

This section will only be updated if updates to the source documents impact the information included in this IP Manual. Subsequent amendments or updates that do not impact this IP Manual will not be included as a reference and will not require an update to this section.

1. C1071030 Protocol Amendment 1, 12 September 2023
2. Dosage and Administration Instructions for PF-06863135 Solution Subcutaneous Injection, 40 mg/mL: C107-INX100434077 V5.0-27-NOV-2023
3. Investigator’s Brochure Iberdomide BMS-986382/CC-220, Version number 15, 19-October-2023

Table of Contents

1. Acronyms/Terms/Definitions

Acronym / Term	Definition
CRS	Cytokine Release Syndrome
DL	Dose Level
FCBP	Females of Childbearing Potential
IP/IMP/Study Intervention	This includes Investigational Product (IP), Investigational Medicinal Product (IMP) (may also be referred to as Study Intervention in the protocol) in either a non-commercial presentation or commercial presentation with over labeling; comparative agents; concomitant medications; background therapies; or commercial products that are supplied by Pfizer Global Clinical Supply or by approved vendors.
IPAL	Investigational Product Accountability Log
IRT	Interactive Response Technology encompassing an IWRS (Interactive Web Response System)
IVIG	Intravenous Immunoglobulin
AxMP (EU)	Auxiliary Medicinal Product A medicinal product used for the needs of the trial as described in the protocol, but not as an investigational medicinal product
PJP	*Pneumocystis jiroveci* Pneumonia
PK	Pharmacokinetic(s)
POR	Proof of Receipt
PPP	Pregnancy Prevention Program
QD	Once Daily
RP2D	Recommended Phase 2 Dose
RRMM	Relapsed/Refractory Multiple Myeloma
SDS	Safety Data Sheet

2. Study Contacts

Contact your primary point of contact with any questions. Refer to the Investigator Site File/Study Operations Manual for study contact information.

3. Study Overview

This is a phase 1b, open-label, prospective, multi-center study to evaluate the safety, efficacy, pharmacokinetic (PK), and pharmacodynamic of **elranatamab (PF-06863135)** in combination with **iberdomide (CC-220 or BMS-986382)** in participants age ≥18 years with relapsed/refractory multiple myeloma (RRMM). The study is composed of two parts:

PART 1 – DOSE ESCALATION:

This part will evaluate the tolerability and safety of elranatamab in combination with iberdomide to select recommended dose(s) [combination recommended phase 2 dose (RP2D)] for further evaluation in Part 2. Two combination dose level(s) (DL) of elranatamab and iberdomide will be selected as RP2D(s) for further evaluation as DL A and DL B in Part 2.

Priming Dose (14-day cycle)

Cycle 0:*
Day 1: Pre-medications[a]
Elranatamab 12 mg subcutaneously *(hospitalization required for 2 days)*[b]

Day 4: Pre-medications[a]
Elranatamab 32 mg subcutaneously *(hospitalization required for 1 day)*[b]

Day 8: Pre-medications[a]
Elranatamab 76 mg subcutaneously

Treatment Period (28-day cycle)

Cycle 1 to Cycle 6:
Elranatamab 76 mg subcutaneously every week (QW) **AND** Iberdomide orally (PO) once daily (QD) from Day 1 to 21 of each 28-day cycle as shown below

Days	IP
Day 1	Elranatamab 76 mg subcutaneously
Day 8	
Day 15	
Day 22	
AND	
Day 1 to 21	Iberdomide PO QD

Cycle 7 to Cycle 12:
Elranatamab 76 mg subcutaneously every 2 weeks (Q2W)[c] **AND** Iberdomide PO QD from Day 1 to 21 of each 28-day cycle as shown below

Days	IP
Day 1	Elranatamab 76 mg subcutaneously
Day 15	
AND	
Day 1 to 21	Iberdomide PO QD

Cycle 13 onwards:
Elranatamab 76 mg subcutaneously every 4 weeks (Q4W) [d] **AND** Iberdomide PO QD from Day 1 to 21 of each 28-day cycle as shown below

Days	IP
Day 1	Elranatamab 76 mg subcutaneously
AND	
Day 1 to 21	Iberdomide PO QD

[a] Premedication is required approximately 60 minutes (±15 minutes) prior to both priming doses (on Cycle 0, Day 1 and Cycle 0, Day 4) and the first full dose of elranatamab (on Cycle 0, Day 8):
- acetaminophen 650 mg (or paracetamol 500 mg) *
- diphenhydramine 25 mg (or equivalent) * PO or intravenously (IV)
- dexamethasone 20 mg (or equivalent) * PO or IV* *Different but comparable doses due to local strength variations per local prescribing information are permissible.*

At other time points, similar premedication may be used based on clinical judgement and presence/severity of cytokine release syndrome (CRS) observed at the discretion of the investigator. Premedication will not be supplied by the sponsor.
[b] Hospitalization required for 2 days (~48 hours) on Cycle 0 Day 1, and for 1 day (~24 hours) on Cycle 0 Day 4 (hospitalization from Cycle 0 Day 1 to Cycle 0 Day 5 may be considered). Outpatient medical observation can be considered part of hospitalization time to allow for flexibility of dosing and sample collections. Hospitalization on C1D1 may be considered based on investigator discretion, according to the safety profile observed on C0D8.
[c] If a participant has received treatment for at least 6 months (6 cycles) and disease response shows at least a partial response or better with responses persisting for at least 2 months.
[d] If disease response shows at least a partial response or better with responses persisting for at least 2 months.

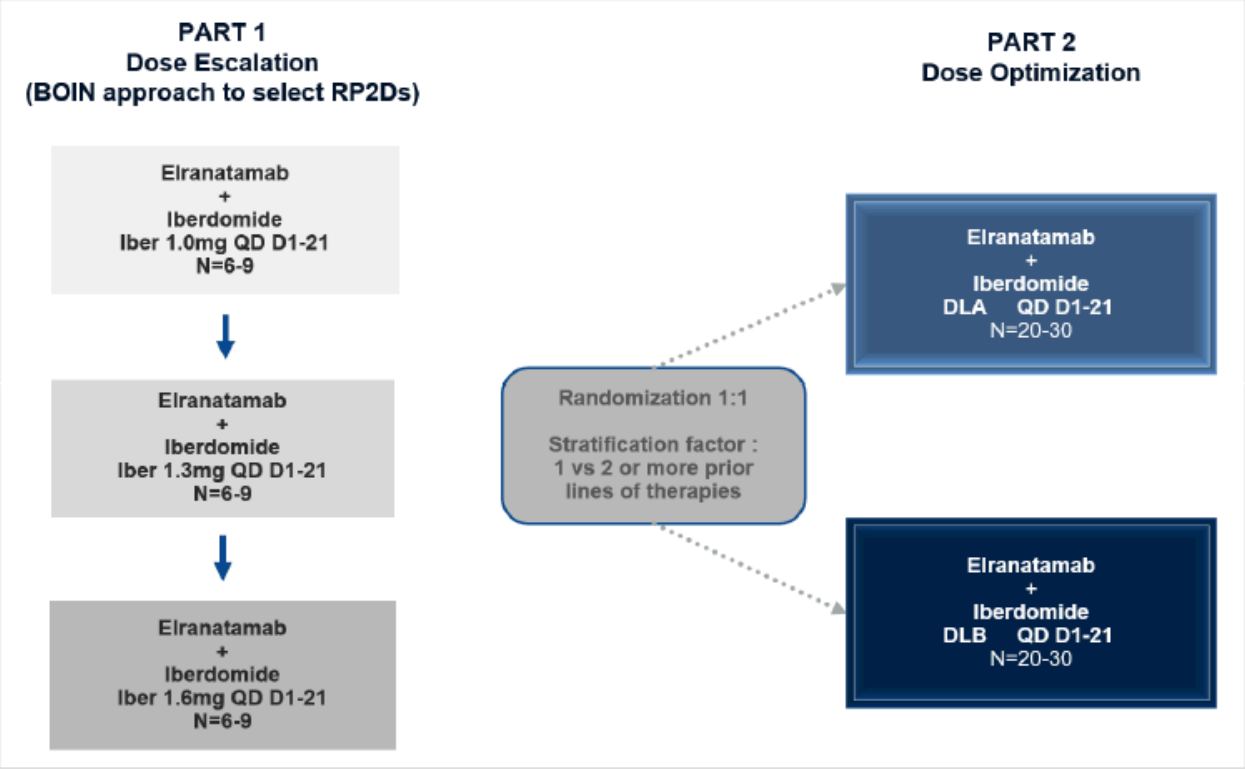
All participants will receive the IP until disease progression, unacceptable toxicity, withdrawal of consent, or study termination.

