

CLINICAL AND TRANSLATIONAL OPERATIONS AND FUNDING (CTOF)

NEWSLETTER

(incorporating information about CTAAC, BIDD, NAC, DC and ECMCs)

Peter Sneddon - New Executive Director of CTOF Directorate • Farewell to Professor Herbie Newell Cancer • Professor Andy Takle - Head of Drug Discovery • Cancer Research UK 5-Year Strategy 2009-2014 • The Biomarkers and Imaging Discovery and Development Committee (BIDD) • Change of CTAAC Remit • Complementary Therapy Research - the need for evidence • UKCRC Registered Clinical Trials Units Website • NCRI Lung Clinical Studies Group • CancerHelp UK website • Experimental Cancer Tool Kit

Peter Sneddon - New Executive Director of the Clinical and Translational Operations and Funding (CTOF) Directorate



I am delighted to have been appointed to the role of Executive Director of the Clinical and Translational Operations and Funding (CTOF) Directorate at Cancer Research UK, just at the time

when we have launched our new strategy for 2009-2014. I very much look forward to working with the CTOF Directorate to deliver our objectives across a wide range of clinical and translational research activities. Before joining Cancer Research UK, I have had a variety of roles as a researcher, academic, research manager and senior civil servant, which I have outlined briefly below.

After obtaining a B.Sc. in Pharmacology from Glasgow University in 1977, I won an MRC research studentship at Oxford University where I was awarded my doctorate in 1980. I then spent three years in the USA doing postdoc-

toral research supported by the National Institutes of Health (NIH). I was then appointed to a lectureship at the University of Strathclyde in Glasgow, where I led a research group for over a decade, focusing on drugs acting on the autonomic nervous system. In 2000 I joined the senior management team at the Wellcome Trust, initially managing their Neurosciences portfolio and then the research funding for all of the Physiological Sciences. In 2004 I moved to the Department of Health where I was the Deputy Director in Research & Development with responsibility for establishing all of the research programmes of the National Institute for Health Research (NIHR).

Farewell to Professor Herbie Newell

Professor Herbie Newell's secondment to CR-UK as Director of Translational Research finished at the end January 2009. We would like to express our gratitude to Herbie for all of the energy and enthusiasm he brought to CR-UK, and for his major contribution to new initiatives in translational research. Specifically, the new schemes we have introduced over the last three years in drug discovery, imaging, biomarkers and experimental medicine infrastructure have substantially enhanced both the quality of and capacity for translational cancer research. He will be greatly missed.



Dr Andy Takle – Head of Drug Discovery.

Andy joins CR-UK in February from GSK and is a medicinal chemist with many years experience in drug discovery. Andy will be responsible for Drug Discovery Programmes, the Discovery Committee (with CRT) and the overall portfolio of small molecule, antibody, immunotherapy and other complex biological therapy research at CR-UK.



**Joint Initiative
for brain tumour
feasibility studies**
See page 7 for further details



SAMANTHA DICKSON
BRAIN TUMOUR TRUST



In the last three years, Cancer Research UK has defined a compelling vision, ambitious goals and clear purpose statements. To complement this, the Executive Board and Trustees have developed a Charity Strategy which sets out how we intend to work towards achieving our 2020 goals over the next five years. The Charity Strategy is directed at reducing mortality from cancer and will guide our decision-making, investment and funding plans and annual operations over the years 2009-2014. Following approval by our Trustees in mid-October, the Charity Strategy was published and is available on our website www.cancerresearch.org.uk. The six points below summarise the Charity Strategy.

1. Cancer Research UK's aim is to reduce the number of people dying from cancer. Over the next five years we will spend around £300million a year supporting research that improves our understanding of cancer and funding innovative translational and clinical research to drive scientific discoveries towards improving survival, including some of the hardest forms of the disease to treat successfully – lung, pancreatic and oesophageal cancer.
2. Research along with information provision and influencing public policy form the Charity's three core purpose activities and we will continue to deliver information to the public about cancer prevention, detection and treatment and to drive the public policy agenda and help shape regulatory and legislative environments, where this will help improve survival.
3. We believe that the right environment for quality research is a combination of our five core funded institutes – LRI, CRI, PICR, BICR & ROB and the network of up to 20 'Centres of Excellence' across the UK (CR-UK Centres) where we will link research activities with patient care, public engagement and prevention initiatives. Each centre will develop a distinct research strategy and be encouraged to develop key areas of focus. These initiatives will provide us with a way to focus more on surgery and radiotherapy which along with chemotherapy are the most important approaches to cancer treatment.
4. To sustain our income we will continue to invest in our proven fundraising winners whilst driving a programme of activities around new product development and radical innovation to deliver our future income growth.
5. We will strive to ensure that new technology developments meet critical business and research needs. Attracting, developing and retaining the very best people in all parts of the organisation from institutes to fundraising will be high on our agenda together with the need to maintain a robust framework to safeguard the charity's assets and reputation (governance).
6. In developing our operating plans we should all challenge what we are proposing and be able to justify the cost – financial and resources in the context of this new strategy. We must also drive out inefficiencies – eradicating duplication and overlap and maintain a flexible and adaptive approach to promote faster reaction times to ever changing circumstances.

