Standard Operating Procedures for

Investigational Product Return

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Standard Operating Procedures for

Investigational Product Return

## PURPOSE

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| The purpose of this standard operating procedure (SOP) is to ensure that all Investigational Products (IPs) distributed to the endTB Clinical Trial sites that are damaged or not used, are returned to the Central Medical Store (CMS) of each participating country/Site (as applicable) and stored in a designated area of the CMS pending for destruction. |

## SCOPE

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| This procedure applies to all designated drugs storage locations in the endTB Clinical Trials.  The procedures described in this SOP are valid for both endTB and endTB-Q trials. However, trial specific forms and logs (see appendices listed in section 8) have to be completed separately for each trial. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| **Site Principal Investigator** | * Accountable for the overall IP Management at the Site |
| **Delegated Site Pharmacist** | * Ensure that all IPs are returned to the CMS and stored in a designated separate area pending for destruction. * Ensure returned IP accountability. * Complete the blister pack preparation forms (when applicable) * Complete the Drugs Global Return logs (Appendix A2) |
| **Responsible nurse or study personnel** | * Perform the reconciliation between actual patients returns and Directly Observed Treatment (DOT) cards * Complete the IP Return Form (Appendix A1) (when blister pack not used) |

## DEFINITIONS and ABBREVIATIONS

*See endTB Pharmacy Manual, paragraph 1 definitions and abbreviations.*

## PROCEDURE

All IPs which are returned from the patients or damaged/expired IPs returned from any storage locations must be tracked until destruction.

To enable the accurate tracking of the returned IPs by the **delegated Site Pharmacist**, all used IP containers/Kits provided to the patients (e.g. blister pack (LS, PK, IN, ZA), small dispensing containers (PE), pill planner boxes (video DOT patients in KZ), plastic bags for extra doses) must be returned by the patients to the IPs distribution points (mostly blister packs) or to the DOT corners (mostly small dispensing containers and pill planner boxes).

**Responsible nurses or study personnel** will check coherence between actual patients returns and DOT cards. The **responsible nurses or study personnel** will sign and date the DOT card to document the review and if changes are required, she/he will annotate the DOT card.

IPs returned from the patient (with or without the container/kit) will be subsequently returned to the CMS and stored in a designated separate area pending for destruction.

Returned IPs from storage locations (expired or damaged) will be also returned to the CMS inside original manufacturer box or plastic bag and stored in a designated separate area pending for destruction.

* Returns from the DOT corners (e.g. KZ and PE): the **responsible nurses or study personnel in the ward and/or the DOT corners** should complete an IP Return Form (see Appendix A1) for each patient and an IP Return Form in case of non-patient specific returns (expired or damage IPs). These forms will be sent back with the returned IPs to the institution pharmacy or directly to the CMS. Returns will be stored in a separated, secured and designated area of the CMS labelled as “returns pending destruction”. The **delegated site pharmacy personnel** should record the returns on the Drugs Global Return Log (see Appendix A2).
* Returns from the “IPs distribution points” (e.g. LS, PK, IN, ZA): after checking coherence between actual returns and DOT cards, the **responsible nurses or study personnel** will return the containers/Kits (mostly blister packs) to the CMS. The **delegated site pharmacy personnel** should record the returns on the blister pack preparation forms (see SOP IP-004-CT adapted version for LS, IN, PK and ZA) and the Drugs Global Return Log (see Appendix A2).

Once returned at the CMS, and following accountability checks and internal monitoring (as per the working instruction for Internal monitoring of the pharmacy), IPs will be removed from the containers/kits and will be stored in a separated and designated area of the CMS labelled as “returns pending destruction”.

Empty IP manufacturer’s containers returned form storage location to CMS can be discarded on site immediately.

Empty containers/kits (as blister pack) returned from the patients that do not contain any more returned IP pills/tablets inside can be discarded on site immediately after any foreseen check has been performed.

As a general rule, in case that the IP containers are not empty when returned from the patients, it is forbidden to use the remaining quantities of IPs left in the containers. All non-empty IP containers returned from the patients and containing any returned IP pills/tablets inside should be stored separately in the CMS, waiting for their destruction according to the national destruction guidelines (see SOP IP-006-CT IP Destruction). Returned, unused IP pills/tablets must be labeled with the notice “do not use, to be destroyed”, and they must be stored separately from the on-use stock.

Drugs which have been distributed outside institution or dispensary pharmacy and that are returned to the CMS or institution pharmacy (ies) cannot be re-used. The returned drugs from patients will never be registered as “IN” on the Drugs Global Accountability LOG of the CMS or institution pharmacy (ies).

Note: Some non-empty IP manufacturer’s containers can be transferred from one institution pharmacy to another (in case of early closure of one site for instance) or from CMS of different sites (in case of risk of shortage in one of the site, for instance). These IPs are not considered as returns but as transferred IPs. In this case transfer procedure must be followed as per SOP IP-004-CT IP Distributing, Dispensing, and Accountability.

**Delegated Site Pharmacist or designee** will compile all return drugs in the “Drugs Global Return Log” (Appendix A2) or equivalent system.

## REFERENCES

None

## SUPPORTING DOCUMENTS

* SOP IP-004-CT IP Distributing, Dispensing, and Accountability (endTB Site Study Documents)
* SOP IP-004-CT IP Distributing, Dispensing, and Accountability adapted by country (Central Investigator File)
* SOP IP-006-CT IP Destruction (endTB Site Study Documents)
* Blister pack preparation form (Appendix 2 to IP-004-CT adapted by country, Central Investigator File)
* Supply and request form (Appendix A1 to IP-004-CT IP Distributing, Dispensing, and Accountability)
* Working instruction for Internal Monitoring of the pharmacy adapted by country (Central Investigator File)
* endTB Pharmacy Manual (endTB Site Study Documents)

## APPENDIX

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| **Number** | **Title** |
| endTB A1  endTB-Q A1 | IP-005-CT\_endTB A1- Return Form  IP-005-CT\_endTB-Q A1- Return Form |
| endTB A2  endTB-Q A2 | IP-005-CT\_endTB A2- Drugs Global Return Log  IP-005-CT\_endTB-Q A2- Drugs Global Return Log |