



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

Making the most of clinical trials • CTAAC's July 2005 Meeting • CTAAC Applications Funded and Endorsed in Principle • International CTAAC Advisory Panel (ICAP) • The Success of developing a CTAAC Application with the Involvement of the NCRI clinical Study Groups • New Application Forms • TRICC Funded Applications • Human Tissue Act 2004 • Clinical Trials Toolkit

## CTAAC News in Brief

### New CTAAC Members:

Dr Stephen Falk  
Dr Heather Payne  
Mr Noel Clarke  
Dr Jim Paul

### CTAAC Members Stepping Down in October 2005:

Professor Malcolm Mason  
Professor Roy Rampling  
Professor David Neal  
Professor Graham Dunn

On behalf of the office we would like to thank you once again for all your hard work.

For the October 2005 meeting of CTAAC we had... 17 Full Applications, 2 Approval Applications and 20 Outline Applications

### The next CTAAC deadlines are:

#### Outline Applications & Endorsements

- 2nd December 2005

#### Full Applications

- 9th December 2006

For more information on CTAAC, including application forms and closing dates, please visit our webpage: <http://science.cancerresearchuk.org/gapp/grantaapplications/cta/?version=6>

## CTAAC and TRICC - making the most of clinical trials

Cancer Research UK is committed to increasing the number of patients entering clinical trials.

In 2000 the charity agreed to a joint application and funding process with the Medical Research Council, to be managed by a new Cancer Research UK committee, the Clinical Trials Advisory and Awards Committee (CTAAC). The aim of this was to speed up the decision making process and get more trials



launched in a timely way. The membership of CTAAC consists of an independent, non-oncologist chairman, 18 expert members (surgeons, medical and clinical oncologists, and statisticians), a consumer and one of the members of the charity's cancer information team. The Committee meets three times a year, reviewing more than 40 applications at each meeting.

Each application is commented on by committee members as well as international experts, to ensure that the trial is asking the optimal question and has the greatest chance of benefiting patients.

In 2004, 31 new trials were funded giving CTAAC a portfolio 123 funded trials, which include trials in development, open for recruitment, recruiting and follow up.

CTAAC-funded trials are not restricted to those looking at new drug combinations. The portfolio also includes: research into reducing the side effects of radiotherapy, for example lymphoedema or swelling of the limbs; chemoprevention trials testing the use of medicines to reduce the risk of developing cancer; and the evaluation of novel methods to detect cancers earlier.

An important area connected to clinical trials is the biological analysis of samples (normal tissue, tumour tissue or blood) from patients. Traditionally this research was viewed as simply additional to a clinical trial. However, in 2002 Cancer Research UK was spending ten per cent of its clinical trials budget on such studies and a better

system was needed to enable their development and funding alongside phase II and III trials. A new committee, the Translational Research in Clinical Trials Committee (TRICC), was therefore established to provide appropriate peer review, funding and monitoring of research associated with trials.

The advantage of using samples from patients participating in a clinical trial is that these patients are treated in a consistent way, according to clearly defined protocols, and are monitored closely during and after their treatment. Furthermore, patients entering a

trial are randomly assigned usually to one of two treatment approaches, the standard treatment or the new treatment plan.

After one year of operation TRICC has already undergone its first strategic review by the Clinical and Translational Research Committee to which it reports. As a result its remit was clarified and expanded with applicants now able to apply for funding under one of three categories.

1. Prospective sample collection and analysis of samples from a clinical trial that is about to

commence or is ongoing

2. Retrospective sample collection and analysis
3. Prospective collection of samples alone from a clinical trial that is about to commence or is ongoing

The strategy for TRICC is also being developed in tandem with the establishment of OnCOREUK (formerly known as the National Cancer Tumour Bank) headed by Dr Brian Clark, please find link below.

[http://www.ntrac.org.uk/Patients/NCTR/PandC\\_NCTR.aspx](http://www.ntrac.org.uk/Patients/NCTR/PandC_NCTR.aspx)

The aim of TRICC is to enable the integration of laboratory and clinical research. The response to this new funding stream has been very positive with more applications received than anticipated. We will continue to streamline and develop processes so that the research community can tap into this important source of funding and hopefully this will assist in taking more research from bench to bedside.