PART 2 – RANDOMIZED DOSE OPTIMIZATION:
This part will further evaluate the safety and preliminary efficacy of elranatamab in combination with iberdomide at RP2D(s). Dose optimization phase will begin once the combination RP2D(s) are identified in the dose escalation part (PART 1).

Alternative dosing schedules for elranatamab may also be tested in PART 2 based on the data generated in dose escalation PART 1.

Participants will be randomized in a 1:1 ratio to DL A and DL B by site personnel using the IMPALA 2.0 Interactive Response Technology (IRT) System (See Section 4 for IRT information).

Study Schema

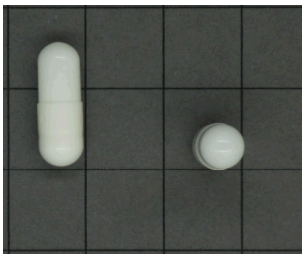


Elranatamab dosing regimen: Priming C0:12/32/76 mg ; 76 mg QW Cycle1-6; 76mg Q2W Cycle 7-12 ; 76 mg Q4W Cycle 13+
DL A = Dose Level A for iberdomide ; DL B : Dose Level B for iberdomide

Refer to protocol sections for guidance on venous thromboembolism (VTE) prophylaxis (Section 6.9.10 and 10.16), intravenous immunoglobulin (IVIG) replacement (Section 10.16), antiviral prophylaxis (Section 10.16), and *Pneumocystis jiroveci* Pneumonia (PJP) prophylaxis (Appendix 16).

3.1. Pfizer Supplied Investigational Products

The table below lists the Investigational Product(s) that will be provided for this trial by Pfizer.

Product Name	Mechanism of Action	Product Physical Description	Representative Picture of IP
Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)	A heterodimeric humanized full-length bispecific IgG2 kappa monoclonal antibody.	Supplied as a clear, colorless to slightly yellow or yellow/brown sterile liquid, packaged in a 5 mL type 1 clear glass vial with a 13 mm serum stopper, and 13 mm flip off seal.	*N/A*
Iberdomide 0.6 mg capsules	A novel cereblon E3 ligase modulator with enhanced tumoricidal and immune stimulatory effects compared with immunomodulatory drugs, currently being evaluated for the treatment of newly diagnosed multiple myeloma (NDMM) and RRMM.	Supplied as a white to off-white, opaque, size 3 hydroxypropyl methylcellulose (HPMC) capsule.	
Iberdomide 0.75 mg capsules			
Iberdomide 1 mg capsules			
Iberdomide 1.3 mg capsules			
Iberdomide 1.6 mg capsules			

Packaging and Labeling

The **Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)** for this study is packaged into a carton containing 1 vial.

The **Iberdomide 0.6 mg, 0.75 mg, 1 mg, 1.3 mg, and 1.6 mg capsules** for this study are packaged into sealed bottles containing 21 capsules per bottle.

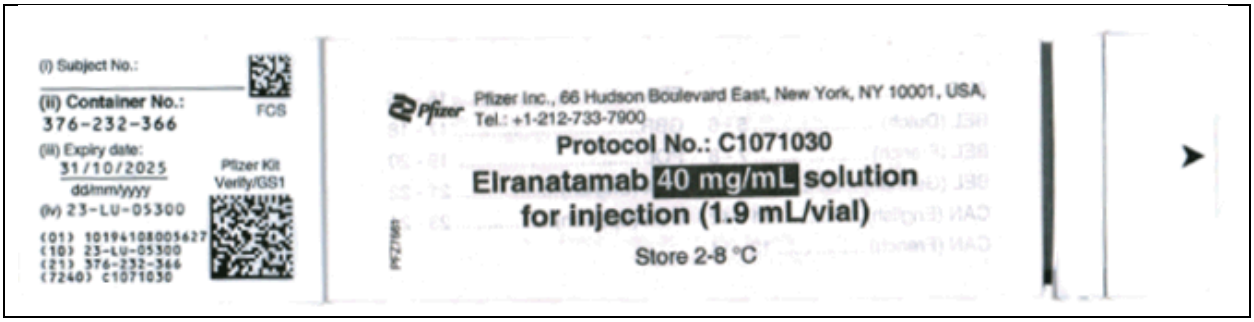
All IP are labeled in a way that is consistent with the study design and with the regulatory requirements for each country in which the study is to be performed.

The IP will be received in the following presentations (note dispensing of the IP will be discussed in Section 7.1):

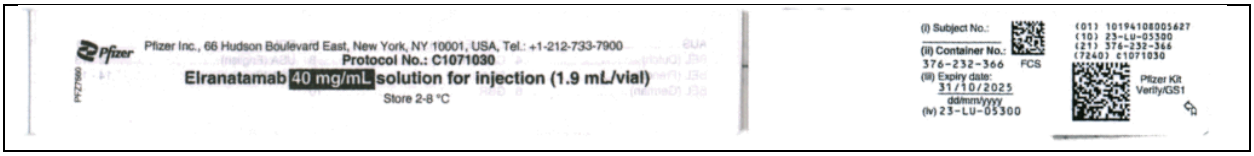
Representative Photos

- Elranatamab 40 mg/mL solution for injection (1.9 mL/vial), packaged in a carton containing 1 vial

Carton Label:

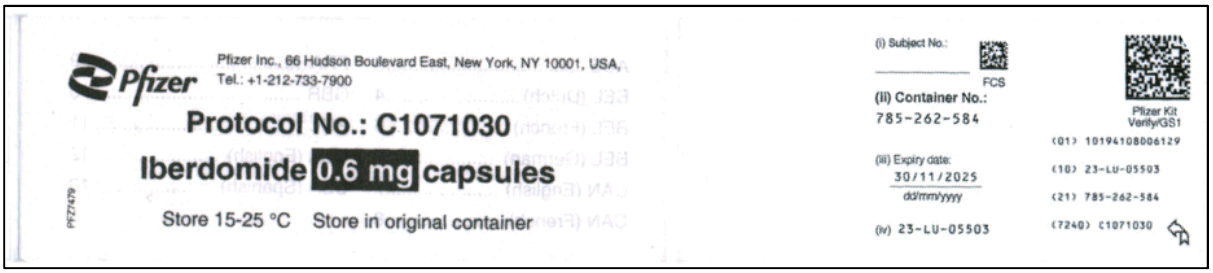


Vial Label:



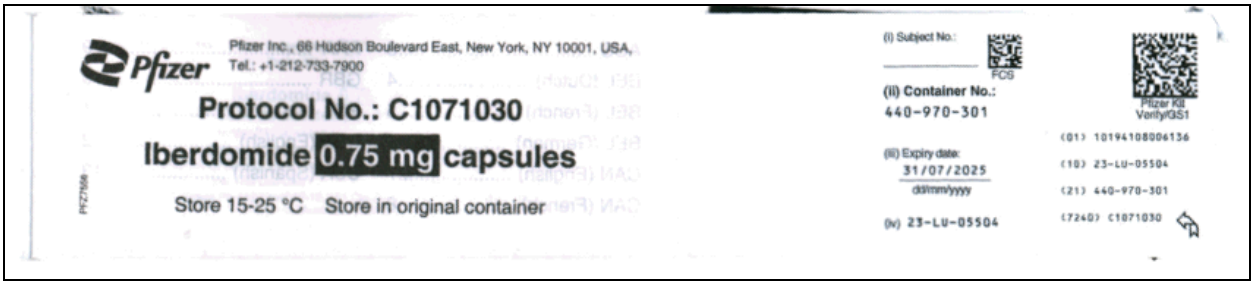
- Iberdomide 0.6 mg capsules, packaged in a bottle containing 21 capsules

  Bottle Label:



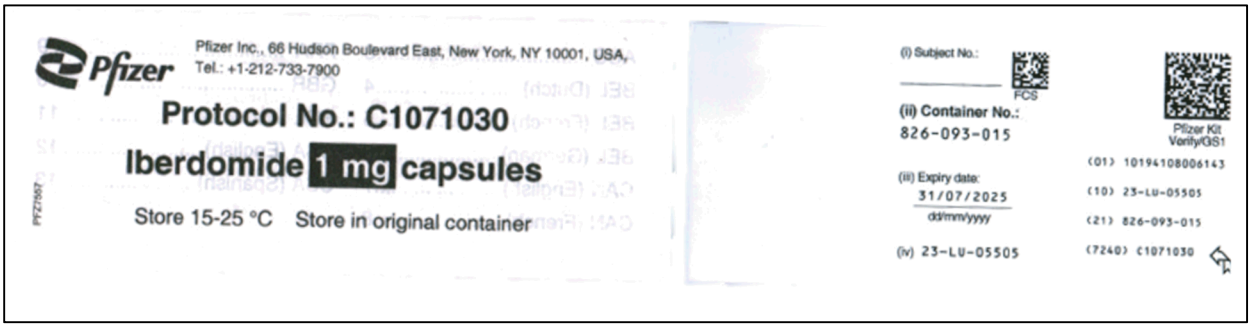
- Iberdomide 0.75 mg capsules, packaged in a bottle containing 21 capsules

