

# CLINICAL TRIALS ADVISORY AND AWARDS COMMITTEE (CTAAC) AND TRANSLATIONAL RESEARCH IN CLINICAL TRIALS (TRICC) NEWSLETTER

The MRC's contribution to CTAAC • Cancer Research UK and NCI PDQ Database • CTAAC Funded Applications • Cancer Research UK Senior Nurses • Feasibility Study Committee (FSC) • FSC Funded Applications • Congratulations to Peter Parker • TRICC Applications Funded • onCoreUK

## The MRC's contribution to the Clinical Trials Advisory and Awards Committee (CTAAC)

### Summary

The Clinical Trials Advisory and Awards Committee (CTAAC) was first established in October 2002 as a joint funding committee for CR-UK and the MRC. Following an international review of CTAAC in June 2005, it was recommended that MRC should provide an equal financial commitment to the future funding of CTAAC. However, the MRC has recently made the decision to divert its contribution away from CTAAC and redeploy this, in part, to the MRC Clinical Trials Unit for use in cancer clinical trials. Therefore, as of 1st April 2006, MRC will no longer be making a contribution to CTAAC funding.

CTAAC will remain committed to reviewing and funding Phase III cancer clinical trials. Both CR-UK and MRC would like to continue to work together in a collaborative manner. One potential future area of collaboration may be large screening and prevention trials being reviewed and funded by PBSC or MRC, with co-funding by NCRI partners as an option.

### Statement from the MRC

The MRC has a long history of committing significant funds to research into the causes, prevention and treatment of cancer. MRC makes major investments into all aspects of cancer research through



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both intra-mural and extra-mural programmes of work. This research spans the spectrum of translational research from basic science underpinning cancer development and treatment, through to development of screening and prevention measures, in addition to a substantial portfolio of clinical trials of potential therapies. Closer working with other funders in this area has been a very welcome development over the past few years. One example of this joint working has been CTAAC (which has funded clinical trials below £100k per annum) to which MRC has contributed financially since its inception.

The MRC has been pleased to be informed of the significant increase in funding from CR-UK to CTAAC. In view of this increase, and with the agreement of CR-UK, MRC has decided to continue its funding of cancer research through alternative mechanisms to CTAAC. All of the funding allocated to CTAAC will continue to be used to support

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## CTAAC News in Brief

### New CTAAC Members

We would like to welcome the following new CTAAC members:  
Professor Duncan Jodrell  
Dr Chris Gallagher  
Dr Alison Jones  
Professor Nigel Bundred  
Dr Alan Hackshaw

### CTAAC Members Stepping down in October 2006

On behalf of the office we would like to thank you once again for all your hard work and invaluable contribution to CTAAC:  
Professor Colin Bird  
Professor Hilary Calvert  
Ms Sally Stenning  
Professor Arnie Purushotham  
Dr Paul Ellis

### New ICAP Members

We would like to extend a warm welcome to our new ICAP members:  
Dr F Lordick -  
Technical University of Munich  
Dr I Chau -  
Royal Marsden Hospital, UK

### New Application Forms

The CTAAC, TRICC and FSC application forms have now been updated with new sections. We recommend that applicants download the current form each time they wish to apply.

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clinical trials in cancer research. The majority of the funds will be committed directly to cancer clinical trials through the Clinical Trials Unit, with the remainder of the funding being used for specific cancer research initiatives.

The MRC remains committed to funding research in the field of cancer and will continue to welcome any cancer trials applications directly submitted to it through the MRC clinical trials route. In particular, we expect to receive applications, and to play a significant role, in screening and

prevention trials, although we will welcome partnerships with other funders for these investments should they wish to contribute to them.



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## Cancer Research UK and the NCI PDQ Database

CTAAC and FSC are collaborating with the NCI to include details of CTAAC and FSC funded trials on the PDQ database.

Once an application has been approved or funded, we will pass

on contact details to the NCI Liaison Office of the clinical trial centre associated with the application. If the trial is not associated with a clinical trial centre, the NCI will contact the principle investigator by email directly with more information.

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### For the June 2006 meeting of CTAAC we had...

10 Full Applications, 5 Approval Applications and 9 Outline Applications

We would like to congratulate one of our CTAAC members, Dr Laurence Collette on recently completing her PhD

The NCRI Cancer Conference 2006 will be held at the ICC, Birmingham, from the 8th-11th October 2006. Details are available at:

[www.ncri.org.uk/ncriconference/](http://www.ncri.org.uk/ncriconference/)

### The next CTAAC deadlines are:

Outline Applications  
& Endorsements - 1st Dec 2006  
Full Applications - 8th Dec 2006

For more information on CTAAC, including application forms and closing dates, please visit our webpage: <http://science.cancerresearchuk.org/gapp/grantapplications/cta/?version=7>

## Clinical Trials Advisory and Awards Committee (CTAAC)

### All Applications Funded and Endorsed in Principle

(applications pending feedback from applicants and final approval from CTAAC Committee).

