Elizabeth Miles

Coordinator - NCRI Radiotherapy Trials QA Group

Mount Vernon Cancer Centre

www.rttrialsqa.org.uk

Dosimetry requirements and QA in a clinical trial

(External beam and brachytherapy)

Importance of Radiotherapy QA

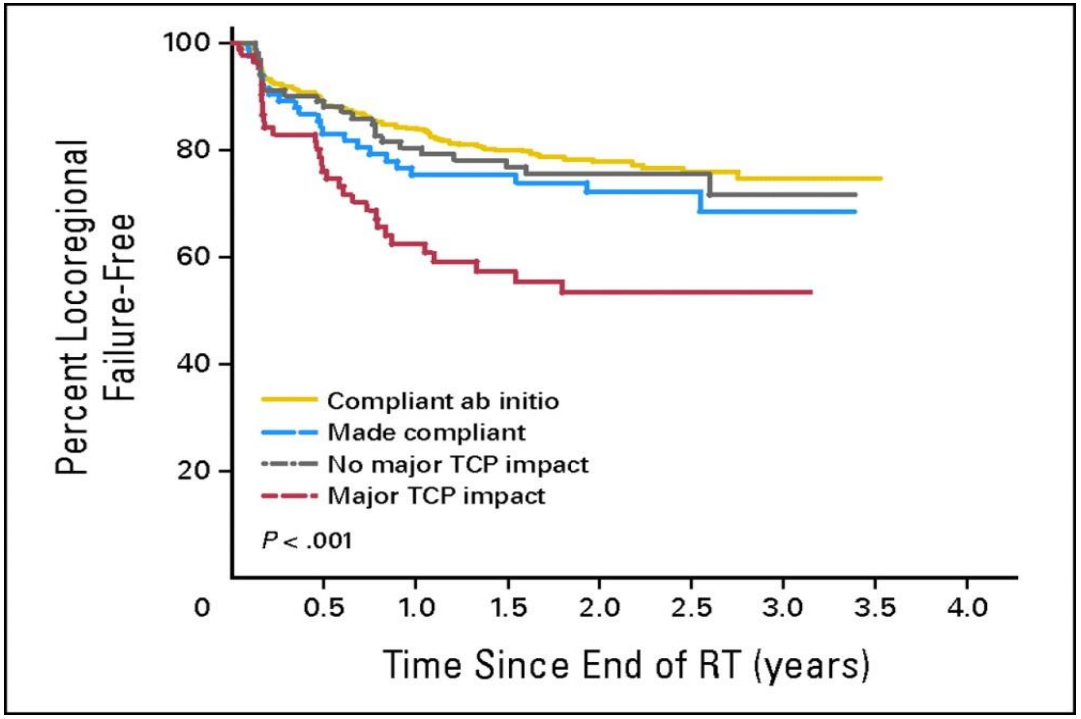
Ensures:

Adherence to a trial protocol

Minimises variations across recruiting sites

Trial outcomes reflect differences in randomised schedules **NOT** departures from protocol

Treatment complies with nationally accepted standards



Peters L J et al. JCO 2010;28:2996-3001 Critical Impact of Radiotherapy Protocol Compliance and Quality in the Treatment of Advanced Head and Neck Cancer: Results From TROG 02.02

Development of UK Radiotherapy QA

1989:

QA associated with individual trials

QA funding within grant application

CHART, START, RTO1, PARSPORT

Independent sites RMH, MVH

2006:

Coordinated approach

RMH, MVH,

2010:

Central funding granted

Secured from the NIHR

Part of the NCRN portfolio

National RTQA central funding:

2010-13

2013-16

Funding approval for a 3yr period

Negotiation on an annual basis

Local RTQA funding:

Investigator site funding

NHS support cost

Activity over and above routine activity

Claimed through CLRNs

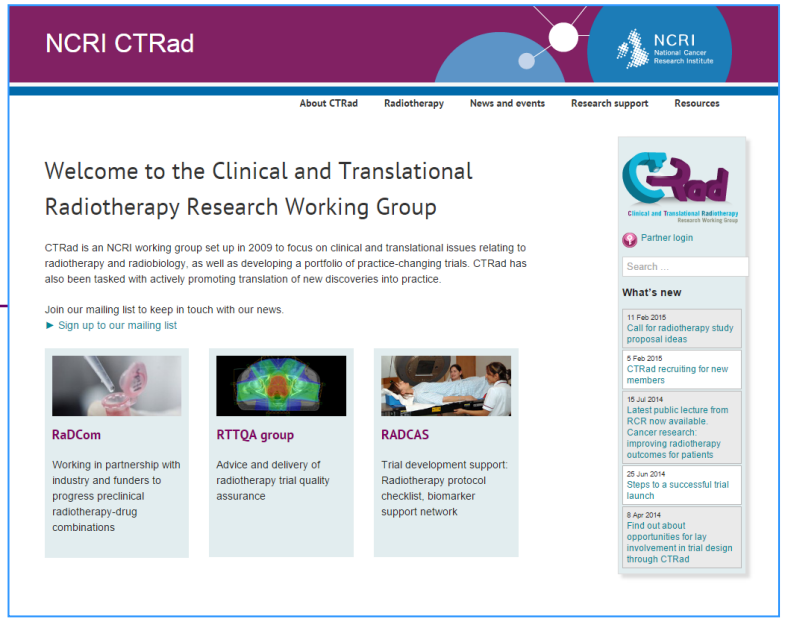
RT QA now seen as a National concern

Multi-professional integrated community

NCRI CTRad

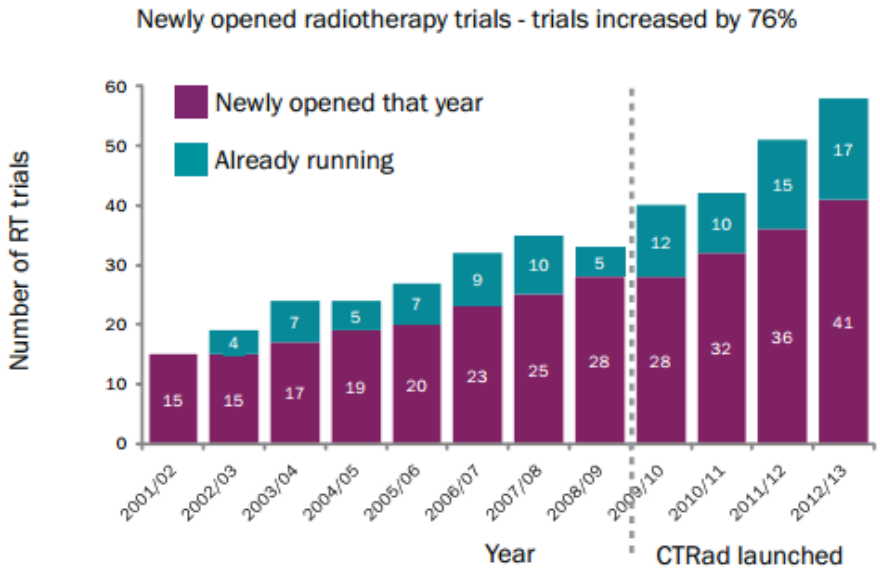
The Clinical and Translational Radiotherapy Research Working Group

