



Standard Operating Procedure: Randomization and Labelling

Purpose

This SOP describes the standard procedures for the preparation of randomization envelopes and randomization drugs boxes for study participants of the PB-SAM trial.

Intended User

study statistician, data manager, Clinical trial coordinator, clinical trial staff, trial pharmacist involved in randomization

Responsibility

1. This SOP applies to the PB-SAM study statistician, data manager, coordinator and other staff involved in the randomization of eligible study participants.
2. The Principal Investigator retains the overall responsibility for the implementation of this SOP.

Definitions

CRF: Case Report Form
SOP: Standard Operating Procedure

Required Materials

Randomization envelopes
Randomization cards
Randomization labels
Randomization list

Procedure

1. The PB-SAM trial will investigate two separate pediatric formulations of pancreatic enzymes and ursodeoxycholic acids in a 2x2 factorial design randomized controlled clinical trial. A factorial design allows more than one intervention to be tested and is useful in assessing a potential package of care.

Two randomizations will be made:

- Pancreatic enzyme/Placebo
 - Ursodeoxycholic acid/Placebo
2. Two independent randomization lists will be generated using STATA with each using a different seed; one for Pancreatic enzyme/Placebo and the other for Ursodeoxycholic acid/Placebo



CHAIN PB-SAM

Standard Operating Procedure: Randomization and Labelling

3. Each randomization list will have 1200 allocations with randomization done in random block sizes.
4. Envelopes will be used for the random allocation of Pancreatic enzyme/Placebo while the Ursodeoxycholic acid/Placebo randomization will be implemented using labels stuck on drug boxes and bottles.
5. Once the randomization lists have been generated, labels will be prepared separately for each arm of the two randomizations.
6. For Pancreatic enzyme/Placebo randomization 3 labels will be generated:
 - A label that will be stuck on the outside of the envelope. This will have a unique study ID.
 - A label that will be stuck on the randomization card. This will have a unique study ID as well as the arm (Pancreatic enzyme/Placebo) to which the study participant has been allocated to.
 - An extra label that will be put in the envelope. This will be stuck on the first page of the CRF during enrolment.
7. Labelling of randomization envelopes for Pancreatic enzyme/Placebo
 - i. The study numbers for Pancreatic enzyme will be separated from those of Placebo.
 - ii. Labels with the study number and the allocation to Pancreatic enzyme will be printed and stuck to the envelope and randomization card at a different time from study numbers randomized to Placebo.

Example of a label to be stuck on an envelope

PB-SAM K0001

Example of a label for a study number randomized to Pancreatic enzyme to be stuck on a card

K0001 Pancreatic enzyme

- iii. Labels for study numbers randomized to Placebo will then be printed out and stuck to the envelopes and randomization card.

CHAIN PB-SAM
Standard Operating Procedure: Randomization and Labelling



Example of a label to be stuck on an envelope

PB-SAM K0052

Example of a label to be stuck on a card for a study number randomized to Placebo.

K0052 Placebo

- iv. Another label will be printed out with the study number and the randomization to which it applies (Pancreatic enzyme/Placebo) and will be put in the envelope to be later stuck on the CRF when the envelope is opened during enrolment.

Example of a label to be stuck on the CRF

K0005	PEP
-------	-----

- v. Once the randomization envelopes for Pancreatic enzyme/Placebo-1 have been prepared, they will be put together and arranged sequentially.
8. For labelling of Ursodeoxycholic acid/Placebo, three labels will be used for every Ursodeoxycholic acid/Placebo drug box
- i. A label stuck on the drug bottle.
 - ii. A label stuck on the drug box
- (These two labels will have only the unique study ID.)
- iii. Another label will be placed within the drug box and will be stuck on the first page of the CRF. This label will have the unique study ID as well as the randomization to which it applies. In this case the Ursodeoxycholic acid/Placebo randomization
 - i. From the randomization list, study numbers allocated to Ursodeoxycholic acid and Placebo will be separated.
 - ii. The labels will then be printed out and stuck to the bottles and drug boxes at different instances. Each randomization arm (Ursodeoxycholic acid and



CHAIN PB-SAM

Standard Operating Procedure: Randomization and Labelling

Placebo) will have a day dedicated to it for sticking the labels on the drug bottles and drug boxes. This is to avoid mislabeling. The labels for the drug boxes for Ursodeoxycholic acid/Placebo will have the trial name and study ID

Example of a label for Ursodeoxycholic acid/Placebo to be stuck on the box

PB-SAM K0003

- iii. The labels that will be stick on the drug bottle will have only the study ID and will appear as below.

K0003

- iv. Another label with the study ID and the randomization to which it applies (Ursodeoxycholic acid/Placebo) will be printed out and put in the drug box. This will be stuck on the first page of the CRF.

Example of the label to be stuck on the first page of the CRF.

K0003	Ursodeoxycholic acid/Placebo
-------	------------------------------

- v. When the Ursodeoxycholic acid drug boxes and the placebo drugs have been labelled, they will all be put together and arranged sequentially.
9. Both the randomization envelopes and the drug boxes will be transported to site based on the study IDs allocated for each site.

Appendices

None

References

PB-SAM protocol

CHAIN PB-SAM
Standard Operating Procedure: Randomization and Labelling



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)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			