#### June 2006 meeting

#### FULL APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Prof A Fiander	RT3 VIN: A randomised phase II multi-centre trial of topical treatment in women with vulval intraepithelial neoplasia
Prof Ian Russell	FIGURE: follow-up In gynaecological cancer units: RCT for endometrial cancer
Prof J Bliss	TNT: triple negative breast cancer trial: A randomised phase III trial of carboplatin compared to docetaxel for patients with metastatic ER- PR- HER2- breast cancer
Prof A Thompson	MINDACT (Microarray In Node-negative Disease may Avoid ChemoTherapy): A prospective, randomised study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in node-negative breast cancer

**CTAAC Members:** ROGER A'HERN • DEREK ALDERSON • JOHN COHEN • HILARY CALVERT • LAURENCE COLLETTE • DAVID DODWELL • PAUL ELLIS • STAN KAYE • MARK MIDDLETON • GARETH MORGAN • MARIANNE NICOLSON • CHRIS POOLE • KATHY PRITCHARD-JONES • ARNIE PURUSHOTHAM • JOHN RADFORD • MATT SEYMOUR • SALLY STENNING • STEPHEN FALK • HEATHER PAYNE • NOEL CLARKE • JIM PAUL • NEIL BURNET

Dr H Ford	COUGAR-02: a phase III randomised controlled trial of docetaxel versus active symptom control as second line treatment in advanced gastric cancer
Prof S Spiro	SEARCH: A randomised controlled trial of surveillance for the early detection of lung cancer in a high-risk group
Dr P Szlosarek	A randomised stratified phase II multicentre clinical trial of single-agent ADI-PEG 20 (pegylated arginine deiminase) in patients with malignant pleural mesothelioma
Dr H Wasan	CUP-ONE: randomised study of epirubicin, cisplatin and capecitabine with and without Erlotinib in carcinomas of unknown primary: incorporating prospective validation of molecular classifiers

## APPLICATIONS ENDORSED

Lead Investigator	Trial Acronym and Title
Dr S Erridge	Phase III trial comparing conventional adjuvant Temozolomide with dose intensive Temozolomide in patients with newly diagnosed glioblastoma
Prof P Johnson	A clinico-pathologic study of primary mediastinal B-cell lymphoma
Prof I Smith	HEALTH: A randomized, open label, pharmacodynamic and efficacy study of Letrozole alone and Letrozole in combination with Herceptin in the neoadjuvant treatment of postmenopausal women with ER+ HER2+ breast cancer
Dr P Hillmen	UKCLL07: Eradication of Minimal Residual Disease (MRD) in patients with Chronic Lymphocytic Leukaemia (CLL) with Alemtuzumab: a Phase II Study

## Cancer Research UK Senior Nurses

Cancer Research UK is funding 15 Senior Nurses across the UK. Based at the Charity's Clinical Centres, they will have an innovative and unique role providing a focus for local fund raising and press activity.

A review of the 5 pilot posts has resulted in a comprehensive role profile being drawn up which will constitute part of the fuller job description, with each centre being able to add their own local requirements. The real focus of these posts is to raise awareness of cancer research and the work of the charity among patients, health professionals and the general public. By linking with local fund raisers and press officers, these Senior Nurses provide an excellent opportunity

to demonstrate how Cancer Research UK helps cancer patients and their families. Additionally, there is a requirement for these Senior Nurses to be identified as funded by Cancer Research UK, further raising the profile of the Charity.

A lead nurse has been appointed to co-ordinate the roll out of these posts and is currently in discussion with local clinical leads at the centres, as well as meeting with key departments within the Charity to ensure that the posts meet everyone's needs.

For more information please contact Anne Croudass Cancer Research UK Lead Nurse on 07973 635207 or [anne.croudass@cancer.org](mailto:anne.croudass@cancer.org)



# Feasibility Study Committee (FSC)

## 9 new studies supported • Electronic review to be piloted

The Feasibility Study Committee (FSC) received 20 applications for funding or endorsement in response to the announcement and call for bids to this new scheme in February. 9 studies were supported (6 funded, 3 endorsed) some of which are pending feedback from the applicant and final approval from FSC (see table below for full list).

The first grant awarded was to Dr Mike Bennett from Leeds for a study entitled 'Transcutaneous electrical nerve stimulation (TENS) in the management of bone pain'. The Committee felt that this study would generate meaningful data on the feasibility of offering TENS to patients with pain that is not responsive to opioids and provide information on whether it might benefit patients, and if so the duration of effect and timepoints that should be chosen to look for an effect. The study would provide an opportunity to clarify which patients should be included or excluded in a subsequent phase III trial, and help identify effective strategies for patient recruitment.