  Bottle Label:



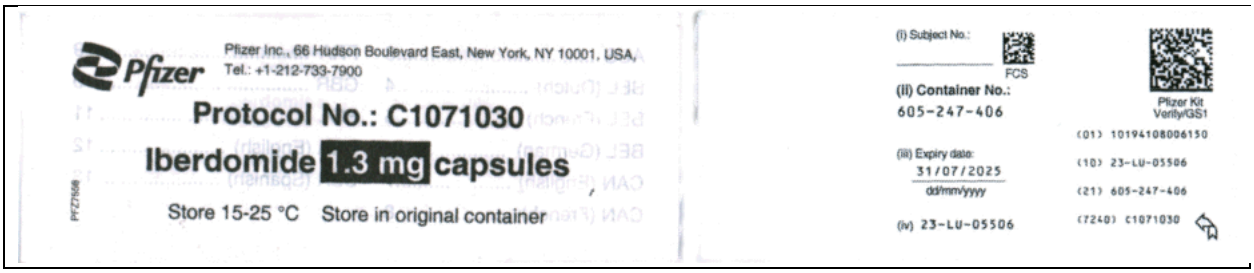
- Iberdomide 1 mg capsules, packaged in a bottle containing 21 capsules

  Bottle Label:



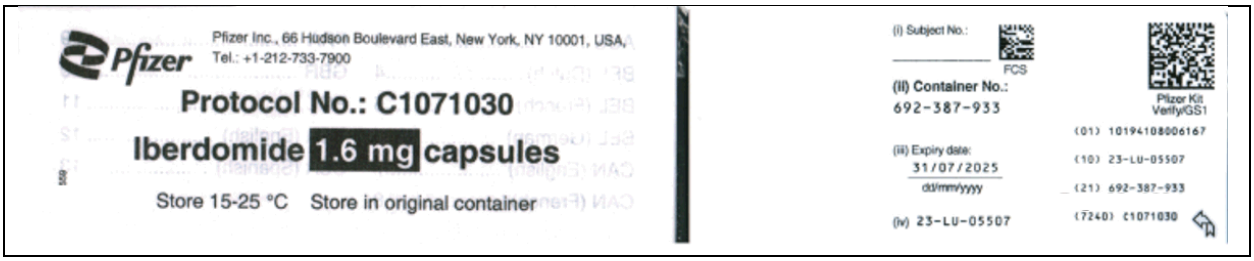
- Iberdomide 1.3 mg capsules, packaged in a bottle containing 21 capsules

  Bottle Label:



- Iberdomide 1.6 mg capsules, packaged in a bottle containing 21 capsules

  Bottle Label:



3.2. AxMP Required by Protocol

In addition to the products listed previously in Section 3.1: Pfizer Supplied Investigational Products, items listed below are required per the study protocol. These items will be sourced by the clinical site. Refer to the table below for the product and supply strategy for each country. See Section 5: Product Ordering, Receipt, and Inventory Management for ordering instructions.

Country	Provided By		Product Name
	Sponsor	Clinical Site	
All Sites		X	Dexamethasone or equivalent[a]
		X	Acetaminophen (Paracetamol) or equivalent[a]
		X	Diphenhydramine or equivalent[a]
		X	Acyclovir or equivalent[b]
		X	Trimethoprim-sulfamethoxazole or equivalent[c]
		X	Immunoglobulin replacement[d] (e.g., IVIG)

[a] Premedications for CRS prophylaxis
[b] Acyclovir or equivalent for anti-viral prophylaxis
[c] Trimethoprim-sulfamethoxazole or equivalent for PJP prophylaxis
[d] IVIG replacement if IgG level ≤400 mg/dL

4. Interactive Response Technology

The Impala 2.0 IRT system is a randomization/assignment and drug management (including shipment receipt) system. The IRT system will also manage the expiry of the supplies with regards to dispensing. The system will not allow for dispensing of materials that could potentially be used past the labeled expiry of the materials.

Web Access: https://www.sharedinvestigator.com
Help Desk Phone Number: (+1) 877-433-2619 option 3 and 2

An Impala 2.0 Quick Reference Guide and Receipt of IP is also provided for this protocol. A copy of this guide can be accessed via a link on the IRT system or provided by your primary point of contact.

5. Product Ordering, Receipt, and Inventory Management

5.1. Product Ordering

Initial Shipment

IP Provided by Sponsor

The initial shipment of IP to the clinical site will be automatically triggered upon site regulatory approval.

Re-Supply or Subsequent Shipments

IP supplied by Sponsor

The IRT system will ensure appropriate levels of IP are present at the site based upon enrollment and the protocol visit schedule. If a site is expecting a significant increase in enrollment rate, the primary point of contact must be alerted.

Shipping Timelines

From the time a shipment order is generated, it will take approximately 5 business days to deliver these supplies to the investigator site. Orders from the distribution warehouses will only be shipped Monday through Thursday (for Iberdomide 0.6 mg, 0.75 mg, 1 mg, 1.3 mg, and 1.6 mg capsules) and Monday through Wednesday (for Elranatamab 40 mg/mL solution for injection), therefore, the clinical site must plan accordingly. These timelines may be extended in countries that require import licenses or proforma invoices for import.

5.2. Product Receipt

Upon receipt of IP shipments, the responsible pharmacist or designee must inspect and inventory the shipment contents as described below to ensure contents match the accompanying shipping documentation [Proof of Receipt (POR)] and are acceptable for dispensing.

The following IP(s) are shipped at 2 to 8 °C (36 to 46 °F) with allowable limits programmed into the temperature monitoring device:

- Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)

The following IP(s) are shipped at 15 to 25 °C (59 to 77 °F) with allowable limits programmed into the temperature monitoring device*:*

- Iberdomide 0.6 mg capsules
- Iberdomide 0.75 mg capsules
- Iberdomide 1 mg capsules
- Iberdomide 1.3 mg capsules
- Iberdomide 1.6 mg capsules

Shipments of IP(s) will include temperature monitoring devices. Follow the temperature monitoring device instructions included in the shipment upon receipt at the clinical site. It is recommended to record the temperature monitoring device number on the POR report to support reconciliation.

NOTE: The temperature monitoring device included in the shipment will only alarm if a temperature excursion occurred during the shipment process. The shipment is acceptable for use unless the monitor has alarmed.

Upon arrival of a shipment, sites must immediately follow the Temperature Monitoring Instruction Sheet included in the shipment. See Appendix 1 for an example.

NOTE: Sites must always print and file or file electronically the shipping temperature data report from USB devices whether alarmed or not. Follow the Temperature Monitoring Instructions sheet included in the shipment. See Appendix 1 for an example.

Upon arrival of a shipment, sites must immediately:

- Stop the temperature monitoring device immediately upon receipt so it does not record any false high temperatures as it is taken out of the box.
- If the shipment consists of more than one shipper each shipper will have its own temperature monitor, so please take note of which monitoring device ID is associated with which shipper. Refer to Appendix 1 for additional temperature monitoring device instructions.
- Inspect the IP to ensure they were received in good condition (i.e., undamaged, with tamper seals intact, etc.). See Section 5.3: Lost, Damaged or Incomplete Shipments.
- Check the amount and condition of the IP against the packing slip or other accompanying document(s).
- Verify the labels to ensure that they match the protocol number and container numbers (Kit IDs) stated on the POR/Clinical Supply Shipment Form.
- The POR will be located in the first shipper ONLY for shipments that consist of multiple shippers. Each box will have the box number designated (i.e., 1 of 2, 2 of 2)
- Place the IP in the appropriate labeled storage conditions as quickly as possible.
- Acknowledge the received shipment as per the instruction on the POR and file in the investigator site file.

- If the IP arrives in satisfactory condition, log in to the IRT system website to acknowledge the shipment per the Receipt of IP Global Guidance. Once the shipment is acknowledged via the IRT system, the site must file and maintain a copy of the IRT system generated shipment confirmation within the local site files.
- Impala 2.0 (IRT) is able to accept both a missing or damaged temperature monitor entry. In these cases, the kits are automatically quarantined in the system until it can be determined if an excursion has taken place. Please follow the instructions listed on the Temperature Monitoring Instruction Sheet in the shipment (Appendix 1).
- If a shipment arrives with a temperature excursion once the excursion data is entered into Impala 2.0, it is automatically put into quarantine in the system and the site does not have to take additional action within the IRT system.
- NOTE: If a shipment arrives with a temperature excursion, be prepared to provide the POR and Temperature data to the Clinical Supply Temperature Excursion Support mailbox, GCSTempExcursionSupport@pfizer.com, copying the primary point of contact.

