

Maintenance of the Clinical Trials List and collection of KPI data for pharmacy clinical trials

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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.

Version	Date Implemented	Details of significant changes
1.0	1 st June 2010	
2.0	2 nd 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 th 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 th 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 th 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.
6.0	24 th December 2019	Update of process to include the more detailed spreadsheet. More in depth description of how to check the data is correct. Added in process of how to gather KPI audit data. Change of title. Change of author. Change of link to R&D website.

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1. Introduction, Background and Purpose

This SOP describes the process for maintaining and updating the Clinical Trials List (CTL) spreadsheet and how to compile the monthly KPI audit data for pharmacy clinical trials.

Purpose:

- To ensure that all expressions of interest received from the Research and Development (R&D) team and all clinical trials that are open to recruitment, pending and closed to recruitment at York, Scarborough and Bridlington Hospitals, which form part of the York Teaching Hospital NHS Foundation Trust, are clearly documented in the CTL.
- To ensure the CTL is updated on a monthly basis so that there is an accurate and easily accessible record of study information for the pharmacy clinical trials team.
- To complete the monthly dispensing audit and update the 'Dispensing Audit CT' spreadsheet accordingly.
- To report the monthly key performance indicator (KPI) data to the KPI co-ordinator for pharmacy and provide a monthly update for the R&D team.

2. Who Should Use This SOP

This procedure must be followed by all members of the Pharmacy Clinical Trials Team, at York Teaching Hospital NHS Foundation Trust.

3. When this SOP Should be Used

This SOP should be used on a monthly basis to update both the CTL and Dispensing Audit spreadsheets and then email the KPI co-ordinator for pharmacy and the R&D team the relevant information from these spreadsheets to review.

4. Procedure(s)

○ Access the CTL

At the start of the 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
- Open the latest CTL spreadsheet, which is the Microsoft Excel File found here: **X:\Clinical Trials\CLINICAL TRIALS LIST**

There are six separate tabs in the spreadsheet:

1. **Expressions of interest:** this tab lists any studies that have the potential to go-ahead in the Trust (where the R&D team will email expressions of interest, requesting "Stage 1: Feasibility"). For a study to be accepted and move onto the pending (in set-up) tab, there must firstly be an assessment of feasibility from pharmacy and approval of the site by the study Sponsor.
2. **Pending (in set-up):** this tab lists the studies that have passed feasibility are planned to go-ahead. These will be set-up in pharmacy through a 4 stage process before being given the pharmacy "green light" to be able to open.

3. **Open to recruitment:** this tab lists the studies that are either open to recruitment or studies where recruitment is closed but investigational products are still being dispensed for patients or stored in the clinical trials dispensary.
 4. **Closed to recruitment:** this tab lists the studies that are closed from a pharmacy perspective and the pharmacy site files are still on-site. For a study to be closed from a pharmacy perspective: the study must be closed to recruitment, there must be no further patients receiving medication from pharmacy and no further investigational products for the study, stored on site.
 5. **Closed and archived:** this tab lists studies that are closed but the pharmacy site files are no longer stored on-site. This means they will have been prepared for close-out and given to the R&D team, so that they can be archived with the investigational site files for the study.
 6. **Abandoned studies:** this tab lists any studies abandoned in set-up and not opened; where due to the quantity of documentation prepared in the study set-up stage, there remains a study file that needs to be stored in the clinical trials dispensary.
- **Review and Update the CTL**

Work through the first three tabs of the spreadsheet (expressions of interest, pending and open) in turn to review the CTL and confirm if the clinical trials are listed accurately. To complete this task, updated information can be found within:

- (1) The “Expressions of Interest”, “Pending Studies” and “Prep for Closeout” whiteboards in the clinical trials office.
- (2) The R&D database: “Edge”.
- (3) The electronic correspondence folder for the individual studies
- (4) The physical study folders in the clinical trials dispensary or office

For the “Expressions of interest” tab:

- Update the date and initials at the top of the page
- Check the details listed on the “Expressions of Interest” whiteboard in the clinical trials office against the existing information on the spreadsheet and update as necessary. If a study is no longer on this whiteboard, it will have either moved onto the “Pending (in set-up)” whiteboard or been withdrawn as an expression of interest.
- Move studies over to the “Pending (in set-up) tab where necessary and delete these from the “Expressions of Interest” tab. You should then check on the X: Drive that the electronic folder for the study has been moved to the “2.Pending (in set up)” location, transferring the file from the “1. Expressions of interest” folder if necessary.
- If it seems that a study may have been withdrawn, check that this has happened by looking through the correspondence from R&D in the relevant email correspondence folder for the study.
- If the expression of interest has been withdrawn, print off the correspondence confirming this and file this along with the contents of the corresponding blue folder (stored in the expressions of interest plastic box in the clinical trial dispensary) into a single plastic wallet. Write the study name clearly on a blank label and stick this to the front of the plastic wallet, before filing this

alphabetically in the relevant “Old Expressions of Interest” folder in the clinical trials office. You should then move the electronic folder for the study into the “EOI older than or not selected” file within the electronic “1.Expressions of Interest” folder for the relevant site on the X:Drive (if this has not been done already).

