

## Maintenance of the Clinical Trials 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/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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) and/or Q-Pulse

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This SOP will normally be reviewed every 3 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.

<b>Version</b>	<b>Date Implemented</b>	<b>Details of significant changes</b>
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.
5.0	18 <sup>th</sup> October 2017	Change of Title, Scarborough and York sites now on different spread sheet tabs. Update of what is recorded on CTL. Removed IB, SmPC, protocol version numbers, Aseptic involvement, and sponsor from list. Directs to Edge or Pharmacy site file for full trial details.

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## 1 Introduction, Background and Purpose

This SOP describes the process for maintaining and updating the Clinical Trials List "CTL"

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 "CTL"
- To ensure the "CTL" 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 on a monthly basis.
- To update the CTL, use the site file information, pending studies board and information found on the R&D database, "Edge"

## 2 Who Should Use This SOP

This procedure must be followed by all 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 "CTL".

### Procedure(s)

- 3.1 At the end of each month you will need to check that the "CTL" is up to date. To access the "CTL":
- Log onto a Pharmacy computer
  - Access the X-drive
  - The spreadsheet can be found under Microsoft Excel File:

**X:/ Clinical trials / Clinical Trials List/ Clinical Trials list 2017 onwards**

- Then select the month and year of the list required once the excel spread sheet is open
  - Select the tab at the bottom of the spread sheet to access Scarborough or York site.
- 3.2 Check that each clinical trial detailed in the “CTL” is a pending or active trial operating within the Pharmacy department. These will be highlighted in green.
- 3.3 Clinical trials that have closed, or closed to recruitment, will also be indicated on the list and highlighted in red.

To do this a member of the Pharmacy clinical trials team will review the ‘CTL’ 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 in York
- (2) The R&D database.”Edge”

The “CTL” should be checked against the R&D database to ensure the information contained within the “CTL” 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.

To access the R & D database “Edge” each member of the pharmacy clinical trials team should have their own individual login details, which must remain confidential. The website to access this site is <http://www.edge.nhs.uk>

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

The “CTL” is a brief overview of each trial and will not contain all of the information that Edge does.

**For each clinical trial detailed in the “CTL” list you must identify:**

- Study name and protocol number if applicable.
- Study drug(s) involved: IMPs and NIMPS.
- 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.
- 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.

- Status of the clinical trial, this is either:
  - Active, Active/Closed to recruitment (highlighted in green)
  - Expression of Interest (EOI), or pending (highlighted in orange)
  - In follow up or Closed (highlighted in red)
  
- Code breaking information in the event of a medical emergency (NB. please keep this description to 255 characters or less). Full unblinding procedures can be found in the Pharmacy trial instructions in Section 1 of the Pharmacy site file.)

- 3.4 Before making amendments to the electronic "CTL" 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
  - 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. If a trial status changes to closed, change the highlighted colour to red as there may still be patients in follow up. The numbers of active, pending, commercial and non-commercial trials will be reconciled automatically and will be indicated at the base of the "CTL"
  - g) Once updated, save the file, named as the month and year it was updated. E.g. "May 2017"