York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S42

Pharmacy Financial Agreement and Invoicing

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Rachel Spooner
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	10th September 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	9th September 2024

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 January 2010		
2.0	4th February 2013		Change of SOP Controller. Removal of reference to the North and East Yorkshire R&D Alliance. Removal of appendix A and B as no longer frequently used. Addition of NIHR Industry costing template as source for pharmacy fees for commercial trials. Removal of references to Pharmacy Clinical Trials Administrator. Addition of Scarborough hospital as a site using this SOP.
3.0	28th October 2013		Removal of references to invoice template Pharm/T14 as this is no longer applicable.
4.0	12th April 2015		Addition of reference to new version of invoice template Pharm/T14. Removal of reference to Pharm/F29 and Pharm/F30 as these are no longer applicable. Addition of reference to Clinical Trials Pharmacy Fee Tracker.
5.0	8th March 2019		Change of author. Change of link to R&D website
6.0	26th July 2022		Change of author. Adjustments to invoicing process, links updated.
7.0	7th October 2024	Rachel Spooner	Change of author. Addition of invoicing process from costs logged on Edge. Removal of specific details for manual invoicing as now not the preferred method.

Contents

1 Introduction, Background and Purpose

For all commercially sponsored clinical trials, Pharmacy Clinical Trials should be reimbursed for the work involved in the set up and running of the trial. This should be written into the Clinical Trials Agreement (CTA) negotiated by the R&D Unit (see R&D/S23).

Trials sponsored by charitable, government and academic organisations may not provide payment for this work. This should be discussed as part of the trial set up and any payments for pharmacy services for the trial negotiated, if applicable, by the R&D Unit. The CTA should make clear whether or not Pharmacy fees have been agreed with the Sponsor.

The purpose of this SOP is to ensure that Pharmacy clinical trials receives payment of Pharmacy fees, and re-imbursement for any drug costs as appropriate.

2 Who Should Use This SOP

This procedure should 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 when:

- Agreeing Pharmacy fees for a trial.
- Raising Pharmacy costs on Edge
- Liaising with Sponsors and the finance department in relation to pharmacy invoices.
- Recording the Pharmacy costs invoiced for from Edge in conjunction with the Pharmacy financial target.

4 Procedure(s)

4.1 Reviewing costing templates and financial agreements

During the set-up process of a pharmacy related clinical trial the RDFs will issue pharmacy with funding documentation – if applicable (most non-commercial studies will not have any funds available for the pharmacy delivery of the trial)

Below are two types of costing templates which the Pharmacy Clinical Trials Manager or Specialist Pharmacy Technician will review against the trial protocol to identify the workload and activities required from pharmacy to run the trial and confirm whether the proposed fees accurately reflect these services. If there are any issues, then these must be fed back to the RDFs for resolution with the sponsor.

Commercial studies - the NIHR Industry Costing Template - a web-based interactive Costing Tool (iCT) that provides a framework for transparent cost display and calculation to support swift local site budget negotiations when planning commercial trials in the NHS.

Portfolio studies - SoECAT - a cost attribution template designed to support correct cost attribution at application for Research Cost funding to ensure that full site level Research Costs are recovered.

Non-commercial trials must be assessed on a case-by-case basis; if additional funding is required and needs to be obtained to run the study, this must be brought to the attention of R&D to see if the funds can be covered. If it is a Trust sponsored/co-sponsored study, the NIHR Industry costing template should act as a guide as to what services may be offered and the corresponding fees, however, consideration must be made as to the levels of funding available from the Sponsor.

Once all the fees are agreed upon, the R&D department will incorporate these into the Clinical Trial Agreement. Pharmacy fees should be requested to be paid directly to Pharmacy and separated from the arrangements for the Investigator fees if possible.

A copy of the Clinical Trials Agreement should be obtained from the R&D department once the study is open to recruitment. It is to be kept in the trial's own dedicated electronic folder on the x:drive under the sub-folder 'Clinical Trial Agreements & Finance'.

