Vall d'Hebron
Hospitals

Unitat d'Assaigs Clínics
Servei de Farmàcia

INFORMATION FOR SITE INITIATION AND PRE-STUDY VISITS

Contact details and medication shipment address

Lead pharmacist: Dr.Pilar Suñé
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Barcelona 08035
E-mail: farmacia.uac@vhir.org

Working hours

Unit opens: Monday to Friday, 8am to 5pm
For monitoring Visits: Monday to Friday, 9am to 5pm (requests sent to farmacia.uac@vhir.org)
For IMP shipments: Monday to Friday, 9am to 2pm

Personnel

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

The Delegation of Authority log will be signed only by site pharmacists at the initiation visit. Credentials for the use of interactive web response systems will be provided for all pharmacists.

CVs and GCP certificates will be available to download from the pharmacy online platform (Fundanet). Staff CVs will be not be updated unless new relevant information is available, and they provide information regarding absence of conflict of interest and authorization to personal data treatment according to local regulations.

All other non pharmacist personnel and pharmacists joining the unit after the initiation visit, will be listed inside an internal delegation log available for review in monitoring visits, audits and/or inspections. Pharmacy staff protocol-specific trainings are documented through "read and understood" signature of the trial internal SOP (document named "Normas de Dispensación"), which is prepared by staff pharmacists after study initiation visits and every time changes in the study affecting pharmacy procedures are implemented.

Before inclusion in online platforms with purposes other than IMP management, a pharmacy staff conformity is required. Pharmacy staff does not perform protocol-specific trainings unrelated to their delegated tasks in the study, or when such training can be documented by any other means (such as previous training certificates or training already documented in the study training log).

Documents required by Pharmacy Service

Study contact list
Protocol (last version, single language)
Pharmacy or IMP Manual (when applicable)
Safety Data Sheet (if the IMP requires manipulation by pharmacy staff)
Regulatory Authorities Approval
Ethics Committee Approval (or other regulatory document listing our site as participant in the trial)
Clinical Trial Site Agreement (signed first page or complete document)

Pharmacy initiation visits will only be scheduled if the minimum regulatory documents are available: RA Approval, EC Approval and Site Agreement signed by all parts.

Documents for the pharmacy file will be provided in electronic format (by e-mail, CD or equivalent). PHYSICAL BINDERS WITH ESSENTIAL DOCUMENTATION IN PAPER FORMAT WILL NOT BE ACCEPTED NOR USED except for source documents (such as packing lists, prescription sheets and any other signed working documents).

Relevant amendments implying changes to pharmacy procedures shall be notified to the pharmacy department as soon as possible, also in electronic format, and with a description of relevant changes. Pharmacy staff will acknowledge receipt of new documentation will be done by replying to the e-mail. Per internal SOPs, no signed and scanned acknowledgments will be sent, and sponsor specific training logs of new versions of documents will not be signed. Site has its own procedure to document receipt and staff training of new relevant documentation, which is available to review by monitors, auditors and inspectors.

Drug receipt, storage and temperature control

The first medication shipment of a clinical trial will be preferably done after, or a maximum of two working days before, the date of the initiation visit. Specific acknowledgement of receipt will not be done until after the initiation visit. The acknowledgement of receipt method will be established during the initiation visit and not more than one method of acknowledgement of receipt will be performed by pharmacy staff. Scanned proof of receipt will never be sent to the monitor when the

acknowledgement has already been performed through another method (IWRS or other electronic method).

All clinical trials medication is stored in a designated area in the Pharmacy Service, separated from the circuit of commercial drugs used in the Hospital and with an access restricted to pharmacy personnel.

The pharmacy service uses specific software for medication accountability. Updated printed copies of the accountability logs will be provided to the monitor for revision. **These logs will only be signed and dated on study close-out visits.**

The software used for IMP accountability is the iFarma module of FUNDANET, and it is a validated software for control and follow up of clinical trials medication. Fundanet iFarma it does not have the consideration of electronic source document. It is the tool the site uses to transcribe the information from paper source documents -which will be available for review on the pharmacy file- into an accountability log. Nevertheless, it is accessed through individual credentials, it is stored in a secure server with daily backups and it provides audit trail for every interaction.