Together we will beat cancer

ECMC News in Brief

The Early Phase Clinical Trial Forum, Chaired by Professor Duncan Jodrell, took place on Thursday 15th January where international and UK experts gave presentations on the theme 'Emerging Targets'. The topics of the afternoon workshops were (1) Imaging in Experimental Medicine, (2) Therapeutic Antibodies in Experimental Medicine and (3) Combination Therapies.

The ECMC Network participated in the AstraZeneca/NCRN pipeline workshops in November/ December 2008. Several academic/industry collaborations are currently under discussion.

The ECMC Initiative has received positive high-profile publicity this year with a two-page feature in the Observer which focussed on the experiences of patients taking part in early phase trials at Belfast, Leeds and Southampton ECMCs. In November, patients treated at the Birmingham ECMC were featured on the One Show on BBC1.

Professor Dion Morton has replaced Professor Paul Moss as the Lead for Birmingham ECMC and Professor John Hartley has been appointed as joint-Lead of the UCL ECMC.

The ECMC Consumer Focus Group was attended by ECMC Leads, consumer representatives and research nurses. The group identified areas within early phase research where patient and public involvement would be beneficial.

Mr Derek Stewart OBE has been appointed as a member of the ECMC Steering Committee to represent patients and the public.

And finally, we're sorry to have to say goodbye to Heather Slade, who over the last 4½ years has worked for CTAAC, TRICC and DC and most recently the ECMC Secretariat. We're very sorry that Heather is leaving us but we wish her all the best in her new exciting post at the MRC.

The Biomarkers and Imaging Discovery and Development Committee (BIDD)

The Science Plan Review on Biomarkers recommended that project grant funding for biomarker and imaging discovery and development should become the responsibility of TRICC, to be renamed the Biomarkers and Imaging Discovery and Development Committee (BIDD) to reflect its activity.

BIDD will support research on all types of biomarkers (predisposition, screening, diagnostic, prognostic, predictive, pharmacological and surrogate response) using invasive and non-invasive (imaging) technologies.

Pathways for biomarker discovery and development have been constructed to streamline the biomarker discovery and development process in a way comparable to the discovery and development of a new drug. Three stages in the pathway have been identified: biomarker discovery, assay development and biomarker qualification.

The remit of BIDD will be as follows:

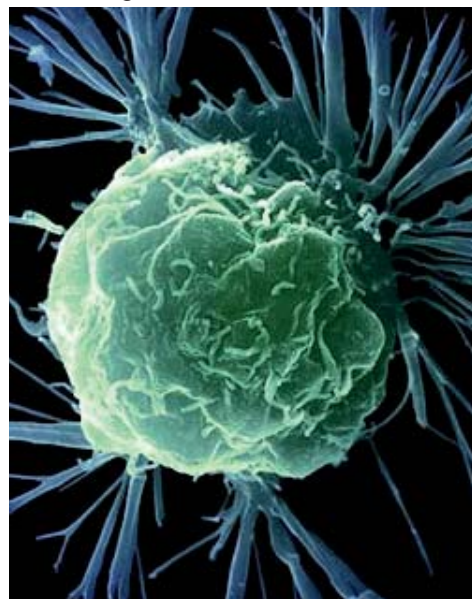
I. Biomarker discovery projects using human samples, including i) discovery of biomarkers; ii) definition of biomarker distribution in a limited number of specimens; and iii) retrospective study of the relationship between the biomarker and clinical outcome.

II. Biomarker assay development projects, to provide increased assur-

ance that biomarker research using clinical samples is being performed to appropriate standards.

III. Biomarker qualification projects, including the prospective study of the correlation between the biomarker and clinical outcome.