Appendix 2: Example Site Temperature Excursion Report Form is only needed in the case of SITE STORAGE excursion ONLY.

- **NOTE:** Failure to complete receipt/acknowledgement in the IRT system in a timely manner will impact the ability to assign IP to participants and impact resupply shipment triggers.

5.3. Lost, Damaged or Incomplete Shipments

If a shipment is lost, incomplete or does not arrive in a satisfactory condition, contact the assigned primary point of contact. Damaged materials must be physically quarantined in a way that prevents inadvertent dispensing. Do not use/dispense/discard until disposition instructions are provided.

Once specific instructions are received acknowledgement can occur in the IRT system as instructed by the Sponsor. If the assigned primary point of contact cannot be reached, call the Help Desk (See Section 4: Interactive Response Technology).

5.4. Inventory Management

Based on the design of this study, the site should expect to have approximately 21 cartons of Elranatamab 40 mg/mL and 4 bottles of each applicable strength of active Iberdomide in inventory at any one time, depending on the site's enrollment. Each Elranatamab 40 mg/mL carton has the approximate dimensions of 64 mm x 64 mm x 48 mm (2.5 in x 2.5 in x 1.9 in). Each Iberdomide bottle has the approximate dimensions of 84 mm x 48 mm (3.3 in x 1.9 in). Ensure that the IP storage location can accommodate this amount of material. See Section 8 for additional information on investigational product accountability.

6. Storage, Handling, and Temperature Monitoring of IP at the Clinical Site

6.1. Storage and Temperature Monitoring of Investigational Product at a Clinical Site

Refer to Section 7.3 for information on the prepared product.

Temperature spikes outside of the labeled storage conditions as noted in the table below are considered reportable temperature excursions based on the Temperature Excursion Reporting Requirements.

NOTE: Shipping temperature range may differ from site storage requirements. Refer to the table below for site storage requirements prior to initial dose preparation. For shipping storage conditions, refer to Section 5.2, Product Receipt.

Product	Storage Condition	Storage Requirement	Temperature Excursion Reporting Requirements	Comments
Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)	Refrigerator	2 to 8 °C (36 °F to 46 °F)	Report excursions ≥ 30 minutes outside of labeled conditions between 0 °C and 25 °C. Report immediately if recorded temperature is below 0 °C or above 25 °C.	Minimize exposure of vials and dosing solutions during storage to room light. Avoid direct sunlight and ultraviolet light exposure.
Iberdomide 0.6 mg capsules	Room Temperature	15 to 25 °C (59 to 77 °F)	Report excursions ≥ 2 hours outside of labeled conditions between 1 °C and 30 °C. Report immediately if recorded temperature is below 1 °C or above 30 °C.	Store in original container.
Iberdomide 0.75 mg capsules				
Iberdomide 1 mg capsules				
Iberdomide 1.3 mg capsules				
Iberdomide 1.6 mg capsules				

The temperature of all locations where IP/study intervention is stored at a clinical site must be monitored continuously and verified as appropriate per the site processes, using a temperature monitoring device that measures minimum and maximum temperatures daily. The site may utilize temperature devices with minimum and maximum memory capabilities to monitor temperatures

when a site is not operational (e.g., weekends and holidays) however the site must be able to verify and document the minimum and maximum temperatures occurring over the entire non-operational periods once normal operations are resumed. Storage temperature must be recorded and monitored consistently by the site personnel in a site-created or Sponsor-provided temperature log. Sites may apply their own policies and procedures as long as the Sponsor requirements are met.

NOTE: Numeric temperature values may be rounded to the nearest whole number to establish if an excursion has occurred (e.g., Values at or above 0.5 are rounded up. Values at or below 0.49 are rounded down).

6.2. Temperature Excursions at Clinical Site

If any of the following occur, the site must **immediately** quarantine the IP supply in the appropriate storage conditions as indicated on the product label. Report all temperature excursions, as defined in Section 6.1, including suspected temperature excursions. Be prepared to complete the Investigator Site Temperature Excursion Report Form (See Appendix 2 as an example) along with site temperature data. E-mail documentation to the Clinical Supply Temperature Excursion Support mailbox GCSTempExcursionSupport@pfizer.com, copying the primary point of contact. Ensure you are utilizing the most current Temperature Excursion Reporting form. This form can also be provided upon request via email to GCSTempExcursionSupport@pfizer.com. In rare cases, primary point of contact can work with sponsor to authorize an equivalent form from the site.

- A temperature excursion occurs while any Sponsor supplied product is at the site
- The temperature is not monitored continuously (for example, a temperature monitoring device malfunctions)
- Advice is needed on whether or not a temperature deviation is considered a temperature excursion
- The documented temperatures and/or duration of an excursion are not available for any reason
- Ensure the temperature excursion form is filled out completely

The site must not use the quarantined supplies until specific instructions are received from the Sponsor. If it is determined that the materials are to be designated “unacceptable for use”, the materials must be physically quarantined in a way that prevents inadvertent dispensing and the Sponsor will initiate a replacement shipment to the site.

6.3. Special Handling of IP

Recommendations in the Safety Data Sheet (SDS) must be followed. The SDS will be provided upon request.

The Ips in this study have special handling requirements. Elranatamab used in this study is hazardous. Iberdomide used in this study is a thalidomide analog, and thalidomide is a known human teratogen.

HAZARDOUS HANDLING INFORMATION

Only qualified personnel who are familiar with procedures that minimize undue exposure to them and to the environment shall undertake the preparation, handling, and safe disposal of hazardous agents.

Elranatamab

Elranatamab has a hazardous rating due to its highly potent nature. When handling, use appropriate personal protective equipment and follow local site procedures. Wash hands thoroughly after handling.

Please refer to the SDS for additional hazardous handling information.

Iberdomide

ATTENTION: Iberdomide has special handling requirements due to risk of embryo-fetal toxicity.

- All sites must follow the Iberdomide Pregnancy Prevention Program (PPP) which applies to all participants receiving iberdomide within the clinical trial.
- Each site must also have two PPP trained counselors.

Iberdomide is a thalidomide analog, and thalidomide is a known human teratogen that causes severe life-threatening human birth defects. Iberdomide has not been studied in pregnant participants and the effects on the human fetus are unknown. However, the possibility of birth defects or death to an unborn baby cannot be ruled out.

Before participants agree to participate in a study, they must receive pregnancy counseling and additional details on pregnancy prevention and pregnancy testing within the study-specific PPP associated with every study protocol. Participants should thoroughly wash their hands with soap and water after handling capsules.

In addition, iberdomide should never be given to another person. Iberdomide should not be handled by nonpatient females of childbearing potential (FCBP) or nonpatient partners of FCBP unless gloves are worn. Disposable gloves must be worn by caregivers and healthcare providers when handling the capsule. If any contact with a broken iberdomide capsule or the medicine in the capsule occurs, the exposed area should be washed immediately and thoroughly with soap and water.

Please be sure your site is following the requirement. Refer to the PPP, and Sections 4.2.3, 5.3.1 and Appendix 4 of the protocol for contraception guidelines.

OTHER HANDLING INFORMATION

For clinical sites that have an off-site location for storage, preparation or administration of IP, an IP transport procedure must be provided to the clinical study team for review. At minimum the procedure must identify the designated operators of the dose preparation and transportation steps, a description of the transport container and process to maintain and record temperature during the transit time, and a method to log departure and arrival times.

6.4. Expired IP Handling

If your site has IP, including AxMP, that has expired, the materials must be physically quarantined in a way that prevents inadvertent dispensing and the Sponsor will initiate a replacement shipment to the site. Do not destroy the quarantined supply until instructed to do so by your primary point of contact.

7. Dosage and Administration Instructions

Elranatamab 40 mg/mL solution for injection (1.9 mL/vial) is to be administered subcutaneously (see Section 7.4.2 for subcutaneous injection site locations). IP will be dispensed and administered at study sites by study site personnel.

Iberdomide 0.6 mg, 0.75 mg, 1 mg, 1.3 mg, 1.6 mg capsules are to be administered orally once daily from Day 1 to 21 of each 28-day cycle. IP will be dispensed to participants by study site personnel. Iberdomide dosing instructions and dosing diary will be provided to participants at each iberdomide dispensing visit.

If participant is required to hold iberdomide at any point during a cycle, administration is held for the remainder of the cycle and can be resumed at Day 1 of the next cycle once dosing criteria in Section 6.6.2.1 and Table 6 of the protocol are met.