- Check the electronic study files and blue study folders for any missing information needed for the “Expressions of interest” tab or “Pending (in set-up)” tab on the spreadsheet.
- Then check in the joint mailbox for any new expressions of interest emails that haven’t yet been written on the “Expressions of interest” whiteboard in the clinical trials office (these will either be filed under “Green Team” in the main inbox or the “EOI” sub-folder).
- If any new studies are found, add the details of these to the “Expressions of interest” tab on the CTL and the “Expressions of Interest” whiteboard in the clinical trials office. Then create an electronic folder for each new study in the “1.Expressions of Interest Folder” on the X:Drive by following the instructions in the “Exporting Outlook Personal Folders” Word document (which can be found in the “Exporting Mail from Outlook” sub-folder of the joint mailbox). Check that the email is saved inside of the new correspondence file created, before deleting the original email from the joint mailbox.
- Finally, check that all the folders inside the electronic file “1.Expressions of Interest” on the X:Drive match with the studies listed on the updated tab of the spreadsheet, so that the spreadsheet, electronic folders and physical folders all correspond.

For the “Pending (in set-up)” tab:

- Update the date and initials at the top of the page
- Check the details listed on the “Pending Studies” whiteboard in the clinical trials office against the existing information in the spreadsheet and update the details on the spreadsheet as necessary. If a study is no longer written on the whiteboard, it will have either been opened (where the study files will have moved to the “Open Studies” roller-racking in the clinical trials dispensary) or been withdrawn.
- Move any opened studies from the “Pending (in set-up)” tab to the “Open to recruitment” tab and then delete these from the “Pending (in set-up)” tab.
- Then move any electronic folders to reflect the relevant changes (if this has not been completed already), where opened studies should be moved to the “3. Open to recruitment (patients receiving treatment)” folder on the X:Drive and withdrawn studies to the “EOI older than or not selected” file within the “1.Expressions of Interest” folder.
- If a study is withdrawn, then the physical study folder will also need to be filed. The physical study folder will either be a blue folder inside the “Expressions of Interest” plastic storage box in the clinical trials dispensary or a ring-binder (labelled with the study details) in the clinical trials office. For studies that only have a blue folder, file these in the same way as the withdrawn expressions of interest and delete the information for the study from the “Pending (in set up)” tab of the CTL. For larger files, store these out of the way in the clinical trials dispensary and transfer the details of the study from the “Pending (in set up)” tab to the “Abandoned Studies” tab in the CTL.
- Check that all the folders inside the electronic file “2.Pending (in set-up)” on the X:Drive match with the studies listed on the updated tab of the spreadsheet.

For the **“Open to recruitment”** tab the CTL should be checked against the R&D database “Edge” to ensure the information it contains is accurate. The CTL is a brief overview of each trial and will not contain all of the information that Edge does.

Each member of the pharmacy clinical trials team should have their own individual login details, which must remain confidential. The “Edge” database can be accessed here: <http://www.edge.nhs.uk>.

Once logged onto the database, review the information for each trial listed in the “Open to recruitment” tab. To find a study:

- Select “global projects” at the top of the “projects” tab in the database.
- Copy across the EudraCT number of a trial to the “EudraCT” search box on Edge.
- If there is no EudraCT number, or this doesn’t work, the R&D number listed in the CTL can be copied into the “Project Local Reference” search box instead.
- The status of each trial will be shown next to the search result on Edge. Trials can be moved to the “Closed to recruitment” tab in the CTL, provided that there are no further supplies of the study drug held in the clinical trials dispensary, no further dispensing for patients and there is email confirmation from R&D that the study is closed.
- Move any closed studies to the “Closed to recruitment” tab and delete this from the “Open to recruitment” tab of the CTL. Count the number of physical study files stored in the roller-racking in the clinical trials dispensary and add this to relevant column in the “Closed to recruitment” tab. The physical folders will then need to be moved to the “Closed Studies” storage area of the roller racking following these changes.
- Then check that all the folders inside the electronic file “3.Open to Recruitment (Patients Receiving Treatment)” on the X: Drive match with the studies listed on the updated “Open to recruitment” tab of the CTL.

The **“Closed to recruitment”** tab of the CTL can be updated once a physical check of the “closed studies” folders in the clinical trials dispensary has been made.