IV. Imaging discovery and evaluation projects, including imaging biomarker studies involving whole body imaging, the development of imaging agents and the application of new imaging technologies.



Prospective sample collections associated with a clinical trial, which do not have a translational hypothesis at the time of review, will become the responsibility of CTAAC.

Change of CTAAC Remit



As a result of the changes to the newly named Biomarkers and Imaging Discovery and Development Committee (BIDD), prospective sample collections of bloods and blocks will be reviewed by CTAAC as a distinct component of the trial application. This arrangement will ensure one point of application and review for the clinical trial and sample collection. It is anticipated that for the next year or so there will be applications to undertake sample collection as part of clinical trials which are already open; these will be submitted to CTAAC. This proposal is well-supported by the clinical community as a mechanism for streamlining the application process and subsequent regulatory authority submissions.

Clinical Trials Advisory and Awards Committee (CTAAC)

Applications Funded in Principle* in November 2008

*Applications pending feedback from applicants and final approval from CTAAC

APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr H Earl	CRUK/08/037 ARTemis: Avastin Randomised Trial with neo-adjuvant chemotherapy for patients with early HER 2 negative breast cancer.
Prof J Bliss (Extension)	CRUK/09/007 The SoFEA Trial: A partially blind phase III randomised trial of fulvestrant with or without continued anastrozole compared with a reference control arm of exemestane in post-menopausal women with ER+ve advanced breast cancer following progression on non-steroidal aromatase inhibitors.
Prof N Wald (Extension)	Helicobacter pylori Screening Study: A randomised stomach cancer prevention trial
Prof P Woll	CRUK/09/009 STS Axitinib: A clinicopathological phase II study of axitinib in patients with advanced angiosarcoma and other soft tissue sarcomas.
Dr E Marshall	SUAVE: A Multi-Centre, Randomised Phase II Study Of Sunitinib and Standard Chemotherapy in Good Performance Status Patients with Metastatic Uveal Melanoma.
Prof A Darzi	CRUK/09/008 LOPERA: Randomised controlled trial of laparoscopic, open and robot assisted prostatectomy as treatment for organ-confined prostate cancer
Prof N James	Phase I/II feasibility study of cetuximab with or without cisplatin with concurrent radiotherapy in muscle invasive bladder cancer.
Dr M Powell	DEPICT (Dose Escalation Pelvic IMRT in Cervical Tumours): A Phase I/II dose escalation study of simultaneous integrated boost intensity-modulated radiotherapy for locally advanced cervical cancer.
Dr C Gallagher	PETROC (PEritoneal TReatment of Ovarian Cancer): Three-arm Randomised Phase II trial of Intraperitoneal Carboplatin or Cisplatin with Intravenous and Intraperitoneal Paclitaxel compared to standard Intravenous Carboplatin and Paclitaxel in Patients with Optimally Debulked Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer following Primary Chemotherapy and Interval Debulking Surgery: A joint collaboration with the NCI Canada.

APPLICATIONS ENDORSED

Lead Investigator	Trial Acronym and Title
Dr P Lorigan	VOICE: A two stage randomised phase I/II open-labelled study to determine the efficacy of VORlnostat given with Cisplatinum + Etoposide in previously untreated extensive stage SCLC patients.
Dr M Michelagnoli	OTIS: A Phase II Study to determine the efficacy and safety of conventional dose Oral Treosulfan In patients with advanced pre-treated Ewing's Sarcoma.

CTAAC Members: JON COHEN (CHAIR) • MATTHEW SEYMOUR (VICE CHAIR) • NEIL BURNET (VICE CHAIR) • MALCOLM MASON (VICE CHAIR) • MICHAEL AITCHINSON • NIGEL BUNDRED • RICHARD CLARK • STEPHEN FALK • CHRIS GALLAGHER • ALLAN HACKSHAW • DUNCAN JODRELL • ALISON JONES • MARK MIDDLETON • MARIANNE NICOLSON • JIM PAUL • HEATHER PAYNE • WILL STEWARD • CORNEEL COENS • JOHN LIU YIN • MICHAEL CULLEN • TIM PERREN • PIPPA CORRIE • DION MORTON • JOHN GRIBBEN • NICK REED • RICHARD GRUNDY • SHARON LOVE