The second study that has been supported was a study submitted for endorsement by Dr Simon Rule from Portsmouth entitled 'A parallel randomised phase II trial of CHOP chemotherapy with or without Bortezomib in relapsed mantle cell lymphoma'. The Committee recognised there was a need for new treatment strategies for this patient group, who have a very poor prognosis and were supportive of a study using a new agent, such as



Bortezomib. In particular, members felt that this would complement ongoing studies and help identify the most appropriate endpoints in any future phase III trial.

### **Rapid review target met – electronic review to be introduced**

One of the aims of the FSC is to provide rapid turnaround of applications to allow these small early phase trials to proceed as quickly as possible. We are delighted to report that there were just two months between the date of submission of an application to a final decision being fed back to all applicants. The decision of the Committee is final and there is no time for appeals as the focus will be on reviewing the next batch of new applications.

A second deadline has just passed and we have received 8 applications for review this time which is a level of activity we had anticipated after

the initial announcement and call for bids. This will enable us to pilot the use of electronic review via a Cancer Research UK secure web site called an eRoom. Applications will be posted on the eRoom and committee members will be able to download them, read them and provide comments on a standard form found on the web site. This information will provide the basis for a teleconference meeting. We hope that this system will save committee members' time travelling to London as well as being more environmentally friendly (funding committee papers are usually at least 4 inches deep!).

### **FSC News in Brief**

#### **The next FSC deadlines are:**

- | October 06
- | January 07
- | April 07
- | July 07

**FSC Members:** PETER JOHNSON • MALCOLM MASON • CHRIS TWELVES • RICHARDS STEPHENS • JUDITH BLISS • JULIA BROWN • PAUL SMITH • DAVID SEBAG-MONTEFIORE • BARRY HANCOCK • GORDON JAYSON • JOHN YARNOLD • PENELLA WOLL • JOHN GRIBBEN • POULAM PATEL • JEFF EVANS • DION MORTON • RICHARD GRUNDY • MALCOLM RANSON • PETER BRENNAN • RICHARD SAINSBURY • IAN JUDSON • IRENE HIGGINSON • JANET RICHARDSON

# Feasibility Study Committee (FSC)

## All Applications Funded and Endorsed in Principle

(applications pending feedback from applicants and final approval from FSC Committee).

### May 2006 meeting

#### APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr S Schey	A phase I dose escalation study of the combination of Lenalidomide (Revlimid), Dexamethasone and Cyclophosphamide in patients relapsing from stable disease with multiple myeloma
Dr D Gillmore	A randomised feasibility study comparing chemotherapy regimens for systemic AL amyloidosis
Dr M Bennett	TENS: Transcutaneous electrical nerve stimulation in the management of cancer bone pain
Prof D Cunningham	GEM-P Hodgkin's: A phase II trial of gemcitabine, cisplatin and methylprednisolone (and rituximab if CD20 positive) for patients with primary progressive or relapsed Hodgkin's disease
Prof D Cunningham	DLBCL: Feasibility study of R-CHOP plus Bevacizumab in patients with diffuse large B-cell Lymphoma
Prof P Price	PACER: A phase II study of image-guided 3-Dimensional conformal radiotherapy with concurrent cetuximab in patients with locally advanced pancreatic cancer

#### APPLICATIONS ENDORSED

Lead Investigator	Trial Acronym and Title
Dr S Rule	A parallel randomised phase II trial of CHOP chemotherapy with or without Bortezomib in relapsed mantle cell lymphoma
Mr M Emberton	HIFU: An evaluation of hemi-ablation therapy using high-Intensity focused ultrasound in the treatment of localized adenocarcinoma of the prostate
Prof D Cunningham	BOXER: Phase II clinical trial of capecitabine and oxaliplatin plus bevacizumab as neoadjuvant treatment for patients with previously untreated unresectable liver-only metastases from colorectal cancer



## Congratulations on behalf of the Translational and Clinical Directorate to Peter Parker

Professor Peter Parker, Chairman to the Translational Research in Clinical Trials Committee (TRICC), has been given an honour that is regarded as one of the highest recognitions a scientist can receive, by being elected as a fellow of the Royal Society. Peter was one of forty-four new fellows that are elected every year to the Society as recognition for their exceptional contribution to science, engineering and medicine. Peter was selected for 'his major contributions to our understanding of the enzymology of signal transduction cascades which link changes in external events to alterations in cellular behaviour' ([www.royalsoc.ac.uk](http://www.royalsoc.ac.uk)).

