

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

UKCRN review of fully-funded commercial trials • CTAAC welcomes the new Chairman  
CTAAC Funded Applications • Expanding Translational Research in CR-UK • Farewell and Congratulations to Colin Bird • TRICC Funded Applications • Experimental Cancer Medicine Centre (ECMC) • Clinical Fellowships • Human tissue act • Update from the Drug Development Office • Update on DoH and PET scanning facilities •

## UKCRN review of fully-funded commercial trials

A series of advisory reports over the last several years (PICTF, Bioscience Innovation and Growth Team -BIGT, AMS Strengthening Clinical Research, RPBWP) have led to the establishment of the UK Clinical Research Collaboration, funding for new networks beyond cancer under the umbrella of the UKCRN – and an explicit emphasis on fostering collaborations between the clinical networks and the UK pharmaceutical, biotech and device industries.

It is probable that the greatest potential lies in ongoing and healthy partnerships that lead to both:

- investigator-initiated research with partial industry support (typically reviewed by CTAAC)
- and contracted trials, often global

in their development, and intended to support licensing

UK industry leaders have, however, made it clear that they consider that the latter category has become progressively more difficult in the UK and have emphasised the need to address this component effectively.

Doing so would not only be useful for the UK economy overall but would also be expected to contribute to assuring that the investigator-initiated partnership arrangements can thrive. Industry is seeking a UK-wide single point of access to the NHS with the capacity to rapidly assess feasibility, and reliably deliver rapid site activation, patient recruitment and high quality data for clinical trials across the full range of medical conditions including rare diseases. The service should be supported by consistent standard procedures and offer value for money.

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## CTAAC News in Brief

For the February 2006 meeting of CTAAC we had...11 Full Applications, 3 Endorsement Applications and 17 Outline Applications

The next CTAAC deadlines are as follows: Outline Applications & Endorsements – 28th July 2006  
Full Applications – 4th August 2006

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

<http://science.cancerresearchuk.org/gapp/grantapplications/cta/?version=6>

## Members Leaving CTAAC

Roy Grainger has stepped down as CTAAC's representative of the NCRI Consumer Liaison Group. We thank him for all of his hard work over the last two years.

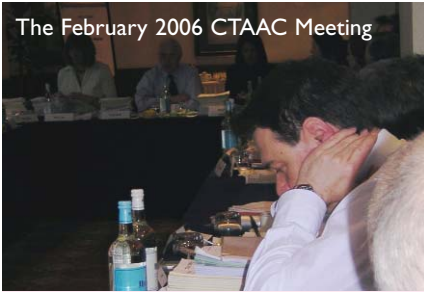
## Feasibility Study Committee (FSC) Project Grants

The Committee are due to meet for the first time at the end of May

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The February 2006 CTAAC Meeting



2006 to review the first batch of applications

The next FSC deadlines are as follows:

1st July 2006

1st October 2006

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

<http://science.cancerresearchuk.org/gapp/grantapplications/fsc/?version=1>

### Proposals developed by the Industry Roadmap Group

The Industry Road Map Group (RMG) was tasked by the Industry Reference Group of the UKCRC with identifying key elements and actions that will make the UK a more attractive environment for pharmaceutical, biotech, and medical devices industry clinical R&D, including developing proposals on how the UK Clinical Research Network (UKCRN), on behalf of the NHS, could best deliver clinical research services to industry and over what timescale, specifying additional needs, and considering industry sector-specific requirements.

An extensive list of recommendations has been developed, many of which relate to potential far reaching changes in governance and Trust R&D approval procedures. These will be considered in the context of the NHS R&D Strategy consultation now under way. Several of these have the potential to improve substantially the environment for all multi-centre clinical trials, not only those under industry sponsorship.

The most controversial issues, however, relate to the level of additional review to be applied when a fully-supported contract trial is offered to a UKCRN network. Issues of the highest importance to large Pharma companies and the DH were how quickly feasibility of

successful recruitment could be assessed and network commitment promised, and how reliably network clinicians could accept the limited design options that often apply when a trial

is developed first and foremost to meet a specific regulatory objective.