An NCRI working group set up in 2009



Aims:

- To develop a portfolio of practice-changing trials in radiotherapy and radiobiology
- To ensure coordination across research
- To actively promote translation of new discoveries into practice

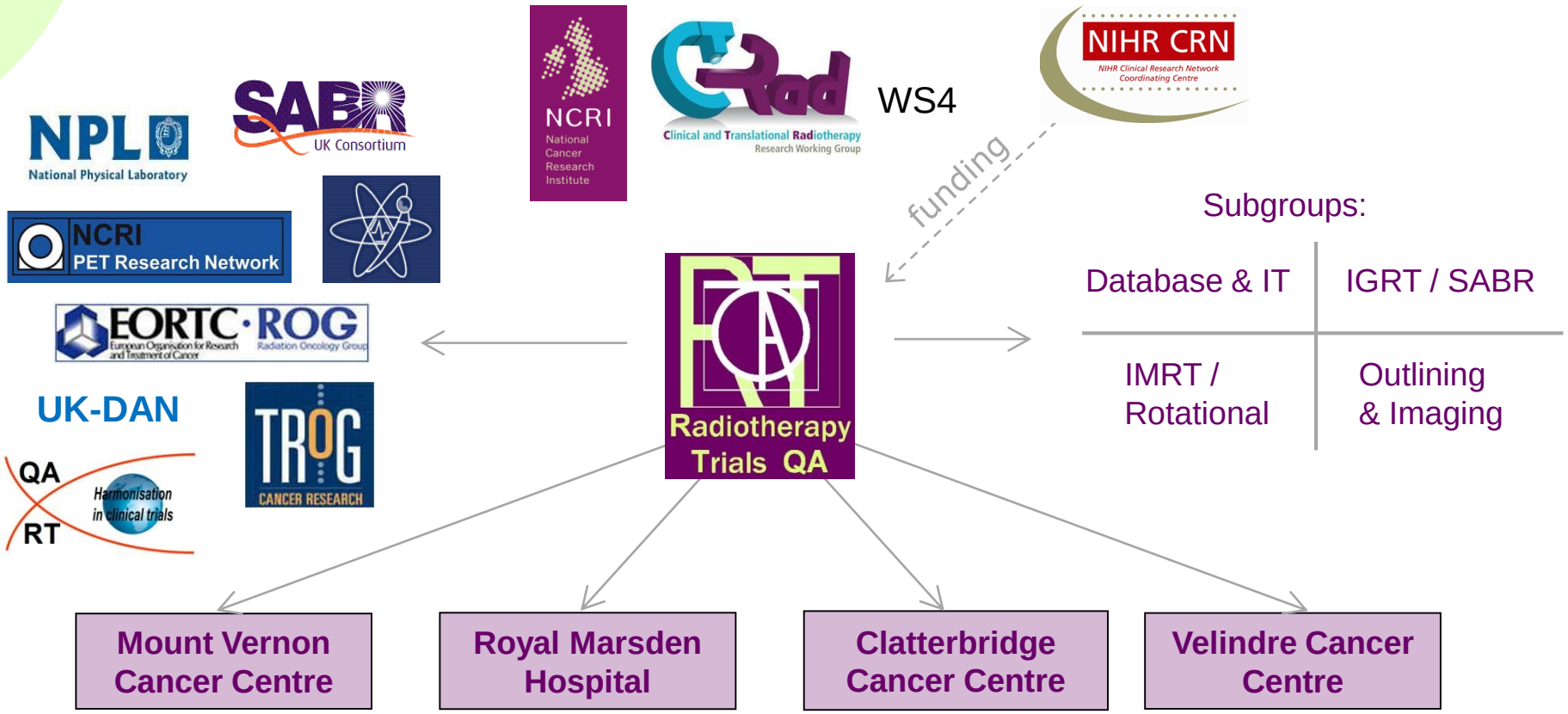


CTRad: national leadership in radiotherapy research – Achievements and vision, 2014

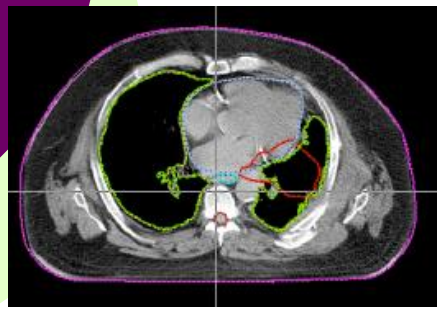
NCRI Radiotherapy Trials QA (RTTQA) Group

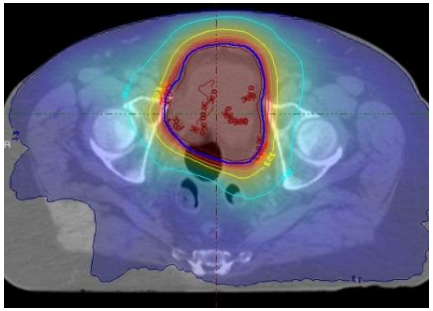
Design and implement Quality Assurance programmes for all NIHR portfolio trials that include a radiotherapy component