## CTAAC's July 2005 Meeting

13 full applications and 25 outline applications were submitted to the Clinical Trials Advisory and Awards Committee (CTAAC), for consideration on the 7th/8th July 2005. However, due to the events in London on the 7th of July 2005, only a small number of members managed to attend the meeting. Therefore CTAAC was only able to consider a few applications where those present had the appropriate expertise. It was agreed that the majority of full proposals for funding would not be considered until it was

possible to give them the appropriate level of discussion and review. Therefore only 5 full applications were considered at the meeting; however all the outline applications were considered, either at the meeting or by correspondence via a virtual meeting after the 7th July.

Of the 5 full applications discussed 3 were approved for funding, and 2 were given CTAAC endorsement. The remainder of the full applications were deferred until the October meeting. For the outline applications

15 were invited to submit full applications, 2 were declined, and the remaining 8 were invited for resubmission.

We would like to take this opportunity to publicly thank the Committee members whom were able to attend the meeting and to all the rest of CTAAC's Committee members for all their involvement and assistance in the virtual meeting, after the 7th July.

**CTAAC Members:** ROGER A'HERN • DEREK ALDERSON • COLIN BIRD • HILARY CALVERT • LAURENCE COLLETTE • DAVID DODWELL • GRAHAM DUNN • PAUL ELLIS • STAN KAYE • MALCOLM MASON • MARK MIDDLETON • GARETH MORGAN • DAVID NEAL • MARIANNE NICOLSON • CHRIS POOLE • KATHY PRITCHARD-JONES • ARNIE PURUSHOTHAM • JOHN RADFORD • ROY RAMPLING • MATT SEYMOUR • SALLY STENNING



# CTAAC Dinner February 2005

from left to right: Kate Law, Roger A'hern, Rick Kaplin, Sally Stenning, Roy Grainger, Daljit Kaur and Derek Alderson

## Clinical Trials Advisory and Awards Committee (CTAAC) - Applications Funded and Endorsed in principle (February 2005 and July 2005 meetings)

\* In principle = applications pending feedback from applicants and final approval from CTAAC Committee.

### February 2005 meeting

#### APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr F Macbeth	LOMOH - A multicentre randomised controlled trial of low weight heparin in lung cancer patients
Dr M Seckl	LUNG-STAR - Pravastatin added to first line chemotherapy in patients small cell lung cancer:
Dr J Shamash	Infusional BleoTE3 - Infusion Bleomycin in patients with IGCCCG.
Mr P Abel	PATCH - A randomised controlled trial of trans-cutaneous oestrogen patches versus LHRH analogues in locally advanced and metastatic prostate cancer
Ms A Francis	NEO-EXCEL - Neoadjuvant trial of pre-operative exemestane or letrozole +/- celecoxib in the treatment of ER positive postmenopausal early breast cancer:
Professor M Sculpher	TACT Economics - A cost effectiveness analysis of the TACT Trial
Professor P Hoskin	FORT- A phase III randomised controlled trial of low dose palliative radiotherapy for follicular lymphoma
Professor A Burnett	AML16: A programme of development in AML
Professor G Hanks	Two step analgesic ladder compared to a three step approach to treat cancer pain
Dr U Mallick	HILO - Radioiodine with and without TSH following surgery thyroid cancer
Dr G Middleton	TELEOVAX - A phase III multicentred randomised clinical trial comparing gemcitabine alone and in combination with telomerase vaccine for the treatment of pancreatic cancer
Dr I Fernando	SECRAB - Chemotherapy & radiotherapy in adjuvant treatment of early breast cancer
Dr S Ablett	Treatment of soft tissue sarcoma in paediatrics

#### APPLICATIONS ENDORSED

Professor TA Lister	PRIMA - Primary Rituximab & Maintenance
Professor TA Lister	DEPOCYTE - A phase II clinical study to determine the efficacy and safety of depocryte
Dr Woll	EORTC - Gastrointestinal stromal tumours expressing KIT receptor and adjuvant Imatinib mesylate therapy
Dr A Pettit	CAM-PRED - Alemtuzumab & high dose methylprednisolone for CLL patients with p53 deletion

### June 2005 meeting

#### APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr P Fields	A phase II multicentre clinical trial of Rituximab, CVP and Gemcitabine for the treatment of patients with newly diagnosed diffuse large B-cell lymphoma considered unsuitable for R-CHOP
Professor M Seymour	PICCOLO: a randomised clinical trial of treatment for flurouracil-resistant advanced colorectal cancer comparing standard single-agent irinotecan plus ciclosporin.
Professor I Jacobs	UKFOCSS: United Kingdom familial ovarian cancer screening Study

#### APPLICATIONS ENDORSED

Dr Ledermann	A randomised placebo-controlled phase II study of BIBF 1120 as maintenance treatment following chemotherapy for relapsed ovarian cancer
Professor R Coleman	Phase III randomised open label multi-centre study comparing GW572016 with Capecitabine (Xeloda) vs. Capecitabine in women with refractory advanced or metastatic breast cancer

# International CTAAC Advisory Panel (ICAP)

Many thanks again to the ICAP members for all their time taken to review the 20 outline applications from the October 2005 meeting! We are currently in the process of recruiting new members to the international panel in order to increase the range of expertise even further and help spread out the workload for our existing members.