The compromise arrangements proposed attempt to seek a middle ground between acceptance of contract trials into the networks based solely on the review procedures that companies themselves have in place and the kind of academically-focused peer review that is the forte of CTAAC and similar funding committees. The proposed adoption process is also designed to work swiftly enough to prevent multi-national companies assigning the work to faster (and almost always cheaper) contract networks in Eastern Europe or elsewhere – with a resulting loss of access by NHS patients to novel agents and trials.

The adoption process has been set up so as to be able to confirm that a trial question has been appropriately framed, that its design is appropriate, and that its potential value to the NHS and its patients is apparent – and that clinicians have an interest in the trial's success.

In this context, UKCRN/UKCRC, working closely with industry leaders, has developed a general plan for rapid consideration of trials for adoption into the portfolio(s).

This plan has been formally endorsed by the UKCRC Board and is now undergoing pilot testing. In principle, adoption will depend upon investigator interest, feasibility, and an assessment by experienced academic investigators that the design is appropriate and that the trial offers something that is of potential benefit to NHS patients and not only to the sponsor. It will not, however, constitute full formal peer review per se.

### Relationship between CTAAC and the commercial trial adoption process

Both CTAAC and Cancer Research UK's Scientific Executive Board (SEB) have discussed a number of alternatives for interactions between CTAAC and the commercial trial adoption process. Perhaps not surprisingly, given the novelty of this scheme, some caution was expressed by members of both of these groups. This centred on the differing levels of peer review required by each process. Given this concern, SEB agreed that, in the first year of operation, there would be no overlap between CTAAC and the commercial adoption process, but that Rick Kaplan would provide CTAAC (and CR-UK) with regular updates on the adoption process and consideration would be given at the end of this period to integrating the two schemes more closely.

Rick Kaplan

Kate Law

**CTAAC Members:** ROGER A'HERN • DEREK ALDERSON • COLIN BIRD • 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

# Clinical Trials Advisory and Awards Committee (CTAAC) – Applications Funded and Endorsed in Principle \* (February 2006)

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

## February 2006 meeting

### APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr E Hall	CHHIP: a randomised phase III multicentre trial of conventional or hypofractionated high dose intensity modulated radiotherapy for prostate cancer
Mr I Hutchison	SEND: The role of elective neck dissection in patients with early oral squamous cell carcinoma (1-3cm primary size) and no clinical evidence of lymph node metastases in the neck (N0)
Dr M Brada	TATA: A randomised controlled trial of temozolomide as adjuvant and/or concurrent treatment in anaplastic (WHO grade III) glioma
Dr T Crosby	SCOPE I: A randomised phase II/III multi-centre clinical trial of definitive chemoradiation, with or without cetuximab, in carcinoma of the oesophagus
Ms L Wyld	ESTEEM: endocrine +/- surgical therapy for elderly women with mammary cancer
Dr M Fallon	Double-blind randomised controlled trial of pregabalin versus placebo in conjunction with palliative radiotherapy for malignant bone pain
Professor W Steward	The efficacy of curcumin in patients with familial adenomatous polyposis - a pilot study
Professor J Primrose	New EPOC: peri-operative chemotherapy in patients with resectable colorectal liver metastases - does the addition of an anti-EGF receptor antibody improve progression free survival?
Dr G Cook	A UK myeloma forum phase III RCT in relapsed myeloma to assess the role of a second high-dose procedure and autologous stem cell transplant, compared to low-dose consolidation therapy

### EXTENSIONS FUNDED

Lead Investigator	Trial Acronym and Title
Professor J Peto	MARS: mesothelioma and radical surgery trial (extension).

### APPLICATIONS ENDORSED

Lead Investigator	Trial Acronym and Title
Dr A Szarewski	Phase III double blind randomised controlled study to evaluate safety, immunogenicity & efficacy of GSK Biologicals' HPV 16/18 L1/AS04 vaccine administered intramuscularly by a 3-dose schedule (0,1,6 months) in healthy 26+ females

## Welcome to the new CTAAC Chairman

Professor Jon Cohen has accepted the invitation to be the new independent Chairman of CTAAC, he will be observing at the CTAAC June 2006 meeting, which will be Professor Bird's final meeting as Chair; and will be chairing his first meeting in October 2006.