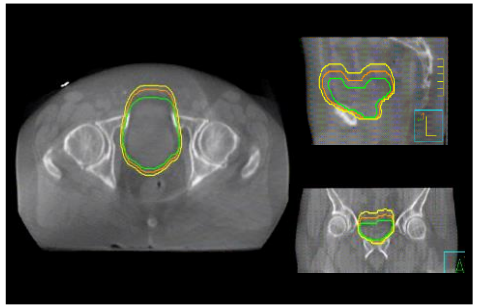
National approach

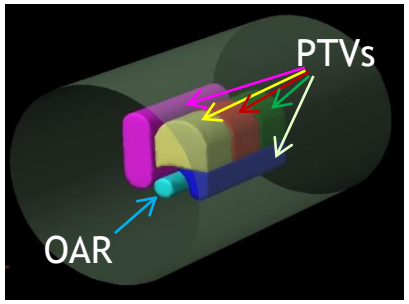


The Radiotherapy process







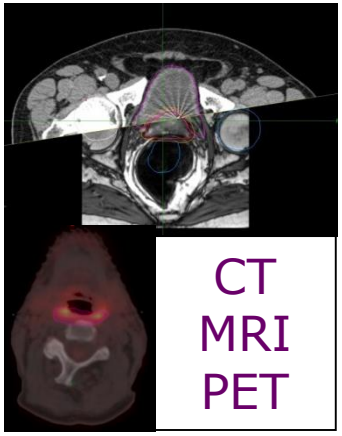


Pre-treatment imaging
Tumour & OAR Outlining

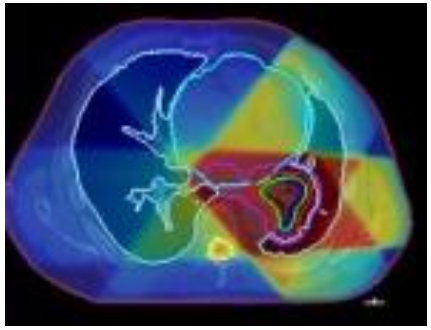
Treatment planning

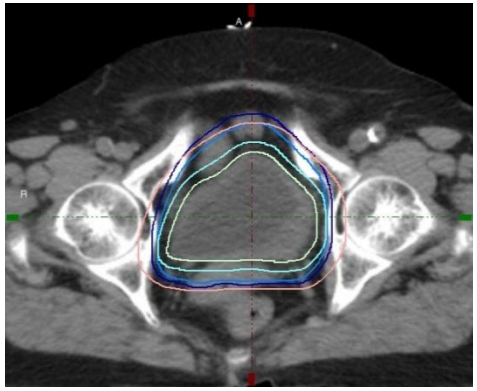
Treatment delivery and verification

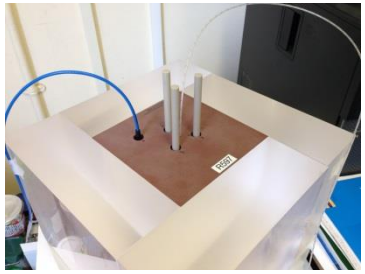
Dosimetry audit



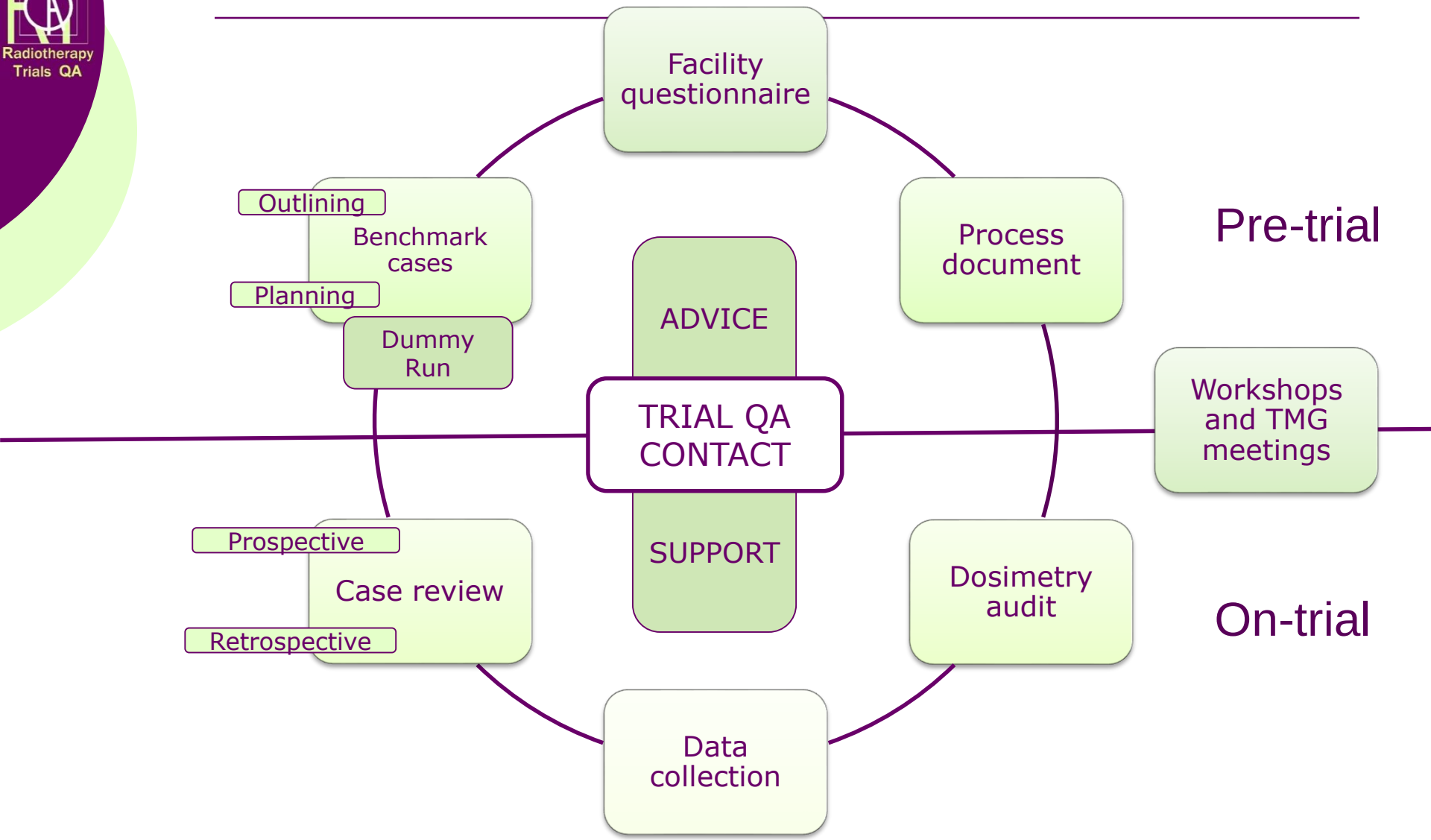
CT
MRI
PET







QA programmes



Radiotherapy Guidelines
Facility Questionnaire & Process Document

HYBRID

A multicentre randomised phase II study of
HYpofractionated **B**ladder **R**adiotherapy with or without **I**mage guided a**D**aptive planning

