

# CLINICAL TRIALS ADVISORY AND AWARDS COMMITTEE (CTAAC) AND TRANSLATIONAL RESEARCH IN CLINICAL TRIALS (TRICC) NEW S L E T T E R

Study shows detrimental impact of EUCTD • Thanks and Farewell to John Toy • CTAAC Applications Funded in Principle • A framework for PET Research in the UK • FSC Applications Funded in Principle • Feasibility Study Committee Applications Invited • Welcome to Louise Jones • Tissue Resources Science Plan Review • TRICC Applications Funded in Principle

## CTAAC News in Brief New CTAAC Members

We would like to welcome the following new CTAAC members:  
Professor Richard Clark  
Mr Michael Aitchison

We would also like to welcome Dr Peter Davidson (Science Support Director, National Coordinating Centre for Health Technology Assessment (NCCHTA)) as an Ex-Officio Member of CTAAC

### Members leaving CTAAC:

Mr Noel Clarke has stepped down as a member of CTAAC as he has been re-appointed as the Chair of the NCRI Prostate Clinical Study Group. We would like to thank him for his valued support.

### Members stepping down from ICAP:

On behalf of the office we would like to thank you for all your hard work and invaluable contribution to CTAAC.

Dr Herve Tilly  
Dr Joseph Pater  
Professor Kathleen Pritchard  
Professor Matti Aapro  
Professor Steven Rosen

### For the February 2007 meeting of CTAAC we had...

11 Full Applications, 2 Extension Applications, 3 Endorsement Applications and 12 Outline Applications

### The next CTAAC deadlines are:

**Outline Applications and Endorsements** – 3rd August 2007  
**Full Applications** – 10th August 2007

For more information on CTAAC, including application forms and closing dates, please visit our web page: <http://science.cancerresearchuk.org/gaapp/clinicaltrialsfund/cta/>

## Study shows detrimental impact of EUCTD

The primary aim of the European 'Clinical Trials' Directive (2001/20/EC) (EUCTD) was to simplify and harmonise the regulation of clinical trials using medicinal products across Europe. The UK Medicines for Human Use (Clinical Trials) Regulations 2004 implemented this Directive into UK law and came into effect on 1st May 2004. A pre-implementation impact assessment had raised significant concerns about the potentially deleterious effect of this legislation on non-commercial clinical trials.

EJC recently published the results of a post implementation study conducted in April 2005 that aimed to assess the actual impact of the EUCTD (Hearn J & Sullivan R, European Journal of Cancer, 43 (2007) 8-13).

Eight UK Clinical Trials Unit (CTUs) were interviewed on six topics covering their involvement in non-commercial cancer clinical trials, their perceptions of the EUCTD, and its impact on all stages of trial development and conduct. Detailed cost data were also collected. The findings indicate that the EUCTD has resulted in a doubling of the cost of running non-commercial cancer clinical trials in the UK and a delay to the start of trials in the order of 6 to 10 months. The lack of central guidance, lack of clarity regarding the interpretation of the guidance notes, and increase in essential documentation and paperwork were causes of major concern for experienced staff who were anxious about whether they were interpreting the Directive correctly.



Pharmacovigilance reporting was felt to be a particularly grey area. Overall, staff felt that they were working beyond capacity and were feeling demoralised in many CTUs. Finally, all seven CTUs that had planned starting up international trials viewed the EUCTD as a significant barrier to doing so

because of the different interpretation of the Directive into law by member states.

CRUK has responded by providing substantial additional money to individual CTUs that it supports to enable them to cope with the impact of the EUCTD, primarily to

fund new posts for IT and trial administration thereby enabling trial co-ordinators to focus on trial conduct and new study development. Lobbying continues in the UK and at the European level to address the lack of harmonised interpretation of the EUCTD.

## Thanks and Farewell to John Toy (MB, ChB, PhD, FRCP, FFPM)

John Toy, a highly respected and valued member of the Clinical and Translational Directorate at Cancer Research UK, retired at the end of May.