DC Members: BOB JACKSON (CHAIR) • MICHAEL OLSON (VICE CHAIR) • FIONA MARSHALL • PETER FISCHER • BRIAN HUNTLY • ANDREW TUTT • PETER STERN • SUE WATSON • KEVIN HARRINGTON • NEIL WILLIAMS • JULIAN BLAGG

DC News in Brief

2009 Meeting Dates:

18th March 2009

17th June 2009

21st October 2009

We would like to welcome the following new members joining the Committee in March 2009:

Professor Sue Watson - University of Nottingham

Professor Julian Blagg - Institute of Cancer Research, Sutton

Professor Neil Williams - University of Bristol

Dr Kevin Harrington - Institute of Cancer Research, Chester Beatty

Discovery Committee

Applications Recommended for Funding in October 2008

Lead Investigator	Trial Title and Host Institution
Prof D Leahy	Multi-Kinase QSAR Profiling: Kinase activity prediction by QSAR Northern Institute of Cancer Research, University of Newcastle
Dr D Fennell	Targeting MCL-1 addiction in mesothelioma: efficacy and molecular predictors of resistance to the BH3 Peptidomimetic obatoclax Queens University, Belfast

Complementary Therapy Research - the need for evidence

What is your experience of complementary therapy use by cancer patients? Are there key issues and clinical needs where you think complementary therapies could be or have been useful? Are there areas of use which you are concerned about? What do you think the research priorities should be?

Approximately 40% of cancer patients access and use complementary therapies alongside conventional treatment during their cancer journey because they feel they help them to manage stress, increase their quality of life, or alleviate the side effects of cancer treatment. This percentage is higher in some site specific cancers e.g. breast cancer. However, there is a real lack of robust scientific evidence available about the safety and efficacy of these therapies. Building a sound evidence base is a need identified by patients and clinicians alike.

Complementary therapies such as acupuncture, aromatherapy and massage are used alongside conventional treatments and are not given with the aim of curing disease. However, some may have a positive effect on a patient's wellbeing and may contribute indirectly to clinical effectiveness by assisting some patients to complete the full course of conventional treatment.

With so many cancer patients now using these therapies, it's vital that there is more research in this area to inform patients and health professionals of the benefits and risks of using complementary therapy alongside conventional treatment. Preliminary evidence is accruing for a

number of therapies e.g. acupuncture for chemotherapy induced nausea, cancer related fatigue, hot flushes and xerostomia, and relaxation techniques for pain and quality of life. Despite this there is still a real need to improve the number and quality of clinical studies and create an informative and balanced evidence base.

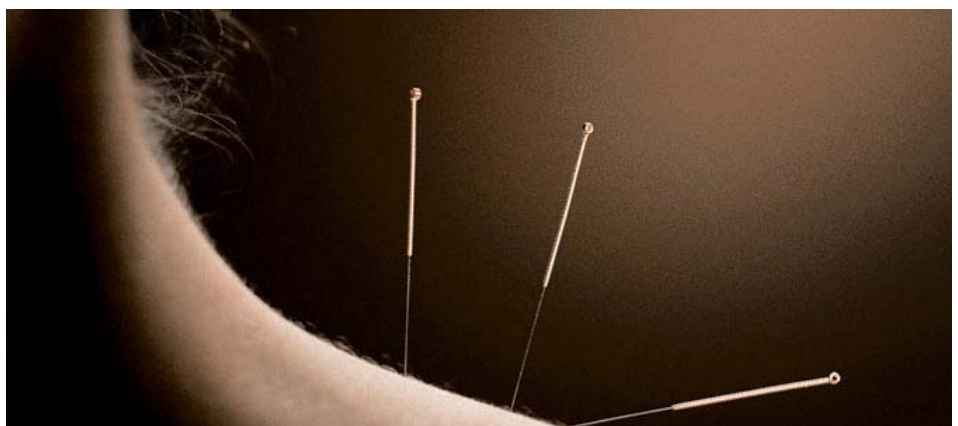
There are a number of challenges in investigating complementary therapies which include, applying appropriate and robust trial methodology, designing trials that reflect how the therapy under investigation is used in practice, and which measure meaningful and clinically relevant outcomes.

The NCRI Complementary Therapies Clinical Studies Development Group (NCRI CT CSDG) has a remit to oversee relevant trials in the NCRN portfolio, propose new trials, consider trials proposed by others and consider new research questions. Currently the CT CSDG has four studies in its portfolio including those which are focussed on acupuncture for cancer related fatigue and quality of life in breast and lymphoma patients.