RADIOTHERAPY PLANNING AND DELIVERY GUIDELINES

Version: 2

Dated: 21/05/2014

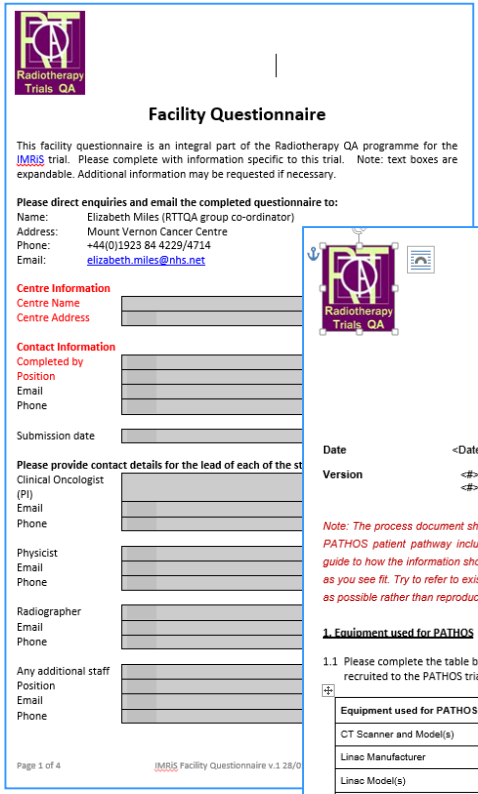
Chief Investigator:	Dr Robert Huddart
Sponsor:	The Institute of Cancer Research
Approval:	Cancer Research UK: Clinical Trials Awards& Advisory Committee (CTAAC)
Funders:	Cancer Research UK
Coordinating Trials Unit:	ICR Clinical Trials and Statistics Unit (ICR-CTSU)
	The Institute of Cancer Research

Main REC Reference Number:	13/LO/1350
ISRCTN:	ISRCTN18815596
ClinicalTrials.gov Identifier	NCT01810757
CRUK Reference Number:	CRUK/12/055

The HYBRID trial has been scientifically approved
by Cancer Research UK's Clinical Trials Awards & Advisory Committee (CTAAC)
The HYBRID trial is part of the National Institute for
Health Research Clinical Research Network Trial Portfolio

CANCER RESEARCH UK

This is a controlled document which should be referred to in conjunction with the HYBRID protocol and should not be copied, distributed or reproduced without the written permission of the ICR-CTSU



Facility Questionnaire

This facility questionnaire is an integral part of the Radiotherapy QA programme for the IMRiS trial. Please complete with information specific to this trial. Note: text boxes are expandable. Additional information may be requested if necessary.

Please direct enquiries and email the completed questionnaire to:
Name: Elizabeth Miles (RTTQA group co-ordinator)
Address: Mount Vernon Cancer Centre
Phone: +44(0)1923 84 4229/4714
Email: elizabeth.miles@nhs.net

Centre Information
Centre Name
Centre Address

Contact Information
Completed by
Position
Email
Phone

Submission date

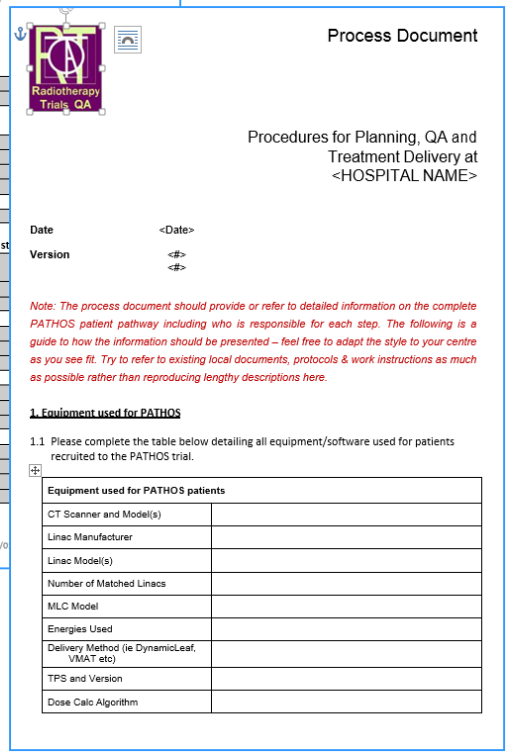
Please provide contact details for the lead of each of the st
Clinical Oncologist (PI)
Email
Phone

Physicist
Email
Phone

Radiographer
Email
Phone

Any additional staff
Position
Email
Phone

Page 1 of 4 IMRiS Facility Questionnaire v.1 28/0



Process Document

Procedures for Planning, QA and Treatment Delivery at <HOSPITAL NAME>

Date <Date>
Version <#>
<#>

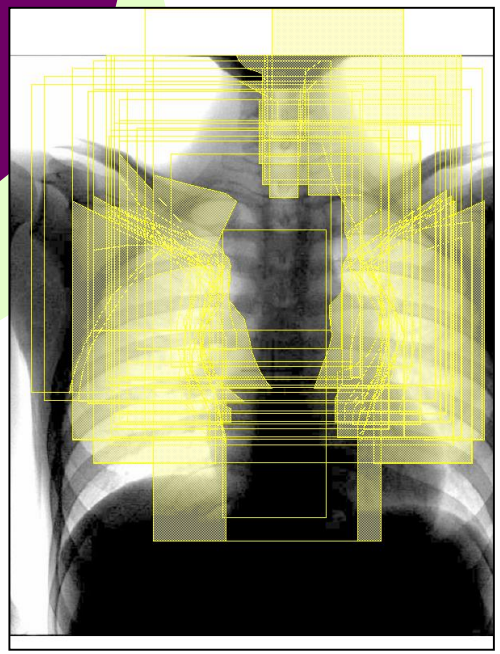
Note: The process document should provide or refer to detailed information on the complete PATHOS patient pathway including who is responsible for each step. The following is a guide to how the information should be presented – feel free to adapt the style to your centre as you see fit. Try to refer to existing local documents, protocols & work instructions as much as possible rather than reproducing lengthy descriptions here.

