

WELCOME MANUAL OF THE VHIR CLINICAL TRIALS UNIT – PHARMACY SERVICE

1. Contact Information and Postal Address for IMP Shipments

Coordination:

Dr. Pilar Suñé

Clinical Trials Unit – Pharmacy Service
General Hospital, Basement Floor –1
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5.1.1

2. Office Hours

Unit opening hours	Monday to Friday (working days): 8:00–17:00
Monitoring visits (request via e-mail to <i>farmacia.uac@vhir.org</i>)	Monday to Thursday (working days): 9:00–17:00 Friday (working days): 9:00–13:00
Package reception	Monday to Friday (working days): 9:00–14:00

Note: For clinical trials in adult onco-hematology, please contact the Oncology Clinical Research Pharmacy Unit (*farmaceuticsvhio@vhio.net*).

3. Staff

Site pharmacists: Pilar Suñé - pilar.sune@vhir.org
Lidia Salse – lidia.salse@vhir.org
Laia Gispert – laia.gispert@vhir.org

Site pharmacists will sign the sponsor's delegation of activities form during the site initiation visit (SIV) and will receive access credentials for electronic IMP management platforms, when applicable.

Pharmacists' CVs and training certificates in Good Clinical Practice (GCP) are available for download on the Pharmacy Service online platform (Fundanet). These CV versions include statements regarding absence of conflict of interest and data protection compliance. Updates will only be issued when relevant new information exists.

Non-pharmacist staff and newly incorporated pharmacists will be listed in an internal delegation document available for review during monitoring visits, audits, and inspections. Copies of the internal delegation log cannot be provided due to data protection regulations.

Training in trial-specific pharmacy procedures is documented via the *Dispensing Rules* document, drafted after each SIV. This document includes all aspects related to IMP handling within the Pharmacy Service (receipt, storage, dispensation and preparation, when applicable) and will be updated if study amendments require changes in procedures.

Pharmacy staff consent is required before being added to online platforms not directly related to IMP management.

Pharmacy staff will not complete protocol-specific online trainings, unless they refer to tasks within their scope of its responsibilities, or when training can be otherwise documented (e.g., previous certifications or SIV training).

4. Pharmacy File

Minimum documentation required:

- Current protocol
- Pharmacy manual or equivalent IMP handling document
- Safety Data Sheet
- Sponsor contact list (including project leader)
- Favourable opinion from the Ethics Committee (CEIM), including HUVH as a site
- CTIS Spain Decision or AEMPS approval
- Contract signed by all parties

No pharmacy SIV will be scheduled until minimum regulatory documentation is available (AEMPS/CTIS authorization and signed contract).

Documentation must be delivered electronically. The unit maintains its own archiving system. NO PHYSICAL BINDERS CONTAINING PAPER DOCUMENTATION WILL BE ACCEPTED OR USED, except for source documents (prescriptions, delivery notes, work documents), which will be stored in paper form.

Relevant amendments affecting pharmacy procedures must be promptly reported by the sponsor/CRA, and updated documents must be delivered electronically with a description of implemented changes. Receipt of this new documentation is acknowledged via email reply. **Signed/scanned acknowledgements or sponsor-specific training logs will not be completed.**

The site has an internal SOP for management of new documentation, available for monitor/auditor/inspector review.

5. Investigational Medicinal Product (IMP) Management

5.2 Shipments

The first shipment of IMP and materials should preferably occur after the SIV, or at most **2 working days before**. No IMP receipt activities will be conducted before the SIV. Only one single method of receipt confirmation will be used. No signed and scanned delivery notes will be sent if receipt confirmation is performed using IWRS or another electronic system.

If temperature loggers are included, devices will be discarded after downloading data; temperature reports will be archived in PDF format.

Reusable thermal boxes (e.g., CREDO) must be automatically collected by the courier at or within 24 hours of delivery. **The site will not keep thermal boxes beyond 24 hours, nor contact the courier for pickup.**

See section 2 for package reception hours.

5.3 Storage

IMP is stored separately from hospital-use medicines in a restricted-access area.

5.3.1. Temperature monitoring

Refrigerators, freezers, and room temperature storage areas have devices recording temperature every 15 minutes.

In the absence of alarms, weekly logs are transcribed documenting max/min/average temperatures. A pharmacist reviews and verifies each log weekly. Original readings are stored indefinitely as source documents and are available for review onsite (no copies provided).