We would like to sincerely welcome Professor Jon Cohen as the new

CTAAC Chairman - we are very much looking forward to working within him.

**Professor Jon Cohen M Sc FRCP  
FRCPATH FRCPE FMedSci**

Professor Cohen is the Dean of the Brighton and Sussex Medical School and a Professor of infectious diseases; his primary research area of interest

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Professor Jon Cohen



is in clinical and scientific studies on severe sepsis and septic shock.

Professor Cohen's research focus is mainly in the pathogenesis and treatment of severe bacterial infections. His research initially focused on Gram-negative sepsis, studies on bacterial endotoxin and on the role of cytokines, in particular Tumour Necrosis Factor in sepsis. His group was one of the first groups

to demonstrate in experimental studies that anti-TNF could be effective in therapy as well as the prevention of Gram-negative sepsis. Additionally, his team was one of the first to administer an anti-TNF antibody.

Daljit Kaur

## We would like to warmly welcome Professor **Herbie Newell** as the new Director of Translational Research.

As Director of Translational Research, Herbie Newell joins Kate Law, Sally Burtles, John Toy and Richard Sullivan in the Clinical and Translational Research Directorate management team at Cancer Research UK. Herbie Newell has a degree in pharmacology and a PhD in cancer pharmacology, and is seconded for 3 days per week from the Northern Institute for Cancer Research at the University of Newcastle.



## Expanding Translational Research in CR UK

Cancer Research UK and its forebears have an outstanding track record in translational research – the exploitation of results from basic research for patient benefit – but much remains to be done. The strategy for translational research is being defined by the ongoing CR UK Science Plan review with two areas completed (Drug Development – led by Sally Burtles – and Drug Discovery – led by Harpal Kumar), and others scheduled for 2006 (Tissue Resources and Imaging) or 2007 (Biomarkers). These reviews will provide CR UK with complementary strategies for the development of novel therapies, and the biomarkers (including imaging) that will be needed for their optimal use.

The clinical and laboratory infrastructure required for

translational research will be provided by the Experimental Cancer Medicine Centre (ECMC) network, which will complement support available through clinical programme and clinical centre grants. Applications for ECMC funding have been co-ordinated by Richard Sullivan and Judith Beswick, and the ca. £35M support for the network from the devolved Departments of Health and CR UK will secure the future of translational research in the UK for the next 5 years.

In addition to infrastructure support, CR UK operates an active response-mode funding mechanism for translational research via the Development Committee (pre-clinical discovery and development), New Agents Committee (early phase clinical trials) and Translational Research in

Clinical Trials Committee (translational research in later stage trials). These committees are now well established with expanding grant portfolios and the ongoing science review process will result in further developments and funding opportunities.

Cancer Research UK and its NCRI partners are well placed to respond to and exploit the opportunities presented by the basic science strengths and clinical research expertise in the UK, and have done so by establishing the translational research funding initiatives outlined above. With this expanding support the UK represents an ideal and highly competitive environment for both academia and industry to undertake translational research.

Herbie Newell

# Farewell and Congratulations to Professor Colin Bird

Professor Colin Bird has chaired the Clinical Trials Advisory and Awards Committee (CTAAC) since October 2003, his three-year period as Chairman, is therefore, due to complete in June 2006. We would like to express our gratitude to

Professor Colin Bird as the Chairman of CTAAC for all of the time and effort that he has put in over the last few years – he will be greatly missed!

Colin may be leaving CTAAC,

however, luckily for Cancer Research UK he will still be very much involved. Colin has become a member of the Council of Cancer Research UK since September 2005; thus we would like to congratulate him and wish him all the very best.

## Funding News

### Experimental Cancer Medicine Centres (ECMC)

The closing date for Experimental Cancer Medicine Centre applications was 9th December 2005. We had an excellent response to the call for applications with 25 full applications being submitted from across the country, Northern Ireland, Scotland and Wales. Funding will be in the form of 5-year programme grants and will provide resources for infrastructure to underpin translational research.