The Group have recently appointed a new Research Development Coordinator to support the Chair of the Group in his nationwide responsibility for overseeing and developing the Group's research portfolio of studies. Julie Flynn, who joined the CSDG from Breakthrough Breast Cancer in August 2008 will help to develop the strategic oversight of the Group's portfolio by working with key stakeholders and other Clinical Studies Groups to identify research needs and gaps in order to ensure a clinically relevant portfolio.

The Group are seeking collaborative input from clinicians/oncologists who have an interest in this area to inform their strategy development. If you or a colleague would like to input into this strategy, or wish to respond to any of the questions raised at the start of the article, please contact Julie Flynn (Research Development Coordinator – NCRI Complementary Therapies Clinical Studies Development Group) on julie.flynn@cancer.org.uk or Mr Andrew Ritchie, Chair on (andrew.ritchie@btuh.nhs.uk).

Contributed by Julie Flynn



UKCRC Registered Clinical Trials Units Website

New signpost to clinical trials expertise.



National Institute for Health Research



igniting our potential

A new comprehensive online resource listing national expertise in the design and conduct of clinical trials was launched in October. The UKCRC Registered Clinical Trials Units website provides, for the first time, centralised information on Clinical Trials Units (CTUs) in the UK with expertise in centrally coordinating multicentre clinical trials from design and development, through to data management, and final analysis.

The new website will be a valuable resource for clinical researchers and funders wishing to identify CTUs that can help them to design and run high quality trials for the benefit of patients. It has been developed and funded by the National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre on behalf

of the UKCRC Partners.

The CTUs listed on the website have all achieved UKCRC Registration status. Using the website, researchers and funders can easily locate CTUs by name or location. In addition, more detailed searching allows users to find suitable CTUs by disease research areas (eg cancer, mental health), methodological research areas (eg economic evaluation, systematic reviews and meta-analysis) or specific types of clinical research study (eg surgical trials, trials of investigational medicinal products). CTUs can also be identified by their experience of working with particular funders of clinical research.

The UKCRC Registered Clinical Trials Units website can be found at: <http://www.ukcrc-ctu.org.uk>

CTAAC News in Brief

For the March 2009 meeting of CTAAC we have...

- 3 full applications
- 1 extension application
- 2 endorsement applications
- 5 outline applications
- 14 feasibility applications
- 5 feasibility applications for endorsement.

The next CTAAC deadlines are:

Outline Applications:

24th April 2009

Feasibility Applications:

24th April 2009

Endorsement Applications:

24th April 2009

Full Applications:

1st May 2009

We would like to welcome the following new International CTAAC Advisory Panel (ICAP) member:

Dr Paul Richardson

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

Members Leaving CTAAC:

Mr Roger A'hern

Professor Chris Poole

Professor Kathy Pritchard-Jones

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

UKCRC Registered Clinical Trials Units



Home Resource Finder About Us CTU Registration Process FAQs

Home

RESOURCE FINDER

Information about the UKCRC Registered Clinical Trials Units in the UK



This site is the authoritative web resource for information about the UKCRC Registered Clinical Trials Units.

What does this site provide?

This site offers a resource for clinical researchers and funders wishing to identify Clinical Trials Units (CTUs) that have expertise in centrally coordinating multicentre clinical trials, as well as in trial design, data management, and analysis.

It provides comprehensive information and direct access to high quality CTUs across the UK which have achieved UKCRC Registration status.

Further information about UKCRC CTU Registration can be found [here](#).

Who is this site aimed at?

The information provided on this site is aimed at the following groups, both within and outside the UK:

- Clinical researchers and investigators
- Clinical research networks
- Funders of clinical research (both industry and non-industry)

Patients and members of the public, please click [here](#).

Please note that this resource is not intended for Clinical Research Organisations (CROs) or Site Management Organisations (SMOs) seeking to identify recruitment sites for clinical trials.

This site has been developed by the NIHR Clinical Research Network Coordinating Centre on behalf of the UK Clinical Research Collaboration.



NHS
National Institute for Health Research

TRICC News in Brief

We would like to welcome the following new TRICC members:

Professor Roz Banks

We would like to thank the following for their valued contribution to TRICC:

Professor Peter Parker

Professor John Primrose

Professor Bryan Young

We would like to welcome the following new ICAP member(s):

Dr Javed Khan

For the October 2008 meeting of TRICC we had...