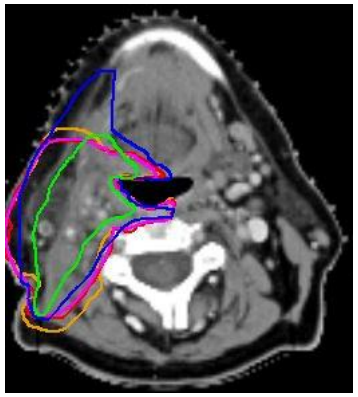
1. Equipment used for PATHOS

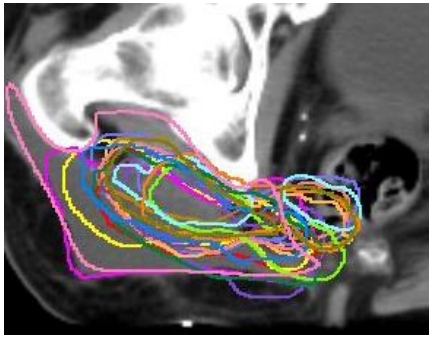
1.1 Please complete the table below detailing all equipment/software used for patients recruited to the PATHOS trial.

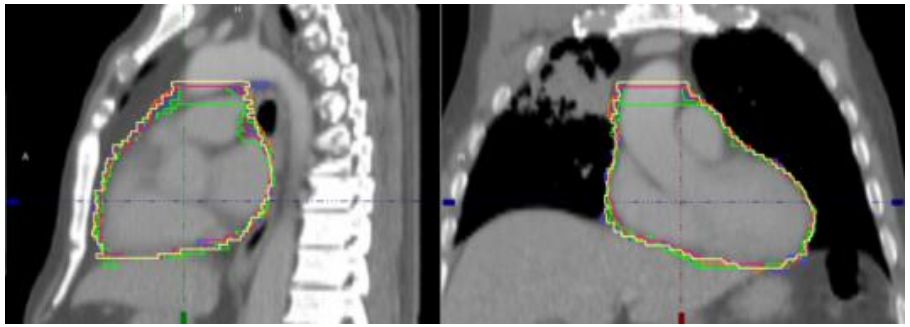
Equipment used for PATHOS patients	
CT Scanner and Model(s)	
Linac Manufacturer	
Linac Model(s)	
Number of Matched Linacs	
MLC Model	
Energies Used	
Delivery Method (ie DynamicLeaf, VMAT etc)	
TPS and Version	
Dose Calc Algorithm	

Tumour & Organ at risk Outlining







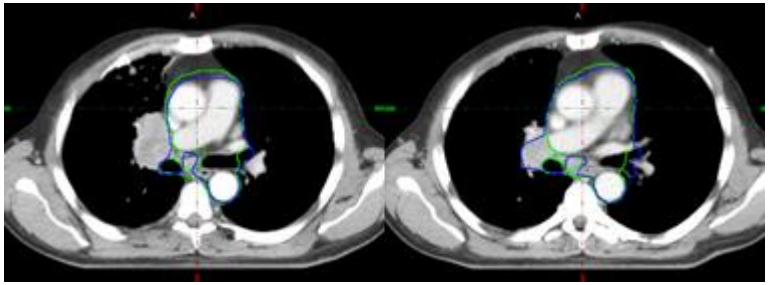


Outlining Benchmark Case

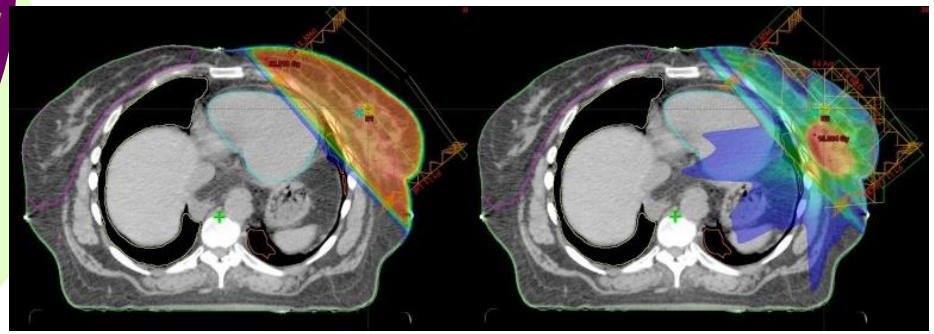
Consensus outlines

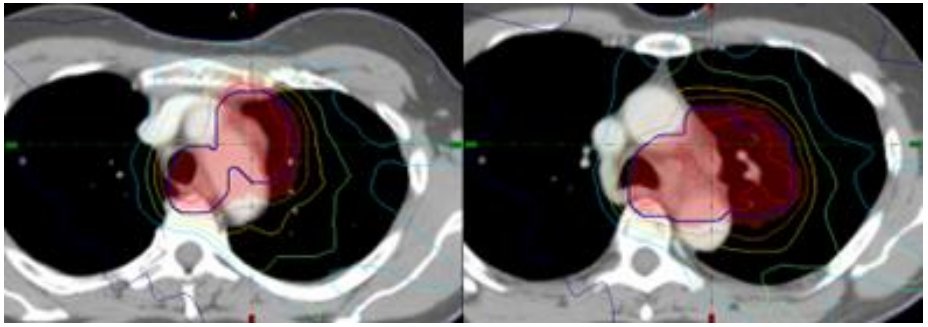
Individual submissions reviewed against this standard

Feedback to centres



Treatment Planning





Dose Constraints	Optimal	Mandatory	Achieved (VODCA)
$D_{99\%}$ CTV	≥95% of prescribed dose		97.6%
$D_{(Total\ Vol\ -1cc)}$ CTV			97.6%
Mean CTV dose	+/- 1% of prescribed dose	+/- 2% of prescribed dose	100%
$D_{99\%}$ PTV	≥90% of prescribed dose		93.2%
$D_{(Total\ Vol\ -1cc)}$ PTV			89.8%
$D_{95\%}$ PTV	≥90% of prescribed dose	≥85% of prescribed dose	96.6%
D_{1cc} PTV		≤107% of prescribed dose	103.5%