See Section 3 for treatment design.

DOSE MODIFICATIONS

Every effort should be made to administer IP on the planned dose and schedule. If elranatamab dosing is withheld or permanently discontinued, iberdomide dosing may be continued. If iberdomide dosing is withheld or permanently discontinued, elranatamab dosing may be continued. See Section 6.6 of the protocol for the complete dosing criteria and dose modifications.

Elranatamab:

Dose reduction of Elranatamab is not permitted; dose delay/interruption is the primary method for managing elranatamab-related toxicities as detailed in Table 5 of the protocol. Starting after Cycle 1 Day 1, if elranatamab cannot be administered on the planned day (within the prespecified window), it should be skipped until the next planned dose.

Iberdomide:

The recommended dose modifications for Iberdomide-related toxicities are presented in the table below.

Table 1. Dose Modifications for Iberdomide-Related Toxicity

Dose Level	Oral Iberdomide Dose (Days 1 to 21 of each 28-day cycle)		
Starting Dose	**1 mg**	**1.3 mg**	**1.6 mg**
DL -1	0.75 mg	1 mg	1.3 mg
DL -2	0.6 mg	0.75 mg	1 mg
DL -3	[redacted]	0.6 mg	0.75 mg

The minimum permitted DL for Iberdomide is 0.6 mg. **No dose re-escalation** is permitted for **Iberdomide.**

Note: If participant is required to hold iberdomide at any point during a cycle, administration is held for the remainder of the cycle. Dose modification for Iberdomide-related toxicities should only occur at Day 1 of the next cycle once dosing criteria in Section 6.6.2.1 and Table 6 of the protocol are met.

7.1. Drug Dispensing Per Visit

The table below describes the product to dispense at each dispensing visit. Refer to the Impala 2.0 Quick Reference Guide for additional dispensing instructions in the IRT.

Elranatamab Dispensing Table

Participant Dose	Instructions for Dispensing
76 mg	**ONE** vial of Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)
32 mg	
12 mg	

Iberdomide Dispensing Table

Participant Dose	Instructions for Dispensing 21-count bottle
0.6 mg	**ONE** x bottle of Iberdomide 0.6 mg capsules
0.75 mg	**ONE** x bottle of Iberdomide 0.75 mg capsules
1 mg	**ONE** x bottle of Iberdomide 1 mg capsules
1.3 mg	**ONE** x bottle of Iberdomide 1.3 mg capsules
1.6 mg	**ONE** x bottle of Iberdomide 1.6 mg capsules

Participant Dosing Instructions:

- Each participant will be given a dosing diary to support at-home dosing of iberdomide.

- Iberdomide will be administered PO QD for 21 days followed by 7 days off treatment for each 28-day cycle.
- Participants should be instructed to swallow iberdomide capsules whole and not to open, chew, crush the capsules, or take capsules that are cracked or broken. After handling capsules, participants should thoroughly wash their hands with soap and water.
- Participants should be encouraged to take their dose at about the same time each day with water and with or without food and should be instructed to record their daily administration in the participant dosing diary.
- If a participant misses a scheduled dose of iberdomide and
    - It is **within 12 hours** of the scheduled dose, the participant should immediately administer the missed dose and resume iberdomide in accordance with the normal administration schedule.
    - If **more than 12 hours** have elapsed since the time of scheduled administration, the participant should be instructed to skip the missed dose and to resume iberdomide in accordance with the normal administration schedule.
    - Participants should not take more than the prescribed dose in one day to make up for a missed dose on another day.
- Participants who vomit any time after taking a dose must be instructed NOT to "make it up" but to resume treatment the next day as prescribed and note this on the diary.
- Participants who inadvertently take one extra dose during a day must be instructed to stop taking the study medication and contact the study clinic immediately. Also refer to and Section 6.8 of the protocol for further details on treatment of overdose, and to Section 8.4.10 of the protocol for further details on medication errors.
- Participants experiencing IP related toxicity may have their dose modified according to Section 6.6 in the protocol.
- Participants should keep all capsules in their original container and not remove any capsules until the time of dosing.
- Participants will be required to return the completed participant dosing diary, and all empty and/or partially filled study drug bottles to the clinic for each study visit for drug accountability.

NOTE:

- **On study visit day, the dose of iberdomide should be held (NOT taken) in anticipation of the study visit.** Dose of iberdomide may be taken after necessary study operations.
- On PK collection day, pre-dose PK samples should be collected **before** administration of ANY premedication or study treatment.
- On study visit days when iberdomide is administered in combination with elranatamab, iberdomide must be administered first, then followed by elranatamab.

7.2. General Preparation Guidelines

Prior to and upon completion of dose preparation, ensure that the working area is clean.

It is strongly recommended that all preparations be carried out in a laminar flow hood/cabinet using aseptic technique for sterile products. If a laminar air flow hood is not available, a Class II – III biosafety cabinet may be used. Class I biosafety cabinets must not be used.

If prepared outside a laminar flow hood or biosafety cabinet, the in-use period should be no more than 4 hours.

Only the necessary materials should be present in the working area during each preparation step.

Only clinical site personnel who are appropriately trained on the procedures detailed in this document may perform the preparation and administration steps specified in this IP Manual. Clinical site personnel involved in these procedures must comply with all applicable regulations and standards. The preparation and administration of all sterile products must be performed using aseptic technique. Utilize local site procedures as appropriate.

7.3. In-Use Shelf Life and Storage Requirements of IP

Product	Storage Conditions	Storage Requirement	Comments
Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)	Unused (unopened) vials outside of refrigerated storage	Not to exceed 25 °C (77 °F)	Unused (unopened) vials can be returned to 2 to 8 ºC (36 to 46 °F) after storage for up to 8 hours at room temperature not to exceed 25 ºC (77 °F). Unused vials should not be left at room temperature for more than 8 hours. Vials left at room temperature for more than 8 hours must not be used and must be discarded.
	Prepared dosing solution in syringes	Up to 30 °C (86 °F)	Prepared dosing solutions in syringes should be used immediately. However, if prepared dosing solutions in syringes cannot be used immediately, stability of the prepared doses in syringes has been demonstrated for up to 24 hours, with a maximum of 6 hours at up to 30 °C (86 °F) and the remainder at 2 to 8 °C (36 to 46 °F). Prepared doses in syringes should only be stored if the syringes were aseptically prepared and capped prior to storage. If preparation of any dosing solutions is performed outside of an aseptic environment, the dose must be administered within 4 hours of initial vial puncture.

7.4. Preparation and Administration for Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)

Key points to note:

- Dose preparation must be performed using sterile handling techniques in compliance with local, state, and national laws/regulations.
- The final IP must be used immediately. However, if prepared dosing solutions in syringes cannot be used immediately, stability of the prepared doses in syringes has been demonstrated for up to 24 hours, with a maximum of 6 hours at up to 30 °C (86 °F) and the remainder at 2 to 8 °C (36 to 46 °F).
- Each vial is for single use only. Each vial is for use in a single participant, for a single dose.

- The IP should not contain any particulate matter and discoloration (i.e., change in color) prior to administration, whenever the solution and container permit. If particulates or discoloration are present, do not use the IP and notify the Primary point of contact.
- If the prepared IP is left at room temperature for more than 6 hours, contact the Primary point of contact.
- Document all steps performed as indicated in the Preparation Record (Appendix 4). The Preparation Record form is required. The use of alternative preparation records must be approved by the Sponsor's Clinical Research Pharmacist.