4.2 Invoicing

The primary and preferred way in which commercial pharmacy fees are claimed is by logging pharmacy activity on Edge by Pharmacy Clinical Trials, which is invoiced to the sponsor by R&D (see Section 4.3)
If for some reason this above method is not suitable a manual invoice will be raised for pharmacy activity carried out as instructed by the sponsor. Send details of the pharmacy related activity and associated costs in the form of a billing request (see Section 4.4)

4.3 Raising Pharmacy costs on Edge

Upon carrying out Pharmacy activities for commercial studies, these activities and consequently their costs, will be logged on Edge by a member of the Pharmacy clinical trials team at the time of completion as per the below process:

- Log onto Edge
- Use the 'Projects' tab to navigate to the specific trial that the activity relates to
- Select 'site', and then the correct site, e.g., 'York Hospital' or 'Scarborough Hospital'.
- Depending on the iCT for that specific study, specific pharmacy activities may be logged in either of 2 locations on Edge –
    1. Under the 'Finance' tab – select 'add templated cost' and use the drop down to locate relevant Pharmacy activity costs.
    2. In the 'Participants' tab (often the case for activities relating to specific subject visits or prescriptions) – select the patient in question, navigate to their specific 'finance' tab, select 'add templated cost', and use the drop down to locate the relevant Pharmacy activity cost. **NOTE:** some pharmacy costs may be located under the 'unscheduled activities' option.

- Select the correct activity and ensure the 'event date' accurately reflects the date that the activity was carried out.
- Ensure the cost being logged is correct. **NOTE:** some costs are charged per hour per staff member – ensure the costs are accurate and free type the correct calculated cost if necessary.
- Add the comment 'please ensure these costs are paid to pharmacy' to the 'comments' section, along with any necessary information e.g., shipment number or IMP receipt, or week/visit number for patient-specific dispensing.
- Click 'Save', and the cost will automatically be logged under the relevant 'finance' section.

All costs logged by Pharmacy for each study can be viewed under the relevant 'finance' tabs for the specific study on Edge, alongside all costs logged by R&D and Labs. It is also indicated next to each cost whether the cost has been invoiced for.

Note: Depending on the iCT, some commercial studies may not allow certain Pharmacy activities relating to patient visits to be invoiced separately to the R&D visit costs. For these studies, there may not be an option to cost for Pharmacy-specific activities for specific patients, e.g., individual dispensing episodes and accountability. In these cases, the Pharmacy costs are included in each 'Visit' cost which is logged by R&D on Edge. It is important NOT to log these visit costs in Pharmacy to prevent raising duplicate invoices.

4.4 Preparing a billing request:

Requests should provide a basic breakdown of the fees that a sponsor is expected to pay for a set period of time and should be prepared using the Pharmacy Billing Request Template (Pharm/T14) located on the York and Scarborough Teaching Hospitals NHS Foundation Trust Research & Development Unit website (https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/pharmacy-sops-forms-and-templates/).

Details required on the invoice vary from sponsor to sponsor, but as a general rule the following information should be included:

At the top of the request:

- The study name
- Your name and the clinical trials address/extension
- The date
- Customer/Sponsor name
- FAO including contact email address
- Payee name and address

In each 'description' entry (maximum 230 characters each):

- The study name
- Site/Site number
- PI

- R&D reference
- EudraCT number
- A short fee description

Quantity – the number of instances being claimed for (this will depend on the type of fee/unit) e.g. 7 if claiming for 7 months of IMP.

Unit – the cost outlined in the Clinical Trial Agreement. This may be per instance, per hour, per month etc.

VAT – VAT is generally added on for every clinical trial and follows the going rate (20%). Some sponsors may be exempt from paying this due to their country of origin; this should be confirmed with them before any billing requests are sent to be raised.

Information about what fees can be claimed for and the sponsor's address/payment details can be found in the 'financial arrangements' section of the study's Clinical Trial Agreement, alongside any additional information that may be required on the invoice e.g. protocol number.

