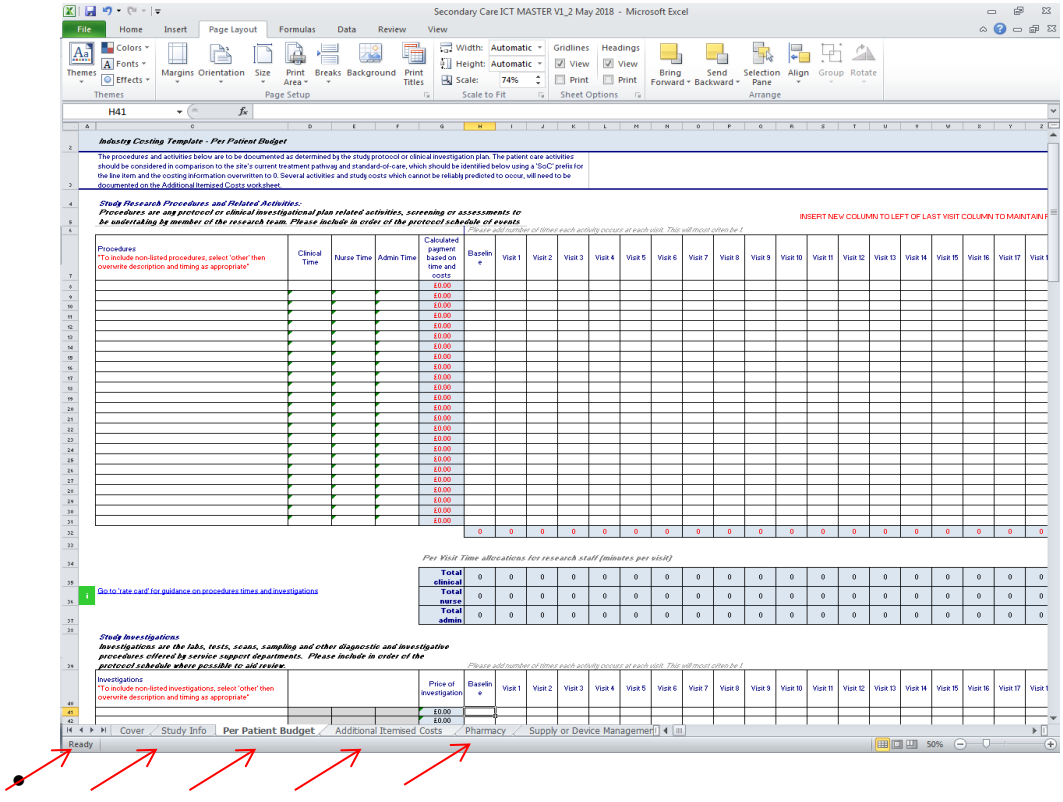
Costing Commercial Studies

Introduction

It is critical that commercial studies are accurately costed. As an NHS organisation, we are unable to underwrite commercial activity and all research activity over and above standard care must be paid for by the commercial sponsor.

- Commercial studies should be costed using the latest version of the NIHR Industry Template. A link to the template can be found https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm
- The template should be completed in the first instance by the commercial sponsor or Contract Research Organisation (CRO) and should include all activity dictated by the protocol with appropriate timings, as well as pharmacy costs where applicable, and set up costs.
- The template has tabs along the bottom relating to per patient costs, additional itemised costs (where something may or may not happen depending on the circumstances of the protocol), pharmacy costs, set up and other costs, device management where applicable, as well as a cover sheet, summary and study information tab.



- The per patient cost details the Procedures (for which staff time is required) and Investigations (tests etc.) required by the protocol, along with how frequently and at which visits they take place, as well as which member(s) of staff carry out the activity (clinical, nursing or administrative).
- Once timings have been added in to the relevant columns, the template then automatically applies costs according to standard staff bands to this activity (Clinical - Consultant grade, nursing – B7, and administrative – B3 / B4. It then automatically applies an overhead of 70% on all procedures, as well as a 20% capacity build cost.
- For investigations (tests), a 20% capacity build cost is automatically added by the template to the investigation cost.
- The template has formulae embedded within it which should not be altered by sponsor or site as the total costs will be affected.
- Once the correct site has been selected on the Study Info tab of the template from the available drop down menu (The Newcastle upon Tyne Hospitals NHS Foundation Trust), there should be an automatic application of a “Market Forces Factor” (MFF) - a local cost adjustment, which adds on a percentage to all costs within the template determined by Trust.

Full guidance on completion of the template can be found https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm

Guidance on appropriate procedure times and details of what is involved in standard investigations included within the template costs can be found in the “rate card” tab on the template itself.

Validation by LCRN

- Portfolio adopted studies should come to us having already been through a “validation” exercise with the lead Local Clinical Research Network (LCRN) where the UK CI is based. This exercise is effectively a “sense check” by the LCRN to ensure that all of the relevant activity in the protocol is included in the template along with the correct visits on which this activity would take place. It should also ensure standard charges for items such as patient travel and CRF (Case Report Form) completion are not omitted by sponsor.
- It should be noted that this validation process does not negate the need for local review of the costing template, and would not account for local variations in charges from those applied automatically by the template, nor ensure that the timings for procedures are correct or appropriate.
- If the costing template has not been validated, the team can either opt to review the template anyhow, or ask the sponsor for a validated version (which may be appropriate if several elements of the protocol look to have been omitted).

