UKALL14 DRUG SUPPLY GUIDELINES

CONTACT DETAILS

For further information on trial drugs, trial protocol, dosing, supply drug and distribution queries please contact:

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VERSION HISTORY

Version number	Date	Summary of changes from previous version	Changes made by	Released to sites on
1.0	29nov10	New Document	N/A	Release of ISF/PSF
1.1	21jul11	Change to Palifermin Ordering Procedure	SP	21jul11
2.0	11.09.12	Change to Rituximab delivery times and change to Oncaspar ordering procedure	JG	19sep12
2.1	25.02.14	Removal of any statements relating to Rituximab coming off patent.	SP	25feb14

UKALL14 DRUG SUPPLY GUIDELINES

CONTENTS

1.0 OVERVIEW

1.1 APPLICABILITY

These drug supply guidelines are applicable to the Lead Pharmacist and any other member of staff who has responsibilities in conducting UKALL14.

1.2 TRIAL INVESTIGATIONAL MEDICINAL PRODUCT

In accordance with the Clinical Trial Authorisation (CTA) granted by the MHRA on the 13th January 2010 the following are classed as Investigational Medicinal Products (IMPs): **Rituximab** (Mabthera®), **Pegaspargase** (Oncaspar®), **Nelarabine** (Atriance®) and **Palifermin** (Kepivance®).

For UKALL14 the following drugs will be provided free of charge to site pharmacies for the duration of the trial:

- Rituximab (IMP) – provided by Roche Products Ltd
- Nelarabine (IMP) – provided by GlaxoSmithKline UK Ltd
- Palifermin (IMP) provided by Swedish Orphan Biovitrum

The following drugs will be provided at sites own cost to site pharmacies for the duration of the trial:

- Oncaspar (IMP) provided by sigma-tau Pharma Ltd

All other drugs specified in the protocol are standard treatment for this disease and are classified as Non Investigational Medicinal Products (NIMPs). NIMPs **will not be** provided for the trial and must be provided from pharmacy stock at participating sites. Pharmacies must ensure they have adequate supplies for the trial.

Sites are responsible for putting systems for traceability of NIMPs in place.

- Daunorubicin (NIMP)
- Vincristine (NIMP)
- Dexamethasone (NIMP)
- Methotrexate (NIMP)
- Imatinib (NIMP)
- Cyclophosphamide (NIMP)
- Cytarabine (NIMP)
- Mercaptopurine (NIMP)
- Etoposide (NIMP)
- Fludarabine (NIMP)
- Melphalan (NIMP)
- Alemtuzumab (NIMP)
- Prednisolone (NIMP)

1.3 PHARMACY REGISTRATION & SET-UP

A designated member of the pharmacy staff, who takes overall responsibility for all pharmacy aspects of the clinical trial should be identified and will be assigned the Lead Pharmacist. This person will be listed on the main Site Delegation Log.

The following stages are required prior to site authorisation:

- Approvals: Local R & D approvals & signed Clinical Trial Site Agreement.
- Confirmation of receipt of Investigator Site File and Pharmacy Site File documentation.
- Site (Principal Investigator & Research Team) & Pharmacy Initiation.

UCL CTC will perform a Site Initiation meeting with the lead Pharmacist (or delegate). This will take place prior to authorisation to recruit patients.

Once a site is ready for activation (pending Site Initiation), a Pharmacy File will be sent to the Lead Pharmacist from UCL CTC. The contents of the file will include copies of forms for drug ordering and accountability logs for UKALL14. All trial related documentation should be retained in the Pharmacy Site File (or a statement of its location).

All sites will need to provide UCL CTC with the following information prior to activation:

- Site Name
- PI Name
- PI GMC Number
- Site Address
- Pharmacy Contact Name, telephone number, email address
- Pharmacy Delivery Address
- Pharmacy specific drug delivery instructions
- UDG order number (If site does not have an account with UDG- you will need to set one up)

When all stages listed above are complete, UCL CTC will formally notify the Site and Pharmacy that potential trial participants can be approached, by sending a site activation letter. The Site Pharmacy will then be able to order the initial supply of trial specific **Oncaspar** only. (Please see Section 2.2).