This is a joint venture between

Cancer Research UK and the four devolved departments of health (England, Scotland, Wales, Northern Ireland), overseen by the NCRI. Professor Herbie Newell, Cancer Research UK new Director of Translational research, will oversee the running of the ECMC coordinating centre. He is keen to maintain the NTRAC coordinating centre's successful activities and build a highly efficient management centre for the successful ECMC centres.

The review panel has been selected and consists of National and International experts, representing both academia and industry. The panel will be reviewing the applications in April and we will contact all applicants in due course.



### Clinical Fellowships

Cancer Research UK aims to fund the best research, but to do this we also need to train good cancer researchers. This year we will spend over £10 million (that is, about 5% of our total research expenditure) on clinical training. We aim to support clinicians who are working on problems that have arisen from their clinical practice, or who want to see the results of their laboratory work applied in the clinic.

We offer fellowships at three main levels. If you are still in clinical training and want to take time out of your training to study for PhD, we have a range of Clinical Research Training Fellowships. Clinicians from any speciality, and in any research area, are welcome to apply. Each year, one fellowship is awarded in partnership with the Royal College of Radiologists and one with the

Royal College of Surgeons of Edinburgh. This year we hope to appoint ten new fellows.

If you already have a PhD or MD, but would like to carry on your research at a post-doctoral level, you should consider applying for a Clinician Scientist Fellowship. This is flexible enough to let you complete your specialist training whilst continuing your research. These awards provide up to five years' funding. They will also support clinicians who are already consultants. There are five fellowships available in 2006.

Cancer Research UK also offers fellowships to clinical researchers who want to establish their own research group. There are two of these Senior Clinical Research Fellowships on offer this year. These awards provide support for six years, and as well as your own salary they

offer salaries for a technician and a post-doc, and running expenses for all the staff.

If you would like to know more about clinical fellowships, please contact Simon Vincent ([simon.vincent@cancer.org.uk](mailto:simon.vincent@cancer.org.uk)) or Christopher Page ([christopher.page@cancer.org.uk](mailto:christopher.page@cancer.org.uk)). Please do have a look at the Grants and Applications section of the website for more information on these schemes, and for the deadlines for applications. The site also has details of other funding opportunities for clinicians, including additional specialist clinical fellowships, research bursaries, and funding for Masters courses.

Simon Vincent

# Human Tissue Act: Codes of practice and secondary legislation

## Human Tissue Act 2004

The Human Tissue Act received Royal Assent on 15 November 2004. It is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specified health-related purposes and public display. The Act applies to England, Wales and Northern Ireland. A new offence of DNA 'theft' applies throughout the UK.

The Act makes consent the fundamental principle underpinning

the lawful retention and use of body parts, organs and tissue from the living or the deceased for specific health-related purposes and public display. It also covers the removal of this material from the deceased. The Act does not cover removal of body parts, organs and tissue from the living, which will continue to be dealt with under common law. Cell lines are excluded, as are live gametes and embryos (the latter are already regulated under the Human Fertilisation and Embryology Act 2004).

The Act repeals and replaces the Human Tissue Act 1961, the

Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992. Scotland has a Human Tissue Bill passing through the Scottish Parliament. Some of the repeals do not extend to Scotland. The Authority is working closely with the Scottish Executive to ensure that both Acts and guidelines in the form of codes of practice or their equivalent in Scotland are compatible

## EU Tissues and Cells Directive

The HTA is responsible for implementing the EU Tissues and Cells Directive (2004/23/EC) in the UK together with the Human Fertilisation and Embryology Authority. The HTA's remit within the legislation includes licensing and regulating all centres in the UK which store human tissue (including tissue banks for bone, corneas and skin, and stem cells taken from adults) for therapeutic applications. The Authority will implement a staged approach to the Directive:

- Centres storing tissue for human application will have to be licensed by the HTA from 7 April 2006 in order to comply with the Directive. They have been asked to provide their contact details by the end of December 2005 via [www.hta.gov.uk/therapeutictissue](http://www.hta.gov.uk/therapeutictissue). Once the detail of the relevant technical annexes is known, the HTA will be in a position to inspect against those standards
- Centres storing human tissue for

research purposes will be licensed under the Human Tissue Act from 1 September 2006

### Key points from CRUK:

1. Of greatest importance is how regulations will work in practice.
2. Licensing requirements need clarification - it is crucial that the HTA produces a sensible framework.
3. Guidance for researchers is needed.

