York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S61

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

IT IS THE RESPONSIBILITY OF <u>ALL</u> 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	18th April 2023
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	Date:	22nd May 2023

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	Reviewers	Details of significant changes
1.0	1st June 2010		
2.0	2nd 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	28th 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	19th 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	18th 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	24th 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.
7.0	13th January 2021		Change of author. Removal of references to label accountability. Updates to the information that needs to be

			sent to the KPI coordinator.
8.0	19th June 2023	Callum Childs	Added in a new process to be completed. Change of file name. Change of author.

Contents

UNCONTROLLED DOCUMENT WHEN PRINTED

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 and Scarborough Teaching Hospitals 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 and Scarborough Teaching Hospitals 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)

o **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 and 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 and 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.

o **Review and Update the CTL**

Work through the tabs of the spreadsheet (expressions of interest, pending studies, open to recruitment, closed to recruitment, closed and archived, and abandoned studies) 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", https://www.edge.nhs.uk
(3) The electronic correspondence folder for the individual studies
(4) The physical study folders in the clinical trials dispensary or office

To review and update the six tabs in the Clinical Trials List spreadsheet, the following process should be followed:
- Update the 'date last updated' and 'updated by' sections at the top of each tab
- Ensure that all the information on the 'Expressions of interest' and 'Pending (in set-up)' tabs match that on the whiteboards in the clinical trials office. All relevant dates and stages should be updated on the spreadsheet so the information on the spreadsheet reflects that on the whiteboard. If any studies have progressed and moved to the next stage in the set-up process, or have been declined, move these studies to the appropriate tab on the spreadsheet. Check that the 'Total' at the top of the tab matches the number of studies on each of the whiteboards and rectify any discrepancies by using the four sources listed above
- When updating the 'Open to Recruitment' tab, use the physical study files in the clinical trials dispensary to check which studies are open. The studies electronic correspondence folders and 'Edge' can also be used to find out whether a study has closed to recruitment. In Edge, studies can be searched for using their Eudract number, R&D reference number, or their name. If a study has closed and there is no remaining IMP on-site, and no patients are being dispensed for, then the study should move across to the 'Closed to

recruitment' tab. Check that the Total at the top of the tab matches the number of study signs on the outside of Bays 5, 6 and 7, and rectify any discrepancies

- As part of the 'Open to recruitment' tab, the 'Potential last patient last visit' date can be estimated. This should be done using Edge for each of the open studies. A study should be searched for in Edge, and then, on the left-hand tab, the correct site should be chosen for where the study is open. Then, fill in the 'planned closing date' and 'estimated closed to recruitment date' columns using the dates given on Edge for each study. Using the updated 'estimated closed to recruitment dates' and the treatment duration information given in the protocols for the studies, work out the 'estimated last patient last visit' date. This date is useful for working out when studies are likely to close and so the team can plan the set-up of studies effectively to ensure the team is not working over capacity.

- Ensure the studies in the 'Closed to recruitment' tab match those on 'Closed to recruitment' bays in the clinical trials dispensary. Also check that the number of closed studies matches the number of study signs on the ends of these bays. The 'Closed Studies- gone to archive' folder in the Clinical Trials office can be checked to see if any of the closed studies have been archived. If this is the case, the study should be moved to the 'Closed and Archived' tab. Check the 'Closed studies priorities' spreadsheet in the 'Clinical Trials List' part of the X:Drive to see if any of the closed studies have been prepared for archive and if so, a note should be made on the 'Closed studies' tab that they are 'waiting for collection'. Ensure that the study signs on the bay, the 'closed to recruitment' tab and the 'closed study priorities' spreadsheet all reflect one another. The close out priorities on the 'closed study priorities' spreadsheet should also be reflected by the order of studies on the 'Prep for closeout' whiteboard in the clinical trials office.

