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Radiotherapy Trials Quality Assurance Service Support Costs
Guidance for Local Radiotherapy Centres and Local Clinical Research Networks

Purpose of Guidance

Radiotherapy Quality Assurance (RT QA) is essential for the safe delivery of radiotherapy trials within the NIHR CRN study portfolio.

This document sets out:

- The difference between central and local RT QA
- The role of the Radiotherapy Trials Quality Assurance (RTTQA) Group in central RT QA
- The funding model for local RT QA activity

This guidance updates and replaces the 2010 Memorandum for the NHS Support Costs at Investigator Sites for Radiotherapy Trials QA issued by Comprehensive Research Network, the National Cancer Research Network and the NCRI Clinical and Translational Radiotherapy Research Working Group.

Why is Central Radiotherapy Trials Quality Assurance Important?

All radiotherapy centres undertake routine quality assurance (QA) of their equipment and practices. This ensures safe delivery of treatment at that centre. The QA activity required for participation in radiotherapy clinical trials may be over and above this routine activity, particularly in trials where advanced radiotherapy techniques are employed which may not be in routine use in that centre.

Central independent RT QA for clinical trials is essential to monitor protocol compliance in a multi-centre setting hence minimise variations and ensure trial outcomes reflect differences in randomisation schedules rather than departures from protocol. Poor quality radiotherapy can compromise the outcome of a trial but there are also negative consequences on patient outcomes; deviations from protocol are associated with increased risk of treatment failure and overall mortality (1-4). There are therefore compelling reasons to have high conformance through central RT QA in multi-centre clinical trials and consequently radiotherapy trials QA has become an integral and essential part of the radiotherapy trial process.

Who are the Radiotherapy Trials Quality Assurance (RTTQA) Group?

The NIHR funded RTTQA Group is a national resource providing central RT QA programmes for all NIHR CRN Portfolio trials that include a radiotherapy component and ensures that radiotherapy trial QA processes are as streamlined as possible to facilitate timely engagement whilst maintaining standards.

The group exists as a single multi-professional network of staff working across a number of NHS sites the funding for which is top-sliced from the total NIHR CRN funding allocation before calculation of LCRN allocations.

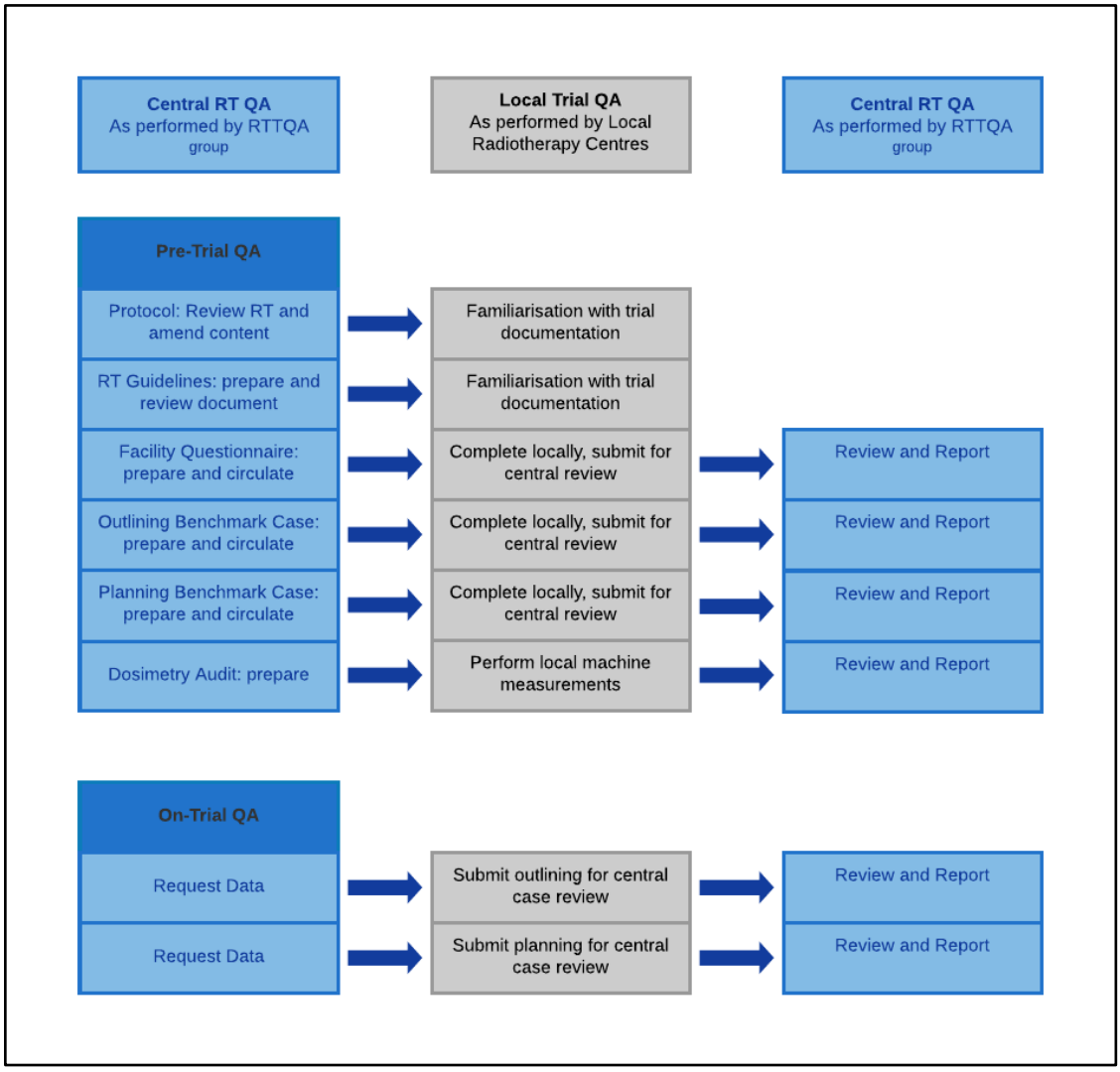
What is the difference between central and local radiotherapy trials quality assurance?

