

## Maintenance of the Trial Status Inventory Dispensary List

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT  
THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit's website and R&D Newsletter for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: [www.northyorksresearch.nhs.uk/sops.html](http://www.northyorksresearch.nhs.uk/sops.html)

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This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

### Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	1 <sup>st</sup> June 2010	
2.0	2 <sup>nd</sup> July 2012	Change of SOP Controller. Removal of North and East Yorkshire Alliance references. Removal of F51 – form, addition of extra column on inventory list indicating how IMP is ordered, removal of reda password
3.0	28 <sup>th</sup> October 2013	Updated to include addition of Scarborough as a site, indicated frequency of reda check as monthly, included reference to new form 'clinical trials monthly QA check form' – Pharm/F90. Other Minor changes.
4.0	19 <sup>th</sup> October 2015	Removed reference to the 'clinical trials monthly QA check form'. Updated what is recorded on the TSIL (IB, SmPC and Protocol version numbers/dates) and other minor changes.

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## 1 Introduction, Background and Purpose

This SOP describes the process for maintaining and updating the Trial Status Inventory List ("TSIL").

Purpose:

- To ensure all clinical trials that are active, pending, closed to recruitment or closed within the Pharmacy department at York and Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust, are clearly documented in the "TSIL".
- To ensure the "TSIL" is updated to maintain Pharmacy awareness of the trial status and provide information to Pharmacists as to the code break procedure.
- To ensure this is an accurate representation of the Clinical Trials of Investigational Medicinal Products (CTIMP's) that Pharmacy provides service to.
- To ensure the correct information is held within Pharmacy and this corresponds with the R&D database.

## 2 Who Should Use This SOP

This procedure must be followed by members of the Pharmacy clinical trials team, at either York or Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust.

## 3 When this SOP Should be Used

This SOP should be used on a monthly basis to update the "TSIL" list and upon receipt of a new protocol, Investigator Brochure (IB) or Summary of Product Characteristics (SmPC).

## 4 Procedure(s)

- 4.1 At the end of each month you will need to check that the "TSIL" is up to date. To access the "TSIL":
  - Log onto a Pharmacy computer and
  - Access the X-drive
  - The spreadsheet can be found under Microsoft Excel File:  
X:\Clinical Trials\Clinical Trials Trackers\TRIALS STATUS INVENTORY LIST (there are subfolders for each year)
- 4.2 Check that each clinical trial detailed in the "TSIL" list is a pending or active trial operating within the Pharmacy department. Clinical trials that have closed, or closed to recruitment, will also be indicated on the list.

To do this;

A member of the Pharmacy clinical trials team will review the 'TSIL' and confirm if the clinical trials are listed accurately. They will cross reference the list against;

- (1) Pending studies held on the whiteboard within the clinical trials office.
- (2) The R&D database.

The "TSIL" should be checked against the R&D database to ensure the information contained within the "TSIL" is accurate and to ensure that all trials Pharmacy are providing Service to (i.e. all CTIMP's) are listed on the R&D database.

Once logged onto the database, review the information for each trial that is listed on the "TSIL" against the information held on the R&D database to validate it.

Once this is completed, the spreadsheet will then be updated and a paper copy will be printed for a senior member of the Pharmacy clinical trials team to review.

- 4.3 For each clinical trial detailed in the "TSIL" list you must identify:
- Study name and protocol number if applicable.
  - IB and SmPC version numbers &/or dates (as applicable).
  - Study drug(s) involved; IMPs and NIMPS.
  - Whether Aseptic dispensing is involved.
  - What IMPs are dispensed by clinical trials?
  - What IMPs are dispensed by Aseptics?
  - Expiry of IMPs manufactured in Aseptics
  - What clinical trial stock is used for manufacture in Aseptics.
  - The indication for which the study drug(s) are to be used (e.g. Acute Coronary Syndrome, Acute Lymphoblastic Leukaemia, etc).
  - The speciality of the clinical trial.
  - EudraCT number specific for each clinical trial.
  - Protocol version number and date for each clinical trial.
  - R&D reference number specific to each clinical trial.
  - Principal Investigator/Consultant responsible for the running of the study at site.
  - Whether the trial is commercial or non-commercial.
  - Sponsor of the clinical trial.
  - R&D approval date.
  - Status of the clinical trial, this is either:
    - Pending, Active, Active/Closed to recruitment, EOI (expression of interest), in follow up or Closed.
  - The site at which the study is open.
  - Code breaking information in the event of a medical emergency (NB. please keep this description to 255 characters or less).

– Contact information for the research team for each trial

- 4.4 Before making amendments to the electronic 'TSIL' on the X drive you will need to create a copy of the worksheet as evidence that this review has been carried out. Do this by actioning the following:
- a) Locate the Microsoft Excel file as described in section 4.1.
  - b) Copy the most recent list, i.e. the most recent Excel Sheet, into a new Excel Sheet under corresponding month and year (e.g. from the Excel Sheet created in July 2009 into the Excel Sheet August 2009 – newly updated for that month, etc).
  - c) Keep working in the new Excel Sheet, and
  - d) Work methodically through the list.
  - e) Add any new clinical trials that are currently pending (insert in alphabetical order).
  - f) Change the status of the clinical trial to reflect changes
  - g) If a trial status changes to closed, delete this trial from the new spreadsheet, but ensure that you update the status of the trial in the previous month's spreadsheet to keep the record accurate.
  - h) The numbers of active, pending, commercial and non-commercial trials will be reconciled automatically and will be indicated at the base of the 'TSIL'.
  - i) Once updated, save the file.
  - j) Print one copy of the newly updated list, obtain accuracy check from Clinical Trials Manager (or Senior Pharmacy Technician), date it with the current month and year and attach it to the appointed location in the Clinical Trials dispensary for Pharmacy staff awareness.
  - k) File the previous months "TSIL" in the designated location in the Clinical Trials Office.
- 4.5 If no new amendments to the "TSIL" are required, only follow the points a, b, i, j and k of the process described in section 4.4.