**Dr Matti Aapro, Switzerland**

Prof Harry Bartelink, The Netherlands

**Prof Bertrand Coiffier, France**

Dr Aron Goldhirsch, France

**Dr Joseph Pater, California, USA**

Prof Derek Raghavan, Cleveland USA

**Prof Steven Rosen Illinois, USA**

Dr Jan Schornagel, The Netherlands

**Prof Kathleen Pritchard, Toronto**

Dr Padraig Warde, Toronto

**Dr Sridhar Ramaswamy, Massachusetts USA**

Prof Richard Simon, Maryland, USA

**Prof Herve Tilly, France**

Dr Hans-Joachim Schmoll, Germany

**Dr Cora N Sternberg, Italy**

Dr Janet Dancey, Maryland, USA

**Dr James Talcott, Massachusetts, USA**

## The success of developing a CTAAC application with the involvement of the NCRI Clinical Studies Groups

Trial applications submitted to CTAAC are developed by individuals or groups of clinicians who may be, (but are not required to be), members of the NCRI Clinical Study Groups. The Groups do, however, comment on all outline proposals.

The table demonstrates that trials either developed or approved by the NCRI Clinical Study Groups have a significantly higher chance of success; for example the success rate can be as high as 75% at the outline stage and 100% at the full proposal stage. This supports CTAAC's decision to encourage applicants to discuss their proposals with the relevant NCRI Clinical Study Group(s), where possible, prior to submission.

**A table illustrating the success of applications submitted by NCRI Clinical Studies Groups.**

	Oct 2002	Feb 2003	June 2003	Oct 2003	Feb 2004	July 2004
<b>Outline Proposals</b>						
Total no. submitted	18	14	26	19	17	20
Total no. invited to submit full applications	9	7	18	10	8	9
No. developed/endorsed by NCRI CSGs	11	11	24	13	12	14
No. of NCRI outlines invited	7	7	18	9	7	9
Success rate of those developed/endorsed by NCRI CSG (%)	63	63	75	69	58	64
Success rate those not developed by NCRI CSG (%)	33	0	0	17	20	0
<b>Full Proposals</b>						
Total no. submitted	4	13	14	25	14	11
Total no. of full applications funded/endorsed	4	9	10	17	10	6
No. developed/endorsed by NCRI CSGs	3	9	9	22	12	8
No. of NCRI full applications funded	3	7	7	15	10	6
Success rate of those developed/endorsed by NCRI CSG (%)	100	80	77	90	83	75
Success rate of those not developed by NCRI CSG (%)	100	50	60	66	0	0

# Launch of New Application Forms

Over the past year Cancer Research UK has launched new application forms for all funding Committees, including TRICC and CTAAC. This has been a major change to the way information about applicants is collected and stored and will also make the application process simpler for the applicant. The majority of the form is common across committees, ie applicant details, CVs, current grants held, equal opportunities, with one or more sections specific to a particular funding stream. Applicants are invited to provide the names of up to five reviewers who would be able to assess their current application critically. The office check these for potential conflicts of interest, and identify a further 5-10 reviewers to send the study to for expert peer review.

All applicants are asked to classify the type of cancer and type of research they are planning to conduct, and to provide specific keywords, so that the National Cancer Research Institute (NCRI) can more easily collate such information from CR UK and other cancer research funders in the future.

The new application forms are the first step towards a more automated Application Management System (AMS) that will aim to cut administration costs, build capacity and improve the quality of information we hold about CR UK research awards. AMS will be introduced in 2006 and a manned helpdesk will be established to help applicants with any queries as they complete the forms.

## TRICC News in Brief

**TRICC welcomes two new committee members** - Professor Brian Young and Dr Cindy Billingham

For the October 2005 meeting of TRICC there were 3 Full Applications, 4 Sample Collection Applications and 4 Outline Applications.

In response to concerns from clinical trials unit staff, closing dates for CTAAC and TRICC are now staggered, as are the deadlines for outline and full applications.

