



## Editorial

## The Radiotherapy Clinical Trial Research Landscape in the UK Between 2004 and 2013: A Cross-sectional Analysis



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Research is a key element of world class radiotherapy [1]. Radiotherapy research is vital for clinical radiation oncology in the UK for three reasons. First, UK clinical trials contribute to the international effort to evaluate advances in radiotherapy technology and practices, with the aim of improving treatments according to evidence-based principles [2]. Second, quality UK clinical trials help to define standardised UK practice [3] and, third, individual clinical radiotherapy departments derive benefit from participation in clinical trials, involvement in which provides the impetus and support to update technology, techniques and quality assurance protocols in order to adhere to trial protocol requirements [1,4].

Historically, as described by the National Cancer Research Institute (NCRI) in 2003, the preclinical and clinical radiotherapy research efforts at the end of last century in the UK were seriously lacking [5]. As a result, UK clinical practice was often empirical, with protocols reflecting local preferences rather than being founded on a strong evidence base [6,7]. There were few academic radiation oncologists to provide leadership in clinical trials, a lack of training in clinical trial methodology within the radiation oncology community and, as a result, few successful applications for competitive funding for UK radiotherapy trials. Acknowledgement of these problems led to the establishment of the NCRI Clinical and Translational Radiotherapy Research Working Group (CTRad) in 2008 [8,9], which was built on the foundations laid down by the NCRI Radiotherapy Clinical Studies Group [10].

The objectives of CTRad include developing a portfolio of high-quality UK radiotherapy and radiobiology trials [8,9]. Four work streams each concentrate on individual aspects of radiotherapy research: preclinical studies and physics; early phase trials; methodology and phase III trials; and new technology and quality assurance. CTRad provides practical workshops to help investigators in the early stages of trial development, supports the development of phase I, II and III trials, promotes academic clinical oncology and provides a platform for engagement with funding bodies, industry and other academic disciplines. The NCRI Radiotherapy Trials Quality Assurance Team (RTTQA) [11], which has close links with CTRad but is an independent body, provides national leadership and expertise in developing and implementing radiotherapy quality assurance for all National Institute for Health Research (NIHR) UK Clinical Research Network (UKCRN) portfolio trials that include a radiotherapy component.

### Cross-sectional Clinical Trial Research Analysis

We undertook a study to describe quantitatively the changes in the UK radiotherapy clinical trials landscape since the creation of CTRad (1 January 2009 to 31 December 2013), compared with the 5 years before CTRad establishment (1 January 2004 to 31 December 2008). The data were collected from the UKCRN database [12], with 'radiotherapy' as the search term; additional data were collected from the NIHR, all UK Clinical Trial Units hosting clinical trials in cancer and/or radiotherapy, CTRad Work Stream 3 and RTTQA. Only UKCRN portfolio trials were included. Statistical analyses

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were undertaken with input from members of the Institute of Cancer Research Clinical Trials and Statistics Unit.

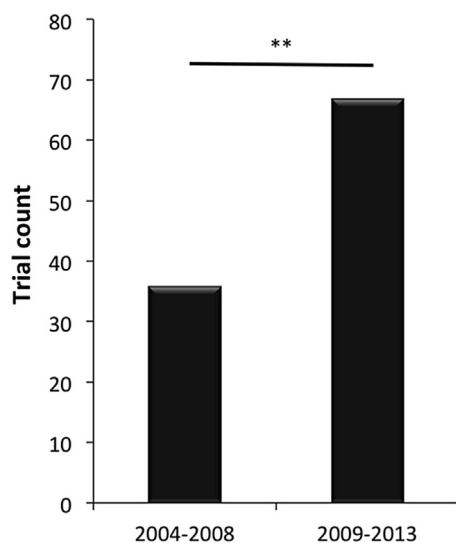
## Main Findings

To our knowledge this is the first quantitative observational analysis of the UK radiotherapy trials landscape from 2004 onwards.