The site will not perform double accountabilities by manually completing sponsor provided logs or reentering data into IWRS platforms.

The medication for clinical trials is prescribed and dispensed through a specific prescription document completed and signed by the principal investigator or a physician co-investigator. The medication is always dispensed in its original container. Pharmacy staff can not make any modification of the primary container resulting in a modification of drug stability, unless specified in the pharmacy manual. If that is the case, the pharmacy manual should include a description of the procedure and an estimation of the impact of such manipulation over the expiry date of the final product.

Patient home delivery of medication from the pharmacy will not be performed unless previous agreement between sponsor and pharmacy service, after performing a risk and impact evaluation of the procedure. When home delivery is contemplated, site management should also be informed and specifications will be included in the site agreement document.

As per internal occupational hazards policy regarding management of potentially hazardous medicinal products, empty or partially full containers used during preparation at the pharmacy facilities, will be immediately destroyed after preparation. Pharmacy staff will provide a signed note to file with details of the local destruction procedures.

<u>Temperature Records</u>

All refrigerators, room temperature space and freezers are equipped with a device that records the temperature every 15 minutes, and with a visual alarm connected to the Pharmacist's office and to the hospital security department. A weekly log is generated with the maximum, minimum and average temperatures reached during the week.

Temperature control devices are configured so alarms are triggered if any reading is detected outside of the following established range:

Refrigerators: <2ºC or > 8ºC
Room temperature: <15ºC or > 25ºC
Freezer -20ºC: < -25ºC or > -15ºC
Ultrafreezer -70ºC: < 80ºC or > 60ºC

In case of temperature deviations above or below the allowable range a temperature alarm document is generated, to determine the temperatures reached and the maximum time during which the temperature deviation occurred. If the deviation is considered relevant, it will be communicated to the monitor and the incidence will be recorded in a document signed by the pharmacist.

In case of refrigerator or freezer malfunction, the affected medication will be immediately moved to a backup refrigerator or freezer.

Temperature control devices are calibrated annually

Paper copies of weekly reports and calibration certificates will not be supplied nor will be filed in the pharmacy study file. Those documents can be reviewed and downloaded through the pharmacy online platform.

Monitoring Visits

Monitoring visits will be attended through previous request for an appointment, addressed to the pharmacy staff preferably by e-mail. Visiting hours are Monday through Friday, from 9 to 17h. The e-mail address to request monitoring visits is farmacia.uac@vhir.org.

During in person visits, the monitor will be able to make copies of the proofs of receipt of shipments, if required by the sponsor. However, the sponsor is responsible for preserving the integrity of pharmacy staff personal data, as established by local regulation, when managing signed source documents.

No copies are allowed of internal prescription sheets or any other document that might contain study subjects personal data.

In case a medication relabeling due to expiration date extension is needed, this activity will be performed by the study monitor, who will be in charge of following sponsor procedures and filling in sponsor forms. Delegated pharmacy stall will sign the form to certify supervision and validate the process.

Weekly temperature reports, and IMP stock and accountability, as well as other documents of interest (pharmacy staff CVs and GCP certificates, calibration certificates

and other) can be reviewed and downloaded through the pharmacy online platform, after access request has been received and approved by pharmacy staff.

Remote monitoring visits can be performed through the Fundanet online site, which allows for review of pharmacy records as available in the platform. Remote monitoring visits by phone or teleconference, or monitoring of source documents involving submission of scanned documents are not possible in any case.

Close-up Visits

All spared medication, both used and unused, will be returned to the sponsor. Local destruction requires a previous agreement between sponsor and the pharmacy department.

Upon trial closure, the following pharmacy documents will be filed in the investigator site file:

- Signed and dated shipment packing lists
- Internal prescription sheets (when applicable)
- Final accountability logs, signed and dated by the responsible pharmacist
- Temperature logs, signed and dated by the responsible pharmacist
- Other signed originals with relevant information (i.e. notes to file, temperature excursions, protocol deviations, relabeling documentation)
- List of amendments received throughout the study signed by the responsible pharmacist.