Planning Benchmark Case

Dose distribution

Adherance to pre-defined dose constraints

Feedback to centres

Treatment delivery and verification

Daily delivery of a fractionated treatment

Correct positioning of patient

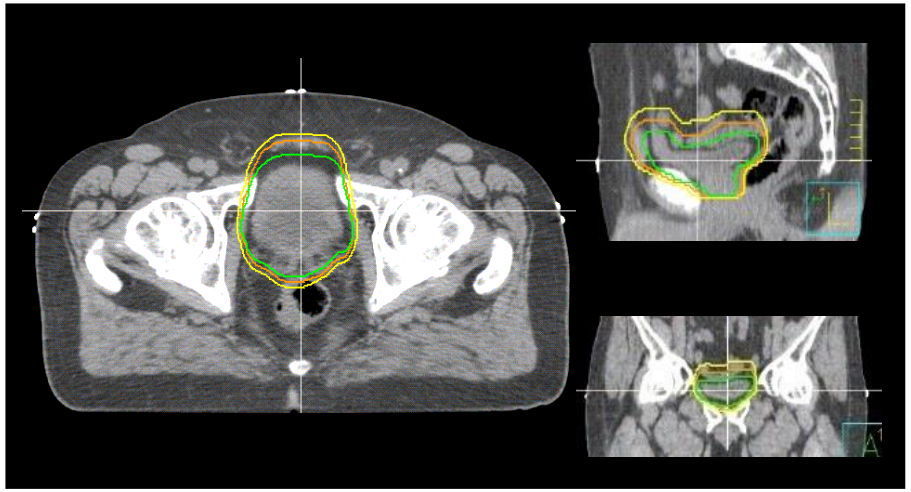
Assess position of target and OARs

Adaptive RT

- Anatomy recognition
- On line plan selection

Assess training and competency

Feedback to centres

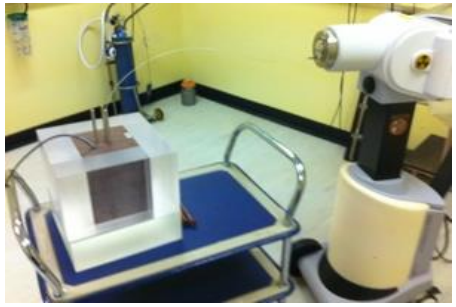


Dosimetry audit

- Independent external review
- Audit of entire treatment planning and delivery process
- Plan dose applied to a phantom, calculated by TPS, infer dose to patient (assumptions made)
- TPS calculated vs delivered dose
- Detector used traceable back to primary standard
- Collaborative work

National Rotational Radiotherapy Audit

National SABR Lung dosimetry Audit



National Brachytherapy HDR/PDR Audit

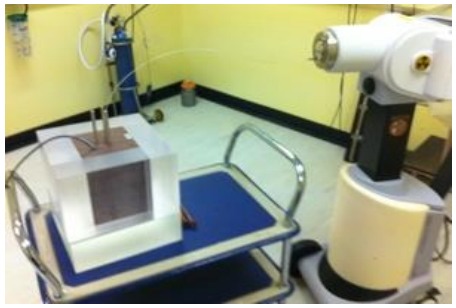
National SRS Audit

Collaboration

- NPL
- Radiation Dosimetry Group
  - Led by Rebecca Nutbrown
- NPL has funding to develop audit of advanced radiotherapy technique
- National and clinical trial implication
- External beam radiotherapy and brachytherapy

National Rotational Radiotherapy Audit

National SABR Lung dosimetry Audit

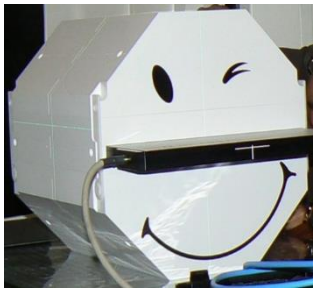


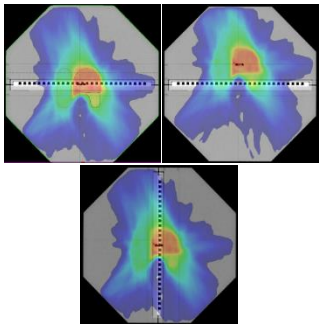
National Brachytherapy HDR/PDR Audit

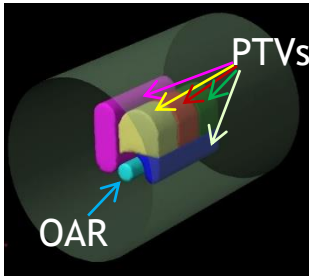
National SRS Audit

UK National Rotation Radiotherapy Audit

- Collaboration
  - NPL, IPEM, RTTQA, Royal Surrey Hospital
- National Audit and Trial credentialing
  - Commercial detector array and alanine
  - PTW Octavius II phantom with PTW 729 2D Array
- Completed visits
  - 44 centres, 47 systems
  - Point dose differences (mean (+/-sd)
    - 0.1 +/- 2.6% (3DTPS test)
    - 0.2 +/- 2% (clinical plan)
  - Accurate TPS modelling and treatment delivery

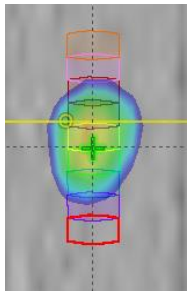


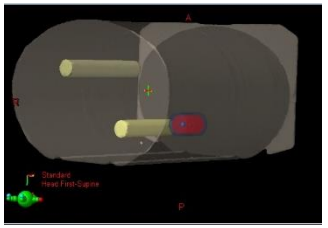
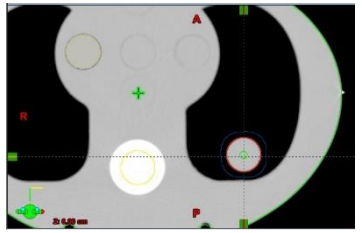