### Regulations

Overall we welcome the draft regulations, however we asked for clarification of requirements for licensing and ethical approval.

### Codes of Practice

These are fairly anodyne and provide a commentary on the legislation, rather than distinct guidance. The Codes are aimed at healthcare professionals, rather than addressing the needs of researchers.

**Licensing requirements** (covered by DH regulations, but HTA oversee):

- These do not provide sufficient

guidance to researchers to allow them to adequately prepare for the introduction of the new legislation.

- We are concerned that all researchers would be required to hold licences, in spite of previous assurances by Government and the DH that this would not be the case, and allow a distinction
- Ambiguity in this area could discourage collaboration between laboratories and the sharing of research materials.
- No distinction is for collections based on size, so requirements will apply equally to researchers holding one slide or a hundred or even a thousand paraffin blocks
- Although time is allowed to hold samples while awaiting ethical approval, no time is given for the time prior to submission for ethical approval, and to the period after a research project has been completed, as researchers will

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need keep tissue after a project has been completed to support the findings of their research. Additional guidance for researchers is needed. It is not clear whether the Human Tissue Authority is planning to provide this. They have said they will be producing guidelines on licensing (as it is their responsibility to inspect and authorise licenses) but we have not been consulted. We understand that in April the Authority will publish the licensing framework, followed by consultation and piloting, coming

into effect on 1 September 2006.

#### **Ethical approval** (DH regulations)

- The current definition in the draft regulations is that of review by Research Ethics Committees.
- However, 'proof of principle' studies, would normally be reviewed by a hospital ethics committee. RECs are better suited to reviewing larger scale studies involving patients.

#### **Consent** (HTA Codes of Practice)

We are concerned regarding the requirements that the person

seeking consent should: 'have sufficient knowledge of the proposed treatment and intended use of the tissue, such as for research...' may have not allow scope for patients to give consent which is 'generic and enduring'. Particularly we welcome the statement that that the nature and duration of consent does not need to be limited to a particular project.

Richard Sullivan

## Update from the Drug Development Office

This is a very busy time for The Drug Development Office. We are working on the development of 38 novel compounds at various stages of development: preclinical, phase I, and early phase II trials. In addition to this and as part of our strategic plan, we are establishing a new initiative

jointly with CRT called Clinical Development Partnerships (CDP). The aim of CDP is to bring to CR-UK for development novel treatments for cancer that have been deprioritised by pharmaceutical companies and are not currently being developed. This was launched internally at the NAC in March.

In parallel with all this we are undertaking a major review of how

we work to improve work practices, processes and procedures to speed up the development of our novel cancer agents. This will not only put us in a strong position to double our activities over the next five years as recommended in the strategy, but will also enable us to ensure that promising new treatments get to cancer patients as rapidly as possible.

## Positron Emission Tomography and Cancer Research

The Department of Health recently published a framework to increase the provision of positron emission tomography (PET) services in England. The framework also recommends that future research into PET scanning is co-ordinated by the National Cancer Research Institute (NCRI). In response to this request, NCRI has established a Strategic Planning Group, comprising representatives from the major cancer research funding organisations, to develop a UK-wide research strategy for PET. This will most likely encompass an organisational framework to facilitate research using PET as well as specific research themes.

The impetus for this work has come from the increasing use of PET for diagnosis and staging of disease, especially lung cancer, although the evidence base for use of PET in many

settings is incomplete. The extension of PET scanning facilities in the UK, to be delivered by the PET Service Framework in England and other initiatives in the devolved administrations, will provide significant opportunities for research. PET is also beginning to find application in the drug development process and is likely to become integral in experimental cancer medicine in the future.