In the clinical trial setting there is a distinct difference in and purpose for the activities of central radiotherapy trial QA as performed by the RTTQA Group, and local radiotherapy trial QA completed at the radiotherapy centre as detailed in Figure 1. It is however important to emphasise that neither functions in isolation and there is always close interaction between the two, particularly when new techniques are being evaluated.

Central trial QA: The national RTTQA Group formulates guidance on the radiotherapy delivery for individual trials, designs radiotherapy trials QA programmes to be implemented for each trial and undertakes the processes required to fulfil the programme thus defining and monitoring the standard and consistency of radiotherapy required for that trial and providing independent external review and verification.

Local trial QA: There are distinct tasks that must be performed by individual centres if they choose to participate in a clinical trial. These tasks are defined by the central RTTQA Group but are performed as part of the trial set up and approval process by staff at the local centre.

Figure 1. Diagram detailing the interaction between the central RTTQA group and local radiotherapy centres showing QA activity undertaken at a national and local level.



How are Local Radiotherapy Trials QA Activities funded?

If the local trial QA activities exceed that undertaken were the same radiotherapy to be delivered outside a clinical trial, it fulfils the definition of an NHS support cost which is fundable through the NIHR Local Clinical Research Networks (LCRN). In 2010, the Department of Health agreed that clinical trial RT QA is over and above routine local QA, and therefore should be defined as a NHS service support cost and funded through local CRN funding.

The RTTQA Group have categorised the QA component of radiotherapy trials as Minimal, Basic, Moderate, and Complex and have estimated the average resources needed for the QA activities required to set up and open a trial at an individual hospital site (Per trial QA) and for the ongoing QA activities required for each patient entering a trial (Per patient QA), table 1. Please visit the RTTQA Group website www.rttrialsqa.org.uk for a full list of categorised studies. The associated workload within each of these categories varies according to the radiotherapy technique employed by the trial.

Table 1. RT QA resource (in hours) required for trial set up (Per trial QA) and patient recruitment (Per patient QA) at local radiotherapy centres.

Activity	Workload in hours according to QA category			
	Minimal	Basic	Moderate	Complex
Protocol and RT guideline review (Per trial QA)	0	17.5	32.5	47.5
Facility Questionnaire submission (Per trial QA)	0	9	9	9
Outlining Benchmark Case submission (Per trial QA)	0	3	6	10
Planning Benchmark Case submission (Per trial QA)	0	4.5	6.5	13
Per trial QA total	0	34	54	79.5
Dosimetry Audit (One off activity)	0	22	22	22
Per patient QA	0	2	4	10.5

Investigators/Clinical Trials Units

Study teams should define RT QA activities in the Schedule of Events and Cost Attribution Tool (SOECAT) as service support costs.

Within the SOECAT all local QA activities should be entered on to the Non-Tariff costs tab first. All QA activities that should be detailed on the Non-tariff costs tab are listed in Appendix 1 along with how to enter them on to the SOECAT. The duration of each activity is very much dependent on the QA Category of each study.

Local Radiotherapy Centres

Tables 2 and 3 show worked examples of the annual resource (in hours) associated with local RT QA activity at a hypothetical site A for the set-up of new trials (table 2) and the recruitment of patients (table 3).

Table 2. Annual resource (in hours) for site A to set up 5 new trials during 1 year.

Category of QA	No. of trials set up in 1 year	Per trial QA activity	Total Activity	One off Activity	Overall total
Minimal	1	0	0		
Basic	1	34	34		
Moderate	2	54	108		
Complex	1	79.5	79.5	22	
					243.5 hours

Table 3. Annual resource (in hours) for Site A to recruit patients to 6 trials during 1 year.