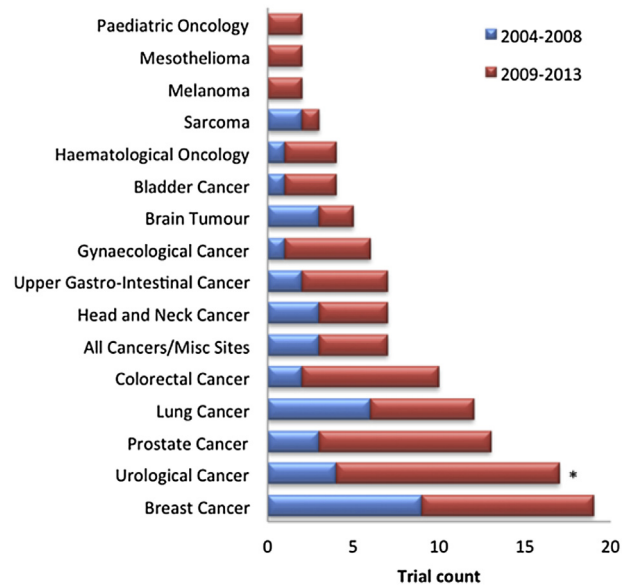
Significantly more radiotherapy trials opened in the UK during the period 2009–2013 than 2004–2008. The number of trials opening nearly doubled, to 67 in 2009–2013, from 36 in 2004–2008 (Figure 1). This is clearly an encouraging indicator of increased clinical radiotherapy research activity in the UK over the past 5 years. This increase in trial numbers coincides with the period since the creation of CTRad in 2008.

Disease site, phase of trial, funding streams and trial quality were also considered. The number of radiotherapy trials opening by disease site before and after 2009 is shown in Figure 2. Significantly increased trial activity was seen in urological cancer (prostate and bladder cancer combined) since 2009 compared with 2004–2008 (13 trials versus 4 trials). It is also noticeable that a number of trials studying rarer cancer types or those not traditionally treated with radiotherapy (mesothelioma, melanoma, paediatric oncology) have opened since 2009, as compared with 2004–2008, when no trials in these disease sites opened. This is a positive step for patients suffering with these cancers, which are traditionally difficult to treat effectively, and new clinical trials may offer further evidence-based interventions in the future.

The period since 2009 also saw a change in the balance of phase III trials to early phase trials (pilot/phase I/phase II). Observational studies were excluded from this analysis. The proportion of early phase trials since 2009 increased



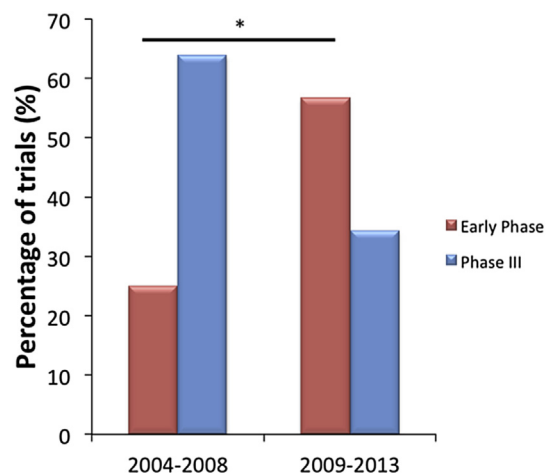
**Fig 1.** Number of UK Clinical Research Network portfolio radiotherapy trials opening in the UK between 2004 and 2008 and between 2009 and 2013. A statistical comparison was carried out using chi-squared analysis.  $**P < 0.01$ .



**Fig 2.** Number of trials by disease site 2004–2008 and 2009–2013. A statistical comparison was carried out using chi-squared analysis.  $*P < 0.05$ .

significantly compared with the earlier period (57% versus 25%; Figure 3). Although phase III trials provide the most robust evidence on which to base practice, we believe increased activity in high-quality early phase trials, including phase I and especially randomised phase II trials, reflects a renaissance of radiotherapy research activity. Such early phase trial work will provide an opportunity to optimise trial design, recruitment strategies and quality assurance protocols, which will help to ensure the success of the next generation of phase III trials and avoid pitfalls resulting in failure or early closure of trials.

The bodies providing research funding for trials are shown in Figure 4. Data were collected on the funding source(s) of each trial, rather than the degree of financial



**Fig 3.** Proportion of early phase and phase III trials opening 2004–2008 and 2009–2013. A statistical comparison was carried out using Fisher's exact test.  $*P < 0.05$ .

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