# Standard Operating Procedures for Investigational Product Release

(Greenlight to MSF Logistique for initial IP shipment to participating countries)

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| **SOP Number**: IP-002-CT | **Effective Date**: |
| **Version Number and Date**: 5.0, 01-Jun-2020 | |

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# Standard Operating Procedures for Investigational Product Release

(Greenlight to MSF Logistique for initial IP shipment to study sites)

## PURPOSE

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| The purpose of this standard operating procedure (SOP) is to ensure that sites involved in the endTB Clinical Trials meet all applicable national regulatory requirements and appropriate drug storage conditions before receiving the first shipment of Investigational Products (IPs) for the study. |

## SCOPE

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| This SOP details all the mandatory regulatory and facility requirements to be met prior to the disbursement of the initial shipment of IPs to the designated Central Medical Store (CMS) in each country participating in endTB Clinical Trials.  The procedures described in this SOP are valid for both the 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** | * Complete the Drug storage Assessment Form and IP Release Form * Ensure that all mandatory documentation for regulatory approvals and/or facility requirements are shared with the Central Trial Pharmacist and filed in the Investigator Site File (ISF) and when applicable in the Central Investigator File (CIF) after approval. |
| **Clinical Trial Pharmacist or designee** | * Ensure that all mandatory documentation for regulatory approvals and/or facility requirements are received from the Site * Complete the storage conformity validation part of the Drug storage Assessment Form * Complete the greenlight part of the IP Release Form * Give greenlight to MSF Logistique for initial IP shipment to CMS of each participating country/site (as applicable). |

## DEFINITIONS and ABBREVIATIONS

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

## PROCEDURE

### Drug Storage Assessment

**Delegated Site Pharmacist** must ensure that the storage conditions at the CMS, dispensary and institution pharmacy(ies) fulfill the storage requirements detailed in SOP IP-001-CT IP Storage. The **delegated Site Pharmacist** must assess the drug storage conditions in each of the designated CMS, dispensary and institution pharmacy and complete one Drug storage Assessment Form (Appendix A1) per storage location and per clinical trial. The **delegated Site Pharmacist** must scan the completed Drug storage Assessment Form(s) and email the electronic copy to the **Clinical Trial Pharmacist or designee**.

**Clinical Trial Pharmacist or designee** should review the completed Drug storage Assessment Forms and complete the storage conformity validation part when all drug storage requirements are met.

### Request of IPs Release

**Delegated Site Pharmacist** is responsible for collecting and filing in the appropriate section of Investigator Site File (ISF) and when applicable in the Central Investigator File (CIF) all mandatory regulatory documents required for IP release to the CMS of each participating country/Site (as applicable):

* National approval from Institutional Review Boards (IRB)/ Independent Ethics Committee (IEC).
* Approval from National Regulatory Authorities.
* Copy of Reference Safety Information Booklet for all IPs.
* Curriculum Vitae(s) of the study staff involved in IPs management (current, dated, and signed).
* Proof of delegated site pharmacy staff’s International Conference on Harmonization - Good Clinical Practice (ICH-GCP) and IP-related SOP training records.
* Import license for IPs and ancillary drugs.
* Drug storage Assessment Form(s) is/are completed and conform (see Appendix A1).

Once all the above documents are obtained,the **delegated Site Pharmacist** must complete the “IP Release Form” (see Appendix A2) and submit the scanned copy to the **Clinical Trial Pharmacist or designee** via email.

### Greenlight for IPs release

**Clinical Trial Pharmacist or** **designee** must review the completed IP Release Form and, if it is conform, should give MSF Logistique the greenlight to proceed with the initial shipment of IPs and ancillary drugs to the country. **Clinical Trial Pharmacist or designee** must inform the **delegated Site Pharmacist** of the greenlight in writing.

 The **delegated pharmacy personnel in charge of the CMS** will distribute IPs and ancillary drugs from the CMS (see SOPIP-004-CTIP Distributing, Dispensing, and Accountability) only once the Investigator site initiation visit will be completed and conform (see SOP SS-003-CT Investigator Site Initiation) and the Site Activation letter will be received from the Sponsor.

For any new storage location not approved at the time of IPs release, the corresponding Drug assessment Storage Form has to be submitted and approved by the **Clinical Trial Pharmacist or designee** as described in 5.1 prior to any IPs distribution to this location.

### Filing of IP Release Documentation

**Delegated Site Pharmacist** is responsible for ensuring that the following documents are filed in the Pharmacy Site File (section of the ISF) and when applicable in the CIF:

* Submitted and Approved IP Release Forms (signed by the **Clinical Trial Pharmacist or designee**).
* Copies of Good Manufacturing Practices certificate for each IP, if required by the national authorities for delivering the import permit.
* Copies of Certificate of Pharmaceutical Product or Marketing Authorization for each IP, if required by the national authorities for delivering the import permit.
* List of the delegated site pharmacy staff and their training records on ICH-GCP and IP-related SOPs.
* Initial import license(s) for IPs and ancillary drugs.
* Completed “Drug storage Assessment Form” with conformity validation signed by the **Clinical Trial Pharmacist or designee**.

## REFERENCES

None

## SUPPORTING DOCUMENTS

* endTB Pharmacy Manual (endTB Site Study Documents)
* SOP IP-001-CT IP Storage (endTB Site Study Documents)
* SOP IP-004-CT IP Distributing, Dispensing, and Accountability (endTB Site Study Documents)
* SOP SS-003-CT Investigator Site Initiation (endTB Trial Master File)

## APPENDIX

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| **Number** | **Title** |
| endTB A1  endTB-Q A1 | IP-002-CT\_endTB A1- Drug storage Assessment Form  IP-002-CT\_endTB-Q A1- Drug storage Assessment Form |
| endTB A2  endTB-Q A2 | IP-002-CT\_endTB A2- IP Release Form  IP-002-CT\_endTB-Q- A2 IP Release Form |