National Cancer Research Institute (NCRI)
Clinical and Translational Radiotherapy Research Working Group (CTRad)

Clinical Trials Workshop – summary report
Monday 25th February 2013

The Institute of Cancer Research, Chester Beatty Laboratories,
237 Fulham Road London SW3 6JB

Aims and objectives of the workshop
This is an educational workshop, objectives:

- To discuss the components of a good clinical trial proposal
- Use specific clinical trial proposals to illustrate and discuss key issues
- Understand the roles and responsibilities of the Chief Investigator

This meeting has been awarded 5 CPD points by the Royal College of Radiologists for full attendance.

Attendees of the workshop

12 Research Fellows
12 Oncologists
12 from various radiology areas
3 Statisticians
2 Trial coordinators
4 Patient advocates

Specific feedback from the attendees can be found in Appendix 1.

Workshop agenda

09.30	COFFEE and REGISTRATION	**Chair: Professor Neil Burnet**
10.00	**Welcome**	**Dr Emma Hall** *Deputy Director (Research) of ICR-CTSU* *Institute of Cancer Research*
10.05	**Introduction** *CTRad progress report and clinical trial proposal assessment process*	**Professor Tim Illidge** Professor of Targeted Therapy and Oncology *University of Manchester*
10.10	**Getting the question right** *Developing the scientific question* *CSG and portfolio fit* *Information required for application*	**Professor Tim Maughan** Professor of Clinical Oncology & Department Director, *Gray Institute for Radiation Oncology and Biology, University of Oxford*
10.35	**Trial design** *Sample size methodology* *Examples of different study designs*	**Professor Cindy Billingham** Professor of Biostatistics *University of Birmingham*
11.00	**Cancer Research UK funding streams** *Overview of CR-UK funding streams* *Trials and programmes*	**Ms Kate Law** Director of Clinical Trials *Cancer Research UK*

11.20	**Clinical perspective from the Clinical Trials Awards Advisory Committee** *How to improve your application* *Common weaknesses*	**Professor Anthony Chalmers** Professor of Clinical Oncology *University of Glasgow*
11.40	**Discussion & Introduction to breakout sessions**	
11.50	COFFEE	
12.05	**Workshop 1** *Delegates will be allocated into discussion groups. Each group will using a real trial example to explore issues relating to:* • *selection of the appropriate trial design* • *selection of the appropriate endpoint* • *how the above impacts on sample size* • *practical considerations such as incidence, proportion of eligible patients, recruitment rates, deliverability, portfolio fit* • *embedding translational research*	*A) PATHOS: Post-operative adjuvant treatment for HPV-positive tumours* *OR* *B) Hybrid PET/fMRI for improved target volume definitions in paediatric RT* *OR* *C) Phase I/II study of dose-escalated conformal RT in locally advanced NSCLC with ABC and using CBCT to confirm margins*
12.50	Networking LUNCH	
13.35	**Workshop 2** *As above*	*Delegates will be allocated a different proposal to that covered in Workshop 1*
14.20	COFFEE	**Chair: Professor Chris Nutting**
14.35	**Role of the clinical trials unit (CTU)** *What does the CTU do?* *What the CTU needs from the clinician.*	**Dr Emma Hall** Deputy Director ICR-CTSU *The Institute of Cancer Research*
14.55	**Radiotherapy trials quality assurance** *The role of RTQA* *When to talk to RTQA team*	**Mrs Elizabeth Miles** NCRI Radiotherapy Trials QA Group (RTTQA) Co-ordinator *Mount Vernon Hospital*
15.15	**National Institute for Health Research (NIHR) funding streams** *Overview of NIHR funding streams* *What does the HTA fund?*	**Dr Jane Robertson** Assistant Director, Health Technology Assessment (HTA) Programme *NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)*
15.35	**Role of the Consumer** *How to improve your funding application* *Common weaknesses*	**Mr Richard Stephens** Chairman *NCRI Consumer Liaison Group*
15.55	**Role of the Chief Investigator** *What is expected from the Chief Investigator* *Lessons learnt*	**Professor John Yarnold** Professor of Clinical Oncology *The Royal Marsden Hospital & The Institute of Cancer Research*
16.15	**Discussion**	
16.30	**CLOSE**	

Appendix 1: Feedback from delegates

Session	Number rated excellent or good (25 feedback forms completed in total)
Tim Maughan's talk on 'Getting the question right'	22
Cindy Billingham's talk on 'Trial design'	24
Kate Law's presentation on 'Cancer Research UK funding streams'	23
Anthony Chalmers' presentation on 'Clinical perspective from the Clinical Trial Awards Advisory Committee'	24
Workshop 1	25
Workshop 2	21
Emma Hall's presentation on 'Role of the clinical trials unit	23
Elizabeth Miles' presentation on 'Radiotherapy trials quality assurance'	22
Jane Robertson's presentation on 'National Institute for Health Research (NIHR) funding	17
Richard Stephens' presentation on 'Role of the Consumer'	24
John Yarnold's presentation on 'Role of the Chief Investigator'	21

In feedback received from 25 delegates, the format of the meeting was rated "excellent" by 11 delegates and "good" by 14; 23 said the meeting was "very useful"; 2 "useful"

Detailed comments included:

"Very interesting meeting. Good range of topics addressing variety of pertinent issues in trial development process. I enjoyed it very much. Thank you."

"Thank you, very informative and useful day!"

"Useful day, especially re: funding and CTAAC vs NIHR."

"Really interesting. A shame John Yarnold was rushed at the end due to other talks over running. Thought the workshops were great. Very interesting and useful to be able to interact and think about the design of trials"

" Really useful meeting! I am at an early stage of my career and it has given me a good appreciation of what to do and not to do when designing a clinical trial.
"Speakers on PPI and CI were good – Patient was excellent but earlier talks overran. Next time give more time to CI and PPI."

"Firstly congratulations to all for organising a great Clinical Trials Workshop yesterday – I was very pleased to be part of it."

"Very useful. Thank you!"

"Excellent meeting. Please repeat."