7.4.1. Study Supplies Required for Preparation and Administration of IP

SUPPLIES
Check that the labelling details on the outer containers of the supplies correspond with these instructions and the clinical protocol. If the supplies available at the site do not correspond with the list below, contact the Primary point of contact.
Supplies Provided by Pfizer
Drug product (Active): Elranatamab 40 mg/mL solution for injection (1.9 mL/vial) These are for single use only. They are for single use in a single participant for a single dose.
Supplies Provided by the Clinical Site
Syringes: Luer lock Latex-free polypropylene or polycarbonate syringes of appropriate size are required. Ensure syringes have appropriate graduations to prepare accurate dose.
Sterile Syringe Cap: If needed for storage and transport of prepared syringes.
Needles: Sterile, stainless-steel needles with bore size 20 gauge or wider are recommended for withdrawal of drug into syringe. Sterile, stainless steel 30 gauge or wider x 0.5" inch needle is preferred for subcutaneous delivery.
Closed System Transfer Devices: (i.e., PhaSeal, OnGuard, Equashield, ChemoLock, ChemoClave*) are acceptable for use during dose preparation when transferring material from vials but may not be used for storage of prepared doses. **ChemoClave "Genie" Vial Access Device is not acceptable for use.*

7.4.2. Preparation and Administration Instructions

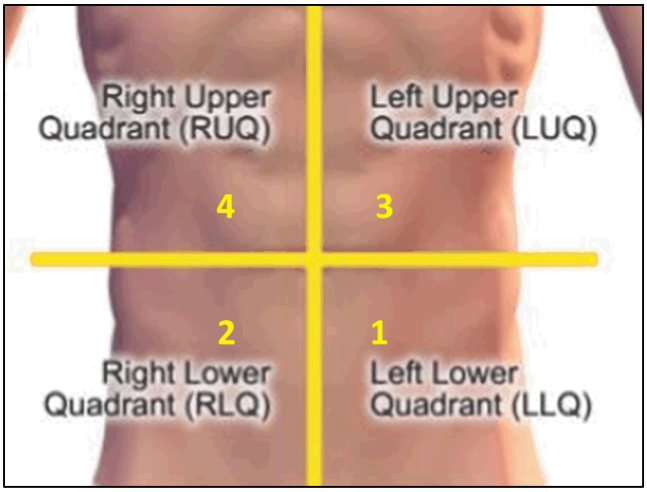
<table>
<tr><th>Step</th><th>PREPARATION OF ELRANATAMAB</th></tr>
<tr><td>1</td><td>Ensure that all materials and equipment required are available before starting the dose preparation.</td></tr>
<tr><td>2</td><td>Dose volume for fixed doses:
<table>
<tr><th>Dose</th><th>12 mg</th><th>32 mg</th><th>76 mg</th></tr>
<tr><td>Elranatamab Volume</td><td>0.3 mL</td><td>0.8 mL</td><td>1.9 mL</td></tr>
</table>
NOTE: For sites that have a maximum subcutaneous injection volume less than 1.9 mL, multiple injections may be required.</td></tr>
<tr><td>3</td><td>Each vial has an extractable volume of at least 1.9 mL.

Remove one vial of Elranatamab from the refrigerator and equilibrate to room temperature for approximately 15 minutes.</td></tr>
<tr><td>4</td><td>Using aseptic technique and an appropriate syringe and needle, withdraw the required dose volume listed in Step 2 in addition to an adequate priming volume from the IP vial(s) according to local site practice.

Remove and discard needle.

If not administered immediately, use a sterile cap to cover the tip of the syringe for storage until ready for administration.</td></tr>
<tr><td>5</td><td>Apply appropriate label to the prepared syringe according to site regulations and practices.</td></tr>
<tr><td>6</td><td>Complete the Preparation Record (Appendix 4 or alternative preparation record approved by Sponsor).</td></tr>
</table>

Administration:

SUBCUTANEOUS ADMINISTRATION INSTRUCTIONS	
1	Prior to dosing the participant, adhere to normal standard of care and aseptic techniques. Prepared solutions that are refrigerated should be allowed to reach room temperature prior to administration. Make sure the prepared dosing solution is not cold to the touch.
2	**Subcutaneous Injection Site Locations:**  Injection site locations include a maximum of **four** unique administration sites distributed across the **two** lower and the **two** upper abdominal quadrants (up to 1 injection location per quadrant). Administer the required number of injections in the following order: 1. Lower left quadrant 2. Lower right quadrant 3. Upper left quadrant 4. Upper right quadrant Injections to the abdomen are preferred. If subcutaneous injections in the abdominal location are not possible, subcutaneous injections can be administered in a distributed manner in the thighs. **Subcutaneous injections in the upper extremities (e.g., deltoid, upper and lower arm) are not permitted.**
3	Record the location, time of each injection and any injection site reactions in the participant's source records and study Case Report Form (CRF).

7.5. Dosing and Dispensing Errors

Any error in the prescribing, dispensing or administration of a medicinal product that may cause or lead to inappropriate medication use or participant harm while in the control of the health care professional, participant or consumer must be reported to the Sponsor and/or primary point of contact immediately. Refer to the study protocol for additional information on how to report a dosing or dispensing error.

7.6. Investigational Product Complaints

Any complaints related to distributed clinical supplies provided by the Sponsor for use in a clinical study that alleges a quality defect of a product, device or its labeling or packaging must immediately be reported. Follow the process below to alert the Sponsor.

Process:

- Upon identification of a product complaint, immediately notify the assigned primary point of contact. Please provide the following information in the notification within one business day of discovery:
  - Protocol Number and Site Number
  - Date of discovery
  - Packaged lot number and kit number if applicable
  - How long the participant has been enrolled in the clinical study if applicable
  - Status of participant within the study (i.e., completed, dose escalated)
  - If there was a missed dose or adverse event due to the complaint
  - Brief description of the complaint
  - Point of discovery (i.e., during drug accountability, or in participant possession)
  - Photo of the sample in question
- Quarantine the IP in the appropriate storage conditions and wait for further instructions.
- The site will be notified if additional information or action is needed by the site. *Do not destroy the product as it may need to be returned to the Sponsor.*
- The site must work with the primary point of contact to complete IP complaint documentation for the Sponsor, and/or if requested to ship the material in question back to the Sponsor. If requested to return the product to the Sponsor, the primary point of contact will support the logistics of this shipment.
- The Sponsor will review the complaint and complete an investigation as needed. Once the review/investigation is complete by the Sponsor, the site will be provided a final response by the primary point of contact.

8. Investigational Product Accountability

IMP accountability is the responsibility of the clinical site. Contact the primary point of contact for any concerns with regards to accountability. Please see Appendix 3 for an example Pfizer Investigational Product Accountability Log (IPAL).

The Pfizer IPAL must be used. Any requests from sites to use alternative accountability log must be approved by the primary point of contact.

9. Investigational Product Destruction

- **<u>If product can be destroyed on site:</u>**
  - All destruction must be fully documented at the time of destruction on the IPAL or equivalent document (See Appendix 3 for an example)
  - For unused/expired IP, once reconciliation and accountability has been performed by the primary point of contact, the primary point of contact may authorize the destruction by the appropriate site personnel (e.g., Pharmacist or Study Nurse/Coordinator) following local environmental requirements and institutional policies.

- For used/partially used products, reconciliation may not be possible if local site procedure is to destroy immediately after use (e.g., product containing sharps or cytotoxic products). Please inform your primary point of contact before destruction if this is the case.

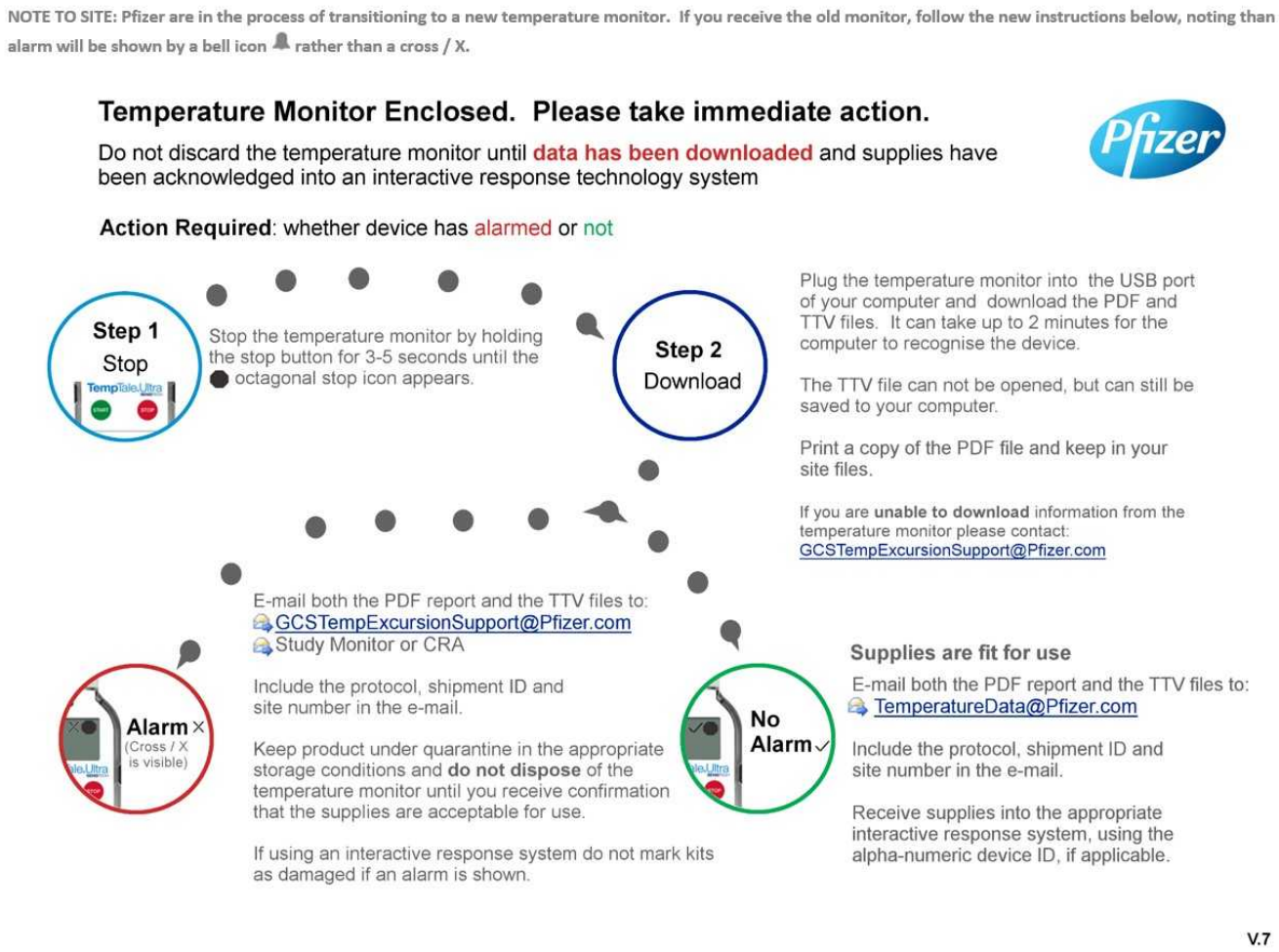
- **If product must be sent out for destruction**:
  - Contact the primary point of contact for return/shipment instructions.
  - NO product should be sent for destruction without prior authorization by primary point of contact.