To do this, look through each of the “closed studies” storage locations in turn, checking that the study names on the folders match with the study name labels stuck to the end of the roller-racking (these should be kept in order).

If study folders can’t be found, remove the study label from the end of the roller racking and check in the “Closed Studies (gone to archive)” folder in the clinical trials office that this has been sent for archiving; otherwise the folders may be in the process of being prepared for close-out in the clinical trials office. If the folders are still in the clinical trials office, the study label should be returned to the end of the roller-racking (as the folders are still on-site).

Once the study labels at the end of the roller-racking match with the physical study folders on-site, count the total number of study labels at the end of the roller-racking for the York closed studies, Scarborough closed studies and Bridlington closed studies separately; writing these numbers down as they will be needed to update the clinical trials statistics in step 4.4 of this SOP (York studies will have a rectangular study label at the end of the roller-racking, Scarborough studies will have an oval label and Bridlington studies will have a hexagon label).

Move any archived studies to the “Closed and archived” tab of the CTL and then delete these from the “Closed to recruitment” tab. Type “Archived” in the “Location”

column on the spreadsheet and the date the folders were passed over to the R&D team in the “Date Archived” column (the date will be written on the relevant closedown form for the study, which will be filed in the “Closed Studies (gone to archive)” folder in the clinical trials office).

Then move the electronic files of any archived studies from the relevant “Files on site” folder to the “Archived Folder or Undetermined Location” folder within the “4. Closed to recruitment (patients not receiving treatment)” folder on the X: Drive (if this has not already been done).

Lastly, check the details listed on the “Prep for Closeout” whiteboard in the clinical trials office against the details written in the “Comments” and “Responsible for closeout” columns of the “Closed to recruitment” tab of the CTL, updating the columns as necessary.

○ **Save a PDF copy of the updated CTL**

After the CTL has been updated and saved electronically, a PDF copy of each spreadsheet page will need to be created, so that there is an ongoing record of the changes made to the spreadsheet each month.

- Make sure the date and initials at the top of all 6 tabs of the CTL have been updated and the spreadsheet saved.
- Open the Microsoft Word document entitled “Saving the Clinical Trials List as PDFs” from the X:Drive (**X:\Clinical Trials\CLINICAL TRIALS LIST\Clinical Trials List Sept 2018 onwards**).
- Follow the instructions listed in the document to save a copy of each tab of the CTL (6 documents in total), saving these in the “PDFs for the previous months” folder (creating a new folder for the current month).

○ **Update the “Clinical Trials Statistics”**

The “Clinical Trials Statistics” poster is located on the back of the clinical trials dispensary door. This should be updated monthly to reflect the changes made to the CTL.

Remove the existing information from the poster using a whiteboard eraser and then use a dry-wipe marker to add the updated data from the CTL and the current date.

○ **Complete the Monthly Dispensing Audit**

Print out 3 copies of the “dispensing collection sheet” from the clinical trials folder on the x:drive (**X:\Clinical Trials\Clinical Trials Trackers\Dispensing monthly data**)

Write in the name of the previous month at the top of each sheet and check that the year typed at the top of the document is the current year.

In the clinical trials dispensary, work through each of the open study folders, in turn to check the following information:

- (1) Whether any dispensing took place for that study in the previous month
- (2) Whether any deliveries were received for that study in the previous month
- (3) Whether further batches of labels need to be produced for the study folder

To check if any dispensing took place for that study in the previous month:

- For studies where medication is dispensed for specific patients on site, check the Study ID Trial Label Accountability form in Section 2 of the study folder, to see if any labels were issued in the previous month. All clinical trials medication dispensed directly for patients will have a Study ID label issued.
- The details of the patient(s) initials, date(s) of dispensing and patient trial ID number(s) can be found on the Study ID Trial Label Accountability form. Write the information for any patients that received dispensed medication in the previous month into the appropriate columns of the “dispensing collection sheet”.
- Next, check the physical prescriptions and/or the patient-specific accountability log for each patient listed in Section 7 of the study folder, to confirm the number of products dispensed, type of prescription, number of items aseptically prepared and number of prescriptions (where the total number of prescriptions for all patients listed for that study, should be written in the number of prescriptions column on the “dispensing collection sheet”).
- For studies where medication is bulk labelled and sent off-site check the Master Accountability Log(s) in Section 7 of the study folder, to see if any items were sent off-site instead of looking at the labels.
- For studies where medication is sent as bulk items that might be returned to pharmacy check the details on the request forms in Section 7 of the study files, as these will show the date and number of items supplied.