**The next TRICC deadlines are:**

**Outline Applications**

– 23rd November 2005

**Full Applications**

– 30th November 2005

**Sample Collections**

– 21st December 2005

## Translational Research in Clinical Trials Committee (TRICC) - Funded Applications (June 2004 to June 2005)

Cancer type / Lead Investigator	Study title and trial details
Breast Dr N Burnet	RAPPER: Radiogenomics: assessment of polymorphisms for predicting the effects of radiotherapy. [Trials: Cambridge IMRT Trial in breast cancer; ongoing trial recruiting 1000 patients, expected closure end 2005; RT01 Trial for prostate cancer; 850 patients, closed Dec 01]
Breast Professor J Yarnold	RACE: Radiation Complications and Epidemiology; inherited predisposition to the late adverse effects of radiation therapy. [Trials: Breast Radiotherapy Fractionation Trial 1986-1998, n=1410; Breast Radiotherapy Dosimetry Trial 1997-2000, n=306]
Breast Professor C Caldas	PG-SNPS: The Pharmacogenomics of Early Breast Cancer Chemotherapy [Trials: NEAT, tAnGo and Neo-tAnGo Phase III adjuvant trials in early breast cancer: NEAT and tAnGo are closed, n=2,028 and 3,152 respectively, Neo-tAnGo ongoing]
Breast Dr J Bartlett	NEATSCIENCE-TOPO: Analysis of Topoisomerases as predictors of benefit from anthracycline therapy in the context of the NEAT/BR9601 trials [Trials: NEAT and BR9601 Phase II adjuvant trials of epirubicin in early breast cancer: Both closed, total n=2,401]
Colorectal Dr J Cheshire	COIN-Trans: Investigating the relationship between DNA repair capacity, response to and side effects from chemotherapy. [Trial: COIN: Phase III trial comparing either COntinuous chemotherapy plus cetuximab or IIntermittent chemotherapy with standard continuous palliative combination chemotherapy with oxaliplatin and a fluoropyrimidine in first line treatment of metastatic colorectal cancer; opened July 2005, target n=2,421]
Head & Neck Dr C West	MARCHON-TRANS: Moderately accelerated radiotherapy, chemotherapy or nimorazole (MARCHON) Translational [Trial: MARCHON trial due to open 05, target n=1,110]
Myeloma Professor G Morgan	GEM-IX: Gene Expression - Myeloma IX [Trial: Myeloma IX: Myelomatosis therapy trial for patients of all age groups. Currently recruited 600 patients out of a target n=1,600]
Ovarian Professor H Gabra	Trans-SCOTROC4: Prospective, multi-modality molecular analysis of the clinical effect of single agent carboplatin in serous ovarian cancer. [Trial: SCOTROC4 opened in March 2004, target n=1,300]
Ovarian Professor H Calvert	ICON3 p53: Evaluation of p53 as a prognostic factor in the outcome to chemotherapy in ovarian cancer [Trial: ICON3 - Phase III trial of paclitaxel plus carboplatin versus CAP or carboplatin alone. Open 1995 to 1998, n=2,074]
Upper GI Professor J Jankowski	CHOPIN: Chemoprevention of Premalignant Intestinal Neoplasia [Trial: ASPECT Aspirin Esomeprazole Chemoprevention trial, due to open 2005]

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

<http://science.cancerresearchuk.org/gapp/grantapplications/tricc/?version=2>

## Human Tissue Act 2004: Draft regulations for consultation

The Department of Health has published, for consultation, draft regulations under the Human Tissues Act 2004. The regulations are an important part of the implementation of the Human Tissue Act and provide detailed policy on a number of issues where broad outlines were given in the primary legislation. The deadline for responses to this consultation was 4 October 2005. The draft regulations and

explanatory notes are available on the Department of Health website at: [www.dh.gov.uk/consultations](http://www.dh.gov.uk/consultations), and the title to look for is Human Tissue Act Regulations. When the Act comes into force in April 2006, all researchers collecting tissue prospectively or holding archival material would require a licence, unless they were collecting for a specific project that had been approved by a Research Ethics Committee.

## 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:

<http://www.ct-toolkit.ac.uk/>

**TRICC Members:** PETER PARKER • GARETH MORGAN • HERBIE NEWELL • ADRIAN HARRIS • MATT SEYMOUR • DAVID GOLDSTEIN • JOHN PRIMROSE • KARIN OIEN • CATHERINE WEST • MITCH DOWSETT • JACK CUZICK • BRIAN YOUNG • CINDY BILLINGHAM

Photograph from the February 2005 CTAAC meeting showing some CTAAC members and CRUK office staff



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