Invoice requests must only cover agreed upon fees that are clearly stated in the Clinical Trial Agreement, such as the following;

- **Set-up fee** – a one-time fee to be raised at the start of the trial once the study is open to recruitment.
- **Per prescription fees (dispensing, accountability etc.), storage fees, trial maintenance or IMP management fees** – to be raised at intervals depending on the activity of the trial. This interval will usually be 3 to 6 months.
- **Close down/miscellaneous fees e.g. time spent updating SOPs due to a substantial amendment (as applicable)** - to be raised after the last Investigational Medicinal Product has been returned to the sponsor or sent for destruction.
- **Re-imbursement of drug costs (as applicable)** – to be raised as these costs are incurred/alongside dispensing fees.

All completed billing requests will be sent to the R&D administrator via email. These emails should clearly state the name of the trial and the payee, and finance will respond with a copy of the invoice once it has been raised.

Note: In circumstances where Pharmacy fees/payments are included within the Investigators fees/payments, notify the R&D administrator to ensure the Pharmacy portion of the fees to be transferred to the Pharmacy Research budget.

Sponsor invoice requests completed billing requests and finance generated invoices should be saved on the X: Drive (Clinical Trials/Finance/Current Invoices) in a sub-folder bearing the trial name.

Any emails relating to finance should be relocated from the joint mailbox to a dedicated 'Invoicing' folder within the trial's Outlook correspondence.

4.5 Payment and Tracking

Periodically, the R&D administrator will collate all costs logged for each study (including Pharmacy, R&D and labs), in-line with the timeline outlined in the study finance agreement. Some costs will be raised monthly or quarterly for example.

The R&D administrator will ensure all pharmacy costs are linked to the Pharmacy Research budget, in-line with the comments added at the time the activity is logged on Edge.

For studies where certain pharmacy activities relating to patient visits and prescriptions are included automatically within the 'visit' costs raised by R&D on Edge, the commercial studies manager will ensure the appropriate costs relating to Pharmacy are separated from the singular visit cost and linked to the pharmacy research budget at the time of invoicing.

The R&D administrator will then send the collated costs as an invoice request to finance for each study. Once finance issues the invoice, this will be sent to the R&D administrator and the Pharmacy clinical trials mailbox for information.

Save the invoice in the 'Current Invoices' folder, under 'Finance' on the X:Drive, and input the details of the pharmacy costs invoiced for onto the 'Clinical Trials Finance Tracker' spreadsheet in the 'finance' section of the X:Drive

All payments for pharmacy clinical trials services/activities will be paid into the Pharmacy Research budget by the Finance department at York and Scarborough Teaching Hospitals Foundation Trust.

Once a month, the finance team will check for payments, and the R&D administrator will then send the **'invoicing spreadsheet'** for that specific month to Pharmacy clinical trials. The 'Pharmacy fees' column displays what Pharmacy fees have been invoiced for and claimed. The spreadsheet also displays the payment status of each of the fees raised.

Ensure the Pharmacy fees that have been invoiced for or paid are added to the '**Clinical Trials Finance Tracker'** spreadsheet in the finance section of the X:Drive. This is essential to ensure the 'total amount invoiced for' is accurate for each financial year, as this also automatically updates the 'percentage of yearly finance target met' on the spreadsheet.

Save the monthly 'invoicing spreadsheet' from the R&D administrator on the X:Drive in Clinical Trials/Finance/R&D reconciled costs spreadsheets'.

Periodically, Edge will be checked against the 'Clinical Trials Finance Tracker' to ensure that for all Pharmacy costs that are ticked on Edge as having been 'invoiced' for, Pharmacy clinical trials have received a copy of the invoice.

If any invoices are missing, contact the finance department or the R&D administrator for a copy of the invoice.

5 Related SOPs and Documents

Pharm/T14	Pharmacy Billing Request
Pharm/S44	The Pharmacy Clinical Trial File