Previous elected fellows include the formidable figures of Charles Darwin, Sir Isaac Newton and Stephen Hawking. Whilst currently head of Cancer Research UK London Research Institute (LRI)

Protein Phosphorylation laboratory and honorary Professor UCL, Peter received his PhD from Oxford University and worked as a postdoc at the University of Dundee and Imperial Cancer Research Fund. He will soon take up a joint appointment with the LRI and King's College London to head the King's Division of Cancer Studies. He will also play a key role in establishing the King's College London Experimental Cancer Centre (KCLECC) funded by Cancer Research UK and The Department of Health, bringing together clinical and non-clinical academics to focus on translational research and the advancement of patient care.

We wish to congratulate Peter and thank him for his commitment to the Translational and Clinical Directorate and to Cancer Research UK.

## TRICC News in Brief

For the June 06 meeting of TRICC there were 4 Full applications, 4 Sample Collection Applications and 13 Outline Applications.

In response to concerns from clinical trials unit staff, closing dates for CTAAC and TRICC are now staggered.

**Closing dates for the 28th September 2006 meeting are:**  
**Outline applications**

– 7th December 2006

**Full applications**

– 28th November 2006

**Sample Collections**

– 11th January 2007

For more information on TRICC, including application forms and closing dates, please visit our webpage:

<http://science.cancerresearchuk.org/gapp/grantapplications/tricc/?version=3>

## Translational Research In Clinical trials Committee All Applications Funded and Endorsed in Principle

(applications pending feedback from applicants and final approval from TRICC Committee).

### June 2006 meeting

#### FULL APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Ms L Wyld	ESTEEM Trial- Endocrine or Surgical Therapy for Elderly women with Mammary cancer
Dr R Adams	COIN- The relationship between Epidermal Growth Factor Receptor and Insulin-like growth factor receptor-I in colorectal cancer: anti-EGFR therapy response and resistance mechanisms explored
Prof P Collins	BRI2: Temozolomide vs PCV chemotherapy in the treatment of recurrent malignant glioma – translational research proposal

#### SAMPLE COLLECTIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr J Green	Molecular markers of prognosis in ovarian cancer through analysis of the EORTC/NCRI randomised phase III study of platinum/taxane chemotherapy ± erlotinib

**TRICC Members:** PETER PARKER • GARETH MORGAN • ROBERT BROWN • ADRIAN HARRIS • MATT SEYMOUR • JAMES BRENTON • JOHN PRIMROSE • KARIN OIEN • CATHERINE WEST • MITCH DOWSETT • BRYAN YOUNG • CINDY BILLINGHAM



## onCore UK

An independent, not for profit organisation named onCore UK, has been created to serve as a national biosample and information resource to equip researchers with the vital human tissues and data they need for the discovery of new interventions against cancer. Of key importance is that onCore UK is a service organisation, not a research unit and that it will provide an honest brokering service between the donors and the researchers without having a vested interest in the samples itself. A prime concern of the organisation is to uphold the donor's altruistic intentions behind their generous donations and to facilitate the journey of the donated sample from the donors, via the healthcare setting, to researchers.

In order for this to be accomplished, the donor's benevolence needs to be matched with willingness on the part of the healthcare and research communities to collect and to share these donated samples even if no direct benefit is realised.

The team at onCore UK have accomplished several key goals towards becoming a fully operational national biorepository. The first successfully accomplished challenge was the relocation of the office in central London to Borehamwood. Furthermore, with the hiring of Anne Carter (Head of Quality and Standards), Tracy Parker (Head of Service Development), a senior database architect and a

senior software developer under Mahendra Navarange's (Head of Informatics and IT) team, several important workstreams have now gathered momentum.

Finally, onCore UK has recognised that the most effective way to create a valuable tissue resource is to share common principles and practices with other cancer biobanks. Discussions have commenced under the auspices of the National Cancer Research Institute with the Wales Cancer Bank, the Leukaemia Research Fund and the Dundee Tissue Bank towards forming a confederation that will unite efforts and harmonise approaches to the collection, storage and distribution of biosamples.

*Tracy Parker*

## Clinical Trials Toolkit

On this site you will find practical help when trying to meet the requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004.

These regulations implement the EU Clinical Trials Directive in the UK:  
[www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk)

## Patient Information

If you are a patient looking for information about clinical trials, please look at the clinical trials database on CancerHelp UK, the patient information website of Cancer Research UK :  
[www.cancerhelp.org.uk/trials/trials](http://www.cancerhelp.org.uk/trials/trials)

## CTAAC and TRICC Contacts

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If you are a patient looking for information about clinical trials please look at the clinical trials database on CancerHelp UK, the patient information website of Cancer Research UK [www.cancerhelp.org.uk/trials/trials](http://www.cancerhelp.org.uk/trials/trials)