- Sites that cannot retain the full product (e.g., toxic or sharps, etc.), information should be provided/agreed upon with sites and outer cartons should be retained if possible to support reconciliation / accountability activities.
- If local site destruction SOP differs, please provide a copy to the primary point of contact for Sponsor review and approval.

Contact the assigned primary point of contact for any questions related to IP return or destruction.

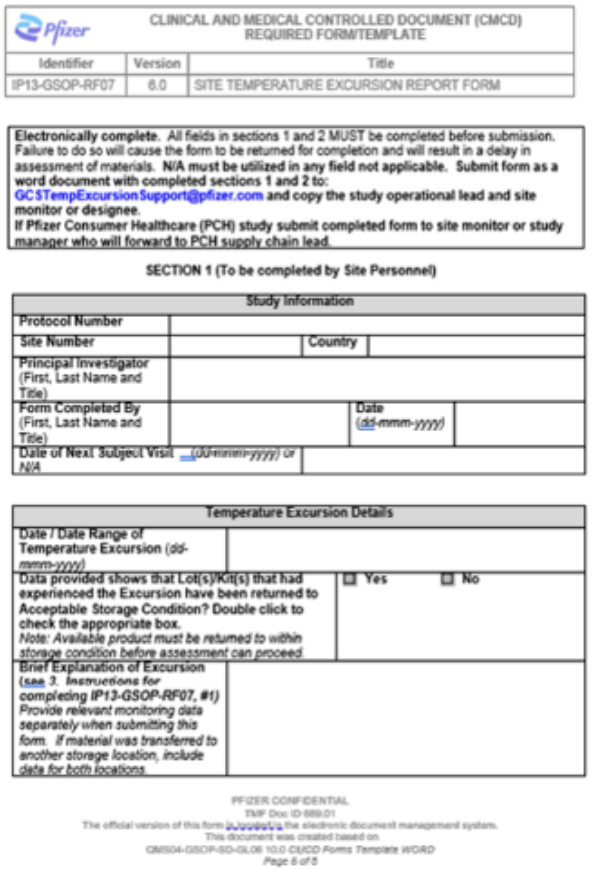
Appendix 1: Example Temperature Monitoring Instruction Sheet

This is an example only. Use the instructions provided in the shipment.



Appendix 2: Example Site Temperature Excursion Report Form

This is an example only. Obtain a copy of the form from the Sponsor.



Pfizer — CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) REQUIRED FORM/TEMPLATE

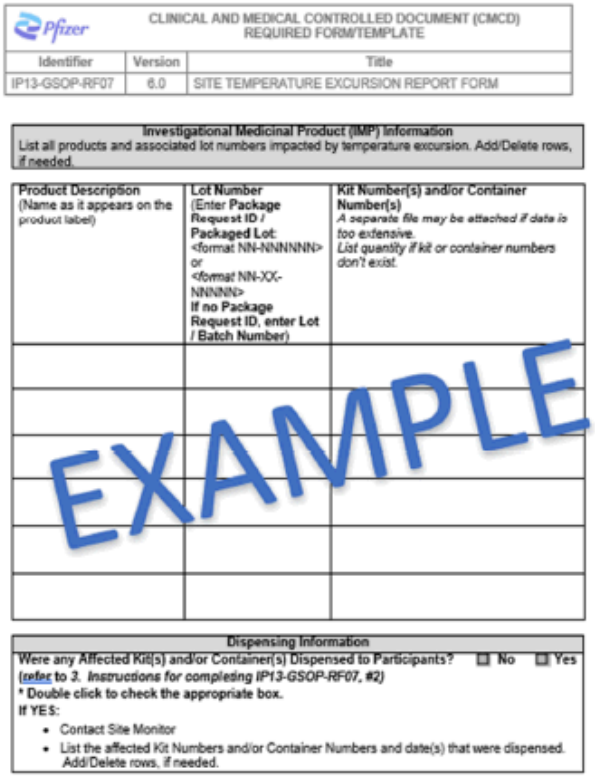
Identifier	Version	Title
IP13-GSOP-RF07	6.0	SITE TEMPERATURE EXCURSION REPORT FORM

Electronically complete. All fields in sections 1 and 2 MUST be completed before submission. Failure to do so will cause the form to be returned for completion and will result in a delay in assessment of materials. **N/A must be utilized in any field not applicable. Submit form as a word document with completed sections 1 and 2 to:** GCSTempExcursionSupport@pfizer.com **and copy the study operational lead and site monitor or designee.**
If Pfizer Consumer Healthcare (PCH) study submit completed form to site monitor or study manager who will forward to PCH supply chain lead.

SECTION 1 (To be completed by Site Personnel)

Study Information			
Protocol Number			
Site Number		Country	
Principal Investigator (First, Last Name and Title)			
Form Completed By (First, Last Name and Title)		Date (dd-mmm-yyyy)	
Date of Next Subject Visit	(dd-mmm-yyyy) or N/A		

Temperature Excursion Details	
Date / Date Range of Temperature Excursion (dd-mmm-yyyy)	
Data provided shows that Lot(s)/Kit(s) that had experienced the Excursion have been returned to Acceptable Storage Condition? Double click to check the appropriate box. *Note: Available product must be returned to within storage condition before assessment can proceed.*	☐ Yes ☐ No
Brief Explanation of Excursion (see *3. Instructions for completing IP13-GSOP-RF07, #1) Provide relevant monitoring data separately when submitting this form. If material was transferred to another storage location, include data for both locations.*	



Pfizer — CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) REQUIRED FORM/TEMPLATE

Identifier	Version	Title
IP13-GSOP-RF07	6.0	SITE TEMPERATURE EXCURSION REPORT FORM

Investigational Medicinal Product (IMP) Information
List all products and associated lot numbers impacted by temperature excursion. Add/Delete rows, if needed.

Product Description (Name as it appears on the product label)	Lot Number (Enter Package Request ID / Packaged Lot: <format NN-NNNNNN> or <format NN-XX-NNNNN> If no Package Request ID, enter Lot / Batch Number)	Kit Number(s) and/or Container Number(s) *A separate file may be attached if data is too extensive. List quantity if kit or container numbers don't exist.*

Dispensing Information
Were any Affected Kit(s) and/or Container(s) Dispensed to Participants? ☐ No ☐ Yes (refer to *3. Instructions for completing IP13-GSOP-RF07, #2)*
* Double click to check the appropriate box.
If YES:
• Contact Site Monitor
• List the affected Kit Numbers and/or Container Numbers and date(s) that were dispensed. Add/Delete rows, if needed.

Pfizer — CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) REQUIRED FORM/TEMPLATE

Identifier	Version	Title
IP13-GSOP-RF07	6.0	SITE TEMPERATURE EXCURSION REPORT FORM

- Submit the form within 24 hours upon discovery of the temperature excursion.

