Radiotherapy Clinical Trials
Roles and Responsibilities
RTTQA Group and Clinical Trials Units

RTTQA-CTU CTRad Working Group

March 2020

SUMMARY

KEY:
- CTU
- RTTQA Group
- Joint CTU and RTTQA Group

CTU to notify RTTQA of funding decision (positive or negative)

CTU to provide RTTQA with trial timelines

CTU to provide RTTQA with information to predict QA workload

RTTQA to provide primary QA contact name and QA email address

RTTQA to lead on facility questionnaire

Protocol and RT guidelines to be developed in parallel by TMG/CTU/RTTQA

TMG/CTU/RTTQA to agree on ownership of data and methods of data collection and storage

CTU to notify RTTQA of patient recruitment in real time

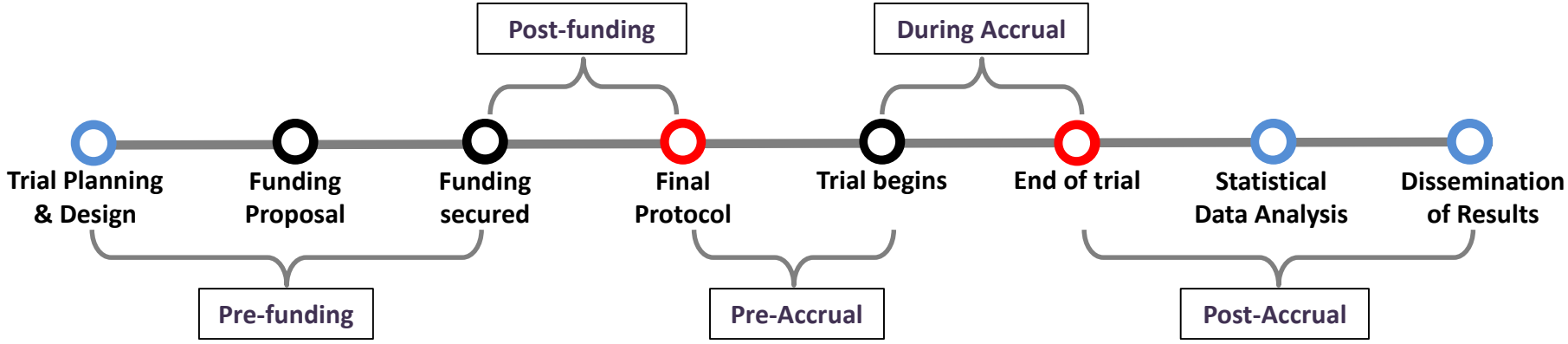
CTU continual update on re-prioritisation of opening centres to recruitment

CTU to notify RTTQA of all trial associated document updates

RTTQA to liaise with recruiting centres on timely submission of QA data

RTTQA to notify CTU on issues with QA

Regular joint trial updates by CTU/RTTQA



CTU to notify RTTQA of new trial work-up if radiotherapy involved and share trial summary/overview with RTTQA

CTU to provide details on number of recruiting centres, number of patients, RT technique so QA workload can be predicted and recorded

RTTQA to provide standard QA support letter and QA programme summary for funding application

RTTQA to highlight requirement for RT lead if applicable

Funding/resources for RT QA related clinical support e.g. for outlining case reviews should be considered in the grant application

CTU continual update to RTTQA on prioritisation of site approval

CTU to distribute trial documentation to appropriate contacts at centres (include RT staff e.g. physicist, radiographer)

RTTQA to provide centres with access to pre-trial QA programme details and associated documents/data sets

RTTQA and TMG to agree on the requirements for pre-trial RT-focused education workshops or any other appropriate training