- Similarly, use the 'closed studies – gone to archive' folder and the 'closed studies priorities' spreadsheet to check if any closed studies have recently gone to archive. If the files have left the department, the study sign should be removed from the end of the 'closed to recruitment' bay in the Clinical Trials Dispensary, and the tab should be updated accordingly, detailing the location of the pharmacy file and the date it was archived.

- Any newly abandoned studies should be moved to the 'abandoned studies' tab of the spreadsheet and the location of the file should be recorded.

Once the tabs of the 'Clinical Trials List' spreadsheet have been updated, check the electronic study folders on the X:Drive and move them if necessary if they have progressed or have been withdrawn.

o **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).

o **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.

o **Update the "Clinical Trials Information board"**

The "Clinical Trials Information Board" is located outside the CT dispensary door in the main pharmacy department corridor. This should be updated monthly to reflect the changes made to the CTL.

The 'pie chart study workload' and 'speciality breakdown' should be changed to contain up to date information about the current studies (**X:\Clinical Trials\Admin File\Clinical Trials Outreach Board\board update monthly**).

This is done by right clicking on the pie chart, then 'edit data' to update the number of studies in each phase (EOI, pending, open to recruitment, closed to recruitment). The speciality breakdown can be worked out using the 'open to recruitment' tab of the CTL.

o **Complete the Monthly Dispensing Audit**

Print out copies of the "Dispensing Collection Sheet" (Pharm/F24) from the R&D SOP webpage https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/pharmacy-sops-forms-and-templates/. Complete the top of the dispensing collection sheet ensuring that the dispensing month is filled in and the name of the person completing the sheet and the date is entered.

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

To check if any dispensing took place for that study in the previous month:
- Check the master and patient-specific accountability logs in Section 7 of the Pharmacy site file to see if any dispensing did take place. If not, the deliveries should then be checked.
- If prescriptions were dispensed the previous month, record the patient's initials, trial ID number, date the prescription was dispensed and the number of products dispensed for the prescription on the 'dispensing collection sheet' (Pharm/F24) for each patient that has been dispensed for. This information can

be found on the accountability logs and/or the prescription. Using the prescription, use the key on the collection sheet to state what type of prescription was used, and whether any products were produced by aseptics or oncology satellite. Aseptics worksheets in section 7 can also be used to find out this information.

- Finally, fill in the total number of prescriptions dispensed for each study on the collection sheet.

To check if any deliveries were received for the study in the previous month:
- Using the Master accountability logs in Section 7 and the delivery documents in Section 8 of the study folder, check 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" (Pharm/F24). 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. Make sure to enter 'zero' in to the dispensing columns if no dispensing has occurred.
- 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 collection sheet as detailed above. 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 accordingly following changes.

o **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 2023).**
- 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.
- Count up the numbers of both York and SGH studies for each column and update the relevant site totals at the bottom of each column. Once this has been done, check that the York and SGH numbers at the bottom of each column add up to the automatic total produced at the bottom of each column.
- 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 file these in the 'Monthly Audit' folder in Bay 1 of the Clinical Trials Dispensary.

o **Produce the monthly KPI data report for the KPI co-ordinator**

Work from the example email which can be found in the front of the 'Monthly Audit' folder (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 for all sites on the "Dispensing Audit CT" spreadsheet for the previous month)

- **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 processed** – (check the amendments tracker on the X:Drive) *(X:\Clinical Trials\Clinical Trials Trackers\Amendments\Amendment Tracking - V3 - updated Oct 19)*

- **Income Generated –** (check the 'percentage of target met' value at the bottom of the 'Clinical Trials Finance tracker' spreadsheet in the 'Clinical Trials Trackers' section of the X:Drive).

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

Work from the example email which can be found in the front of the 'Monthly Audit' folder (or your saved email from the previous month).

Information needed:

1) A scan of the temperature graphs for the previous month and any relevant file notes explaining temperature excursions. These temperature records can be found in the 'Monthly Temperature Graphs' folder in the Clinical Trials Office.

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 the study 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**

5   Related SOPs and Documents

Pharm/F24   Dispensing Collection Sheet