John's role as Medical Director of the Charity was wide and varied, reflecting his vast experience, including advisor to the policy team, media spokesperson and advisor to the Drug Development Office. He was an invaluable source of knowledge and advice to many and will be particularly missed by Kate and the Clinical Trials Team.

In addition to his role at CR-UK, John was also the Director of Research and Development in the North East London Cancer Network of the NHS, having previously been the area's Clinical Lead for Research

and involved in establishing its clinical trials contributions to the National Cancer Research Network (NCRN) portfolio.



John originally trained as a physician and medical oncologist at Leeds, the Royal Marsden Hospital and St Bartholemew's. Later he worked as a consultant oncologist at the

Hammersmith Hospital.

As John's career flourished he held senior clinical research positions in the pharmaceutical industry, including that of Vice-President of Clinical Investigations at SmithKline Beecham. Prior to joining Cancer Research UK, he worked in the Department of Health as a Senior Medical Officer helping to establish its Research and Development Division, led by Sir Michael Peckham, and introducing the concept of Multicentre Research Ethics Committees with the then CMO, Sir Kenneth Calman.

John and his wife (a GP who retired at the same time) are looking forward to spending more time in their second home, enjoying the Yorkshire countryside and hospitality.

**CTAAC Members:** :JOHN COHEN (CHAIR) • STAN KAYE (VICE CHAIR) • MATT SEYMOUR (VICE CHAIR) • ROGER A'HERN • MICHAEL AITCHISON • DEREK ALDERSON • NIGEL BUNDRED • NEIL BURNET • RICHARD CLARK • LAURENCE COLLETTE • DAVID DODWELL • STEPHEN FALK • CHRIS GALLAGHER • ALLAN HACKSHAW • DUNCAN JODRELL • ALISON JONES • MARK MIDDLETON • GARETH MORGAN • MARIANNE NICOLSON • CHRIS POOLE • KATHY PRITCHARD-JONES • JIM PAUL • HEATHER PAYNE • JOHN RADFORD

# Clinical Trials Advisory and Awards Committee (CTAAC)

## Applications Funded in Principle\*

\*Applications pending feedback from applicants and final approval from CTAAC

### February 2007 Meeting

#### APPLICATIONS FUNDED

Lead investigator	Trial Acronym and Title
Professor M T Fallon	KPS (Ketamine Pain Study): A randomised double-blind controlled trial of s-ketamine versus placebo in conjunction with best pain management in neuropathic pain in cancer patients
Dr J K Joffe	TRISST: Trial of Imaging and Schedule in Seminoma Testis
Dr A Rockall	FDG-PET/CT and nanoparticle-enhanced MRI in the diagnosis of lymph node metastases in surgically-staged endometrial and cervical carcinoma
Professor J Bliss	POETIC: Trial of Perioperative Endocrine Therapy – Individualising Care
Dr D Sebag-Montefiore	ARISTOTLE: A phase II/III trial comparing standard versus novel CRT as pre-operative treatment for MRI defined locally advanced rectal cancer
Professor P Johnson	SABRE I: Randomised controlled trial of brachytherapy versus radical prostatectomy in good risk prostate cancer: a feasibility study
Dr M Powell	PORTEC 3: Randomized Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma

#### EXTENSIONS FUNDED

Lead investigator	Trial Acronym and Title
Professor K Pritchard-Jones	SIOP WT 2001: International Society of Paediatric Oncology Wilms Tumour 2001 Clinical Trial and Study
Dr C Nutting	PARSPORT: A multicentre randomised study of parotid sparing intensity modulated radiotherapy versus conventional radiotherapy in patients with head and neck cancer

#### APPLICATIONS ENDORSED

Lead investigator	Trial Acronym and Title
Professor W Artl	FIRM-ACT: First International Randomized trial in locally advanced and Metastatic Adrenocortical Carcinoma Treatment
Professor C Boshoff	DORA: A phase I and randomised phase II study of docetaxel and RAD001 (everolimus) in advanced/recurrent or metastatic squamous cell carcinoma of the head and neck
Professor I Smith	ALTTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Study



### New Application Forms:

The application forms for CTAAC, TRICC and FSC are frequently updated with additional questions. Applicants are requested to regularly check the website and download the current form each time they wish to apply.