TMG/CTU/RTTQA to agree on policies for publication and presentation

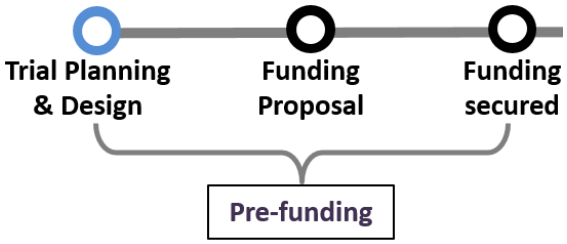
CTU to provide final trial report/summary for TMG to review

RTTQA to provide final report/summary of trial RT QA for TMG to review

Data collection and storage: Typically RTTQA to collect/store the RT data on behalf of the sponsors and CTU to collect/store the trial outcome data on behalf of the sponsors

RTTQA and CTU to discuss opportunities for RT QA related publications for TMG to review

Pre-funding submission



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RTTQA to highlight requirement for RT lead if applicable

Funding/resources for RT QA related clinical support e.g. for outlining case reviews should be considered in the grant application

- CTU to notify RTTQA of new trial work-up if radiotherapy involved
- CTU to share trial summary/overview with RTTQA
- RTTQA to provide a QA summary for the funding application (if required)
- RTTQA to provide a letter of QA support for the funding application
- RTTQA to highlight requirement for RT lead when CI is not a Clinical Oncologist
- CTU/CI to provide information re: number of recruiting centres, number of patients, RT technique so QA workload can be predicted and recorded
- RTTQA should be named as formal collaborator/co-investigator on funding applications for trials with a radiotherapy QA programme (remit will depend on complexity of QA)
- Funding/resources for RT QA related clinical support e.g. for case reviews should be considered in the grant application
- Protocol development group and TMG to include RTTQA representations if applicable
- RTTQA will only assign a named RTTQA contact to a trial once funding is approved. Initial contact will be with the new trials management team within RTTQA newtrialsqa.enh-tr@nhs.net

Post funding approval

(before recruiting sites engage in RT QA programme)

CTU to notify RTTQA of funding decision (positive or negative)

CTU to provide RTTQA with trial timelines

CTU to provide RTTQA with information to predict QA workload

RTTQA to provide primary QA contact name and QA email address

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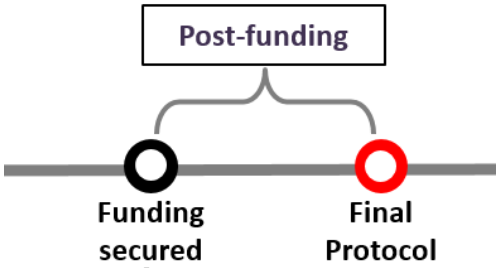
Protocol and RT guidelines to be developed in parallel by TMG/CTU/RTTQA

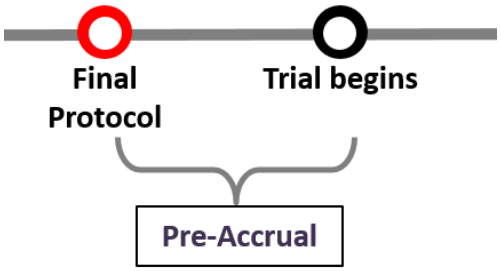
TMG/CTU/RTTQA to agree on ownership of data and methods of data collection and storage



- CTU to notify RTTQA of funding decision (positive or negative). Advise on future plans if not a positive response
- CTU to have more formal engagement with potential recruiting sites to determine who will take part in the trial and how many patients they will recruit
- RTTQA to provide generic trial QA email address for all correspondence (and primary QA contact name)
- CTU to provide RTTQA with trial timelines
- CTU to clarify the number of trial participating centres, site activation process and prioritisation of centres for approval
- Decisions to be made on frequency and type of meetings during the document development stage (protocol and RT guidelines)
- RTTQA to lead on Facility Questionnaire (liaising with CTU to prevent repetition)
- Protocol and RT guidelines to be developed in parallel. CI/CTU to lead on protocol, CI/RT lead/RTTQA to lead on RT guidelines
- Protocol and RT guidelines, along with subsequent amendments, to be reviewed by the TMG and signed off appropriately
- Protocol and RT guidelines should both be finalised before the QA programme can begin
- CTU responsible for version control and issuing of all trial documentation (including RT guidelines). Document updates must be discussed with RTTQA
- CTU/RTTQA/TMG to agree on data ownership and methods of all data collection/storage