11 full applications

2 sample collection applications

11 outline applications

For the February 2009 meeting of TRICC we have...

11 full applications

5 sample collection applications

7 outline applications

For more information on TRICC, including application forms and closing dates, please visit our webpage: <http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/tricc/>

We are also sad to say goodbye to Tasneem Ahmed, who has provided invaluable support to TRICC over the past year and also assisted in the implementation of the Tissues Resources Science Plan. We wish her the best of luck in her plans to go travelling and teach English in Spain.

TRICC Members: ANDREW HALL (CHAIR) • JAMES BRENTON (VICE CHAIR) • LUCINDA BILLINGHAM • ROBERT BROWN • JUDE FITZGIBBON • JOHN GRIFFITHS • ANDREW HUGHES • MARK MIDDLETON • KARIN OIEN • SARAH PINDER • JORGE REID FILHO • CURZIO RUEGG • CATHERINE WEST • ROZ BANKS • MITCH DOWSETT (OBSERVER)

Translational Research In Clinical Trials Committee (TRICC)

Applications Funded in Principle* in October 2008 & February 2009

*Applications pending feedback from applicants and final approval from TRICC

APPLICATIONS FUNDED

Lead Investigator	Trial Acronym and Title
Dr J Timms	Identification of serum biomarkers of pancreatic cancer
Prof D Neal	Assembling the tissue samples from the ProtecT trial
West	BCON-TRANS: Translational research linked to the BCON trial: investigation of the ability of a hypoxia-associated gene signature to predict benefit from hypoxia-modifying therapy
White	POMC as an exploratory circulating biomarker for Small Cell Lung Cancer
Jones	Prospective Study of Outcomes in Sporadic versus Hereditary (POSH) breast cancer: Pathology Biomarker Study



Joint Initiative for funding feasibility studies in brain tumours

Samantha Dickson Brain Tumour Trust and Cancer Research UK are delighted to announce a joint call for proposals for feasibility studies in primary brain tumours, recognising the need for further clinical research in this area.

Closing date for applications: 14th August 2009
Decision date: November 2009

For more details on the application process, please contact rowena.sharpe@cancer.org.uk

Please note, more details will be made available on the CR-UK website (shown below) by the end of February 2009.

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

<http://www.braintumourtrust.co.uk>

NCRI Lung Cancer Clinical Studies Group: The Clinical Trials Unit representatives

Sub-Group and register of new trials.

Background and introduction

The National Cancer Research Institute (NCRI) Clinical Studies Groups (CSG) represent a central component of the new framework for cancer research in the UK, providing the primary route through which new ideas for clinical trials are developed. Over the last three years the CSG in lung cancer has been developing a formal registration and review system for proposals received by the lung CSG for new clinical trials.

Like other CSGs the lung cancer CSG developed a series of clinical sub-groups whose members are able to focus on key questions in various subdivisions of the tumour type/therapeutic area. When the system was being formalised in 2006 two additional sub-groups that crossed the clinical areas were proposed. The translational sub-group which was established to identify and develop the translational research potentials of each new proposal supported by the clinical sub-groups. The second additional sub-group proposed was a group representing Clinical Trials Units (CTU) with an on-going interest in the conduct of trials in lung cancer.

CTU representatives sub-group of the lung CSG

This group was proposed and accepted as a new sub-group to the lung CSG in July 2006 and in November 2006 the founding members surveyed all accredited CTUs to identify the level of current, and planned, involvement in lung cancer trials and CTUs with lung portfolios were invited to join the sub-group.

An important objective in forming the CTU representatives sub-group was to ensure CTUs were involved in working up new trials from as early a stage as possible, and in particular to ensure that CTUs were approached to work on funding proposals in plenty of time for deadlines.

The main aims in forming the sub-group were:

- to support the lung CSG in developing a full and balanced lung cancer portfolio by offering early advice and guidance on trial methodology to proposers of new trials that have been supported by the clinical sub-groups.
- to help match proposers and CTUs to ensure new proposals and their

Protocol Development Group receive CTU support to take proposals forward, if a CTU is not already involved. The sub-group might also comment on the adequacy and appropriateness of trial conduct, support and resources if these have already been identified.

The sub-group also observe and monitor the spread of lung cancer trials work within CTUs. As with all NCRI CSG sub-groups it is represented at CSG meetings by the sub-group Chair. The majority of the work of the CTU representatives sub-group can be undertaken by email, or teleconference.