1.4 Patient Cards

Trial participants will be issued with a **Patient Card** at time of trial registration. The card details Patient Name, Trial Number, Sponsor name & contact details, Name of Investigator, Telephone number and address. These will be issued to trial participants by attending clinical staff at time of registration. Blank patient cards will be supplied to sites at initiation.

2.0 INDIVIDUAL DRUG INFORMATION:

2.1 RITUXIMAB

2.1.1 SUPPLY OF RITUXIMAB

Rituximab will be supplied free of charge by Roche Products Ltd.

Following activation of a site, the Lead Pharmacist will receive (from Roche) a site specific pre-populated **electronic drug order form** for Rituximab, along with a blank Certificate of Clinical Trial Supply form.

Once a site Pharmacy has confirmation from the Research Team of a patient randomisation to arm B2 (Phase 1 Induction plus Rituximab), the electronic order form should be completed and emailed to welwyn.cpg_general@roche.com.

Orders placed before 4pm will be processed for next day delivery. Orders placed after 4pm will be delivered within 2 days. Orders placed before 4pm on a Friday will be delivered on a Monday. Sites in remote areas or in Northern Ireland should allow additional time for delivery and expected delivery dates can be provided at the time of placing the order.

***Rituximab is given on Day 3 of Induction, therefore the order must be sent to Roche as soon as possible after randomisation, to allow for delivery.**

The above delivery arrangements should ensure that Rituximab arrives at site in time to give the Day 3 dose. If the site anticipates that there may be problems obtaining Rituximab in time for the Day 3 dose, UCL CTC should be contacted to discuss alternative arrangements which may include expedited delivery or permission to order Rituximab before randomisation.

Rituximab will be delivered labelled as commercial stock and therefore it is important that it is segregated on receipt. Copies of all **Drug Order** forms must be retained in the relevant section of Pharmacy Site File.

2.1.2 RECEIPT OF RITUXIMAB

Following delivery of Rituximab, please inspect and verify the contents and conditions of the shipment. It is important to log receipt of each batch of Rituximab received on the Accountability Log in a timely manner and store the drug appropriately. Pharmacy must confirm receipt of Rituximab by completing the **Certificate of Clinical Trial Supply** form and returning it directly by fax to Roche on 01707 383 146. Pharmacy must also file a copy of the **Certificate of Clinical Trial Supply** form in section 4.3 of the Pharmacy File.

If the Rituximab has not arrived by the expected date and time, pharmacy must contact UCL CTC in the first instance. Details can be found at the beginning of this document.

If the Rituximab arrives damaged, pharmacy must detail this in the **Certificate of Clinical Trial Supply** form, quarantine the product, and contact UCL CTC. All correspondence relating to delivery problems or any other problem with respect to Rituximab should also be documented and filed in section 4.3 of the Pharmacy Site File.

2.1.3 LABELLING OF RITUXIMAB

Rituximab will be labelled as commercial stock. Therefore Pharmacy **MUST** add a label upon receipt to designate its use in a clinical trial. Approved wording for labels is provided in section 4.2 of the Pharmacy Site File. Pharmacy must supply a copy of the label to be used to UCL CTC.

For dispensing, Pharmacy must label the prescription with the minimum suggested labelling content as below:

FOR CLINICAL TRIAL USE ONLY
UKALL14 (EudraCT No 2009-012717-22)
Principal Investigator (Provide name of the Site PI for the UKALL14 Trial as drug information contact)
Subject Number (patient's trial number)
Cycle/visit details

2.1.4 DISPENSING & RECORDING OF RITUXIMAB

The Investigator/additional clinicians are responsible for ensuring Rituximab is prescribed appropriately for a patient on the trial. Please refer to the trial protocol for dosing schedules for Rituximab.