National SABR Lung dosimetry Audit

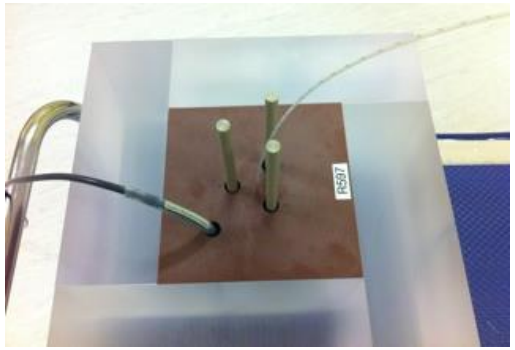
- Collaboration
  - NPL, UK SABR consortium, RTTQA
- National Audit
  - Pilot audit - solid water block using alanine
  - Phantom audit - CIRS thorax phantom with alanine and gafchromic film
  - Subsequent trial credentialing
- Completed visits
  - 21 centres
  - The absolute dosimetry results show that modelling and delivery was within +/-3% accuracy for 18/21 of centres

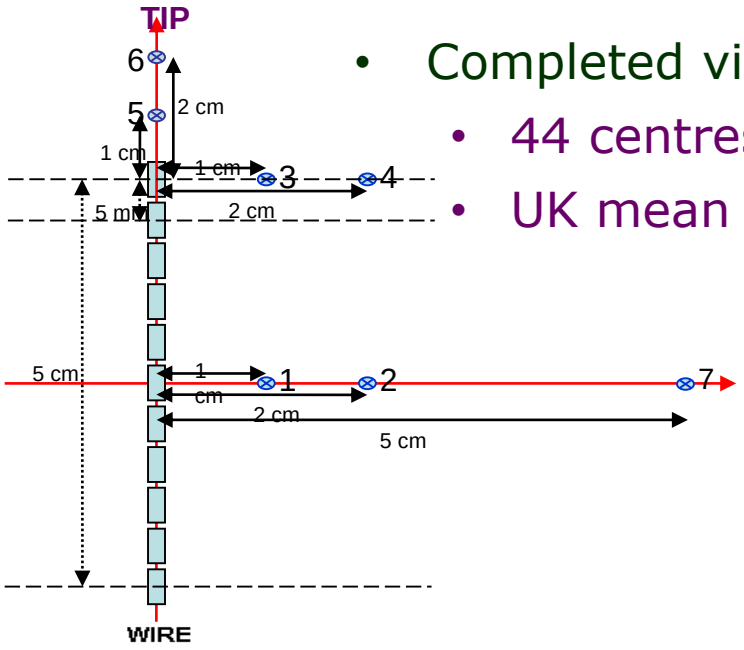


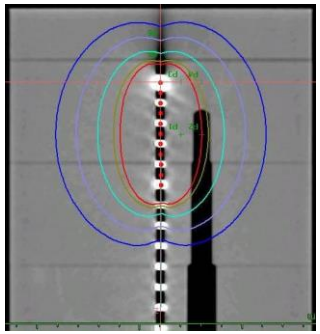
National Brachytherapy HDR/PDR Audit

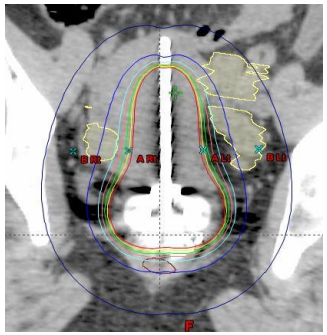
- Collaboration
  - RTTQA, NPL, IPEM
  - First full UK brachytherapy audit
- National Audit and Trial credentialing
  - Ion chamber and alanine dosimetry
- Completed visits
  - 44 centres
  - UK mean dose 2% higher than TPC calculated





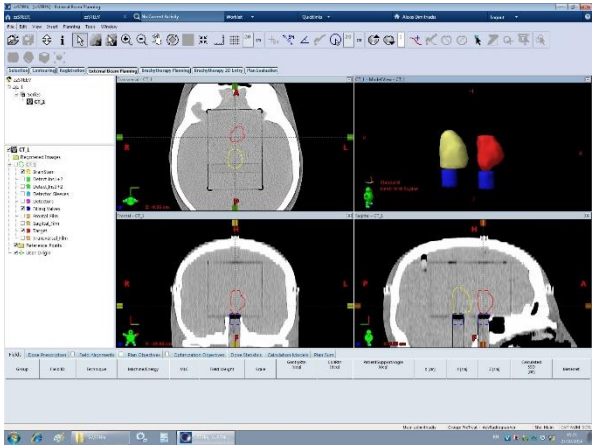
Line source in phantom & typical cervix plan





National SRS audit

- Collaboration
  - NPL, Royal Surrey Hospital, RTTQA
- National Audit and Trial credentialing
  - Ion chamber and film dosimetry
- Visits
  - Planned June 2015-June 2016
  - End-to-end: Image-Plan-Deliver