When the sponsor sends the populated costing template to the study team, the relevant member of staff should:

- Confirm receipt with the sender.
- Check that the costing template has been validated by the lead LCRN as above (this information is available on the cover sheet).
- Ensure that they have a copy of the final protocol with which to review the template.
- Request a copy of any lab/pharmacy manuals.
- Check that sponsor has received a copy of the NuTH Finance Guidance for Commercial Sponsors, and that an introduction to the relevant clinical trials pharmacy contact has taken place.

Please note that pharmacies review and negotiate their own costs.

Reviewing the template

Using the NIHR costing template provided by the sponsor, the team should make any necessary adjustments to the proposed budget based on a thorough review of the protocol and local practice. Key information can be found in the Schedule of Events/Study Procedures section of the protocol and the member of staff reviewing the cost should refer to narrative detail within the protocol as well as any tables of procedures and footnotes to ensure all items are accounted for. Any proposed adjustments to the template based on protocol information should be highlighted on the costing tool in yellow.

Some common reasons for adjustments might include insufficient staff time allocated for a particular activity, a local cost variation or a local requirement to conduct aspects of the study out of hours. Two other areas where adjustments are commonly required relate to set up fees and the investigations sections of the template.

As a result of a comprehensive review exercise there are some instances where the cost of an investigation at NuTH differs from those fixed costs included in the template. These are detailed in the Costing & Prices tab of the most recent version of the Non Commercial NuTH costing tool. As such where the cost of undertaking an investigation at NuTH is more than the cost which is included in the NIHR template the team should make an adjustment to the template to reflect the NUTH actual cost of the investigation and highlight this adjustment.

Lab costs can be confirmed by labs. The laboratory manual should be provided to: tnu-tr.NewcastleLaboratories@nhs.net along with a request for confirmation of any costs required. If Radiology is to be utilised please email a copy of the reviewed costing and protocol to the Radiology Department to confirm that the costs for this element are appropriate.

If the MR Centre is to be used, please email a copy of the reviewed costing and protocol to the MR Centre team (scanner.bookings@newcastle.ac.uk) to confirm they are willing to participate in the study and for confirmation of their costs.

Things to consider

Screen Failures

Any stipulated screen failure amounts should be removed from the costing tool and the sponsor should be advised that the screen failure rate will be prorated as per the screening visit on the “per patient” tab. Wording should be entered into the contract by them to this effect. Please note that screen failures must be reimbursed fully by sponsor to the point that the patient fails screening. We are unable to accept a ratio of payments for screen failures to randomised patients, as this exposes the Trust to the risk of not being reimbursed for screening procedures unless a particular number of patients then go on to be randomised. We can accept an overall cap on the numbers of patients for which sponsor will pay screen failure costs, provided that sponsor and the team are aware that once this cap is reached, screening should cease until this cap has been renegotiated. The number will depend on the particulars of the study and should be agreed by the research team.

Data Management

CRF/eCRF completion should be added in per visit in the per patient costs tab.

Monitoring Visits

These entail clinical, nurse and admin time and can involve a lot of work, particularly for the Data Manager. The monitor will usually want to spend some time with the study PI and the Data Manager/Nurse will need to be available during the entire visit to answer queries. The research team should agree how much time should be costed per monitoring visit and this should be reflected within the costing template as an additional itemised cost.

Please note; NuTH will expect sponsor to ensure monitoring is undertaken quarterly throughout the study (as a minimum) to ensure invoicing can be undertaken in a timely fashion. Some sponsors opt for “remote monitoring” where the CRA does not actually come to site. Remote monitoring calls should be charged at an hourly rate for the staff involved and any preparation time accounted for in the costs. This can be costed in the Per Patient tab or the Additional Itemised Costs, depending on how the team want to invoice for the visits.

Overnight Stays

If participants are required to stay overnight (for multiple day visits, or visits starting early in the morning/lasting until late at night when patients live a distance from the study site etc.), these should be costed appropriately in the Per Patient Costs for the relevant visits. Consider also adding an overnight stay to the Additional Itemised Costs in case of an additional stay being needed (or in the event that an overnight stay may be required, but isn’t

certain). Consider whether the overnight stay can be in a local hotel (a preferential rate may be able to be negotiated if this is going to be a regular hotel used for booking overnight stays for clinical trial patients).

If the patient stay needs to be as an inpatient/within the Clinical Research Facility, this also needs to be costed appropriately by consulting with the team involved. Things to consider include facility fees, staffing costs at an overnight rate, meal costs, and lab processing if needed.

Unscheduled Visits

On occasion, unscheduled visits need to take place e.g. to repeat an assessment or take an additional blood sample. This should be addressed in the Additional Itemised Costs with a statement by sponsor included in the contract that assessments that are conducted as part of an Unscheduled Visit will be costed as they appear in the Per Patient costs.