Sites should develop their own trial specific prescriptions. Prescriptions must be signed by an appropriate member of staff (as detailed on the staff delegation log) and a copy must be retained in the Pharmacy Site File.

The Rituximab **Master Accountability Log** must be completed to record each dose of Rituximab dispensed for each trial participant. This must be retained in the relevant section of the Pharmacy Site File, and a copy must be returned to UCL CTC upon request.

Trial specific Rituximab must not be prescribed to patients who are not registered in the UKALL14 Trial.

2.1.5 ACCOUNTABILITY OF RITUXIMAB

It is the responsibility of the pharmacist to maintain drug accountability records for Rituximab. The pharmacist must record the receipt and dispensing of Rituximab on the appropriate **Accountability Log** found in section 4.6 of the Pharmacy Site File. UCL CTC will request copies of the accountability logs as necessary during the course of the trial.

2.1.6 HANDLING & STORAGE OF RITUXIMAB

Please refer to the current SmPC for Rituximab for details of storage, handling and incompatibilities.

Rituximab exposed to temperatures outside of the permitted excursions must be quarantined. UCL CTC must be notified and will liaise with Roche to obtain advice on its use. The **Notification of Temperature Deviation** form found in section 4.4 of the Pharmacy Site File must be completed and faxed or emailed to UCL CTC.
Rituximab supplied for the trial should be ring fenced in a separate area to non-trial products. Details of the storage location should be recorded in the Pharmacy Site File.
Details of temperature monitoring systems for the area where the trial specific Rituximab is stored should be retained in the Pharmacy Site File.

2.1.7 RECALL OF RITUXIMAB

In the event of Rituximab recall, UCL CTC will notify pharmacy and liaise with Roche to ensure replacement product is supplied.

2.1.8 RECONCILIATION OF RITUXIMAB

Rituximab reconciliation will be performed by UCL CTC. To facilitate this, pharmacists must return the following documents to UCL CTC upon request:

- Drug Order form (section 4.3 of the Pharmacy Site File)
- Drug Receipt form (section 4.3 of the Pharmacy Site File)
- Master Rituximab Accountability Log (section 4.6 of the Pharmacy Site File)

2.1.9 DESTRUCTION OF RITUXIMAB

Once reconciled the Rituximab can be destroyed using approved local pharmacy policy and a **Destruction Log** found in section 4.6 of the Pharmacy Site File must be completed and filed in the relevant section. NB. No trial drug is to be returned to Roche.

Destruction should also be recorded in the **Drug Accountability Log** found in section 4.6 of the Pharmacy Site File. Expired trial specific Rituximab must be quarantined. Notify UCL CTC who will liaise with Roche for advice on its use.

Please include a copy of the local Drug Destruction Procedure/Policy in section 4.6 of the Pharmacy Site File.

2.2 ONCASPAR

2.2.1 SUPPLY OF ONCASPAR

Oncaspar will be supplied at cost to sites by Sigma Tau Pharma Ltd and will be distributed by Movianto.

Oncaspar must be ordered directly from Movianto using the **Oncaspar Drug Order** form. Sites are permitted to order an initial supply of Oncaspar following receipt of the Drug Order form. This form will be forwarded to the Lead Pharmacist (or delegate) when a Site is authorised to approach patients. This is to ensure Trial stock does not arrive at Site before all approvals are in place.

Following activation of a site, the Lead Pharmacist will be instructed to order the initial supply of 2 vials of Oncaspar for the site.

1. Complete the site specific order form provided to the Lead Pharmacist in the Pharmacy Site File and email the order form to Movianto at orders.uk@movianto.com copying in ctc.ukall14@ucl.ac.uk.
2. If email is not possible, the form may be faxed to Movianto on **01234 248705**
3. Sites will receive delivery within 48 hours of placing the order. Orders received on a Friday will be delivered on the following Monday or Tuesday.

Site pharmacies will be responsible for maintaining an adequate supply of Oncaspar for each patient randomised on the UKALL14 Trial at their site. Re-ordering of Oncaspar is to be done by the site pharmacy using the Drug Order form.

