West Midlands Cross Regional Radiotherapy Clinical Trial Referral SOP

Revision History

Version	Date	Summary of changes
0.1	Dec 2022	Initial draft Gemma Allen
0.2	January 2023	Re-draft by Gemma Allen following comments from the task and finish group meeting
0.3	February 6th 2023	Comments and amendments added by Dr. Chan
0.4	February 6th 2023	Re-draft following comments from Dr. Chan
0.5	February 13th 2023	Re-draft following regional comments from V. Sturges
0.6	March 1st 2023	Re- draft following comments at the R&D strategy meeting
0.7.1	March 21st 2023	Re-draft following comments from Dr. Chan
0.8	March 28th 2023	Re-draft following comments from Dr. Chan
0.9	May 2nd 2023	Re-draft following comments from tasks and finish group 2
1.0	June 6th 2023	No comments received following regional circulation. Final version for approval.
1.1	June 6th 2023	Updated to section 6 by Dr. Chan.
1.1	June 6th 2023	Regional review.
1.2	Sept 27th 2023	Inclusion of financial considerations and data governance sections; and list of WM trusts - following discussion at task and finish group meeting
1.3	October 6th 2023	Inclusion of further details regarding information to be included at the point of referral – following feedback on final draft
1.3	October 13th 2023	WM RT EAG Ratified the document
2.0	November 10th 2023	WM RT ODN NOG Approved

Approved by

This document has been agreed by the following people:

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Objective

To provide a streamlined pathway between radiotherapy centres for cross regional radiotherapy trial referrals with the aims of ensuring that patients can have access to appropriate radiotherapy clinical trials in another centre where this is not locally available.

Scope

All patients within the West Midlands region who are suitable for an appropriate radiotherapy clinical trial where this is not locally available at the referring hospital and there is not a service level agreement (SLA) in place with another hospital for patients to be referred to.

This SOP will be used by all trusts in the West Midlands providing radiotherapy:

- Royal Wolverhampton Hospitals NHS Trust
- Shrewsbury and Telford Hospitals NHS Trust
- University Hospitals Birmingham NHS Foundation Trust
- University Hospitals Coventry & Warwickshire NHS Trust
- University Hospitals of North Midlands NHS Trust
- Worcestershire Acute Hospitals NHS Trust

Following a discussion between the clinician and the patient, and the patient wishes to be considered for a radiotherapy clinical trial in another hospital, referrals to another radiotherapy department should be made on the guidance and express direction of a clinical oncologist with the consent of the patient.

Open and available trials to be presented at the Radiotherapy Expert Advisory Group (EAG)

1. Radiotherapy trials information is collated by the NIHR based on tumour site and radiotherapy departments on a bimonthly basis.
2. The Radiotherapy Operational Delivery Network (ODN) office will produce a regional radiotherapy trial tracker document from the information provided by the NIHR.
3. This will be distributed at the West Midlands Radiotherapy Expert Advisory Group (EAG) to Clinical Leads, individual Research and Development (R&D) teams and tumour specific MDT co-ordinators with an accompanying covering letter.
4. Trial information will be further distributed at the EAG by the Radiotherapy Managers to the Clinical Teams.
5. R&D will distribute the regional trial information to the Radiotherapy Trial delivery teams and relevant tumour site MDT leads.
6. Links to trial information/trial criteria will be embedded into the document.
7. Open trial information will be uploaded on the Radiotherapy ODN Website with Provider contact details and hyperlinks for access to the trial information.
8. An information sheet with QR code and email links to the West Midlands Radiotherapy Clinical Trials Portfolio webpage will be made available in clinic rooms for patients and Clinicians.

Identification of patients

1. Tumour-site specific MDT meetings provides an excellent forum for the early identification of patients who may be suitable for an appropriate radiotherapy clinical trial and MDT teams are encouraged to consider and identify suitable patients. Suitable clinical trials for patients can be recorded in MDT outcomes.

2. Clinician teams to discuss potential available trials with the patient.

3. Links/signposting to information about the trial will be provided by the clinician or research radiographer or clinical trials nurse.

4. Referral to another hospital undertaking the radiotherapy trial will be done as a consultant-to-consultant referral letter. It is helpful that the referring consultant makes early contact with the radiotherapy centre offering the clinical trial to ensure the patient meets the eligibility criteria, the trial is still open and that there is capacity to treat the patient.

5. Minimum referral information is required to ensure that patients are referred and seen in a timely manner, and sufficient information is available to facilitate an assessment on suitability of the trial.

Minimum information required for the referral:

1. The referring clinic letter should include the following:
   - Diagnosis, TNM staging and all relevant immune markers
   - WHO performance status and co-morbidities
   - Appropriate imaging reports
   - Histopathology reports
   - Any other relevant clinical information which is necessary for the selected trial (eg. renal function) including treatments received so far

2. Relevant imaging is to be transferred by the referring hospital.

3. Transfer of documents will follow the same pathway as per routine practice of seeking an external clinical opinion and will be secure and confidential.

4. To minimise any delays with the patient starting treatment, histopathology reports can be accepted by the recipient hospital unless there is a clinical concern or discrepancy which would need histopathology review.

At the point of referral

Referring clinician & research radiographer/nurse to ensure patient is aware of cross regional referral

1. Patients should be booked into the treating Clinicians clinic (at treating hospital) for a clinical assessment on suitability and a discussion on the relevant clinical trial.

2. Providing the patient meets the eligibility criteria and is agreeable to treatment within the clinical trial, the patient is consented for radiotherapy and for the trial.

3. Ensure that the patient is signposted to the correct trial information.

At the recipient hospital

1. Provide written trial information to the patient.
2. Be responsible for the trial conduct including gaining written informed consent for the trial and for any randomisation involved in the trial.
3. Conduct research activities according to standard operating procedures.
4. Appropriate written communication that the patient has been successfully entered into the trial and relevant updates relating to the patient progress will be made to the referring clinician and GP

Post treatment

1. Appropriate follow up according to the radiotherapy clinical trial will be completed by the recipient/treating hospital or as agreed and facilitated with the referring Clinician.
2. Patients may choose to return to their local centre for follow up if this is an available option if more convenient at which point the local centre should provide sufficient follow up data in order for the patient to remain within the clinical trial and for the purposes of meeting the clinical trial endpoints.
3. Ensure the patient has appropriate appointments and follow up contacts
4. If a patient requires further investigations following completion of the radiotherapy treatment either for the cancer or for another condition, this should continue at the local hospital.

Financial considerations

1. In the event that a trial agreement makes provision for financial reimbursement of activities undertaken by the referring centre, the appropriate distribution of income would be agreed between the referring hospital and recipient hospital on a trial-by-trial basis.
2. The patient will always take priority, and discussions regarding finances should not cause delays to the patient journey.

Data governance

1. Where research participant information is to be shared between the referring and recipient centre, appropriate Information Governance measures should be in place to allow this. This may include the need for Data Sharing Agreements