The register of proposals for new trials

In 2006 the lung CSG Chair and members of the CTU representatives sub-group also developed the system currently in use for registering and reviewing new proposals for lung cancer trials. The register is a record of all new lung proposals received by the lung CSG and holds information on the progress of the proposal through the review process.

Proposers are asked to submit their proposal as a summary. A template form, which also outlines the subsequent review process, is available to potential proposers on the NCRN website at: <http://ncrndev.org.uk/downloads/csg/NCRI Lung CSG Trials Proposal Form v6.012-05-08.doc>.

Review of proposals for new trials

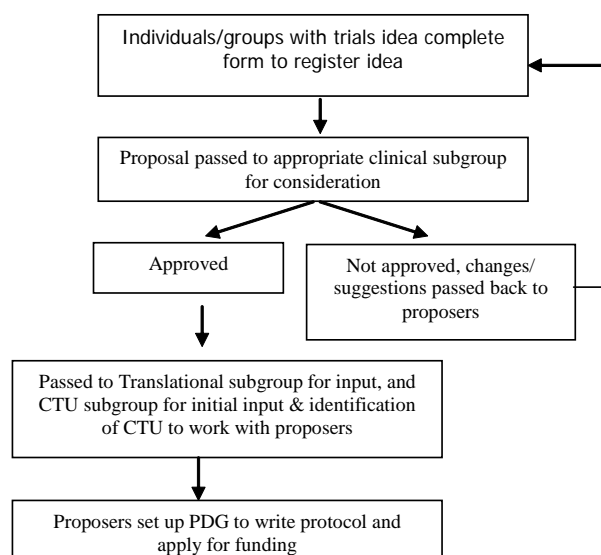
When registered the proposal is allocated a number, which is sent as acknowledgement of receipt to the pro-

poser and the proposal is sent to the relevant clinical sub-group Chair for review by their sub-group. Comments are collected from the sub-group by the Chair, who sends a summarised report to the proposer. The sub-group may: support the proposal, ask the proposer for clarifications or reject the proposal. Correspondence is copied to the lung CSG Chair and to the register so that progress through the system can be monitored. If the proposal is supported by a clinical sub-group then it is forwarded to the CTU reps sub-group and translational sub-group Chairs.

The CTU representatives sub-group members review the proposal and send comments via the Chair who summarises these and provides comments to the proposer together with information about which CTUs have expressed an interest in running the trial (if a CTU is not already linked with the proposal). The proposer will then be supported by a CTU in forming a Protocol Development Group, submitting a funding proposal and initiating other necessary steps on the path to setting up a clinical trial.

The registration and review process is summarised in the diagram below.

In 2008 the lung cancer CSG was awarded funding for a project officer to further develop the registration and review system as it was considered important that the system now receives wider publicity and that it is formally evaluated. If considered to be effective it is hoped that the structure may be rolled out and used in other CSGs.



NAC News in Brief

For the September 2008 NAC we had....

3 full proposals:

- 2 exploratory & preclinical development
- 1 Phase II single agent trial

3 preliminary proposals:

- 2 exploratory & 1 combination trial

For the December 2008 NAC we had...

3 full proposals:

- 1 exploratory & preclinical development
- 1 adult Phase I combination
- 1 paediatric Phase I combination

For the March 2009 NAC we have....

3 full proposals:

- 1 exploratory & preclinical development
- 1 Phase I combination
- 1 Phase I single agent

1 preliminary proposal:

- A Phase II vaccine trial

The NAC welcomed the following new members:

Professor Asim Khwaja
Dr Kate Vallis

For his valued contribution over 6 years on the NAC we would like to thank:

Professor Malcolm Mason

The next NAC deadlines are:

Full proposals: 17 April 2009

Preliminary proposals: 8 May 2009

Annual renewals: 15 May 2009

NAC contacts:

Kate Searle
Research Manager (Drug Development)
Secretary of NAC
kate.searle@cancer.org.uk
020 171 6929

Lauren Knight
Administrative Assistant
lauren.knight@cancer.org.uk
020 171 6965

More about the NAC at: <http://science.cancerresearchuk.org/gapp/clinicaltrialsfund/nacg/?version=1>

More about the Drug Development Office (DDO) and the Clinical Development Partnerships (CDP) initiative at: www.cancerresearchuk.org/drugdevelopment/
www.clinicalpartnerships.com

CancerHelp UK Website Updates



CancerHelp UK (www.cancerhelp.org.uk) is the patient information website for Cancer Research UK. It has over 6,000 pages of information covering 45 main cancer types. We specialise in comprehensive, easy to understand information about cancer and all our information is written in plain English.