Kit/Container Number Dispensed	Date Dispensed (dd-mmm-yyyy)

SECTION 2 (To be completed by Medicinal Sciences/PCH supply chain only)

Temperature Excursion Decision	
TE Number	Summary of Excursion (Date/Date range of Temperature excursion)

Insert rows in the table below to add product specific decision, if needed.		
Product Name (As listed in section 1- IMP information)	Lot Number (As listed in section 1 - IMP information)	Assessment Decision ☐ Acceptable ☐ Not Acceptable

Completed by (First and Last Name)	Date (dd-mmm-yyyy)

Appendix 3: Example Pfizer Investigational Product Accountability Log (IPAL)

Contact your primary point of contact for a copy of the IPAL for this study.

INVESTIGATIONAL PRODUCT ACCOUNTABILITY LOG (IPAL)

Protocol Title:	**IRT in use:** ☐Yes ☐No	☐ Blinded Document ☐Unblinded Document[1]
Site Principal Investigator:	**Site ID:**	**Protocol #:**
Investigational Medicinal Product Name:	**Strength:**	**Dosage Form:**
Units Per Container:	**Storage Requirement (refer to product label):**[2]	

Receipt or Dispense Date[3] dd/Mmm/ yyyy	**Method of Delivery**[4]	**Shipment ID #[5] Or** *☐ Lot Number ☐ Kit Number ☐ Container Number ☐ Other (specify)*	Subject ID Number[6]	Quantity of Containers Received (R) or Dispensed (D) or Undispensed (U)[7]	Balance (Containers)[8]	Staff Initials[9]	Subject Returns[10]			Disposition[11]		
							Quantity of Units Returned (N/R for not returned)	Date Returned dd/Mmm/ yyyy	Staff Initials	Returned (R) or Destroyed (D)	Date of Disposition dd/Mmm/ yyyy	Staff Initials
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											
	☐N/A (Receipt) ☐In person ☐Delivered by courier											

EXAMPLE

Comments:[12] ______________________________ Page[13] ____ of ____

PFIZER CONFIDENTIAL
INV02-INV04-GSOP-RF11 10.0 *Investigational Product Accountability Log (IPAL)*
TMF DOC ID: 292.02

Example Pfizer Investigational Product Accountability Log (IPAL) – Continued

Pfizer

INVESTIGATIONAL PRODUCT ACCOUNTABILITY LOG (IPAL)

Instructions for completing Investigational Product Accountability Log (IPAL)

This form is used for investigational or commercial products. For any fields where data is not applicable; write N/A (not applicable).

1. **Blinded or Unblinded Document:** (Pre-populated by study manager or designee). In a blinded study, if unblinded document box is checked, this document is only accessible to unblinded site personnel and requires an unblinded site monitor. Where designated as unblinded, the IPAL must not be filed to the TMF until after the study has been unblinded.
2. **Storage Requirement:** (pre-populated by study manager or designee). Enter appropriate storage requirement (refer to product label).
3. **Receipt or Dispense Date:** dd/Mmm/yyyy.
4. **Method of Delivery:** Indicate the method of delivery when applicable (use N/A for receipt). "In Person" is selected when investigational product is provided to the subject in person at the site. "Delivered by courier" is selected when investigational product is provided to the subject via courier.
5. **Shipment ID # OR Lot, Kit, Container Number, Other (if other, specify)** For shipments received, enter shipment ID number (do not list individual container/kit numbers); when dispensing, enter only one kit or container number per line.
6. **Subject ID Number:** Subject's assigned study number (in some cases this will be randomization number).
7. **Quantity of Containers Received (R) or Dispensed (D) or Undispensed (U):** Indicate as R +10 (for received 10 containers), D -1 (for dispensed 1 container), U-1 for undispensed (accounted for or lost/displaced). Note: Documentation of undispensed containers may be completed by the site monitor but requires verification by site personnel.
8. **Balance (Containers):** Write container balance calculated at each receipt of investigational medicinal product or dispensation to a subject (this number should always reflect the number of undispensed containers available at site); in cases where a bulk bottle is received and dispensing of single units is required from that bottle change "(containers)" to "(units)" as appropriate (all changes should be indicated by drawing one line through incorrect entry, initial, date and enter correction).
9. **Site Staff Initials:** Two designated site staff members document dispensing of investigational medicinal product and one or two staff member(s) document receipt of investigational medicinal product by initialing the form.
10. **Subject Returns:** Site staff completes when subject returns unused investigational medicinal product (open bottles, partial blister packs, etc.). Enter N/R if not returned by the subject.
    - Quantity of Units Returned: This is number of "units" (eg, 31 tablets), not containers OR if product was prepared but not administered to subject and is returned to pharmacy, this should be indicated here (additional comments, if needed may be placed in comment section).
    - Date Returned: dd/Mmm/yyyy (this is the date the subject physically returns the investigational medicinal product to the site or when it received by the site if returned by courier).
    - Staff Initials: Site staff performing reconciliation (number of units returned) initials the form.
11. **Disposition:** Site staff completes this at time of investigational medicinal product return or destruction.
    - Indicate "R" for return to sponsor/designee, "D" for destruction at site.
      - When R is selected, the sponsor will complete the IP13-GSOP-RF06 *Investigational Medicinal Product Destruction or Return Form.*
    - Date of Disposition: dd/Mmm/yyyy (for investigational product returns, date of disposition is the date that return has been initiated [investigational medicinal product is packed and prepared for shipment]).
    - Staff Initials.
12. **Comments:** Use this section to comment on any problems or deviations.
13. **Page ___ of ____:** Number pages consecutively; do not fill in "of ____" until study completion.

EXAMPLE

PFIZER CONFIDENTIAL
INV02-INV04-GSOP-RF11 10.0 *Investigational Product Accountability Log (IPAL)*
TMF DOC ID: 292.02

Appendix 4: Preparation Record for Elranatamab 40 mg/mL solution for injection (1.9 mL/vial)

Elranatamab Subcutaneous Administration

This form is **required**. The use of alternative preparation records must be approved by the Sponsor's Clinical Research Pharmacist. Prepared by and verified by must be completed by two separate site personnel, one of which is a licensed healthcare provider.

Protocol Number: C1071030		
Subject ID Number (SSID):		**Participant Dose:** _____ **mg**
Date of dose Preparation (DD-MMM-YYYY)**:**	**Dose preparation start time** (HH:MM)**:** ***(Time needle is inserted into vial)***	**Expiry Date and Time of prepared dose** (DD-MMM-YYYY; HH:MM): ***Expiry is 6 hours from the start of dose preparation***
NOTE: *If the prepared dosing solution in syringe(s) cannot be used immediately, stability has been demonstrated for up to 24 hours, with a maximum of 6 hours at up to 30 °C (86 °F) and the remainder at 2 to 8 °C (36 to 46 °F). Prepared doses in syringes should only be stored if the syringes were aseptically prepared and capped prior to storage.* *If preparation of any dosing solutions is performed outside of an aseptic environment, the dose must be administered within 4 hours of initial vial puncture*		

Participant Dose Volume: One vial of Elranatamab will be needed for each dose level

Dose	**12 mg**	**32 mg**	**76 mg**
Elranatamab Volume	0.3 mL	0.8 mL	1.9 mL

Preparation of SUBCUTANEOUS Doses		**Verification**
1.	Use the table above to determine the volume of IP to be administered. Remove **ONE** vial of Elranatamab 40 mg/mL solution for injection (1.9 mL/vial) from refrigerated storage and allow to reach ambient/room temperature for approximately 15 minutes prior to preparing dose.	_____ mL
2.	Using an appropriately sized syringe(s) and needle(s), withdraw the appropriate dosing volume of Elranatamab (per the table above) from the vial. If not administered immediately, use a sterile cap to cover the tip of the syringe(s) for storage until ready for administration. **NOTE:** For sites that have a maximum subcutaneous injection volume less than 1.9 mL, multiple injections may be required.	Volume per Syringe: 1: _____ mL 2: _____ mL (N/A if not used)
3.	Apply appropriate label to the prepared syringe(s) according to site regulations and practices. The label must clearly indicate to administer only the exact dose volume.	☐ Completed

	Printed Name	**Signature**	**Date**
Prepared By:			- -
Verified By:			- -

Contact your primary point of contact immediately to report any dose preparation deviations.

Comments (record any deviations from preparation instructions, storage time and conditions, etc.)

_____

_____

_____

Document Approval Record

Document Name:	IP Manual for C1071030
Document Title:	IP Manual for C1071030

Signed By:	Date(GMT)	Signing Capacity
Crawford, Lindsey	11-Mar-2024 13:19:21	Business Line Approver
Kim, Hui	13-Mar-2024 04:31:50	Business Line Approver
O'Connell, Ashleigh	14-Mar-2024 11:58:16	Business Line Approver
Gjonbalaj,Avdyl	18-Mar-2024 15:45:50	Manager Approval