Training

Sponsors should provide information up front regarding training requirements for staff members so that this can be incorporated into the costing template accordingly (usually in set up costs). Protocol Amendments often require that study staff perform additional training. Consider also adding an hourly cost to the Additional Itemised Costs tab for staff training on Amendments/study updates.

Re-Consent

Consider including time in the Additional Itemised Costs for the PI to re-consent any patients, as necessary (e.g. if there is an update to the Patient Information Sheets and Informed Consent Forms).

Additional Assessments

In the protocol, it may state that additional assessments may be performed, at the discretion of the Investigator and Medical Monitor e.g. blood results may need to be repeated. Consider adding these assessments to the Additional Itemised Costs tab. If the assessment is a sample that needs to be processed/sent away, include these costs also.

Coordination of Patients to Other Departments

If the study involves the patient attending a number of departments within the hospital as part of their study visit and a member of staff is required to accompany them, discuss this with the relevant member of staff and input time into the Per Patient tab accordingly to cover this.

Set up and Other Costs Tab

There are 4sections included on this sheet; each section should be reviewed in line with the requirements of the study:

1. Set-up, management and close-down costs

- The standard fee included within the template is £1019 excluding overheads and MFF. NuTH charges an R&D set up fee of £1019 where the model Clinical Trials Agreement (CTA) is used. If the model CTA is deviated from, a fee of £1500 will be charged. The contract will be reviewed by the Trust's R&D Department and a decision made as to which fee is applicable.
- If not included, add department set up fees for all support departments necessary including Pathology and Radiology.
- Ensure EITHER a CRF set up fee OR a study coordination fee is included (see below for further detail)
- Ensure a Category A or B amendment fee is included
- Check if archiving will be undertaken by the sponsor, if not add the archiving fee. Please note the NIHR standard cost in the template for archiving is for one box for a minimum of 15 years. If more boxes are required, or the study is an ATIMP (where archiving is required for 30 years) this will need to be amended accordingly.
- £400 Coordinator fee

2. Site Initiation Including Study Specific Training Activities

- **This should cover the time for all required staff to attend the Site Initiation Visit, as well as any training site staff need to complete specific to the study – sponsor should advise what is required early to ensure this can be costed accurately.**

3. Primary Care Participant Identification Centre (PIC) Costs

- **If the study involves the use of PIC sites, costs should be included in the PIC costs section of the Set-up and other costs tab. The template suggests standard fees for this – these should be confirmed by the PIC sites as acceptable or negotiated accordingly.**

- **4. Additional Costs Refreshments:** This should be included where any visit will take more than 3 hours or where a fasting test is required as part of the protocol
- **Inconvenience Payment for Patients as Agreed by Ethics**: This should only be included if this has been approved by the ethics committee, please check the ethics approval document.
- **Maximum Patient Travel Costs per Visit:** Travel should be included for all patients and carers and should be in line with the ethics approval. If the sponsor requires an estimated maximum cost per visit, this should be reviewed in line with the expected patient population and sponsor advised if this needs to be amended. Sponsor should

be advised that this is an estimate and if expenses are expected to be higher than this they will contacted to request prior approval before entering a patient onto a study.

If IRMER or ARSAC will be needed these should be added to the set up section.

NuTH applies the industry-recommended fee for use of an NIHR Clinical Research Facility (CRF) where the requirements of the protocol dictate a CRF is required. NuTH benefits from having CRF's at the Royal Victoria Infirmary (RVI), The CRF in the Dental Hospital, The Clinical Ageing Research Unit (CARU) at the Centre for Ageing and Vitality (CAV), and the Sir Bobby Robson Cancer Trials Research Centre (SBRU) at the Freeman Hospital.

Study Coordination Fee

Where a CRF is not being used NuTH will include a study coordination fee of £200 for an observational study and £400 for an interventional study (+MFF). This fee is to support the trial coordination and site file management.

Pharmacy Tab

- This should be populated by sponsor and reviewed/negotiated directly with pharmacy. Pharmacy will then provide a table of costs to be inserted into the contract by sponsor.

Team Lead review and agreement of costs:

The costing should, at this stage, be reviewed by the Team Lead and then sent to sponsor for confirmation that the changes made are acceptable. Changes made should be clear, transparent and justification provided to sponsor where necessary.

Where support is required with cost negotiation, please email trustindustry@nuth.nhs.uk

Once sponsor have approved the costs, and they have been signed off by the Team Lead, these should be transcribed exactly into the financial appendix of the contract, along with the pharmacy fees which have been agreed directly with pharmacy, to form part of a valid submission to R&D.

Obtaining a New Cost

If you require a cost which is not included on the costing tool please send email R&dfinancepreaward@nuth.nhs.uk with the following details:

- Name of procedure/investigation.
- Where the procedure will take place/investigation?
- Who will undertake the procedure/investigation?

For unsocial hours and on call costs please contact R&DFinancepreaward@nuth.nhs.uk