To check if any deliveries were received for the study in the previous month:

- Check through the delivery documents in Section 8 of the study folder to see if any deliveries were received during the previous month.
- Write the number of deliveries received in the appropriate column of the “dispensing collection sheet”. If the study has had no dispensing in the previous month then this information will need to be entered onto a new line, along with the study name (crossing a line through the columns that relate to dispensing activity on the collection form).
- Write in the total number of products processed in the deliveries in the final column of the form. Each item in the delivery will be counted as a single product (so if there is a box of 15 vials delivered, this will be counted as 15 products, but a bottle/box of tablets will be a single product).
- After completing the audit of the folders in the clinical trials dispensary, check in the delivery notes section of the “Monthly stock checks and hospital stock ordering” folder in the clinical trials office, to see if there have been any hospital stock deliveries in the previous month (these will be stored in a plastic pocket labelled for the previous month).
- Add each hospital stock order delivery to the dispensing audit collection sheet in the same way as before, totalling the figures in the columns as necessary. Each box in the delivery will be counted as a single product on the collection form. The relevant study the stock was ordered for can be found by checking the drug name against the hospital stock top-up form on the X:Drive (X:\Clinical Trials\Admin File\Assistant (ATO) Documents\Stock Checks\ CLINICAL TRIALS Hospital Stock Top Up List) which should be updated according to following changes.

To check whether further batches of labels need to be produced for the folder:

- Check the Label Accountability form(s) in Section 2 of the study folder, to see if there are sufficient labels for the next month's dispensing by looking at the dates when the previous labels were issued and the number of labels issued each time.
 - If it looks as though labels are needed, make sure that additional labels have not already been printed, by checking if there are spare labels behind the Label Accountability Form and cross-referencing the last label number on the form with the "Record of Labels Printed" form for the relevant Study Label ID Reference in Section 2 of the study folder.
 - Where new labels are needed, write the name of the study and the details of the label(s) needed at the bottom of the whiteboard in the clinical trials dispensary, under the title "labels to be printed."
- **Update the "Dispensing Audit CT" spreadsheet**
- Open the dispensing audit spreadsheet from the X:Drive.
(X:\Clinical Trials\Clinical Trials Trackers\Dispensing monthly data\Dispensing audit CT 2018, 2019).
 - Make a copy of the last tab and re-name this to reflect the month that was checked in the audit (remembering to also change this in the title at the top of the new tab).
 - Delete/amend/add data on the new tab, until this matches the information collected on the dispensing audit collection sheets.
 - Filter the end column of the spreadsheet tab to show the statistics for the different hospital sites in turn (i.e. YORK and then SGH). Count up the numbers that show in each column after doing this and update the relevant site totals at the bottom of each column. When the site totals have been updated, remove the filter from the end column and check that the site totals equal the column totals calculated by the spreadsheet.
 - Once the new tab of the spreadsheet has been fully completed to reflect the dispensing audit, save and close the document, then staple the collection sheets together and give these to the Pharmacy Clinical Trials Manager to be filed.
- **Produce the monthly KPI data report for the KPI co-ordinator**

Work from the example email (or your saved email from the previous month)

Information needed:

- **Escaped errors** - (ask the Pharmacy Clinical Trials Manager)
- **Volume of dispensing activity** – (Total number of items dispensed/prepared for all sites on the "Dispensing Audit CT" spreadsheet for the previous month)
- **Number of expressions of interest** – (check the total number of expressions of interest either on the updated "Clinical Trials Statistics" poster or updated CTL spreadsheet)

- **Number of new studies in set up** - (check the total number of pending studies either on the updated “Clinical Trials Statistics” poster or updated CTL spreadsheet)
- **Number of amendments received** – (check the amendments tracker on the X:Drive)
- **Number of amendments processed** – (check the amendments tracker on the X:Drive)

(X:\Clinical Trials\Clinical Trials Trackers\Amendments\Amendment Tracking - V3 - updated Oct 19)

- **Produce the monthly update for the R&D team**

Work from the example email (or your saved email from the previous month

Information needed:

1) A scan of the temperature graphs for the previous month (only scan the graphs for the storage areas currently in use for storing investigational products) **and any relevant file notes explaining temperature excursions** (the additional data relating to any temperature excursions is not required).

2) Study Data (check the totals either on the updated “Clinical Trials Statistics” poster or updated CTL spreadsheet)

- **Current expressions of interest**
- **Pending studies (studies in set-up)** –which should include a table of tstudy names and corresponding stage of set-up
- **Studies open to recruitment (patients receiving treatment/prescriptions)**
- **Closed study to archive/in follow up**

3) Dispensing data for the previous month (check the “Dispensing Audit CT” spreadsheet completed for the previous month)

- **Number of prescriptions/orders processed**
- **Number of items dispensed/prepared**
- **Number of patients dispensed prescriptions for**
- **Number of deliveries received**
- **Number of items processed in the deliveries**