Dosimetry audit

Nationwide credentialing for clinical trials

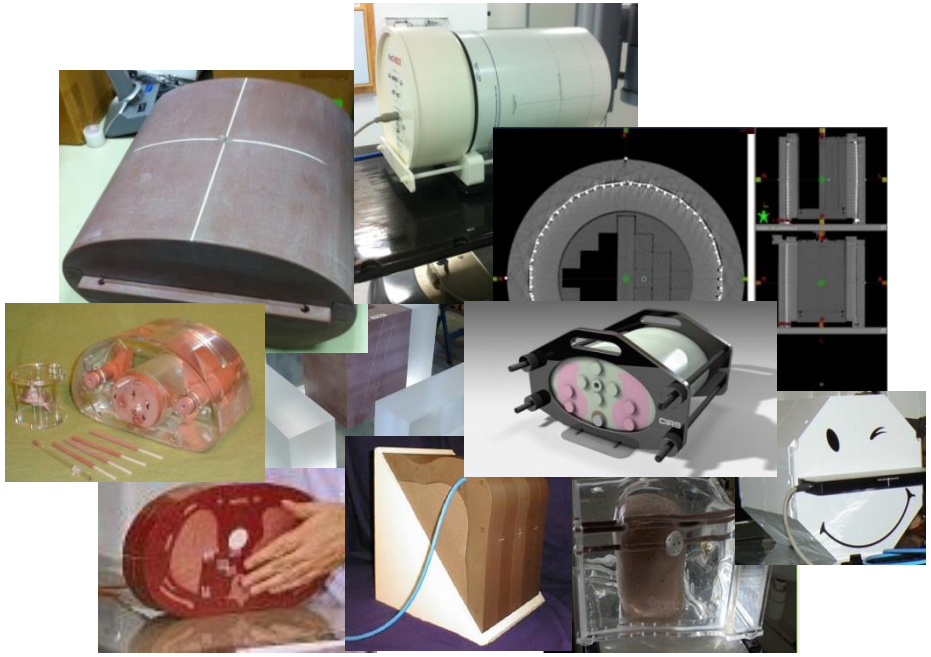
Multiple centre dose audit feasible

50 centres IMRT/VMAT dosimetry audit in last 5 years

44 centres brachytherapy audit

58 centres have received a dosimetry audit

UK dosimetry audit network
www.uk-dan.co.uk



Looking to the future

Metrology for accuracy of clinical dose delivery in hadron therapy

- Objectives: long-term multidisciplinary pan-European support for the successful and effective implementation of hadron therapy
- Addressing steps of clinical dose delivery:
  - Beam characterization and modelling
  - Dosimetry techniques for complex beam delivery
  - Verify accuracy of clinical and secondary dose delivery: end-to-end assessments of delivery accuracy
  - Design of protocols and guidelines for quality control and inter-centre comparisons: Audit procedures for inter-centre verification

Looking to the future

Global Harmonisation Group

www.rtqaharmonisation.org

- Encourage collaboration between global clinical trial QA groups
- Standardise RTQA procedures for RT clinical trials
- Promote consistency in reporting
- Develop standards for credentialing of new techniques
- Automation of RTQA processes

UK clinical trial RTQA programmes

- Facilitates initial adoption of new technology and advanced techniques
- Driver for change
- Promotes improvement in techniques
- Allows discussion of technical issues within a wide forum
- Establish within routine clinical practice

Inherent difficulties but substantial achievements

MRT QA??

- RTTQA timeline 1989-2010 (21 years!!)
- MRT Build on RTTQA experience
- CTAAC funded trial
- CTRad: MRT member representatives

  Recent appointment of person to review MRT research capability in the UK

What can be taken from existing RTQA processes for external beam and brachytherapy?

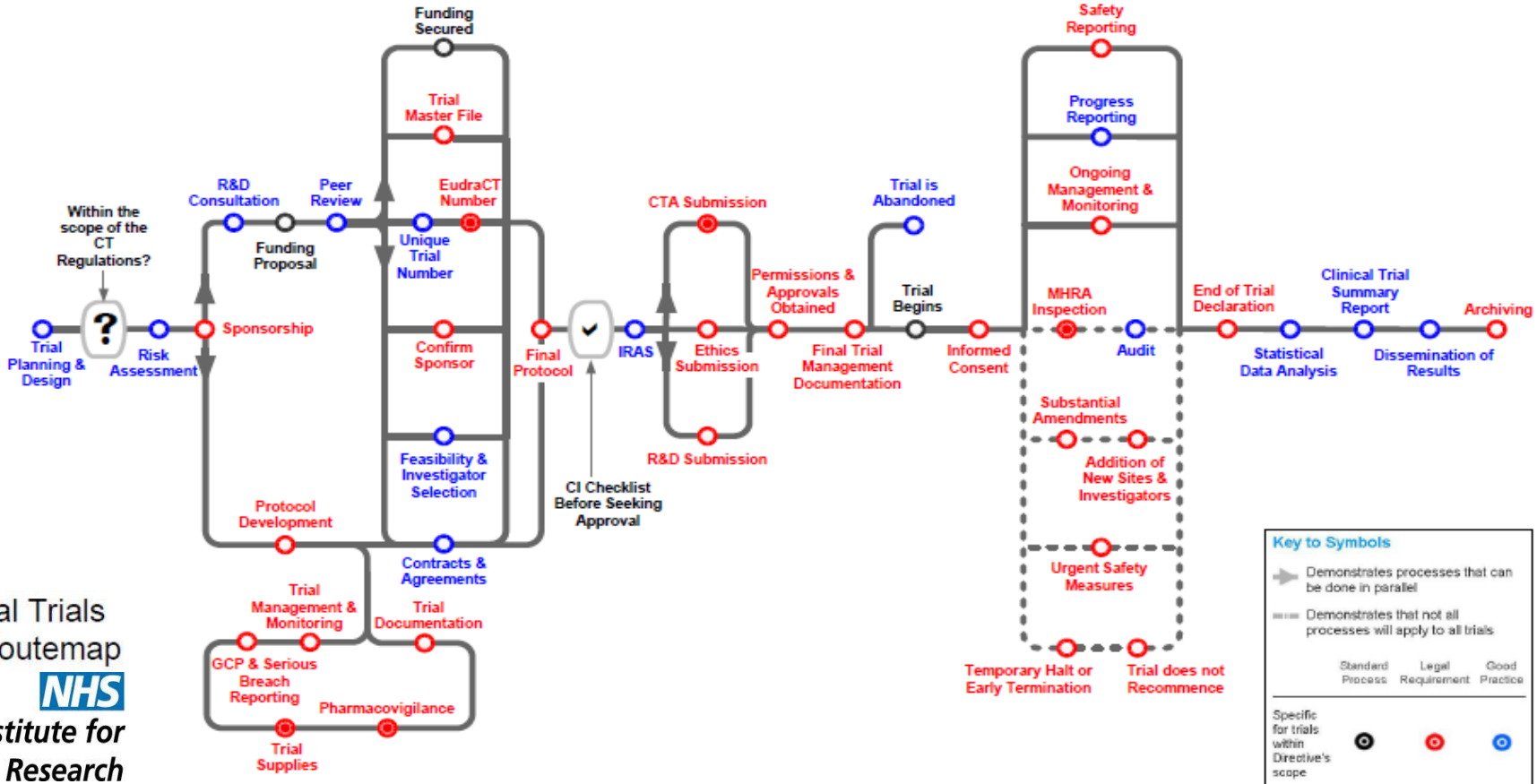
What are the equivalent QA processes for MRT?

What development work is needed?

Increase in the number of multicentre MRT trials?

Where does QA fit into the trial process?

RTQA is now a recognised requirement for multi-centre trials



The Clinical Trials Toolkit - Routemap

NHS National Institute for Health Research

*Version 1.1 – August 2013. Please visit www.ct-toolkit.ac.uk to ensure you have the latest version of the routemap.

Where does QA fit into the trial process?