### PBSC Newsletter:

The Population and Behavioural Science Committee (PBSC) now produce a newsletter similar to this, the fourth issue of which will be available in Autumn 2007. If you are interested in being added to the mailing list for this newsletter or if you are interested in producing an article for this newsletter then please contact [luke.biggin@cancer.org.uk](mailto:luke.biggin@cancer.org.uk).

## A Framework for PET Research in the UK

The National Cancer Research Institute (NCRI) recently published a report examining the current state of play of PET research in the UK, analysing the needs and opportunities, particularly in cancer research, as well as identifying problems and barriers, many of which also apply to the wider use of PET. PET scanning has the potential to provide a major advance in how treatment for cancer patients is managed, preventing the inappropriate use of radical therapy and, in the future, it may guide drug and radiotherapy treatments more precisely to improve patient outcomes. PET is also used as a tool to improve the process of developing new drugs and it is likely that this use will grow, both for cancer and other diseases.

PET is, however, a complex and expensive technology to use. There are significant infrastructure requirements and a number of challenges that must be overcome to realise the full benefits. The main recommendation from the

report, therefore, is that a coordination function will be established to provide national leadership and to enable organisations to work together to facilitate PET research. The UK PET Research Steering Committee and associated coordination unit are designed to work with existing structures and processes such as the UK PET-CT Advisory Board, which has overlapping concerns with training and audit, the National Cancer Research Network and the network of Experimental Cancer Medicine Centres.

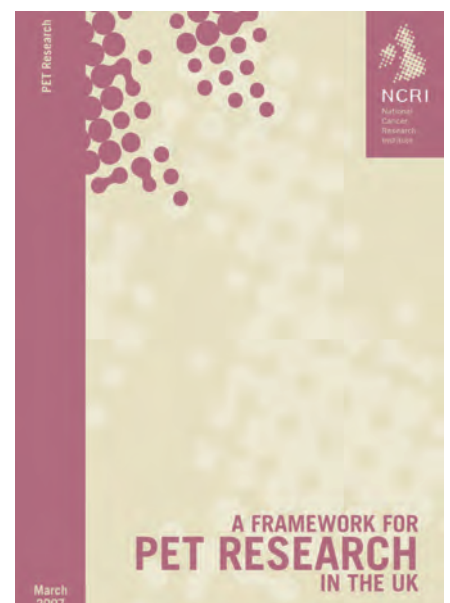
The NCRI is delighted that Professor Sir Michael Peckham, formerly Director of R&D at the Department of Health, has agreed to chair the UK PET Research Steering Committee. Sir Michael has a strong interest in PET scanning and the NCRI Board is confident that he, together with the proposed coordination function, will provide the necessary leadership to drive PET research forward. A call for expressions of

interest to run the PET research coordination unit will be issued shortly.

If you would like copies of the report, please email [info@ncri.org.uk](mailto:info@ncri.org.uk) or download the report from the NCRI web site ([www.ncri.org.uk](http://www.ncri.org.uk)).

**Rebecca Stratford**

Scientific Programme Manager,  
National Cancer Research Institute



## FSC News in Brief

For the March FSC Meetings there were . . . 7 applications

The next FSC deadlines are:

1 July 2007, 1 October 2007, 1st January 2008

For more information on FSC, including application forms and closing dates please visit our web page:  
<http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/fsc/>

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

## Feasibility Study Committee (FSC)

### Applications Funded in Principle\*

\*Applications pending feedback from applicants and final approval from FSC

#### March 2007 Meeting

#### APPLICATIONS FUNDED

Lead investigator

Trial Acronym and Title

Dr S Pereira

PHOTOSTENT-02: Porfimer sodium photodynamic therapy plus stenting versus stenting alone in patients with advanced or metastatic cholangiocarcinomas and other biliary tract tumours: a multicentre randomised phase II study.

