Standard Operating Procedure: Drug Accountability Procedure

Purpose

This SOP outlines the procedural steps for study drug management. It aims to ensure appropriate implementation of specific drug accountability procedures of the study protocol across all study sites.

Intended Users

Clinical trial pharmacist, clinical trial staff, study/trial nurse, trial coordinator

Responsibility

1. The principal investigator or designee has the ultimate responsibility for the accountability of the study drugs.
2. The trial coordinator, the pharmacist, study clinicians and study nurses are responsible for keeping accurate records with sufficient information to provide a full audit trail from the receipt of the study products to their removal from site or destruction.

Definitions

SOP	Study Operating Procedure

Required Materials

Lockable storage cabinets.

Study files

Drug accountability logs

Drug shipment records

Procedure

a) Accountability for study drugs at the clinical trial pharmacy

1. Before study start, all study drugs will be kept by the clinical trial pharmacy. The clinical trial pharmacy will maintain drug shipment records as well as a temperature log to ensure that the drugs are maintained in the appropriate temperature.

2. At study initiation, all drugs will be issued to study sites by the pharmacist at the clinical trials pharmacy through the study coordinator. Documentation of the drugs issued to the sites will be maintained by the pharmacist at the clinical trials office. The study sites will also maintain documentation of drugs received at site.

b) Accountability for study drugs at the study sites

1. The study sites will use the clinical trial pharmacy for storage of study drugs. Alternatively, they can utilize the clinical trial office for storage of drugs.

2. In the wards, the study drugs will be stored separately from normal stock in a drug cabinet with restricted access.
3. Documentation of drug movement between the pharmacy/trial office and the ward will be completed in separate drug accountability logs for Pancreatic enzymes/Placebo (20g of granules/bottle) and Ursodeoxycholic acid/Placebo (reflecting the strength of 250mg/5ml) (See drug accountability log upon admission/hospitalization appendix 1.2).
4. All drug will be received at study sites already pre-labelled with a randomization number.
5. Study drugs such as Pancreatic enzymes/Placebo and Ursodeoxycholic acid/Placebo will be received in the sites' clinical trial office by the study staff. Upon receipt of the study drugs, ensure that the information on the drug reception log (appendix 1.1) matches exactly with what has been sent to site, including, Lot/Batch Number and quantity. The receiving study staff will sign on the drug reception log appendix 1 after confirmation.
6. The study drugs will be collected from the clinical trial office/pharmacy for use in the ward by the study nurse. Documentation of drug movement between the clinical trial office and the ward will be completed in separate drug accountability logs for each drug (drug accountability log appendix 1.2),
    1. Pancreatic enzymes/Placebo containing 20g of enzyme granules per bottle. Scoops of granules will be issued according to weight bands.
    2. Ursodeoxycholic acid/Placebo (reflecting the strength of 250mg/5ml) will have 50ml in each bottle. Volume will be issued according to weight Bands.
7. The drug bottles will be retained for checking during drug accountability assessment by study monitors
8. At discharge, study drugs will be issued by the study staff for a total of 21 days in the following manner.
    1. One-two bottles of pancreatic enzymes will be issued according to weight bands
    2. Up to two bottles of Ursodeoxycholic acid/Placebo will be issued according to weight bands
9. Documentation of drug issuance upon discharge will be completed in separate drug accountability logs for each drug (drug accountability log upon discharge appendix 1.3).
10. At discharge, clear instructions will be given for the patient to return the bottles on Day 21 follow-up.

Appendices

Appendix 1.1: Study drug reception log

PB-SAM STUDY SHIPMENT LOG
SITE :

Pancreatic Enzyme/Placebo			**Ursodeoxycholic acid/Placebo**			**Issued by (Pharmacy Staff Initials)**	**Checked by (Staff Initials)**	**Received by (Staff Initials)**
Batch No:			**Batch No:**					
Expiry:			**Expiry:**					
	Strength in g	No of bottles		Strength in mg/ml	No of bottles			

Appendix 1.2 Study Drug Accountability Log upon admission/hospitalization

Drug: Pancreatic enzyme/Placebo					
Strength:		**Batch:**		**Expiry date:**	
Date:	**Opening balance:**	**Received**	**Issued**	**Total in hand**	**Staff initials**

Drug: Ursodeoxycholic acid/Placebo					
Strength:		**Batch:**		**Expiry date:**	
Date:	**Opening balance:**	**Received**	**Issued**	**Total in hand**	**Staff initials**

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Appendix 1.3 Study Drug Accountability Log on discharge

Drug: Pancreatic enzyme/Placebo					
Strength:		**Batch:**		**Expiry date:**	
Date:	**Opening balance:**	**Received**	**Issued**	**Total in hand**	**Staff initials**

Drug: Ursodeoxycholic acid/Placebo					
Strength:		**Batch:**		**Expiry date:**	
Date:	**Opening balance:**	**Received**	**Issued**	**Total in hand**	**Staff initials**

References

PB-SAM study protocol.

Document History

Version	Author	Approved by	Dated
1.01 CHAIN PB-SAM Drug accountability SOP	Amber Farooqui		29-01-2021

Site Training Record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM

SOP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SOP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SOP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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