To re-order:
Site pharmacies must complete the **Drug Order** form found in section 4.3 of the Pharmacy Site File and fax or email it directly to Movianto (at orders.uk@movianto.com copying in ctc.ukall14@ucl.ac.uk) for Oncaspar every time a new patient is randomised at site. Sites will receive delivery within 48 hours of placing the order. Orders received on a Friday will be delivered on the following Monday or Tuesday.

Amounts to re-order:
When re-ordering further supplies of Oncaspar, please ensure that a minimum order of 2 vials of Oncaspar is made for each re-order.

Oncaspar will be delivered labelled as commercial stock and therefore it is important that it is segregated on receipt.

Copies of all **Drug Order** forms must be retained in the relevant section of Pharmacy Site File.

2.2.2 RECEIPT OF ONCASPAR

It is important to log receipt of each batch of Oncaspar received on the Accountability Log in a timely manner and store the drug appropriately.

If the Oncaspar has not arrived by the expected date and time, pharmacy must contact UCL CTC in the first instance. Details can be found at the beginning of this document.

If the Oncaspar arrives damaged, pharmacy must quarantine the product, and contact UCL CTC. All correspondence relating to delivery problems or any other problem with respect to Oncaspar should also be documented and filed in section 4.3 of the Pharmacy Site File.

2.2.3 LABELLING OF ONCASPAR

Oncaspar will be labelled as commercial stock. Therefore Pharmacy **MUST** add a label upon receipt to designate its use in a clinical trial. Approved wording for labels is provided in section 4.2 of the Pharmacy Site File. Pharmacy must supply a copy of the label to be used to UCL CTC.

For dispensing, Pharmacy must label the prescription with the minimum suggested labelling content as below:

FOR CLINICAL TRIAL USE ONLY
UKALL14 (EudraCT No 2009-012717-22)
Principal Investigator (Provide name of the Site PI for the UKALL14 Trial as drug information contact)
Subject Number (patient's trial number)
Cycle/visit details

2.2.4 DISPENSING & RECORDING OF ONCASPAR

The Investigator/additional clinician are responsible for ensuring Oncaspar is prescribed appropriately for a patient on the trial. Please refer to the trial protocol for dosing schedules for Oncaspar.

Sites should develop their own trial specific prescriptions. Prescriptions must be signed by an appropriate member of staff (as detailed on the staff delegation log) and a copy must be retained in the Pharmacy Site File.

The Oncaspar **Master Accountability Log** must be completed to record each dose of Oncaspar dispensed for each trial participant. This must be retained in the relevant section of the Pharmacy Site File, and a copy must be returned to UCL CTC upon request.

Trial specific Oncaspar must not be prescribed to patients who are not registered in the UKALL14 Trial.

2.2.5 ACCOUNTABILITY OF ONCASPAR

It is the responsibility of the pharmacist to maintain drug accountability records for Oncaspar The pharmacist must record the receipt and dispensing of Oncaspar on the appropriate **Accountability Log** found in section 4.6 of the Pharmacy Site File. UCL CTC will request copies of the accountability logs as necessary during the course of the trial.

2.2.6 HANDLING & STORAGE OF ONCASPAR

Please refer to the current SmPC for Oncaspar for details of storage, handling and incompatibilities.

Details of excursions within permitted range must be documented in Pharmacy Site File. Oncaspar exposed to temperatures outside of the permitted excursions must be quarantined. UCL CTC must be notified and will liaise with sigma-tau Pharma Ltd to obtain advice on its use. The **Notification of Temperature Deviation** form found in section 4.4 of the Pharmacy Site File must be completed and faxed or emailed to UCL CTC.

Oncaspar supplied for the trial should be ring fenced in a separate area to non-trial products. Details of the storage location should be recorded in the Pharmacy Site File.

Details of temperature monitoring systems for the area where the trial specific Oncaspar is stored should be retained in the Pharmacy Site File.