CancerHelp UK also includes a unique searchable clinical trials database on www.cancerhelp.org.uk/trials/trials. We currently include lay summaries of both CRUK and non-CRUK funded trials that are open

to recruitment in the UK. But due to increased public interest and to help promote 'transparent' research, in future we will include trials that have finished recruiting patients, and add lay summaries of the results as they become available.

We are in the process of writing results summaries and we hope to launch this new section of the trials database when we launch the new look CancerHelp UK website in spring 2009. We are currently contacting trial teams regarding results of closed trials, so you may hear from us soon!

If you would like more information or would like us to include a summary of your trial results, please contact Clair Lawrence via email clair.lawrence@cancer.or.uk, or by phone on 0207 061 6022.

Experimental Medicine Tool Kit

In November the MRC Regulatory Support Centre launched the Experimental Medicine Tool Kit that aims to provide practical help with the legislative and good practice requirements relating to experimental studies in the UK (<http://www.em-toolkit.ac.uk>). Completing the family of research Tool Kits, the EM Tool Kit is specifically designed to support experimental medicine studies that are:

- Academic led
- Small scale
- Interventional
- Involve humans, either healthy volunteers and/or patients

The information provided is based on the AMS report 'Microbial challenge studies of human volunteers', published in 2005, with significant input from experimental medicine investigators, microbial challenge investigators, and regulators (<http://www.acmedsci.ac.uk/p48prid2.html>). The tool kit leads users through a formal risk assessment of studies, and encourages the devel-

opment of risk proportionate management and monitoring. Appropriate risk assessment and risk management is central to Good Clinical Practice (GCP). Information on how to comply with the Medicines for Human Use (Clinical Trials) regulations, Human Tissues Acts and the laws surrounding data protection and confidentiality is provided elsewhere (in the Clinical Trials Tool Kit <http://www.ct-toolkit.ac.uk> and the MRC Data and Tissues Tool Kit <http://www.dt-toolkit.ac.uk>). The Experimental Medicine Tool Kit supports users in identifying relevant legal frameworks within the UK and directs them to further sources of information that provide practical help in how to comply with the law. The site has been developed for the UK research community in its widest sense, including researchers, research managers, research ethics committee members and interested members of the public. It was developed by the MRC, in close collaboration with UK-CRC partners.

NAC Members: ALAN MUNRO (CHAIR) • GORDON JAYSON (VICE CHAIR) • ERIC ABOAGYE • JOS BEIJNEN • JOHANN DE BONO • JEFF EVANS • FRANK FILDES • JOHN HARTLEY • ASIM KHWAJA • STEVEN MATHER • TIM MEYER • CHRISTIAN OTTENSMEIER • ANDY PEARSON • RUTH PLUMMER • MIKE SECKL • NEIL STEVEN • JOSEP TABERNERO • DENIS TALBOT • CHRIS TWELVES • KATE VALLIS • GILLES VASSAL • PETER WARNE • RICHARD WILSON

New Agents Committee (NAC)

New projects approved in September & December 2008 for preclinical & clinical development by Cancer Research UK's Drug Development Office (DDO)

APPLICATIONS APPROVED FOR DEVELOPMENT

Investigators	Trial Acronym and Title
Prof R Begent, Prof T Illidge Dr C McNamara	A Phase II trial of radioimmunotherapy with a radiolabelled monoclonal antibody targeting IL-2r, in relapsed Hodgkin's Lymphoma
Dr J Spicer Dr S Karagiannis Prof H Gould Prof P Blower Prof S Kaye	Exploratory and preclinical development and a Phase I trial of a monoclonal antibody targeting the folate receptor, in advanced cancer
Dr D Hargrave Prof R Plummer	A Phase I trial of a PARP inhibitor, combined with temozolomide and irinotecan in paediatric patients with advanced solid tumours

APPLICATIONS INVITED BACK AS REVISED PROPOSALS

Lead Investigator	Trial Acronym and Title
Clinical Development Partnerships (CPD) initiative	Preclinical development and a Phase I trial of a polo kinase inhibitor, in patients with advanced cancer
Dr S Blagdon Prof C Coombes Prof A George	Preclinical development and a Phase I trial of a monoclonal antibody targeting Notch and DLL4

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