Pre-accrual

(QA programme engagement)



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RTTQA and TMG to agree on the requirements for pre-trial RT-focused education workshops or any other appropriate training

TMG/CTU/RTTQA to agree on policies for publication and presentation

- CTU to continually update RTTQA on prioritisation of site approval
- Continual update on site approval status between CTU and RTTQA
- Continual update on changes to contact details for recruiting centres, CTU and RTTQA
- CTU to distribute trial documentation to appropriate contacts at centres (to include RT staff e.g. physicist, radiographer etc.)
- RTTQA provide centres with access to pre-trial QA programme details and associated documents/data sets
- Review frequency and type of meetings between CTU and RTTQA during the approval stage
- RTTQA and TMG to agree on the requirements for RT-focused training, pre-trial education workshops or any other appropriate training (information to be included in the SIV slides/visits)
- If not covered in the trial protocols, agree policies for publication and presentation:
  - Define authorship requirements
  - Define acknowledgement requirements (Trial sponsors and RTTQA funding)
  - Define procedures and timelines for abstract/presentation/publication circulation

During accrual

CTU to notify RTTQA of patient recruitment in real time

CTU continual update on re-prioritisation of opening centres to recruitment

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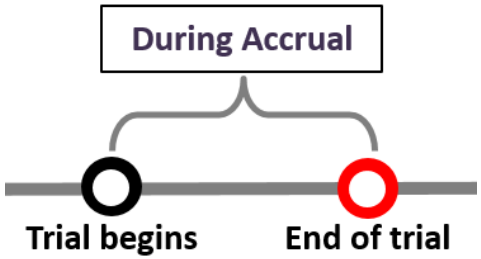
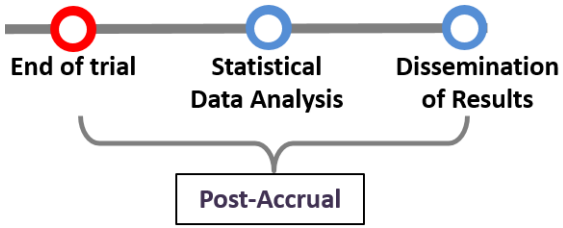


- CTU to notify RTTQA of patient recruitment in real time
- RTTQA to liaise with recruiting centres on timely submission of prospective and retrospective QA data submission. Support from CTU as required
- RTTQA to notify CTU on issues with prospective/retrospective individual case review QA
- CTU to continually update on re-prioritisation of opening centres to recruitment
- CTU to notify RTTQA of all trial associated document updates
- Ongoing updates of changes to individual contact details at recruiting centres
- Regular joint trial updates by CTU/RTTQA. To include RT QA summary

Post accrual



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- Data collection and storage: Typically RTTQA to collect/store the RT data on behalf of the sponsors and CTU to collect/store the trial outcome data on behalf of the sponsors
- Data ownership: Typically RTTQA to own pre-accrual RT QA trial data and Sponsors (CTU) to own recruited patient trial data
- RTTQA and CTU to discuss opportunities for RT QA related publications for TMG to review

Acknowledgements

- Working group members:
  - Natalie Abbott - RTTQA Group, Velindre Cancer Centre
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  - Alexandra Smith - University of Leeds, Leeds, UK
  - Yat Tsang - RTTQA group, Mount Vernon Cancer Centre

ICR The Institute of Cancer Research

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Radiotherapy Trials Quality Assurance

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NCRI National Cancer Research Institute

CTRad NCRI Radiotherapy Research Group