The NCRI PET Strategic Planning Group is in the process of arranging a series of workshops with experts and stakeholders to harness a wide range of expertise and opinion. Workshops have been held on clinical research issues, use of PET in experimental medicine and cancer biology and on the technological base needed to support these areas of investigation. A fourth workshop on the use of PET in radiotherapy

planning will be held in July. The likely completion date for development of the NCRI PET research strategy is late 2006. Researchers with an interest in imaging may also like to know that the Dept of Health has announced plans to establish a dedicated funding stream to support the NHS costs of selected technology platforms to support health research in NHS providers. The first funding round will support diagnostic imaging and further information and application details can be obtained from <http://www.dh.gov.uk/ProcurementAndProposals/RDCallsForProposals/fs/en>

Further information on the NCRI PET Strategic Planning Group is available from Rebecca Stratford ([rebecca.stratford@ncri.org.uk](mailto:rebecca.stratford@ncri.org.uk)).

Rebecca Stratford

## Translational Research in Clinical Trials Committee (TRICC) Funded Applications (February 2006)

### February 2006 meeting

#### FULL APPLICATIONS

Lead investigator	Trial Acronym and Title
Dr J Bartlett	TEAMWORK-HER: tumour molecular profile predicts when to initiate treatment with aromatase inhibitors
Dr D Berney	Tissue database for immunochemical and molecular investigation of patients treated in MRC RE01 study comparing alpha interferon and medroxyprogesterone acetate in renal cell carcinoma
Dr A Wotherspoon	MAGICTrans: Tumour expression of prognostic and predictive factors in a randomised trial of perioperative chemotherapy for gastric cancer (MAGIC)

#### SAMPLE COLLECTIONS

Lead investigator	Trial Acronym and Title
Professor Walker (UKCCSG)	TRANSCAL: Translational Study for Children and Adolescents with Low Grade Glioma
Professor M Seymour	PICCOLO: Biological sample collection from patients entering into the PICCOLO clinical trial
Dr T Eisen	TRANslational Resource - A phase III randomised controlled study comparing SOrafenib with placebo in patients with Resected primary renal CELL carcinoma at high or intermediate risk of relapse- TRANSORCE
Dr T Meyer	A randomised Phase II trial comparing capecitabine plus streptozocin with or without cisplatin chemotherapy as treatment for unresectable or metastatic neuroendocrine tumours

## TRICC News in Brief

We would like to welcome Professor Robert Brown from Cancer Research UK Beatson Laboratories, University of Glasgow as our new TRICC member

For the February 06 meeting of TRICC there were 3 Full applications, 7 Sample Collection Applications and 6 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 – 12th July 2006

Full applications – 19th July 2006

Sample Collections – 11th August 2006

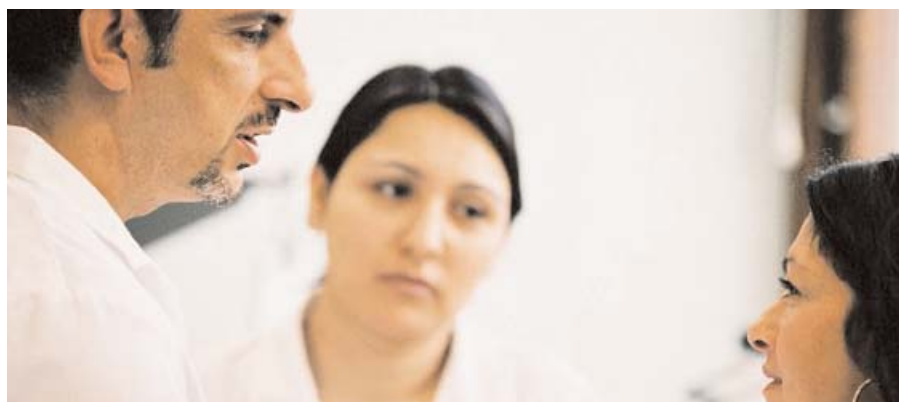
For more information on TRICC, including application forms and closing dates, please visit our webpage:

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

## 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 [www.cancerhelp.org.uk/trials/trials](http://www.cancerhelp.org.uk/trials/trials)

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