Professor J Radford

A phase I study to investigate dose escalation of doxorubicin in cycles 1-3 of ABVD chemotherapy for Hodgkin lymphoma and to correlate this with biomarkers of tumour response and toxicity

## Feasibility Study Committee Applications Invited

We would like to encourage applications to the Feasibility Study Committee (FSC), which aims to provide support for clinical studies testing the feasibility of a future Phase III trial, or pilot work. In the past year 15 studies have been recommended for funding and 4 studies have been endorsed.

The majority of studies funded via this scheme aim to provide the background data to support a future application for funding of a phase III trial via the Clinical Trials Awards and Advisory Committee (CTAAC).

Studies funded by the FSC that are 'successful' upon completion, can then be submitted to the CTAAC directly as full applications for funding, i.e., the outline application stage of review has already been completed via the FSC.

We would welcome applications for projects in the order of £25K per annum (up to a maximum of £40K in exceptional cases) for a period of up to 24 months. Academically-led studies receiving educational grants and/or free drug can be submitted for approval. If you are unsure as to

whether or not this scheme is suitable for you please contact Matthew Freegard ([matthew.freegard@cancer.org.uk](mailto:matthew.freegard@cancer.org.uk)). CRUK has a designated budget to spend on these types of trials and at present only a small portion of this budget has already been allocated following the FSC meeting in March.

For further information about the FSC and on how to apply for funding please visit our website: <http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/fsc/>.

The application deadlines are fixed for each year; these are as follows:

Application Deadline	Decision Date
1st Jan *	End Feb
1st April *	End May
1st July *	End August
1st October *	End November

\*Or by 10am the next working day.

## TRICC News in Brief

For the February 2007 meeting of TRICC there were...

7 Full Applications, 5 Sample Collection Applications and 3 Outline Applications

Closing dates for the 10th October 2007 TRICC meeting are:

**Outline Applications**

– 10th July 2007

**Full Applications**

– 26th July 2007

**Sample Collections**

– 24th August 2007

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

<http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/tricc/>

Dr Maria Lioumi (Research Manager - Translational Research) is currently on maternity leave and her position will be covered by Louise Jones (see article).

Welcome back to Dr Alison John, Research Manager (Discovery Committee), who has recently returned to Cancer Research UK after 6 months maternity leave.

## Welcome to Louise Jones

Dr Louise Jones joined the Translational Research team from Barts and the London Hospital in October 2006, where she worked within the Department of Paediatric Oncology. Whilst working as a Non-Clinical ICRF lecturer she was also responsible for setting up the Children's Cancer Group in 2000. Her primary research interests have focused on adult and paediatric leukaemia. Her current role is as Research Manager for Tissue Resources and Translational Research platform

technologies. Louise is providing maternity cover as TRICC Secretary and is currently conducting the Science Plan Review in tissue resources.



## Tissue Resources Science Plan Review

The Translational Research Team is in the process of conducting two Science Plan Reviews (Tissue Resources and Biomarkers) as part of the Science Plan process approved by CRUK's Council Research Strategy Group (CRSG) in September 2004. These reviews, while distinct, are complementary in the outcome of likely recommendations. The Scope of the Review for Tissue Resources includes an assessment of the current status of CRUK tissue resources; what we do and how we do it. This will explore the different funding streams which are currently in place to fund CRUK tissue collections; the future role of onCore UK (a venture, jointly funded by CRUK, the MRC and the

DOH) and the emerging role of the Confederation of Biobanks which has representatives from many of the major UK based tissue banks. Issues surrounding the impact of the Human Tissue Act on the collection, storage and use of human tissue in research will be discussed together with the need for standardisation or harmonisation of operating practices across tissue banking in the age of high throughput 'omics' technologies. In addition, the review will cover examples of non-CRUK based approaches to tissue resources and tissue banking, looking at the benefits of both centralised and dispersed models of tissue collection and how we can use these models as exemplars. Key opinions are

essential to the success of this review and are currently being sought from a wide range of scientific and commercial disciplines, including consumer (patient) groups. Information gathering is well underway using a combination of workshops e.g. the NCRI Late Phase Clinical Trials Forum 5th July, questionnaires and interviews; the final report is due to be presented to SEB in Early September. It is expected that recommendations resulting from this Review will complement those from earlier Reviews and will further help promote translational research within CRUK.

