Internal Rules of the clinical trial team of the University Hospitals Leuven (UZL) pharmacy

GENERAL

- The Sponsor agrees to the internally deduplicated temperature monitoring system during storage. (I.e., the pharmacy does not take into account the use of externally supplied continuous temperature loggers (once received) that are permanently present during storage (e.g., Mini-Tag®), nor the use of externally supplied tablets or other devices to monitor temperature during storage.)

- During reconstitution of clinical trial medication, only locally sourced ancillary supplies and equipment from the pharmacy will be used. If the Sponsor cannot agree to this due to compatibility issues, the Sponsor must provide alternative ancillary supplies and equipment. Closed System Transfer Devices (CSTD) are an exception. It is not allowed to use devices provided by the Sponsor. The standard policy of the pharmacy is preparing with 'ChemoClave®' of ICU Medical for both cytotoxic and non-cytotoxic products. If this isn't possible due to very specific reasons (for example compatibility problems), syringe and needle can be used. The pharmacy requires in such specific cases a written motivation of the sponsor.

- Used vials are not stored, but are sent for destruction immediately after a final identity check by the responsible pharmacist due to safety reasons.

- If clinical trial medication needs to be (re)labeled in the pharmacy, the Sponsor must provide their own labels.

- Study-specific training is preferably done by self-study, but can also be done face-to-face or by means of an online meeting by the CRA, but **not by using online training platforms**.

- Documentation of training (e.g., for a new version of the Pharmacy Manual) is done by using our own internal specific 'training registration pharmacy' log.

- It is the Sponsor's responsibility to inform the clinical trial team of the UZL pharmacy in **a timely manner** (at least two months in advance) in the event of a scheduled audit.

DELIVERY

- Clinical trial medication can only be delivered **after** the pharmacy Site Initiation Visit (SIV) has taken place.

- Collection of temperature loggers (e.g., TempTale®) and empty reusable boxes (e.g., Credo Cube™) can be done no earlier than **24 hours after** the delivery in our pharmacy warehouse.

- For each product supplied, a batch release certification, "Certificate of Analysis" (CoA), has be provided for each new batch and each new expiration date in accordance with EU Regulation 536/014 (revised Annex 13 of EU PIC/S GMP Guide and new Annex 16 of EU PIC/S GMP Guide).

DOCUMENTATION

- The Sponsor agrees to the use of internal templates for accountability documents (e.g., Master Investigational Product Inventory Log) and preparation worksheets. These templates will not be adjusted (e.g., addition of supplementary columns) in the event that the relevant additional data have already been documented elsewhere in a structured manner.

- No transfer documents (e.g., chain of custody) are maintained during reconstitution of clinical trial medication in the pharmacy.

- The pharmacy does not prepare a certificate of destruction (but does record the date of sending for destruction on the accountability documents) according to the pharmacy's SOP *STU-APO-08 Destruction of study medication*.

- The Sponsor agrees to the use of internal preparation labels which a.o. include the following data: patient name (no patient study number), name and dose of IMP, and preparation date and time.

- No documentation about delivery and receipt, accountability and (re)labeling will be provided for Standard of Care (SOC) medication. No preparation data and documentation about reconstitution of SOC will be provided.

- The pharmacy does not maintain accountability documentation in the following situations:
  - Medication that is not reimbursed by the Sponsor (e.g., SOC medication);
  - Non-IMP/non-comparator products that are reimbursed by the Sponsor;
  - Patient-specific accountability for clinical trials in which the clinical trial medication is to be dispensed (i.e., without prior reconstitution in the pharmacy).
  - Patient-specific accountability for clinical trials in which the clinical trial medication needs to be reconstituted prior to dispensing (unless the site is blinded, while the pharmacy is unblinded).