Trial	Category of QA	Annual patient accrual	Per patient QA activity	Total	Overall total
1	Minimal	2	0	0	
2	Minimal	8	0	0	
3	Basic	24	2	48	
4	Moderate	35	4	140	
5	Moderate	11	4	44	
6	Complex	5	10.5	52.5	
					284.5 hours

The NHS service support costs should be reimbursed to radiotherapy departments (based on NHS Terms and Conditions (AfC) pay scale mid-point band 7) to enable delivery of the QA function by the most appropriate local means e.g. by employing physics or radiotherapy staff who will undertake these functions as part of their job plan or by providing overtime payments.

Who Can I Contact for Further Information?

For any questions about RT QA costings your first port of call should be your local Research and Development office.
For any specific queries relating to trial RT QA complexity and activity please contact the National Radiotherapy Trials Quality Assurance (RTTQA) Group on rttrialsqa.enh-tr@nhs.net.

References

1. Fairchild A, Straube W, Laurie F, Followill D. Does Quality of Radiation Therapy Predict Outcomes of Multicenter Cooperative Group Trials? A Literature Review. Int. J. Rad. Oncol. Biol. Phys. 2013;87(2):246-260
2. Peters, L.J., et al., Critical impact of radiotherapy protocol compliance and quality in the treatment of advanced head and neck cancer: results from TROG 02.02. J Clin Oncol. 2010;28(18):2996-3001.
3. Ohri N, Shen X, Dicker AP, Doyle LA, Harrison AS, Showalter TN. Radiotherapy Protocol Deviations and Clinical Outcomes: A Meta-analysis of Cooperative Group Clinical Trials. J Natl Cancer Inst. 2013;106(6):387-393

4. Abrams RA, Winter KA, Regine WF, Safran H, Hoffman JP, Lustig R, Konski AA, Benson AB, Macdonald JS, Rich TA, Willett CG. Failure to adhere to protocol specified radiation therapy guidelines was associated with decreased survival in RTOG 9704-a phase III trial of adjuvant

Appendix 1: How to Add in Local Radiotherapy QA Activities into the Schedule of Events and Cost Attribution Tool

1. Open the SOECAT and go to the Non-Tariff Costs tab
2. Add rows into the table and enter the different local RT QA activities as detailed below:

Non-Tariff Costs

Guidance

Where standard of care, general activities or per participant activities involve procedures and/or investigations that are not present in the drop-downs (please first check the List of Activities tab for the alphabetical list of what is included in the drop-downs) additional procedures and/or investigations may be added below. These non-tariff costs, once added below, will be selectable from the Specific Activity drop-down on all tabs, if 'Non Tariff Cost' is first selected in the Area of Activity cell for that row.

Care should be taken in selecting whether a manually entered item is a procedure or an investigation. Procedures do not have fixed costs but are calculated by the cost of the time taken by an individual employed at a specific payscale to undertake (i.e. If your non tariff cost item is a procedure you should not enter a cost for it below but instead provide answers under the 'Duration' and 'Undertaken By' columns in the relevant tabs). Investigations do have fixed costs, which include the associated staff time costs. Where your manually entered item is an investigation, you should provide the cost below.

It is acknowledged that actual costs will change both over time and between NHS organisations. Costs provided here, including staff time and grade estimates, can only be indicators. This is true also of the tariff costs incorporated into the tool. Text in column A (Activity) should be limited to 250 characters. Please do not make duplicate entries as they will be ignored. Any duplicate entries will be highlighted in pink.

Activity	Activity Type	Cost (IF INVESTIGATION)
Local RT QA: Protocol and RT Guideline review (per trial)	Procedure	
Local RT QA: Facility Questionnaire (per trial)	Procedure	
Local RT QA: Outlining Benchmark Case (per trial)	Procedure	
Local RT QA: Planning Benchmark Case (per trial)	Procedure	
Local RT QA: Dumy Run (per trial)	Procedure	
Local RT QA: Dosimetry Audit (per trial)	Procedure	
Local RT QA: Per patient QA (recruited patients)	Procedure	

3. These activities should now be visible on the General Activities tab in the ‘Specific Activities’ Column when you select ‘Non-Tariff Costs’ in the ‘Area of Activity’ Column where you will detail all study level activities (per trial activities) and on the Per Participant Activities tab where you will detail all the per patient activities.
4. On the General activities tab you will need to complete details such as the Duration and Undertaken by. The duration will be defined by the QA category assigned to an individual trial (Minimal, Basic, Moderate, or Complex). Please refer to Table 1 in this document for a detailed breakdown of the amount of time taken for each activity by QA category. For a full list of QA categorised studies please visit the RTTQA group website www.rttrialsqa.org.uk. Lastly in the Undertaken by Column you should choose medical staff.
5. On the per patient tabs you will need to complete similar information.