2.2.8 RECALL OF ONCASPAR

In the event of Oncaspar recall, UCL CTC will notify pharmacy and liaise with sigma-tau Pharma Ltd to ensure replacement product is supplied.

2.2.9 RECONCILIATION OF ONCASPAR

Oncaspar reconciliation will be performed by UCL CTC. To facilitate this, pharmacists must return the following documents to UCL CTC upon request:

- Drug Order form (section 4.3 of the Pharmacy Site File)
- Drug Receipt form (section 4.3 of the Pharmacy Site File)
- Master Oncaspar Accountability Log (section 4.6 of the Pharmacy Site File)

2.2.10 DESTRUCTION OF ONCASPAR

Once reconciled the Oncaspar can be destroyed using approved local pharmacy policy and a **Destruction Log** found in section 4.6 of the Pharmacy Site File must be completed and filed in the relevant section of the Pharmacy Site File. NB. No trial drug is to be returned to sigma-tau Pharma Ltd or Movianto.

Destruction should also be recorded in the **Drug Accountability Log** found in section 4.6 of the Pharmacy Site File.

Expired trial specific Oncaspar must be quarantined. Notify UCL CTC who will liaise with sigma tau Pharma Ltd for advice on its use.

Please include a copy of the local Drug Destruction Procedure/Policy in section 4.6 of the Pharmacy Site File, and ensure the UCL CTC has been sent a copy.

2.3 NELARABINE

2.3.1 SUPPLY OF NELARABINE

Nelarabine will be supplied free of charge by GlaxoSmithKline.

Nelarabine must be ordered from GlaxoSmithKline using the **Nelarabine Drug Order** form. This form will be forwarded to the Lead Pharmacist (or delegate) when a Site is authorised to approach patients. This is to ensure Trial stock does not arrive at Site before all approvals are in place.

Once a site Pharmacy has confirmation of randomisation from the Research Team of a patient to arm T2 (Phase 2 Induction plus Nelarabine) please follow the process below:

1. Complete the Nelarabine order form and email to ctc.ukall14@ucl.ac.uk
2. The UKALL14 Trial team will forward your order on to GSK.
3. Nelarabine stock will be delivered within 3 working days.

Nelarabine will be delivered labelled as commercial stock and therefore it is important that it is segregated on receipt.

Copies of all **Drug Order** forms must be retained in the relevant section of Pharmacy Site File.

2.3.2 RECEIPT OF NELARABINE

It is important to log receipt of each batch of Nelarabine received on the Accountability Log in a timely manner and store the drug appropriately.

If the Nelarabine has not arrived by the expected date and time, pharmacy must contact UCL CTC in the first instance. Details can be found at the beginning of this document

If the Nelarabine arrives damaged, pharmacy must quarantine the product, and contact UCL CTC. All correspondence relating to delivery problems or any other problem with respect to Nelarabine should also be documented and filed in section 4.3 of the Pharmacy Site File.

2.4 LABELLING OF NELARABINE

Nelarabine will be labelled as commercial stock. Therefore Pharmacy **MUST** add a label upon receipt to designate its use in a clinical trial. Approved wording for labels is provided in section 4.2 of the Pharmacy Site File. Pharmacy must supply a copy of the label to be used to UCL CTC.

For dispensing, Pharmacy must label the prescription with the minimum suggested labelling content as below:

FOR CLINICAL TRIAL USE ONLY
UKALL14 (EudraCT No 2009-012717-22)
Principal Investigator (Provide name of the Site PI for the UKALL14 Trial as drug information contact)
Subject Number (patient's trial number)
Cycle/visit details

2.5 DISPENSING & RECORDING OF NELARABINE

The Investigator/additional clinicians are responsible for ensuring Nelarabine is prescribed appropriately for a patient on the trial. Please refer to the trial protocol for dosing schedules for Nelarabine.

Sites should develop their own trial specific prescriptions. Prescriptions must be signed by an appropriate member of staff (as detailed on the staff delegation log) and a copy must be retained in the Pharmacy Site File.