**TRICC Members:** PETER PARKER (CHAIR) • GARETH MORGAN (VICE CHAIR) • CINDY BILLINGHAM • JAMES BRENTON • ROBERT BROWN • MITCH DOWSETT • ADRIAN HARRIS • MARK MIDDLETON • KARIN OIEN • JOHN PRIMROSE • CATHERINE WEST • BRYAN YOUNG

# Translational Research In Clinical Trials Committee (TRICC)

## Applications Funded in Principle\*

\*Applications pending feedback from applicants and final approval from TRICC

### February 2007 Meeting

#### APPLICATIONS FUNDED

Lead investigator	Trial Acronym and Title
Professor C Coombes	Integroup Exemestane study pathology sub-study (Breast Cancer)
Professor S Freeman	AML 16: Evaluation of the prognostic impact and optimal use of immunophenotypic monitoring of residual disease in patients with acute myeloid leukaemia recruited to AML 16
Professor N James	STAMPEDE Bone Study (Prostate Cancer)
Dr M Middleton	PROM: Predicting Relapse of Melanoma at High Risk of Recurrence
Dr R Midgley	COGENT: Gene Expression profiling as a Generic Test for personalised Treatment in Colorectal Cancer patients

#### SAMPLE COLLECTIONS FUNDED

Lead investigator	Trial Acronym and Title
Mr G Griffiths	T-FRAG: Collection and storage of tumour and blood samples from patients with lung cancer in the FRAGMATIC clinical trial for future translational research
Mr G Griffiths	T-SCOPE: Collection and storage of tissue and blood samples from patients with oesophageal cancer in the SCOPE I Clinical trial for future translational research.
Dr J Bartlett	Tissue banking from brain metastases in Herceptin treated breast cancer (Trans ACCOG-VI)



The Office would like to extend their thanks to the International Committee Advisory Panels (ICAP – CTAAC and TRICC), all standing Committee members and all external peer reviewers for their help and support.

## 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/>

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 –  
<http://www.cancerhelp.org.uk>

## Race for Life:

On Wednesday 2nd May 2007 many of the female members of the Clinical and Translational Research and Research Strategy Directorate (CTRARS) and Research Funding (RF) took part in the Race for Life at Battersea Park to help to raise money for the charity.



## CTAAC and TRICC Contacts

\*\*\*Please note change of telephone numbers\*\*\*

\*\*\*Postal address has NOT changed\*\*\*

Dr Daljit Kaur  
Research Manager (Clinical Trials)  
Secretary of CTAAC  
[daljit.kaur@cancer.org.uk](mailto:daljit.kaur@cancer.org.uk)  
(020) 7438 5391

Ms Julie Hearn  
Senior Research Manager (Clinical Trials)  
Secretary of FSC and CTRC  
[julie.hearn@cancer.org.uk](mailto:julie.hearn@cancer.org.uk)  
(020) 7438 5393

Dr Louise Jones  
Research Manager (Tissue Resources & TRICC)  
Secretary of TRICC  
[louise.jones2@cancer.org.uk](mailto:louise.jones2@cancer.org.uk)  
(020) 7438 5386

Miss Nicola Keat  
Research Officer (Clinical Trials)  
[nicola.keat@cancer.org.uk](mailto:nicola.keat@cancer.org.uk)  
(020) 7438 5392

Mr Matthew Freegard  
Research Officer (FSC and CTRC)  
[matthew.freegard@cancer.org.uk](mailto:matthew.freegard@cancer.org.uk)  
(020) 7438 5394

Ms Heather Slade  
Translational Research Officer (TRICC)  
[heatherslade@cancer.org.uk](mailto:heatherslade@cancer.org.uk)  
(020) 7438 5385

### Editorial Team

**Editor** Miss Nicola Keat **Editorial Team** Ms Kate Law, Dr Daljit Kaur, Ms Julie Hearn, Mr Matthew Freegard, Dr Louise Jones, Ms Heather Slade, Miss Dominique Parr