Alarm thresholds:

- **Refrigerators:** <2°C or >8°C
- **Ambient:** <15°C or >25°C
- **Freezer -20°C:** <-25°C or >-15°C
- **Freezer -70°C:** <-80°C or >-60°C

Readings outside the threshold will generate an automated alarm report and IMP affected will be quarantined until sponsor assessment. Temperature alarms are visually detected in a device located in the pharmacy main working area, and also automatically communicated via phone alerts sent as SMS messages to the pharmacist on duty to ensure 24/7 cover.

The hospital has an autonomous auxiliary power supply system that covers potential power failures. In the event of a refrigerator or freezer malfunction, the affected medication will be transferred as soon as possible to a backup refrigerator/freezer within the Pharmacy Service, together with the calibrated temperature probes.

Temperature control devices are recalibrated annually. Calibration certificates and weekly logs are available and downloadable in Fundanet (no paper copies will be provided until trial close-out).

5.4. Accountability

IMP accountability is managed via **Fundanet iFarma**, a validated commercial software. Throughout the study, printed accountability reports will be provided on monitoring visits. Those partial prints will not be signed and dated until study closure.

The software used for medication accountability is the iFarma module within the Fundanet application, which is validated for the control and tracking of investigational medicinal products in clinical trials. Fundanet iFarma is not considered an electronic source document; rather, it is the tool used to transcribe paper source documentation, which is available for review in the pharmacy file. Users access the system using individual credentials, it is hosted on a secure server with daily backups and provides an audit trail of all interactions.

Under no circumstances will medication accountability be duplicated by manually completing sponsor forms or by re-entering data into IWRS platforms.

5.5. Dispensation

IMP is prescribed and dispensed upon presentation of a specific clinical trial prescription signed by the PI or sub-investigator.

IMP is always dispensed in its original primary container. Manipulations affecting stability are not allowed unless they are described in the pharmacy manual, which should include the impact of the described manipulations on IMP shelf life.

No direct to patient IMP shipments will be conducted unless previously agreed with the Pharmacy and included in the institutional contract. Hospital approval of home IMP delivery and administration will be preceded by a case by case benefit-risk assessment.

5.6. Preparation

If the trial involves IMP preparation at the Pharmacy Service, **in-house materials** will be preferably used, when compatible. **Preparation sheets and labels** will follow site templates (*NTF Internal Preparation Forms and Labels*).

Preparations are performed in a Class II Telstar/BIO-II Advance 4 Plus laminar flow hood.

Due to internal safety policy, empty or partially empty IMP containers used during preparation are destroyed immediately. An explanatory note to file can be provided.

5.7. Return and Destruction

Expired medication or remaining medication at the close-out visit will be returned to the sponsor. Local destruction of unused medication will only be performed in exceptional circumstances agreed upon during the SIV.

Potentially hazardous medication returned by patients will be destroyed immediately after counting, and this destruction documented using an internal form. The handling process for this type of medication is duly described in the SOP ***Management and Destruction of Potentially Hazardous Oral Medication Returned by the Patient***.

6. Monitoring Visits

On-site monitoring is allowed by prior appointment via farmacia.uac@vhir.org, and subject to availability.

Hours:

- Monday–Thursday: 9:00–17:00
- Friday: 9:00–13:00

Monitors may copy IMP delivery notes. However, copies of the internal delegation log, internal prescriptions (purple forms), or any documents containing patient personal data **cannot** be provided.

Remote monitoring may only be performed through Fundanet.

No remote monitoring via phone or scanned source documents is allowed.

Re-labelling due to expiry extension is performed by the monitor, following sponsor procedures; pharmacy staff will supervise and validate with signature.

Temperature logs, stock reports, and other documents (CVs, GCP certificates, calibration certificates, archive notes) are available in Fundanet.

Audits must be communicated as soon as possible: dates must be agreed with the pharmacy unit coordinator.

7. Close-Out Visits

All unused IMP must be returned to the sponsor unless alternative procedures were agreed with Pharmacy. Local destruction is not permitted unless previously approved. The sponsor commits to collecting expired/damaged IMP periodically or within **30 days** of pharmacy request.

At study completion, the following pharmacy documents will be merged with the investigator site file:

- Signed IMP delivery notes
- Internal dispensing prescriptions (if applicable)
- Final IMP accountability log (signed and dated)
- Temperature logs (signed and dated)
- Original signed documents (archive notes, temperature alarms, protocol deviations, re-labelling records, etc.)
- Record of reviewed amendments (signed)