The Nelarabine **Master Accountability Log** must be completed to record each dose of Nelarabine dispensed for each trial participant. This must be retained in the relevant section of the Pharmacy Site File, and a copy must be returned to UCL CTC upon request.

Trial specific Nelarabine must not be prescribed to patients who are not registered in the UKALL14 Trial.

2.6 ACCOUNTABILITY OF NELARABINE

It is the responsibility of the pharmacist to maintain drug accountability records for Nelarabine The pharmacist must record the receipt and dispensing of Nelarabine on the appropriate **Accountability Log** found in section 4.6 of the Pharmacy Site File. The UCL CTC will request copies of the accountability logs as necessary during the course of the trial.

2.7 HANDLING & STORAGE OF NELARABINE

Please refer to the current SmPC for Nelarabine for details of storage, handling and incompatibilities.

Nelarabine supplied for the trial should be ring fenced in a separate area to non-trial products. Details of the storage location should be recorded in the Pharmacy Site File.
Details of temperature monitoring systems for the area where the trial specific Nelarabine is stored should be retained in the Pharmacy Site File.

2.8 RECALL OF NELARABINE

In the event of Nelarabine recall, UCL CTC will notify pharmacy and liaise with GlaxoSmithKline to ensure replacement product is supplied.

2.9 RECONCILIATION OF NELARABINE

Nelarabine reconciliation will be performed by UCL CTC. To facilitate this, pharmacists must return the following documents to UCL CTC upon request:

- Drug Order form (section 4.3 of the Pharmacy Site File)
- Drug Receipt form (section 4.3 of the Pharmacy Site File)
- Master Accountability Log (section 4.6 of the Pharmacy Site File)

2.10 DESTRUCTION OF NELARABINE

Once reconciled the Nelarabine can be destroyed using approved local pharmacy policy and a **Destruction Log** found in section 4.6 of the Pharmacy Site File must be completed and filed in the relevant section of the Pharmacy Site File. NB. No trial drug is to be returned to GlaxoSmithKline.

Destruction should also be recorded in the **Drug Accountability Log** found in section 4.6 of the Pharmacy Site File. Expired trial specific Nelarabine must be quarantined. Notify UCL CTC who will liaise with GlaxoSmithKline for advice on its use.
Please include a copy of the local Drug Destruction Procedure/Policy in section 4.6 of the Pharmacy Site File.

2.4 PALIFERMIN

2.4.1 INITIAL SUPPLY OF PALIFERMIN

Palifermin will be supplied free of charge by Swedish Orphan Biovitrum.

Palifermin must be ordered directly from Swedish Orphan Biovitrum using the **Palifermin Drug Order** form. This form will be forwarded to the Lead Pharmacist (or delegate) when a Site is authorised to approach patients. This is to ensure Trial stock does not arrive at Site before all approvals are in place.

Once a site Pharmacy has confirmation of a patient's allocation to a myeloablative transplant, please follow the order process below:
Complete the Palifermin order form and email Peter.Luhrs@sobi.com copying in ctc.ukall14@ucl.ac.uk.
Palifermin will be delivered within 5 working days.

Palifermin will be delivered labelled as commercial stock and therefore it is important that it is segregated on receipt.

Copies of all **Drug Order** forms must be retained in the relevant section of Pharmacy Site File.

2.4.2 RECEIPT OF PALIFERMIN

It is important to log receipt of each batch of Palifermin received on the Accountability Log in a timely manner and store the drug appropriately.

If the Palifermin has not arrived by the expected date and time, pharmacy must contact UCL CTC in the first instance.

If the Palifermin arrives damaged, pharmacy must quarantine the product, and contact UCL CTC. All correspondence relating to delivery problems or any other problem with respect to Palifermin should also be documented and filed in section 4.3 of the Pharmacy Site File.

2.4.3 LABELLING OF PALIFERMIN

Palifermin will be labelled as commercial stock. Therefore Pharmacy **MUST** add a label upon receipt to designate its use in a clinical trial. Approved wording for labels is provided in section 4.2 of the Pharmacy Site File. Pharmacy must supply a copy of the label to be used to UCL CTC.

For dispensing, Pharmacy must label the prescription with the minimum suggested labelling content as below:
FOR CLINICAL TRIAL USE ONLY
UKALL14 (EudraCT No 2009-012717-22)
Principal Investigator (Provide name of the Site PI for the UKALL14 Trial as drug information contact)
Subject Number (patient's trial number)
Cycle/visit details

2.4.4 DISPENSING & RECORDING OF PALIFERMIN

The Investigator/additional clinicians are responsible for ensuring Palifermin is prescribed appropriately for a patient on the trial. Please refer to the trial protocol for dosing schedules for Palifermin.
Sites should develop their own trial specific prescriptions and a copy should be sent to CTC for information.
Prescriptions must be signed by an appropriate member of staff (as detailed on the staff delegation log) and a copy must be retained in the Pharmacy Site File.

The Palifermin **Master Accountability Log** must be completed to record each dose of Palifermin dispensed for each trial participant. This must be retained in the relevant section of the Pharmacy Site File, and a copy must be returned to UCL CTC upon request.

Trial specific Palifermin must not be prescribed to patients who are not registered in the UKALL14 Trial.

2.4.5 ACCOUNTABILITY OF PALIFERMIN

It is the responsibility of the pharmacist to maintain drug accountability records for Palifermin. The pharmacist must record the receipt and dispensing of Palifermin on the appropriate **Accountability Log** found in section 4.6 of the Pharmacy Site File. UCL CTC will request copies of the accountability logs as necessary during the course of the trial.

2.4.6 HANDLING & STORAGE OF PALIFERMIN

Please refer to the current SmPC for Palifermin for details of storage, handling and incompatibilities.

Palifermin exposed to temperatures outside of the permitted excursions must be quarantined. UCL CTC must be notified and will liaise with Swedish Orphan Biovitrum to obtain advice on its use. The **Notification of Temperature Deviation** form found in section 4.4 of the Pharmacy Site File must be completed and faxed or emailed to UCL CTC.
Palifermin supplied for the trial should be ring fenced in a separate area to non-trial products. Details of the storage location should be recorded in the Pharmacy Site File.
Details of temperature monitoring systems for the area where the trial specific Palifermin is stored should be retained in the Pharmacy Site File.

2.5 RECALL OF PALIFERMIN

In the event of Palifermin recall, UCL CTC will notify pharmacy and liaise with Swedish Orphan Biovitrum to ensure replacement product is supplied.

2.6 RECONCILIATION OF PALIFERMIN

Palifermin reconciliation will be performed by UCL CTC. To facilitate this, pharmacists must return the following documents to UCL CTC upon request:

- Drug Order form (section 4.3 of the Pharmacy Site File)
- Drug Receipt form (section 4.3 of the Pharmacy Site File)
- Master Palifermin Accountability Log (section 4.6 of the Pharmacy Site File)

2.7 DESTRUCTION OF PALIFERMIN

Once reconciled the Palifermin can be destroyed using approved local pharmacy policy and a **Destruction Log** found in section 4.6 of the Pharmacy Site File must be completed and filed in the relevant section of the Pharmacy Site File. NB. No trial drug is to be returned to Swedish Orphan Biovitrum.

Destruction should also be recorded in the **Drug Accountability Log** found in section 4.6 of the Pharmacy Site File. Expired trial specific Palifermin must be quarantined. Notify UCL CTC who will liaise with Swedish Orphan Biovitrum for advice on its use. Please include a copy of the local Drug Destruction Procedure/Policy in section 4.6 of the Pharmacy Site File.

3 RANDOMISATION

3.1 PROCEDURE

When a patient is randomised, UCL CTC will provide randomisation confirmation details to the site pharmacy. This confirmation should be filed in section 4.7 of the Pharmacy Site File.

Only authorised pharmacy personnel have access to the randomisation details.